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CLOSING THE KITCHEN? DIGESTING THE IMPACT OF THE FEDERAL MENU LABELING LAW IN THE AFFORDABLE CARE ACT

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INTRODUCTION

Obesity, and with it diabetes, are the only major health problems that are getting worse in this country, and they are getting worse rapidly.

- Dr. Thomas R. Frieden, Director of the U.S. Centers for Disease Control and Prevention[1]

What's for dinner tonight? A Burger King Triple Whopper With Cheese and Medium Fries is 1690 calories,[2] a large Quiznos Tuna Melt is 1740 calories,[3] and Panera's Italian Combo Sandwich alone is 1040 calories.[4] Even a seemingly innocent Buffalo Chicken Salad at Chili's amounts to over 1000 calories.[5] What about dessert? Most people would probably guess that a slice of Carrot Cake from the Cheesecake Factory is not healthy, but many people would probably be shocked to learn that

1. Steven Reinberg, Almost Ten Percent of U.S. Medical Costs Tied to Obesity, ABC NEWS, July 28, 2010, http://abcnews.go.com/Health/Healthday/story?id=8184975&page=1.

2. BURGER KING, http://www.bk.com/en/us/menu-nutrition/ index.html (last visited Oct. 2, 2010).

3. QUIZNOS, http://www.quiznos.com/subsandwiches/Menu/PDFs/NutritionInfo.pdf (last visited Oct. 2, 2010).

4. PANERA, http://www.www.panerabread.com/pdf/nutr-guide.pdf (last visited Oct. 2, 2010).

5. CHILI'S, http://www.chilis.com/EN/Nutrition%20Information/Chilis_Nutrition_Menu_Generic.pdf (last visited Jan. 22, 2011).

a single slice contains over 1500 calories.[6]

Obesity is a significant and rapidly growing problem that is largely preventable and results in many health complications and avertable deaths. In the United States, two-thirds of adults and almost one-third of children and teens are currently considered overweight or obese.[7] Obesity is related to over 20 chronic diseases, including heart disease and diabetes.[8] The economic burden of obesity is substantial. Studies that estimate the annual medical spending due to obesity range from $92.6 billion (in 2002) to as high as $117 billion.[9] According to the Congressional Budget Office, spending per capita for obese adults exceeded spending for adults of normal weight by about 8% in 1987 and by about 38% in 2007.[10] Another study found that obesity adds over $2,800 to a person's annual medical bills.[11] Compounding the issue, a large proportion of the financial burden of obesity and relating complications falls on taxpayers because the federal government publically funds medical services for certain populations through Medicaid, Medicare, and related programs.[12]

A successful mandatory menu labeling regulatory scheme is one approach to address the growing obesity problem in the United States. This Note will analyze federally required calorie disclosures on menus as one approach to combating obesity, exploring problematic uncertainties and proposing an alternative framework of regulation. Part I provides a brief history of nutrient disclosure laws in the context of federalism choice, analyzing the impact of certain federal floors, ceilings, and failed legislation. Part I concludes with a discussion of regulations that states and localities have implemented to address nutrient disclosure in restaurants. Next, Part II gives an overview of § 4205 of the recently enacted ACA, which mandates calorie disclosures

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6. Center for Science in the Public Interest, Anyone's Guess: The Need for Nutrition Labeling at Fast Food and Other Chain Restaurants, Nov. 2003, http://www.cspinet.org/restaurantreport.pdf (last visited Jan. 1, 2011).

7. JEFFREY LEVI ET AL., F AS IN FAT; HOW OBESITY THREATENS AMERICA'S FUTURE, 4 (2010).

8. *Id.*

9. Joan R. Rothenberg, *In Search of the Silver Bullet: Regulatory Models to Address Childhood Obesity*, 65 FOOD DRUG L.J. 185, 188 (2010).

10. Congressional Budget Office, How Does Obesity in Adults Affect Spending on Health Care?, Sept. 2010, www.cbo.gov/ftpdocs/118xx/doc11810/09-08-Obesity_brief.pdf (last visited Jan. 4, 2011).

11. USA Today, *Obesity Costs U.S. $186 Billion, Study Finds.* Oct. 2010, http://www.usatoday.com/yourlife/fitness/2010-10-18-obesity-costs_N.htm. (last visited Jan. 4, 2011).

12. Tamara Schulman, Note, *Menu Labeling: Knowledge for a Healthier America*, 47 HARV. J. ON LEGIS. 587, 591 (2010). A 2003 study concluded that approximately one half of medical expenditures attributed to obesity were financed by Federal and State governments through Medicare and Medicaid. Eric A. Finkelstein et al., *State-Level Estimates of Annual Medical Expenditures Attributable to Obesity*, 12 OBESITY RES. 18, 18 (2004).

at certain restaurants, and discusses the FDA's interpretation of § 4205's language. Part III discusses concepts of federalism choice and experimentalism, and then evaluates § 4205 and the potential impacts and consequences of its ceiling preemption. Finally, Part IV argues that § 4205 should be rewritten as a federal minimum standard. In the alternative, this Note offers suggestions for courts, states, localities, regulatory agencies, and businesses to combat the obesity epidemic and address the problems inherent to implementing the statute.

I. A HISTORY OF NUTRIENT DISCLOSURE LAWS IN THE CONTEXT OF FEDERALISM CHOICE

Policymakers in the United States have long struggled with the amount and type of regulation needed regarding food and health. For example, to combat growing obesity rates throughout the years, governments at every level have implemented many different policies and regulations, including total prohibition of transfats, mandating exercise in schools, and regulating marketing and advertising of food.[13] These regulations, however, exist in constant tension with individual rights and freedoms, because most foods are not inherently dangerous,[14] and how much a person eats and exercises are considered to be personal choices.[15] This tension creates the need for politicians to constantly balance the strong public policy considerations behind obesity regulations with these individual liberty concerns. Given that the FDA bases its nutrition labels on an average daily calorie intake of 2,000 calories, and many restaurant dishes, not just fast food, contain close to or in excess of that number, it is easy to understand why many public health advocates and policymakers argue for restaurant disclosure regulation to address the obesity epidemic in the United States.[16] Such advocates believe that with more information, consumers will make healthier choices, thus reducing their calorie consumption and thereby reducing obesity.[17]

Americans over the age of eight eat, an average of 218 restaurant meals per year.[18] Eating outside the home is a growing trend. In 2006,

13. Rothenberg, *supra* note 9, at 194–96, 201.

14. LAWRENCE A. GOODMAN ET AL., LAW IN PUBLIC HEALTH PRACTICE 413, 2d (2007).

15. Katherine Mayer, Note, *An Unjust War: The Case Against The Government's War on Obesity*, 92 GEO. L.J. 999, 1008 (2004).

16. U.S. Food and Drug Administration, How to Understand and Use the Nutrition Facts Label, http://www.fda.gov/food/labeling nutrition/consumerinformation/ucm078889.htm (last visited Jan. 7, 2011).

17. Brent Bernell, *The History and Impact of the New York City Menu Labeling Law*, 65 FOOD DRUG L.J. 839, 843 (2010).

18. Center for Science in the Public Interest. *Anyone's Guess: The Need for Nutrition*

Americans spent 48% of their food dollars on meals outside of their homes, up from 25% in 1955.[19] Restaurant meals are linked to drinking less milk and the consumption of substantially more calories, more saturated fat, and fewer fruits and vegetables than eating at home.[20] Further, it is common for restaurants to serve portions two to three times larger than what is considered a standard serving size by the U.S. Department of Agriculture.[21] Additionally, studies show that patrons have a difficult time assessing calorie content in restaurant food,[22] and often underestimate calorie content in restaurant dishes.[23] Reacting to this and other information voids, the federal government, as well as state and local governments have a history of requiring some type of disclosure on food and drug products.[24] Section A of this Part first describes both successful and attempted past federal nutrient disclosure laws, and their preemptive effects. Section B then discusses state and local attempts to regulate nutrient disclosure in restaurants, and subsequent effects.

A. *Past Federal Action*

Historically, federal environmental and health rules have served as a floor of minimum protections, allowing states to enact more stringent requirements.[25] In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA), which created national food and drug safety standards and mandated FDA approval for all marketed drugs.[26] Interestingly, the FDCA does not contain an express preemption clause

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Labeling at Fast Food and Other Chain Restaurants (2003).

19. National Restaurant Association, 2008 Restaurant Industry Pocket Factbook, www.restaurant.org/pdfs/research/2008forecast_ factbook.pdf (last visited Oct. 10, 2010).

20. S.A. French et al., *Fast Food Restaurant Use Among Adolescents: Associations With Nutrient Intake, Food Choices and Behavioral and Psychosocial Variables*, 25 INT'L J. OBESITY, 1823–33 (2001).

21. Center for Science in the Public's Interest, *Anyone's Guess: the Need for Nutrition Labeling at Fast Food and Other Chain Restaurants*, Nov. 2003, http://www.cspinet.org/restaurantreport.pdf (last visited Oct. 6, 2010).

22. L.R. Young et al., 53 *Portion Sizes in Dietary Assessment: Issues and Policy Implications*, NUTRITION REVS. 149–58 (1995). For a discussion of preemption, see *infra* Part III.

23. W.G. Johnson et al., *Dietary Restraint and Eating Behavior in the Natural Environment*, 15 ADDICTIVE BEHAVIORS 285–90 (1990). *See also* Mark Berman & Risa Lavizzo-Mourey, *Obesity Prevention in the Information Age: Calorie Information at the Point of Purchase*, 300 J. AM. MED. ASS'N 433, 433 (2008).

24. Margaret Sova McCabe, *Loco Labels and Marketing Madness: Improving How Consumers Interpret Information in the American Food Economy*, 17 J.L. & POL'Y 493, 498 (2009).

25. Nina Mendelson, *Bullies Along the Potomac*, N.Y. TIMES (July 5, 2006), http://www.nytimes.com/2006/07/05/opinion/05mendelson.html.

26. Charles R. Yates, III, Note, *Trimming the Fat: A Study of Mandatory Nutrition Disclosure Laws and Excessive Judicial Deference*, 67 WASH & LEE L. REV. 787, 790 (2010).

that applies to the entire Act, which has sparked years of Supreme Court litigation.[27]

In contrast to the FDCA, the Nutrition Labeling and Education Act (NLEA) of 1990 contains an express ceiling preemption clause.[28] The NLEA added two sections to the FDCA, requiring packaged foods sold in grocery stores to disclose nutrient and calorie content on labels.[29] The NLEA provides the FDA with a mandate to oversee nutrition labeling for all food products and review claims on packaging.[30] Further, the NLEA requires ingredient disclosure on packaged food labels, and declared that the FDCA preempts most state food labeling laws.[31] Accordingly, the NLEA operates as a uniform federal ceiling by not allowing states and localities to enact laws that differ from the NLEA's provisions with regard to packaged food labels.

National uniformity helps avoid additional costs resulting from multiple labeling requirements, facilitating the national distribution of products.[32] In this situation, ceiling preemption can be viewed in a positive light because the NLEA takes steps to alleviate information asymmetries between producers of packaged food and individual consumers throughout the country. Ceiling preemption, however, does not leave room for states and localities to enact laws that target the specific needs of their communities. For example, under the NLEA, states cannot impose additional requirements for nutrient disclosure on food packages. Moreover, the NLEA does not include any language directed at regulating restaurant nutrient disclosure, except when restaurants make health claims about an item. In fact, the NLEA expressly exempted restaurants from its nutrition requirements, but did

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27. Anthony Gostanian, Note and Article, *How the FDA Can Overturn* Wyeth v. Levine, 36 AM. J.L. & MED. 248, 252 (2010). *See, e.g.*, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008); Wyeth v. Levine, 129 S. Ct. 1187 (2009). For instance, pharmaceutical regulation under the FDCA preempts many state and local pharmaceutical laws, based on the rationales that pharmaceutical products, distributed nationally, would benefit from uniform standards, and that companies capitalize on economics of scale.

28. "[The Act] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted [by the NLEA]." 21 U.S.C. § 343-1, note on Construction.

29. Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2352 (codified at 21 U.S.C. § 343 (2006)). NLEA amended the 1938 Food, Drug and Cosmetic Act that established a system of "uniform labeling of certain food products in interstate commerce." Devon E. Winkles, Comment, *Weighing the Value of Information: Why the Federal Government Should Require Nutrition Labeling for Food Served in Restaurants,* 59 EMORY L.J. 549 (2009).

30. Nutrition Labeling and Education Act of 1990, *supra* note 29.

31. Schulman, *supra* note 12, at 592.

32. *See* Winkles, *supra* note 29, at 575–76 ("In enacting the NLEA, 'Congress sought to free manufacturers from . . . fifty or more different labeling requirements and from the threat of fifty different type lawsuits . . . .' Congress agreed to preempt most inconsistent state labeling laws to get the support of the food industry." (citations omitted)).

not preempt all state laws regarding restaurants.[33]

Thirteen years after the enactment of the NLEA, Representative Rosa DeLauro (D-CT) introduced the Menu Education and Labeling Act of 2003 (MEAL Act) which aimed to require restaurants to disclose nutrition information under the NLEA.[34] Under the MEAL Act, chain restaurants would have had to post the total number of calories, grams of saturated fat and milligrams of sodium next to items on menus, and vending machines would have to post total calories for each item.[35] In support, Senator Tom Harkin (D-IA) remarked, "we must build prevention into the very fabric of our society. We must provide consumers with the tools and the support that they need to make the healthy choice the right choice."[36]

The MEAL Act would not have precluded states from passing more stringent regulations, thus serving as a federal minimum floor rather than a unitary ceiling for restaurant nutrient disclosure.[37] While the MEAL Act would have set minimum uniform standards across the nation, states and localities would have been free to free to tailor additional provisions to fit the needs of specific populations and communities. Many businesses were opposed to the floor preemption in the MEAL act because of the possibility of a patchwork of inconsistent regulations throughout the nation.[38]

Congress never passed the MEAL Act, and in 2008, Senator Tom Carper (D-DE) and Senator Lisa Murkowski (R-AK) introduced the Labeling Education and Nutrition Act (LEAN Act) in the Senate.[39] This bill required a uniform nutrition labeling standard for chains with 20 or more establishments, thus operating as a federal floor and ceiling. In contrast to the MEAL Act, the LEAN Act set a low bar for restaurants to obtain and calculate nutrition analysis of their products by minimizing penalties for potential noncompliance, and only required

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33. Schulman, *supra* note 12, at 592. However, the Second Circuit found that NLEA preempted expressly preempted 81.50 because 81.50 applied *only* to restaurants that *voluntarily* published calorie information. *See infra* note 46.

34. MEAL, H.R. 3895, 110th Cong. (2007).

35. *Id.*

36. 155 CONG REC S5502, 5522–23.

37. Jodi Schuette Green, Note, *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, 743 (2010). "Nothing in this clause precludes a State or political subdivision of a State from requiring that a restaurant or similar food establishment provide nutrition information in addition to that required under this clause." HR 3895, 110th Cong. (2007).

38. "Restaurants were exempted from the 1990 law, and rightly so, says the National Restaurant Association, because it wouldn't be practical." Meal Act Seeks Nutrition Labels for Fast Food, FOX NEWS, http://www.foxnews.com/story/0,2933,102426,00.html (last visited Jan. 3, 2011).

39. Green, *supra* note 37, at 743; LEAN Act of 2008, S.3575, 110th Cong. (2008).

calorie disclosure on menus.[40] Representative Jim Matheson (D-UT) introduced the bill to the House of Representatives as a "compromise effort that will allow consumers to make informed decision," explaining that localities have enacted "a patchwork of regulation that can be confusing to the consumer and is burdensome to restaurant chains."[41]

The LEAN Act was openly supported by the National Restaurant Association as empowering consumers, although they had previously argued that menu labeling was unnecessary.[42] However, mirroring the fate of its predecessor, the LEAN Act did not pass.[43] Accordingly, prior to the passage of the ACA, the only nutrition regulations faced by restaurants were those imposed by the NLEA when making claims about food items; otherwise, restaurants remained exempt from NLEA's other obligations, leaving regulation to the states.[44]

B. *State and Local Actions and Their Effects*

Meaningful federal regulation addressing nutrient disclosures on menus in restaurants was not ultimately successful until states and localities began to experiment with such laws. In 2006, the New York City Board of Health adopted Health Code § 81.50, becoming the first locality to require restaurants to disclose calorie content on menu boards.[45] Although the Southern District of New York struck down the first version of the regulation as preempted by federal law, the Board of Health re-wrote the regulation.[46] The Second Circuit held that this new version was acceptable, after undertaking a federal preemption and First Amendment analysis.[47] The revised version requires restaurants with

40. Green, *supra* note 37, at 743–44.

41. 155 CONG. REC. E 597.

42. Green, *supra* note 37, at 744–45.

43. *Id.*

44. *See supra* note 33.

45. Green, *supra* note 37, at 746. The City of New York explained that § 81.50 was enacted because "There is a calorie information gap. . . . Providing information about the calorie content of foods and beverages being served in chain restaurants in a time, place, and manner that can inform decisions will help bridge this gap." N.Y. City Bd. Of Health, Notice of Intention to Repeal and Reenact § 81.50 of the New York City Health Code at 8 (Oct. 2007), http://www.nyc.gov/html/doh/downloads/pdf/public/notice-intention-hc-art81-50-1007.pdf (last visited Jan. 2, 2011).

46. N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 509 F. Supp. 2d 351, 363 (S.D.N.Y. 2007). In the case, the New York State Restaurant Association argued that § 81.50 was expressly preempted by NLEA and violated the First Amendment's protection of commercial speech. The court held that the city retained the authority to require restaurants to include nutrition information of menus, but the court still granted summary judgment against the New York City Board of Health because NLEA expressly preempted 81.50 because § 81.50 applied *only* to restaurants that *voluntarily* published calorie information. *Id. at* 352–53.

47. N.Y State Restaurant Ass'n v. N.Y City Bd. of Health, 556 F.3d 114 (2d Cir. 2009). As part of its decision, the court explained that the NLEA allows for state regulation of nutrition information for restaurants consistent with § 343(q), and held that New York City was within its

more than 15 locations to post calorie information on menus and menu boards in a prominent font.[48]

Soon after § 81.50's enactment in New York City, other localities began passing similar laws.[49] For example, in California in 2009, Governor Arnold Schwarzenegger signed into law the first statewide menu labeling law in the United States.[50] As of 2010, five more states have followed suit.[51] In addition, as of 2010, sixteen states, Washington D.C., and numerous local governments had introduced legislation to require restaurants to post nutrition information on menus.[52] Many jurisdictions have gone beyond only requiring calorie disclosure, and mandate other nutrition information postings on menus and menu boards, such as disclosure of saturated fat, transfat, carbohydrate content, and sodium content.[53]

Early evidence regarding the effectiveness of calorie disclosures on menus to influence healthier choices has been mixed, but some research regarding local menu labeling laws shows that on average, patrons bought foods with fewer calories where menu labels were present.[54] Public health advocates often argue that menu labels empower people to take control of their intake and make healthier decisions, and thus reduce obesity.[55] This policy is analogous to the FDA's enactment of

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authority to create a mandatory labeling requirement for restaurants to display factual information consistent with the NLEA, but not assertions. *Id.* at 120.

48. N.Y. HEALTH CODE LAW § 81.50 (2008).

49. Nutrition Labeling in Chain Restaurants: State and Local Bills/Regulations—2009-2010, http://cspinet.org/new/pdf/mlbill_summaries_09.pdf (last visited Oct. 2, 2010).

50. *See* CAL. HEALTH & SAFETY CODE § 114094 (West 2009) (requires chain restaurants with 20 or more locations to post calorie information for standard items on menu boards and menus).

51. LEVI ET AL., *supra* note 7, at 7. The five states are: California, Massachusetts, Maine, New Jersey, and Oregon. *Id.* at 46.

52. *Id.*

53. Jennifer L. Pomeranz, *Compelled Speech Under the Commercial Speech Doctrine: The Case of Menu Label Laws*, 12 J. HEALTH CARE L. & POL'Y 159, 163 (2009). *See e.g.* City of Philadelphia Bill No. 080167-A (amending Philadelphia Health Code tit. 6, § 102; § 308); King County Health Code tit. 5 ch. 5.10.015.

54. A study in Los Angeles, which has many fast food chains, estimated that community weight gain would decrease by 38% annually if California's new state menu labeling law, which is similar to § 4205, induced only 10% of fast food customers to eat 100 calories less at each fast food meal. *See generally* Tony Kuo et al., *Menu Labeling as a Potential Strategy for Combating the Obesity Epidemic: A Health Impact Assessment*, 99 AM. J. PUB. HEALTH 1680 (2009).

55. *See* Juliann Schaeffer, *Big Changes Ahead—Calorie Counts and Prevention Are Key Ingredients in Health Reform*, TODAY'S DIETITIAN (June 2010), http://www.todaysdietitian.com/newarchives/060210p20shtml. Clyde W. Yancy, president of the American Heart Association sees menu labeling laws as:

> a big step forward for Americans' health: "I can't believe that providing information is intrusive in any way. Simply having the information, ironically, emancipates us. If you put this in a context of freedom of choice, you don't have that freedom now because if you select a menu item, you may perceive it

similar labeling requirements under the NLEA for packaged food.[56]

At Starbucks, when calories were posted on menu boards in New York City, the average calorie content per transaction declined by an average of 6% but did not result in a decrease in overall sales.[57] A study released in July 2011 surveyed lunch receipts for approximately 8000 people before and after the implementation of New York's law. The study found that for the three main restaurant chains studied, customers on average purchased between 44 and 80 fewer calories after the law took effect.

Conversely, a recent study that analyzed nutrition data from 14 Taco Time restaurants in California found that calorie disclosure on menus had no significant impact on the amount of calories patrons purchased.[58] However, the study only looked at one chain, which already had a "Healthy Highlights" icon on menus.[59] Further, such studies have not measured what impact calorie disclosures on menus may have on other food choices over the course of a day; for example, a customer who consumes a hamburger and realizes it contains 1000 calories may compensate by eating fewer calories during the rest of the day. Accordingly, more research is needed to study the long-term effects of menu labeling laws, impacts of repeated exposure, and impacts on different ethnic and age groups of consumers.

Some commentators predict that menu labels do not create net losses for the restaurant industry, and instead cause a shift of revenue from chains offering mostly high calorie items to restaurants with lower calorie choices.[60] If so, every restaurant would likely be incentivized to offer lower calorie meals, thus benefiting even non-observant consumers, as menu items will gradually become lower in calorie content when restaurants realize consumers are choosing to purchase lower calorie offerings. Further research on this question is needed.

> as healthy because of one or two buzzwords like spinach and not realize the calorie count. But if the spinach is coated in Parmesan-crusted cheese, that just changed the whole nutrition content of that dish. So my sense is that this actually is empowering and gives us the freedom . . . of choice."

Id.

56. Schulman, *supra* note 12, at 588.

57. Bryan Bolinger et al., *Calorie Posting in Chain Restaurants* (Nat'l Bureau of Econ. Research, Working Paper No. 15648, 2010), *available at* www.stanford.edu/~pleslie/calories.pdf (last visited Oct. 10, 2010).

58. Katherine Hobson, *Study Finds Menu Labeling Didn't Change Eating Habits*, WALL ST. J. HEALTH BLOG (Jan. 14 2011), http://blogs.wsj.com/health/2011/01/14/study-finds-menu-labeling-didnt-change-eating-habits.

59. *Id.*

60. Mark Berman & Risa Lavizzo-Mourey, *Obesity Prevention in the Information Age: Calorie Information at the Point of Purchase*, 300 J. AM. MED. ASS'N 433, 434 (2008). *See generally* Michelle I. Banker, *I Saw the Sign: The New Federal Menu-Labeling Law and Lessons from Local Experience*, 65 FOOD DRUG L.J. 901, 914–15 (2010).

Another study that analyzed menu labels and menu boards with a contextual phrase reading "the recommended daily caloric intake for an average adult is 2000 calories" found that when people were presented with labels and contextual information, they consumed an average of 250 fewer calories during the day.[61] Conversely, another study that focused on low-income minorities in New York City did not find any change in calorie consumption when calorie content was posted on menu boards, although patrons did report that it influenced their choices.[62] However, this second study only included customers who voluntarily visit fast food restaurants, excluding consumers who already avoid fast food.[63] Another study found that where menu labeling is required by law, restaurants were 58% more likely to offer food with lower calorie options.[64] In addition, a survey in New York City found 89% of respondents were in favor of the New York menu labeling law.[65] Again, further research is needed regarding the connection between more comprehensive menu labeling and consumer decisions to make healthier purchases.

Opponents of menu labeling generally argue that the policy is a paternalistic and unnecessary government imposition on personal autonomy and the free market, with costs that will burden restaurants.[66] Countering this argument, Judge Richard Posner points out that "a law aimed at reducing obesity would be paternalistic if obesity did not produce external costs, but it does, because obese people consume a disproportionate amount of medical resources, and there is extensive public and private subsidization of medical expenses."[67] In addition, critics argue that the cost of implementation of menu labeling for restaurants will be extreme. One report notes that the cost of implementing the New York City regulation has been estimated from $2,000-$5,000 for each restaurant,[68] but the Federal Obesity Working

61. Christina A Roberto et al., *Evaluating the Impact of Menu Labeling on Food Choices and Intake*, AM. J. PUBLIC HEALTH (forthcoming 2011).

62. Brian Elbel et al., *Calorie Labeling and Food Choices: A First Look at the Effects on Low-Income People in New York City*, HEALTH AFF., 1110–21 (2009).

63. Schulman, *supra* note 12, at 600 (2010).

64. Bolinger et al., *supra* note 57.

65. Technomic, Inc. Executive Summary: Consumer Reaction to Calorie Disclosure on Menus/menu Boards in New York City, Feb. 2009.

66. 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.

67. Richard A. Posner, *Compelled Disclosure of Food Characteristics*, Becker-Posner Blog (July 27, 2008), http://www.becker-posner-blog.com/2008/07/compelled-disclosure-of-food-characteristics--posner.html (last visited Oct. 7, 2010).

68. Tiffini Diage, *Menu Calorie Postings in Restaurants: Policy Intervention to Prevent and Reduce Obesity*, 9 U. WIS. POPULATION HEALTH INSTITUTE ISSUE BRIEF NO. 4, at 2 (Nov. 2009), http://uwphi.pop health.wisc.edu/publications/issueBriefs/issueBriefv09n04.pdf.

Group Report explains that obtaining nutrition information "is easier today because nutrient composition databases and software for labeling are readily available," leaving the updating of menu boards as the only substantial cost.[69] Opponents also argue that menu labels will reduce restaurant revenue, but as discussed above, the data on this point is currently inconclusive.

II. OVERVIEW OF § 4205

On March 23, 2010, President Obama signed the Affordable Care Act into law. Section 4205 of the ACA mandates uniform regulations for large chains, but generally does not directly interfere with individual and small scale businesses. Section A of this Part provides an overview of § 4205, and section B explains the legal requirements of the statute. Finally, section C outlines enforcement and implementation uncertainties.

A. *Introduction to § 4205*

Modeled after existing local and state laws, § 4205 amends the FDCA to require chain establishments of covered entities with 20 or more national locations with the same name and essentially the same menu items to post calorie information, along with the number of calories recommended for daily consumption, in a prominent location. Section 4205 explicitly preempts state or local laws that are *different* from § 4205 regarding nutrient disclosure on menus, thus disabling localities from implementing regulations that require greater disclosure.[70] In addition, with respect to vending machines, no state or locality may implement requirements that are not identical to the federal requirements, regardless of how many vending machines a particular corporation owns or operates.[71] The House Committee on Energy and Commerce reports that the purpose of § 4205 is to "give consumers important health information, and allow them to exercise choice and responsibility about what they and their children eat."[72] However, by creating a unitary federal ceiling in the name of uniformity, the law

69. U.S. Food and Drug Administration, *Calories Count: Report of the Working Group on Obesity* (July 1, 2009), http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081770.htm (last visited Jan. 7, 2011).

70. LEVI ET AL., *supra* note 7, at 46 ("An identical state or local law may make it possible for state or local personnel—who generally do not enforce federal law—to effectively monitor compliance with menu labeling standards."). *Id.*

71. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205 (to be codified at 21 U.S.C. § 343(q)(5)(H)).

72. H.R. REP. NO. 111-299, at 2562 (2009).

effectively stifles the potential for localities to experiment with different regulations.[73]

Initially, the restaurant industry resisted federal menu labeling regulation, claiming that it is a "paternalistic intervention" and that it "enfeebles the notion of personal responsibility."[74] As more localities began to implement menu labeling regulations and the Second Circuit upheld New York City's § 81.50 Ordinance, the industry, perhaps recognizing the inevitability of the laws, and wanting to have standardized regulations throughout the country, shifted its standpoint. The National Restaurant Association supported the federal nutrition disclosure standard in the ACA, stating that the existing "patchwork of regulation is confusing to the consumer . . . [and] difficult and expensive for operators."[75] Still, not all politicians were convinced. Representative Donald Manzullo (R-IL) argued that federal menu labeling contributes to the "micromanag[ing] [of] all aspects of Americans' health."[76]

Already, § 4205 is spurring a great deal of discussion, as restaurant and vending machine owners attempt to understand their new obligations, and some scholars have also begun to comment on § 4205.[77] On its face, § 4205 may appear to be a public health victory, but this new law presents problematic uncertainties. Most significantly, the law serves as a unitary federal ceiling that preempts stricter regulations and new disclosure approaches at the state and local level.

B. *Legal Requirements of § 4205*

Section 4205 outlines some specific rules regarding nutrient disclosure, and leaves the promulgation of regulations to the FDA.[78] In restaurants and other covered establishments under § 4205, calorie content must be posted on menus, menu boards, drive through displays,

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73. For instance, Philadelphia's law requires more nutrition information than calories to be posted on the menu or menu board. City of Philadelphia Bill No. 080167-A (amending Philadelphia Health Code tit. 6, § 102; § 308).

74. Michelle M. Mello et al., *Obesity: The New Frontier of Public Health Law*, 354 NEW ENG. J. MED. 2601, 2602 (2006), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMhpr060227.

75. National Restaurant Association, Public Policy Issue Briefs, 2010, http://www.restaurant.org/advocacy/issues/issue/?Issue=menulabel; Janet Adamy, *Coming Soon: Theaters, Airplanes to Post Calories*, WALL ST. J. (Aug. 31, 2010), http://online.wsj.com/article/SB10001424052748704323704575462021475610064.html.

76. 155 CONG. REC. H12902 (2009).

77. *See, e.g.*, Banker, *supra* note 60, at 901 (comparing federal menu labeling to state and local requirements).

78. The FDA is an agency within the Department of Health and Human Services, and is responsible for implementing § 4205.

internet and take-out menus if they are the primary menu used for ordering, or other avenues in close proximity to the item.[79] Buffets, salad bars, and other displays are included.[80] Seasonal items that are on menus for less than 60 days, market testing of food items for less than 90 days, condiments, and custom orders are exempt.[81] The FDA has not yet issued final regulations for "variable items," such as deli sandwiches that are assembled using an assortment of toppings, but has proposed options under consideration in its proposed rules.[82]

Covered establishments must also be able to provide additional information in writing, including fat, sodium, and sugar content, if requested, and menus must include a statement stating that such written nutrition information is available to customers upon request.[83] The Secretary of Heath and Human Services (HHS) may require disclosure of additional nutrient information in a written form if the Secretary determines that such disclosures are necessary to keep the public informed.[84] Additionally, establishments must also "post prominently" a statement of the FDA's recommended average calorie intake, which has not yet been released in final form.[85] Finally, vending machine operators must also post calorie information, visible in a clear and conspicuous manner for consumers to view, before the point of purchase for food items.[86] The law does not affect state or local labeling requirements that concern the safety of food, such as warning statements, consumer advisories, or allergen labeling.[87]

Restaurant chains and covered establishments with less than 20 establishments nationwide are exempt from § 4205, and are required to

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79. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205 (to be codified at 21 U.S.C. § 343(q)(5) (H)). The FDA released proposed rules on April 1, 2011, and proposed that retail food establishments be defined as "an establishment whose primary business activity is the sale of food to consumers," or in the alternative as an "establishment where the sale of restaurant or restaurant-type food--as opposed to food in general--is the primary business activity of that establishment." Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (Proposed Apr. 1, 2011) [hereinafter *Proposed Rules*].

80. *Id.*

81. *Id.* One could foresee restaurants evading disclosure requirements by keeping its entire menu, or just the unhealthiest offerings, as seasonal items or market test items.

82. *Proposed Rules, supra* note 79.

83. *Id.*

84. *Id.* ("If the Secretary determines that a nutrient, other than a nutrient required under subclause (ii)(III), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under subclause (ii)(III).").

85. *Id.*

86. *Id.*

87. U.S. Food & Drug Adm'n, *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*, Aug. 24, 2010, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm223266.htm [hereinafter *Draft Guidance*].

comply with any applicable state or local menu labeling laws. However, such establishments may voluntarily opt into compliance with § 4205, which is an effective exemption from state or local regulation.[88] While such a policy was likely enacted to insulate small businesses from the cost of calculating nutrient content, this gap in disclosure is a significant missing link from making calorie content available for all consumers and achieving public health goals of information dissemination and obesity reduction.

Section 4205 includes a reasonable basis standard for restaurants to use when determining and presenting nutrition information.[89] This standard recognizes there will be inevitable variability in preparation of foods, and gives restaurants some degree of flexibility when determining nutrition data. Restaurants may calculate nutrition data using "nutrient databases, cookbooks, laboratory analyses, and other reasonable means."[90] The degree of flexibility permitted, and how the FDA will enforce the standard, is still unclear.[91] In addition, § 4205 directs the FDA to "specify the format and manner" of the nutrient postings and promulgate regulations for implementation.[92] Depending on how the FDA decides to enforce the statute, violations of § 4205 will likely render a food item misbranded under the FDCA, which could result in civil and criminal penalties.[93]

In August 2010, the FDA released a Draft Guidance document, which was subsequently withdrawn in January 2011 to incorporate many comments received by the FDA.[94] The withdrawn guidance indicated that § 4205 does apply to alcoholic beverages, which would present a disclosure inconsistency because alcoholic beverages sold at

88. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205 (to be codified at 21 U.S.C. § 343(q)(5)(H)). For example, New York City's ordinance will continue to apply to chains with 15 to 19 locations nationally unless the restaurant chains voluntarily comply with the federal regulations. *See* N.Y. HEALTH CODE LAW § 81.50 (2008), *available at* http://24.97.137.100/nyc/RCNY/Title24_81_50.asp?zoom_highlight=81.50.

89. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205 (to be codified at 21 U.S.C. § 343(q)(5)(H)) (for pertinent information, refer to 124 Stat. 574.).

90. *Id.*

91. The FDA will determine if restaurants must provide exact numbers, or can instead display rounded estimates. One study found that the actual calorie content varied by an average of 18% between numbers posted on menus and what was actually contained in the dishes. Banker, *supra* note 60, at 924.

92. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205 (to be codified at 21 U.S.C. § 343(q)(5)(H)) (for pertinent information, refer to 124 Stat. 574.).

93. *Proposed Rules, supra* note 79.

94. *See* U.S. Food & Drug Adm'n, *Withdrawal of Draft FDA 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,* http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm240574.htm ("FDA now intends to complete the notice and Article rulemaking process for section 4205 before initiating enforcement activities.") [hereinafter *Withdrawal of Draft Guidance*].

grocery stores and other non-covered restaurants do not have to disclose such information on packages and bottles.[95] The proposed rule released by the FDA for comment in April 2011 "tentatively concludes that the new menu labeling requirements do not apply to alcohol beverages."[96] Thus, the final impact on alcoholic beverages remains unclear.

Finally, exactly which establishments beyond conventional restaurants fall under the regulations is yet to be determined, and will likely be finalized in 2012. The withdrawn draft guidance took a broad interpretation of covered entities, including establishments such as coffee shops, movie theaters, and airlines, which are not traditional restaurants.[97] The proposed rules offered options for determining which entities were covered more narrowly, suggesting that only establishments whose primary business activity is serving food may be covered.[98] Again, the FDA's final interpretation of covered entities is not yet clear.

The FDA should also release guidance or regulations explaining how franchises are regulated under § 4205. The language of § 4205 specifies that covered establishments are chains "with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items."[99] The FDA has stated that the determination of "whether a chain has 20 or more locations does not depend on the type of ownership of locations," and the FDA should clarify exactly how the statute applies to franchises.[100] For example, it remains uncertain whether the franchisee is required to undertake an independent nutrition analysis, or if a franchisee could rely on nutrient data provided by the franchisor, and who would be held accountable for any violations.[101]

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95. *Draft Guidance*, *supra* note 87 ("alcoholic beverages are considered food as defined in the FDCA. . . . the nutrition disclosure requirements in section 4205 apply in cases where these foods are listed on a menu or menu board or are otherwise covered under section 4205, even though they may be regulated by other agencies in other circumstances"). However, there is some discussion about requiring alcohol manufactures to provide nutrition labels on bottles. Washington Post, *Alcohol Industry Battles Among Itself Over the Issue of Nutrition Labels*, Dec. 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/12/30/AR2010123004789.html (accessed Jan. 3, 2011).

96. "FDA recognizes that at least one court has held that TTB has exclusive jurisdiction over the labels of the alcohol beverages it regulates under the FAA Act. Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976)." *Proposed Rules*, *supra* note 79.

97. *Draft Guidance*, *supra* note 87.

98. *Proposed Rules*, *supra* note 79.

99. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205 (to be codified at 21 U.S.C. § 343(q)(5)(H)). Although counter to business motives, one could envision a new phenomenon of restaurant chains with 19 locations nationally.

100. *Proposed Rules*, *supra* note 79.

101. Anthony J. Marks, *Menu Label Laws: A Survey*, 29 FRANCHISE L.J. 90, 96 (2009) ("Will a franchisee have a reasonable basis if it relies on the franchisor's information?"); Banker, *supra* note 60, at 925.

C. *Implementation and Enforcement of § 4205*

Section 4205 is currently in effect, although the FDA has decided to delay enforcement, explaining that the agency:

> is aware that industry may need additional guidance from FDA and time to comply with the provisions of section 4205 that became requirements immediately upon enactment of the law. Accordingly, FDA expects to refrain from initiating enforcement action until after a time period established in the final guidance.[102]

In August 2010, the FDA released its first guidance document, which explains that states and local governments cannot "directly or indirectly impose any nutrition labeling requirements that are different from, or not imposed by (or contained in) section 4205, or the related implementing regulations."[103] However, § 4205 does allow states and localities that meet certain criteria to apply for an exemption from § 4205, but as of January 2011, none have been filed. The draft guidance released by the FDA in August 2010 addressed the issues of which establishments are covered under the statute, food items requiring labels, disclosure of nutrition information, and compliance timing,[104] but the FDA later withdrew the guidance in January 2011, explaining that the

> FDA received many comments on the draft guidance and on a public docket which FDA opened to solicit comment. Based, in part, on these comments, FDA now intends to complete the notice and comment rulemaking process for section 4205 before initiating enforcement activities and will not be publishing a final guidance on menu labeling at this time.[105]

On April 16, 2011, the FDA released proposed rules and options under consideration, titled "Food Labeling; Nutrition Labeling of

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102. *Draft Guidance*, *supra* note 87. However, this draft guidance was later withdrawn. *Withdrawal of Draft Guidance*, *supra* note 94.

103. U.S. Food & Drug Adm'n, *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 on State and Local Menu and Vending Machine Labeling Laws*, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm223408.htm [hereinafter *Guidance for Industry*]. However, "FDA's guidance documents . . . do not establish legally enforceable responsibilities. Instead, guidance . . . should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited." *Id.*

104. *Draft Guidance*, *supra* note 87.

105. *Withdrawal of Draft Guidance*, *supra* note 94.

Standard Menu Items in Restaurants and Similar Retail Food Establishments" and "Food labeling: Calorie labeling of articles of food in vending machines," for public comment although final rules have not been released.[106]

An issue that has caused some confusion is the extent to which § 4205 is self-executing, as opposed to dependent on the issuance of specific regulations from the FDA. The statute itself explains that "not later than 1 year[107] after the date of enactment of this clause, the Secretary of HHS shall promulgate proposed regulations to carry out this clause," but there is uncertainty as to the scope and depth of the guidance the FDA, the implementing agency, will issue.[108] The FDA is in the process of accepting comments on the proposed rules, and as of October 2011, the FDA has indicated that they plan to have final regulations in place by June 2012[109] and make the regulations effective six months later.[110] Further, some confusion has existed regarding when the preemption provisions will go into effect, and thereby changing regulations that are in effect in states and localities. In the first guidance document, the FDA explained that the preemption of state and local laws that are not operationally identical to § 4205 was immediate upon the enactment of the ACA on March 23, 2010.[111] Even so, the FDA has stated that it will give restaurants time to comply before it begins to enforce the law.[112] Although that timing is not clear, it will likely be articulated in subsequent releases of guidance. In the proposed rules released in April 2011, the FDA tentatively projected that "the final rule become effective six months from the date of its publication," but noted that such a deadline was not certain.[113] Many restaurants are not expected to begin compliance until enforcement begins.[114] In addition, to the extent that litigation arises over the statute and regulations, actual implementation may be further delayed.[115]

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106. *Proposed Rules*, *supra* note 79.

107. March 23, 2011 will be one year after the enactment of the ACA. However, as of March 30, 2011, the FDA had not released guidance documents.

108. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205(b) (to be codified at 21 U.S.C. § 343(q)(5)(H)(i)) (for pertinent information, refer to Patient Protection, 124 Stat. 575.).

109. Food and Drug Administration, Implement Section 4205 of the Patient Protection and Affordable Care Act, http://www.accessdata.fda.gov/FDATrack/track-proj?program=healthcare-reform&id=ACA-4205-Implementation (last visited Oct. 20, 2011).

110. 76 Fed. Reg. 19192, 19219 (2011).

111. *Guidance for Industry*, *supra* note 103.

112. *See supra* text accompanying note 102.

113. *Proposed Rules*, *supra* note 79.

114. Janet Adamy, *Coming Soon: Theaters, Airplanes to Post Calories*, WALL ST. J. (Aug. 31, 2010), http://online.wsj.com/article/SB10001424052748704323704575462021475610064.html.

115. For example, is possible to imagine chains with fewer than 20 establishments arguing that § 4205 "impliedly preempts local menu-labeling laws to the extent that imposing stricter regulations on smaller chains defies the intent of Sec. 4205." Although those smaller chains

III. ANALYSIS OF § 4205 IN THE CONTEXT OF FEDERALISM: STATE EXPERIMENTALISM VERSUS UNIFORM FEDERAL STANDARDS AND RESULTING CHALLENGES

The U.S. Constitution does not expressly give Congress the power to promulgate specific public health regulations. Historically, public health has been an area of law and regulation reserved for the states.[116] A recent congressional report explained, "[f]ederal law has traditionally been a 'floor' in the health, safety, and environmental area, mandating minimal federal protections but allowing states to adopt more stringent requirements."[117] Over time, the role of the federal government in legislating in the name of public health has increased. Congress's power to act in the name of public health derives from the Commerce Clause, the Taxing and Spending Clause, and the Necessary and Proper Clause.[118] Presently, both the states and the federal government carry out public health practice as part of a system of cooperative federalism, where regulatory power is not neatly assigned into independent state and federal layers.[119] One of the most enduring features of federalism in the United States is the tension between the federal government and state government for control over policy.[120]

Regulation at each level of government has specific benefits and downfalls. The level of government best suited for addressing specific public health issues depends on the evidence identifying the nature of the problem, the resources available to each level to address the problem, and the probability of success.[121] For example, the federal government "has more resources and expertise in many areas and can address issues that cross state lines, while states have the ability to craft

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could simply opt into § 4205 voluntarily, the possibility of litigation to attempt to be exempted from any regulation still lingers. Banker, *supra* note 60, at 926. Furthermore, litigation could potentially proceed under the constitutional argument that § 4205 compels commercial speech improperly. In more recent years, the Supreme Court has been expanding the protection of commercial speech, so an argument of this nature is a potential, but weak, legal hurdle. Michelle M. Melo et al., *Obesity- The New Frontier of Public Health Law*, 354 NEW ENG. J. MED., 2601–10 (2006). *See, e.g.*, Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 571 (2001) (striking-down Massachusetts regulations restricting advertising of tobacco products within 1000 feet of schools).

116. *See, e.g.*, Gibbons v. Ogden, 22 U.S. 1 (1824); Willson v. Black-bird Creek Marsh Co., 27 U.S. 245 (1829).

117. Congressional Preemption of State Laws and Regulations, US House of Representative, Committee on Government Reform- Minority Staff, Special Investigations Division (June 2006).

118. GOODMAN ET AL., *supra* note 14, at 52–53.

119. Michele E. Gilman, *Presidential Power in the Obama Administration: Early Reflections: Presidents, Preemption, and the States*, 26 CONST. ARTICLEARY 339, 343 (2010).

120. GOODMAN ET AL., *supra* note 14, at 73.

121. LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 79, 3d (2008).

creative solutions to complex local problems and implement the solutions at local levels."[122] This Part first explores the benefits and consequences of different regulatory systems in section A, and then discusses the implications and resulting inconsistencies of the § 4205 regulatory ceiling under the following headings in section B: (1) Preemption of State and Local Laws; (2) Disparate Impact on Small Businesses; (3) Possible Preemption of State Common Law Tort Suits; (4) Potential Creation of a Regulatory Freeze; and (5) Additional Inconsistencies and Implementation Challenges.

A. *Federalism: Federal Floors and Ceilings*

The degree to which local, state, and federal forces are involved in each regulatory scheme varies, although it is rare for any level to surrender power completely.[123] Under the Supremacy Clause of Article VI of the Constitution, when a direct conflict exists between a federal and state statute, the federal law trumps the state law.[124] However, the Supreme Court has explained there is a presumption against preemption: "we start with the assumption that the historic police powers of the States [are] not to be superseded by [federal law] unless that was the clear and manifest purpose of Congress."[125]

In some cases, the political environment will impact the scope and reach of discretionary federal preemption in certain areas. During the Bush Administration, from 2001-2006, Congress enacted 27 statutes that preempt state health, safety and other regulations.[126] Conversely, in May 2009, President Obama released a memorandum emphasizing the important role of the states in protecting the health and welfare of the United States.[127] President Obama cautioned "preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption."[128]

Federalism and preemption can take varying forms, with different levels of government retaining different amounts and types of power. In some cases of cooperative federalism, the federal and state governments

122. GOODMAN ET AL., *supra* note 14, at 55. Often, public health regulations devised at the federal level are actively implemented at the state or local level through grant and incentive programs.

123. William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1550 (2007).

124. GOODMAN ET AL., *supra* note 14, at 51–52.

125. Wyeth v. Levine, 129 S. Ct. 1187 at 1194–95 (2009) (quoting Medtroinic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

126. GOSTIN, *supra* note 121, at 82.

127. Memorandum from President Barack Obama, http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption.

128. *Id.*

share multilayered authority.[129] Most often, the federal government will enact a legislative floor, or minimum requirement, and preserve the ability of states and localities to add additional requirements.[130] Within this structure, states and localities are not permitted to go below the floor, but can adopt more restrictive rules, thus preserving some autonomy.[131] This is a common approach for environmental laws.[132] When given the opportunity to improvise and make policy for the public's health, states "have led the way on countless matters, from requiring health insurers to cover mammograms to stringently regulating mercury emissions from power plants."[133] States are able to reach distinctive and optimal decisions that reflect the preferences of the geographic population.[134] Further, legal scholar Nina Mendelson notes that for other states and the federal government "an opportunity to learn from a particular state's unique attempts to solve its local problems is a value that accrues nationally."[135] Under such regulatory schemes, the benefits of multiple regulatory voices, creative implementation approaches, and common law litigation are retained to some extent.[136]

Conversely, when the federal government engulfs an entire sphere of regulation, it enacts a regulatory unitary federal ceiling, above which states may not regulate. Unitary federal ceilings prohibit states from adding to federal requirements in a particular area of law. In addition, ceilings do not permit state and local laws that are less stringent than the federal standard as well.[137] Until recently, unitary federal ceilings were a rarity.[138]

Different rationales exist for separate levels of government having responsibility for various issues. Preemption can be seen a positive policy or a negative policy depending on one's perspective and position.[139] "Preemption power is beneficial . . . when the context

129. *See also* ROBERT A. SCHAPIRO, POLYPHONIC FEDERALISM TOWARD THE PROTECTION OF FUNDAMENTAL RIGHTS 96 (2009) (for a discussion of polyphonic federalism, which promotes "the dynamic interaction" of multiple sources of overlapping power).

130. Buzbee, *supra* note 123, at 1554.

131. Ted Mermin, *Preemption: What it is, How it Works, and Why it Matters for Public Health*, NATIONAL POLICY & LEGAL ANALYSIS NETWORK TO PREVENT CHILDHOOD OBESITY, http://www.nplanonline.org/nplan/products/preemption-and-public-health (2009).

132. Robert R.M. Verchick & Nina Mendelson, *Preemption and Theories of Federalism*, *in* PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION 98, 101 (William W. Buzbee ed., 2009).

133. Mendelson, *supra* note 25.

134. SCHAPIRO, *supra* note 129, at 74–75.

135. Mendelson, *supra* note 25, at 767.

136. Buzbee, *supra* note 123, at 1555–66.

137. Mermin, *supra* note 131.

138. Buzbee, *supra* note 123, at 1552.

139. JAMES T. O'REILLY, FEDERAL PREEMPTION OF STATE AND LOCAL LAW: LEGISLATION, REGULATION AND LITIGATION 21 (2006) ("Different perspectives on federal preemption relate to the incentives of the viewer: '[W]here you stand on it depends on where you sit.'").

justifies the political choice to impose a single nationwide answer to a complex social concern."[140] In some cases, it is more efficient to address matters locally, and other times, a national scale provides greater efficiency.[141]

The principles in support of enacting unitary federal ceilings that preempt additional regulation are uniformity, certainty, consistency, stability, and convenience for business owners.[142] Invalidating state laws through ceiling preemption prevents a patchwork of differing laws and saves companies from accommodating each state's specific regulations.[143] For instance, corporations may favor federal preemption when it reduces potential liability and spells out uniform compliance standards, which in turn avoids balkanization and reduces production and transaction costs.[144] Businesses often argue that the costs of complying with multiple jurisdictions' heightened requirements are too expensive, and that uniformity and predictability are vital to "reducing costs and preventing inadvertent violations," and achieving economies of scale.[145] Further, some argue that the federal government has vast resources and scientific expertise with which they can better address complicated health problems.[146]

In contrast, many preemptive laws have diminished the level of protection previously afforded by local regulations. Individuals may be frustrated with preemptive regulations when such policies impose limits on damages awarded for negligent industry practices.[147] Some argue that the "patchwork" defense of ceiling prevention tends to be more "hypothetical than real," because businesses have managed to adapt to different regulations both in the United States and abroad, and other countries often have more stringent regulations regardless.[148] Often, "the unfortunate result [of ceiling preemption] is that big businesses' revenues are being shielded, while protections for consumers and the environment are being stripped away."[149] Further, complete preemption reduces the amount of debate over and education about local policies,[150] and often fails to fit local needs because the "unit of governance closest

140. *Id.* at 210.

141. ERWIN CHEMERINSKY, ENHANCING GOVERNMENT: FEDERALISM FOR THE 21ST CENTURY 119 (2008).

142. GOODMAN ET AL., *supra* note 14, at 73.

143. Mermin, *supra* note 131.

144. Gilman, *supra* note 119, at 383; Robert L. Glicksman & Richard E. Levy, *A Collective Action Perspective on Ceiling Preemption by Federal Environmental Regulation: The Case of Global Climate Change*, 102 NW. U. L. REV. 579, 591 (2008).

145. Mermin, *supra* note 131.

146. GOSTIN, *supra* note 121, at 109.

147. Gilman, *supra* note 119, at 383.

148. Mermin, *supra* note 131.

149. Mendelson, *supra* note 25.

150. GOODMAN ET AL., *supra* note 14, at 74.

to the people is likely to be most responsive to people's needs."[151] Preemption ceilings can result in a regulatory freeze, where the law does not change because there is little energy and incentive to improve existing laws and make them better. As Justice Brandeis explained, "[i]t is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[152] When states are not afforded the ability to experiment, interact, and try new approaches due to federal ceilings, there is often little opportunity and incentive to adjust existing federal laws.[153] In such cases, preservation of common law tort and nuisance liability can also be used to retain incentives to continuously improve operations and makes changes to reduce risk.[154]

In addition to quashing incentives to improve existing laws, federal regulatory ceilings are often administered through agencies, which can present another layer of separation from states' interests. Nina Mendelson complains that federal agencies often lack the capacity to weigh the values of "abstract federalism," such as the impact of regulations "upon a state's dignity or a state's function as a policy 'laboratory' or center of democratic activity."[155]

B. *Problematic Uncertainties of § 4205 in the Context of Federalism*

As explained in Part II, § 4205 explicitly preempts state and local laws regarding nutrient disclosure on menus that do not use the language of § 4205 itself.[156] This section first explores the preemption

151. O'REILLY, *supra* note 139, at 209.

152. New State Ice Co. v. Liebmann, 285 U.S. 262 (1932) (Brandeis, J., dissenting).

153. What may seem like a good trade now may consequently prevent even better regulations in the future. For example:

> In the 1980s having separate sections for smokers and nonsmokers in restaurants seemed like a bold proposal. But, if to secure a statewide "smoking section" law, advocates had agreed to then preempt all local laws having to do with smoking in restaurants, there would have been no opportunity a decade later to enact local laws banning smoking from restaurants entirely.

Mermin, *supra* note 131.

154. Buzbee, *supra* note 123, at 1588. Buzbee notes "As the Supreme Court majority concluded in the *Bates*, such common law incentives can reinforce and supplement the protections provided in regulatory regimes." *Id.* at 1588–89.

155. Mendelson, *supra* note 135, at 781–82.

156. For a comparison of some existing local laws to the federal law, *see generally* Center for Science in the Public Interest, Comparison of Menu Labeling Policies, http://cspinet.org/new/pdf/comparison_of_ml_policies_6-9.pdf (last visited Aug. 1, 2011).

provisions of § 4205, and examines the possibility of exemptions to the preemption requirements. This section then explores how different stakeholders will likely receive § 4205, the potential preemptive effect of § 4205 on state common law tort suits, and the potential for § 4205 to create a regulatory freeze, and will identify additional problematic uncertainties of § 4205.

1. Section 4205 Expressly Preempts State or Local Laws Regarding Nutrient Disclosure that are Different From § 4205, But Exemptions from Preemption May Be Available

Public health advocates see § 4205 as a mixed blessing. In one sense, § 4205 expands menu disclosures to states and localities that would probably not have enacted regulations on their own. On the contrary, § 4205 usurps local power, preventing states and localities from implementing regulations that require greater disclosure, and limiting their ability to develop their own innovative approaches to the problem of food labeling.

Some states and localities enacted anticipatory regulations predating § 4205 to actively prevent menu disclosures. For example, in Georgia, the General Assembly passed a ceiling preemption provision that prohibits local menu labeling laws, even though Georgia has no state menu labeling law.[157] Conversely, some localities already had menu labeling regulations prior to the passage of the ACA that exceeded the level of disclosure in § 4205. Those laws are essentially void for chains with over 20 locations, unless the localities apply for, and are granted, an exemption from the FDA.

Additional disclosures on menu boards may be an important and timely public health tool. For example, in 2007, Metropolitan King County City Council of Washington amended the Board of Health regulations to require chain restaurants (any restaurant with more than 10 establishments under the same name in the United States) to provide the total number of calories, fat, saturated fat, carbohydrates, and sodium on menu boards, beginning in 2008.[158] Further, in January 2011, a report on the U.S. Dietary Guidelines was released that recommended that people reduce sodium intake to 2300 mg per day, and those with certain complicating factors (which includes approximately half of the population) further reduce intake to 1500 mg per day.[159] Sodium is a

157. GA. CODE ANN. § 26-2-373(a) (2009). "[N]o county board of health or political subdivision of this state shall enact any ordinance or issue any rules and regulations pertaining to the provision of food nutrition information at food service establishments." *Id.*

158. King County Health Code tit. 5, ch. 5.10.015. *See also* City of Philadelphia Bill No. 080167-A, 2008 Leg. Sess. (amending Philadelphia Health Code tit. 6, § 102; § 308).

159. U.S. DEPT. OF AGRICULTURE & U.S. DEPT. OF HEALTH AND HUMAN SERVICES DIETARY GUIDELINES FOR AMERICANS (7th ed. 2010).

significant public health challenge, and foods that are low in calories are not necessarily low in sodium.[160] Certainly, a clear and prevalent announcement of sodium content in restaurant foods on menus may help people make informed decisions resulting in reduced sodium intake, and the same rationale may be extended to other ingredients and consequential health complications.

In a guidance document that was released in August 2010, the FDA explained that states and localities that had their own nutrition labeling requirements prior to the enactment of the ACA may apply for an exemption from the preemption provision in the law.[161] The Secretary of HHS may grant such exemptions if the state requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement (21 U.S.C.S. § 343-1(a)).[162] It is unclear how liberal the FDA will be in granting exemption petitions, and as of January 2011, no exemption petitions have been filed. While the guidance seems to imply that only state and local laws that were enacted before the ACA qualify, it would not be unreasonable for the FDA to also consider exempting state and local regulations that were proposed, but not enacted, prior to the enactment of the ACA.[163]

2. Section 4205 Exempts Restaurants with Fewer than Twenty Establishments From the Federal Regulations, Thus Smaller Businesses Will Not Bear Equal Responsibility for America's Weight Crisis

Section 4205 created a fundamental inconsistency between chains of twenty or more locations and those of less than twenty locations. As such, restaurants with fewer than twenty establishments will not necessarily bear equal responsibility for America's weight crisis. With the passage of the ACA, small chains and single establishment restaurants still fall under local and state jurisdiction regarding menu-labeling disclosures. Some state and local laws currently in effect apply to restaurant chains with 15 or more outlets nationwide, a broader reach than the new federal law.[164]

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160. For example, Chili's Chicken Enchilada soup only has 400 calories but has 1630 mg of sodium. Chili's, http://www.chilis.com/EN/Nutrition%20Information/Chilis_Nutrition_Menu_Generic.pdf (last visited Feb. 12, 2011).

161. *See Guidance for Industry*, *supra* note 103 (explaining that the FDA's regulations allow any State or locality to petition the FDA for an exemption from preemption, and describing the procedure).

162. 21 U.S.C.S. § 343-1(b).

163. *See infra* note 241 and accompanying text.

164. Banker, *supra* note 60, at 909; *see, e.g.*, King County Health Code tit. 5, ch. 5.10.015 (2007); City of Philadelphia Bill No. 080167-A (amending Philadelphia Health Code tit. 6, §

With the passage of the ACA, small businesses could be subject to more stringent local laws if states or localities enact laws applying to restaurants with fewer than 20 locations. However, even if such laws are passed regulating restaurants with fewer than 20 locations, if establishments would prefer to operate under § 4205, they can opt in.[165] Of course, localities could pass local laws that are identical to § 4205, in effect eviscerating the option of small businesses to opt in to the federal statute. At the same time, it is likely that many localities may not pass local laws, because localities may not have much of a political incentive to devote resources to regulating restaurants with fewer than 20 locations and such restaurants can still opt into § 4205 compliance. Thus, such restaurants would be exempt from any disclosure regulations, and would therefore have a potential economic advantage over larger establishments.[166] Conversely, according to one estimate, businesses with 20 or more outlets covered by § 4205 comprise only 25% of the restaurant industry, so localities may still try to regulate smaller businesses.[167]

Accordingly, small chains and individual establishments will likely wait to see if localities enact new regulations. If local laws are nonetheless enacted, the restaurants and chains with less than 20 locations will likely compare those regulations to § 4205, and likely opt in to § 4205 if those standards are more desirable.[168] This policy was likely enacted to protect small businesses from costs of nutrient calculation and posting, but this inconsistent treatment of establishments by size will create an informational vacuum for the consumer. Chains without any menu disclosure may skew patrons' perceptions of what is actually healthy.[169] Patrons will have a limited awareness of calorie counts, and because they are exempt from regulation under the ACA, there are no incentives for smaller chains to offer healthier dishes. The ability to choose which regulations, if any, to operate under creates inefficiency based on the size of restaurant businesses and creates a disparate burden for large restaurant establishments as opposed to smaller enterprises.

102; § 308).

165. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205(b) (to be codified at 21 U.S.C. § 343(q)(5)(H)(i)).

166. While the Starbucks study found no loss in revenue when calories were posted, more research must be done to fully understand the economic impact of calorie postings and lack thereof. Bolinger et al., *supra* note 57.

167. Banker, *supra* note 60, at 928 (citing Julie Jargon, *Menu Labeling Stirs Controversy*, WALL ST. J., July 17, 2009, http://online.wsj.com/article/SB124786160526159703.html).

168. *Id.* at 925.

169. One could compare this discrepancy to foods sold in grocery stores. Typically, the unlabeled foods (*e.g.*, fruits and vegetables) are healthier than the packaged food with nutrient disclosures.

An additional potential challenge exists regarding establishments that may not fall under the FDA's definition of covered entities; if the FDA construes § 4205's language narrowly, such businesses would fall outside preemption exemption existing in § 4205 that allows for state and local regulation of chains with less than 20 establishments.[170] For example, if the FDA does not include hospitals as a covered establishment, then a state or locality may be prohibited from regulating the hospital because it is not a covered entity with less than 20 locations. Such an interpretation "would risk creating a regulatory gap that would be inconsistent with the purposes of section 4205." The FDA should clarify its interpretation and allow states and localities to require nutrition labeling for food sold by entities not covered under § 4205 per the FDA's final rules.[171] America's obesity crisis is a public concern with public implications, and policies should be designed so that responsibility is borne equally by all business leaders.

3. Section 4205 is Silent Regarding Possible Preemption of State Common Law Tort Suits, Presenting a Problematic Uncertainty and Potentially Eroding Consumer Safety

In addition to express preemption issues, there are other consequences of § 4205 preemption to consider. For instance, § 4205 is silent on its potential preemptive effect on fast food lawsuits. This is problematic because the provision could be interpreted as a barrier for recovery in tort suits, which often serve as a safety valve for the general public and can catalyze improvements in laws.

a. Fast Food Tort Lawsuits

Tort litigation can be an effective tool to promote the public's health, although the litigation system does impose economic costs and other burdens on stakeholders, such as restaurants and the general public whose taxes fund the court system.[172] To date, fast food lawsuits predicated on restaurant foods as the cause of health problems have not fared well in courts, but considering the evolution of tobacco litigation, it is not implausible to imagine some tort success against fast food restaurants in the future. The general unwillingness of courts to entertain lawsuits involving claims for obesity related health issues resulting from fast food consumption rests on the ideas of personal responsibility and individual rights.[173] The danger of restaurant food is

170. *Proposed Rules*, *supra* note 79.
171. *Id.*
172. GOSTIN, *supra* note 121, at 182.
173. *See generally* Glenna Novack, *Lawsuits in the Fast Food Nation*, 52 WAYNE L. REV.

less clear because food in general is not inherently dangerous and causal conclusions may be more difficult to draw.[174] Regardless of the strength of their suits, some plaintiffs file simply to arouse negative publicity for the food or beverage manufacturer or restaurant, or in order to compel restaurants to change their menu offerings to include healthier choices.[175]

Pelman v. McDonald's Corp. is the first fast food tort lawsuit claiming damages from obesity related health problems as the result of fast food consumption.[176] In *Pelman*, two minors brought a suit against McDonald's, claiming that the fast food chain made them overweight, and as a result, contributed to multiple health problems including heart disease, diabetes and elevated cholesterol levels.[177] The plaintiffs brought multiple causes of action against McDonald's, including deceptive advertising and business practices, negligence in selling unhealthy and dangerous products, failure to warn, and negligence in marketing.[178] The consumers claimed that McDonald's promoted frequent use of its products through advertising, despite knowing that the products were dangerous.[179] Further, the plaintiffs claimed McDonald's was negligent because it knew the dangers of fast food and did not properly disseminate this information to the general public.[180] The District Court in New York dismissed the case, based on rationales of personal responsibility and common knowledge of the dangers of fast food.[181] Essentially, while the plaintiffs were able to establish that they relied on McDonald's advertising in purchasing large amounts of its products, they could not show that the consumption of McDonald's products was the principal cause of the their health problems, or that the McDonald's advertisements were "objectively deceptive."[182] On appeal,

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174. GOODMAN ET AL., *supra* note 14. Sarah Taylor Roller et al., *Obesity, Food Marketing and Consumer Litigation: Threat or Opportunity?*, 61 FOOD DRUG L.J. 419, 443 (2006) ("Consumers cannot prevent diet-related disorders solely by avoiding particular food products."). Some plaintiffs argue that restaurants should give warnings and instructions adequate to inform consumers of the possible risks of eating fast food. Rothenberg, *supra* note 9, at 225.

175. Rothenberg, *supra* note 9, at 203; Alyse Meislik, Note, *Weighing in on the Scales of Justice: The Obesity Epidemic and Litigation Against the Food Industry*, 46 ARIZ. L. REV. 781, 795 (2004) ("Thus, even though Pelman was unsuccessful in the courts, the lawsuit most likely was a significant motivating force for McDonald's to offer its customers healthier dietary choices").

176. Pelman v. McDonald's Corp., 237 F. Supp. 2d 512 (S.D.N.Y. 2003).

177. *Id.* at 519.

178. *Id.* at 521.

179. *Id.* at 527–29.

180. *Id.* at 529.

181. *Id.* at 516, 543.

182. Donald R. Richardson, Note, *"Want Fries With That?" A Critical Analysis of Fast Food Litigation*, 107 W. VA. L. REV. 575, 583 (2005).

the U.S. Court of Appeals for the Second Circuit allowed the plaintiffs' claims alleging deceptive representation of the nutrition benefits of McDonald's food to proceed to trial, and remanded the case for further proceedings to give the plaintiffs the opportunity to prove the causal relationship between consumption of McDonald's food items and their poor health.[183] Following the District Court's decision in *Pelman*, numerous other plaintiffs tried to bring similar lawsuits, but none have succeeded.[184]

b. Parallels to Big Tobacco Litigation

Like *Pelman* and similar lawsuits, tobacco lawsuits also initially failed in court. It was only after a movement in societal perception, which "shifted public sentiment from a focus on personal responsibility to a concentration on holding big tobacco responsible," did such litigation ultimately succeed.[185] Accordingly, it is possible, and indeed many scholars think probable, that attitudes regarding fast food, potential addictive properties of fast food,[186] obesity as an illness, and notions of corporate responsibility could shift and create a social and legal environment that is more receptive to fast food tort litigation.

Before the risks of smoking, and the tobacco industry's knowledge of such risk, were widely understood, the public generally objected to

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183. *Pelman*, 396 F.3d at 508. Pelman is still active. In October 2010, the District Court denied the Plaintiffs' motion for class certification. Pelman v. McDonald's Corp., 2010 U.S. Dist. LEXIS 114247 (S.D.N.Y. Oct. 27, 2010).

184. *See, e.g.*, Hoyte v. Yum Brands, Inc., 489 F. Supp. 2d 24, 26 (2007) (Where a physician brought a class action suit against Yum Brands, Inc., which owns KFC, alleging that KFC failed to disclose the presence of transfat in its food and that KFC's statement that its food could be part of a healthy lifestyle was negligent misrepresentation. The District Court found that the physician failed to allege injury and the advertising claim was puffery.).

185. Novack, *supra* note 173, at 1313.

> Just as tobacco companies had to help defray the health costs their products created, fast food companies could be held liable in order to help pay for the obesity epidemic their product helped create. Fast food companies may be liable for creating this disease in people in the same way they would be liable if they put addictive drugs in their food.

Id. at 1322. *See generally* Joshua Logan Pennel, Article, *Big Food's Trip Down Tobacco Road: What Tobacco's Past Can Indicate About Food's Future*, 27 BUFF. PUB. INTEREST L.J. 101 (2008).

186. *See* Roni Caryn Rabin, *Can You Be Addicted to Foods?*, N.Y. TIMES (Jan. 5, 2011), http://well.blogs.nytimes.com/2011/01/05/can-you-be-addicted-to-foods/?ref=health (explaining that the type of high-sugar, fat, and salt laden foods served at fast food chains can actually change brain chemistry and trigger a "neurological response that stimulates people to crave more food, even if they're not hungry. The sense some people have that they cannot control their intake may in fact be true"). *See generally* Jennifer Pomeranz et al., *Innovative Legal Approaches to Address Obesity*, 87 MILBANK Q., 185, 195–97 (2009).

holding cigarette companies liable for the "consequences of what was seen as purely a personal choice."[187] Similarly, some scholars seem convinced that "fast food suits will almost certainly succeed at some point"[188] if deception by the food and beverage industry is discovered,[189] and feel that "the history of tobacco litigation is the future of the fast food industry."[190] However, the comparison of obesity to tobacco has a major limitation; cigarette smoking is an inherently dangerous practice, while consumption of food is essential for life. Even so, most fast food is arguably not inherently healthy either, and fast food litigation certainly has the potential to increase in frequency and legitimacy.

c. Federal Reaction to Fast Food Tort Lawsuits

As the incidence of obesity related lawsuits grew following *Pelman*, a Senate subcommittee analyzed the need for tort reform in order to protect restaurants and food companies from frivolous lawsuits claiming that plaintiffs' obesity is the result of long term consumption of certain types of food.[191] Such a strong government response may indicate, in fact, that such lawsuits are not entirely frivolous.[192] The Personal Responsibility in Food Consumption Act of 2005 (nicknamed the "Cheeseburger Bill") was proposed to prevent civil liability actions brought against food manufacturers, marketers, distributors, advertisers, sellers and trade associations for claims of injury relating to "a person's weight gain, obesity or any health condition associated with weight gain or obesity."[193] Although the federal bill failed to become law, restaurant and food production companies lobbied states and donated millions of dollars toward the development of similar state limits on fast food tort suits.[194] As of 2010, twenty-four states have passed legislation that limit

187. GOSTIN, *supra* note 121, at 213.

188. Novack, *supra* note 173, at 1326.

189. For example, "manipulating sugar and fat content or portion size, targeting children, or misleading the public." GOSTIN, *supra* note 121, at 213.

190. Franklin E. Crawford, *Fit for Its Ordinary Purpose? Tobacco, Fast Food, and the Implied Warranty of Merchantability*, 63 OHIO ST. L.J. 1165, 1169 (2002).

191. S.908. Common Sense Consumption: Super-Sizing Versus Personal Responsibility: Hearing before the Subcomm. on Admin. Oversight and the Courts of the S. Judiciary Comm., 109th Cong. (2005).

192. Meislik, *supra* note 175, at 782. "[T]he food industry and the government behave as though the obesity suits are not frivolous. As of August 2003, state lawmakers had filed more than 140 bills aimed at obesity." *Id.*

193. Rothenberg, *supra* note 9, at 206; H.R. 554, 109th Cong. (2005).

194. Melanie Warner, "The Food Industry Empire Strikes Back: Lobbying Effort to Shield Companies from Court Action is Gaining Ground," N.Y. TIMES (July, 7 2005), http://www.nytimes.com/2005/07/07/business/07food.html?scp=1&sq=the%20food%20industry%20strikes%20back&st=cse ("[i]n the 2002 and 2004 election cycles, the food and restaurant industry gave a total of $5.5 million to politicians in the 20 states that have passed

obesity liability by preventing individuals from suing restaurants, food manufacturers and marketing firms for contributing to unhealthy eating, weight gain and related health problems.[195] Regardless of commonsense consumption laws, tort claims based on grounds that products are unreasonably dangerous, and a reasonable alternative design exists, may still be viable.[196]

d. Section 4205 and Potential Preemption of State Fast Food Tort Suits

Section 4205 does not include any language that specifically addresses its impact on potential state tort lawsuits, but does note that it shall not be construed to preempt any provision of state or local law, except regarding covered disclosures. There are many cases that address the question of interpreting federal statutes that do not specifically address potential preemption of state common law suits.[197] In some cases, the Supreme Court has held that federal law can preempt state lawsuits. The Court has been willing to assert federal authority in areas of regulation traditionally reserved for the states, such as products liability and state tort law.[198] However, in preemption cases, the Supreme Court has noted "'and particularly in those in which Congress has legislated . . . in a field which the States have traditionally occupied,' . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[199]

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laws shielding companies from obesity liability.").

195. LEVI ET AL., *supra* note 7, at 47. ("Twenty-four states have passed obesity liability laws: Arizona, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Louisiana, Kansas, Kentucky, Maine, Michigan, Missouri, New Hampshire, North Dakota, Ohio, Oregon, South Dakota, Texas, Tennessee, Utah, Washington, Wisconsin and Wyoming."). Interestingly, Georgia, for example, both limits obesity liability and before the enactment of the ACA also passed a law to prevent state and local menu disclosures. In effect, Georgia did not allow consumers to gain access to information, nor bring lawsuits, thus eviscerating consumer protection to a large degree. *See* GA. CODE ANN. § 26-2-373(a) (2009); GA. CODE ANN. § 26-2-432 (2011).

196. GOSTIN, *supra* note 121, at 114.

197. However, some statutes have express preemption provisions. For example, courts have held that the express preemption provision in the NLEA explicitly preempts certain state laws that address specific subjects covered under the NLEA and the FDCA. John B. Reiss et al., *Your Business in Court: 2008-2009*, 64 FOOD DRUG L.J. 755, 797 (2009). For a recent discussion of labeling regulation and preemption, see Holk v. Snapple Bev. Corp., 575 F.3d 329, 339, 342 (3d Cir. N.J. 2009).

198. Jack M. Beermann, *The Supreme Common Law Court of the United States*, 18 B.U. PUB. INT. L.J. 119, 152, 154 (2008).

199. Wyeth v. Levine, 129 S. Ct. 1187, 1194 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (2006) (in turn quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (internal quotation marks omitted).

The most recent Supreme Court decisions that are applicable to the question of preemption in food labeling addressed preemption in the field of medical device and drug labeling. In 2007, the Supreme Court held in *Riegel v. Medtronic* that Section 360k(a) of the Medical Device Amendments to FDCA preempts state law claims seeking damages for injuries caused by medical devices that received premarket approval from the FDA.[200] In *Riegel*, Justice Scalia noted the ineffective nature of the tort system because juries do not engage in cost-benefit analysis.[201] Further, state tort law that would require devices to be safer, but less effective than the FDA's model, "disrupts the federal scheme."[202] A similar argument could be applied to § 4205, specifically that common law tort suits may be an ineffective approach to nutrient regulation. However, premarket approval of medical devices is an arduous and thorough process that weighs benefits and risks, while menu labels simply present information. Thus, the application of *Riegel*'s holding to § 4205 is tenuous, at best.

Two years later, in *Wyeth v. Levine,* the Supreme Court found that a FDA label approval for a warning label on a drug product did not preempt state laws and shield the manufacturer from damages.[203] The Court differentiated *Wyeth* from *Riegel* because:

> [i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices . . . Congress has not enacted such a provision for prescription drugs.[204]

Similarly, Congress declined to enact such a provision for menu labeling when it designed § 4205. Moreover, the Court rejected the argument that requiring drug manufactures to "comply with a state-law duty to provide a stronger warning . . . would obstruct the purposes and objectives of federal drug labeling regulation" as an "overbroad view of an agency's power to preempt state law."[205] Such reasoning can also be extrapolated to the additional layer of safety resulting from common

200. 552 U.S. 312 (2008).

201. *Id.* at 325 (2008).

202. *Id.*

203. 129 S. Ct. 1187 (2009) (In this case, there was evidence that Congress did not intend for the FDA to be the only avenue for ensuring drug safety and effectiveness.). The Vermont Supreme Court held that "Plaintiffs negligence and product-liability claims fall squarely within the scope of traditional state regulations, so it is appropriate to apply the presumption against preemption here." Levine v. Wyeth, 944 A.2d 179, 187 (Vt. 2006).

204. Wyeth, 129 S. Ct. at 1200.

205. *Wyeth*, 129 S. Ct. at 1190.

law tort suits.

As the Supreme Court continues to refine its analysis of preemption cases,[206] it is unclear how courts will interpret the scope of § 4205, which is silent regarding state common law tort suits. Courts will likely find that Congress has not regulated the entire field of menu labeling in § 4205, and there is room left for states to consider tort actions. After *Riegel* and *Wyeth* it appears that congressional intent will be the "touchstone" used to determine the existence of both implied and express preemption under the FDCA.[207] Accordingly, § 4205 will likely not be read to preempt state common law because there is no express congressional intent that it should preempt state common law tort suits. Simple compliance with a regulatory scheme not intended to provide safety measures should not necessarily be seen as a source of immunity.[208] In addition, the menu label mandated by § 4205 simply provides information, but does not assert to guarantee a level of safety. Calorie labels present information and do not make claims or warnings about consumption, while warning statements make a clear claim or provide explicit instructions regarding safety. Further, because § 4205 reflects a compromise with large businesses (in that they will not be subject to a patchwork of local and state regulation), Congress's declination to include any language referring to protection of state tort lawsuits may, in fact, further imply that such lawsuits are not preempted.

Finally, state tort law has historically been a question for state judicial systems. In addition to being a state law issue, preserving the ability of plaintiffs to bring tort suits will help to ensure continuing consumer protection and safety by bringing to light otherwise hidden information, offsetting weak regulation,[209] raising awareness about issues, stimulating fruitful dialogue, and potentially compelling innovation and reform in food policy, particularly where increased regulations are not available.[210]

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206. 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, 772 (2008).

207. Reiss et al., *supra* note 197, at 789.

208. O'REILLY, *supra* note 139, at 88 ("compliance with regulatory norms is usually a minimum, not a source of immunity from liability").

209. William Funk et al., *The Truth about Torts: Using Agency Preemption to Undercut Consumer Health and Safety*, CENTER FOR PROGRESSIVE REFORM, Sept. 2007, *available at* http://www.progressiveregulation.org/articles/Truth_Torts_704.pdf.

210. GOODMAN ET AL., *supra* note 14, at 430. For example, in 2003, BanTransFat.com filed a lawsuit against Kraft, alleging that Oreos contain trans-fats, which are not safe for consumption. The plaintiffs ultimately dropped the lawsuit when Kraft announced an overhaul of its food products as a result of the public attention the case created. Meislik, *supra* note 175, at 792.

4. Section 4205 is Vulnerable to Creating a Regulatory Freeze That Does Not Tailor Interventions to Fit Community Needs

The uniform ceiling created by § 4205 is inherently vulnerable to creating a regulatory freeze, both federally and locally.[211] The statute does not reward nor require the FDA to reexamine, reassess, and improve upon past regulations and actions.[212] Because agencies must balance limited resources, the FDA could very well focus on more immediate crises rather than act to improve or reexamine § 4205.[213]

In addition, many public health problems, including obesity, are not distributed uniformly across the United States; obesity challenges may differ between urban and rural populations, different ethnicities, and other factors.[214] Some scholars argue that centralized solutions often fail because such approaches cannot account for "the wide variation in circumstances among individuals, ranging from differences in genetics to environmental factors."[215] Thus, the ceiling preemption in § 4205 essentially erases the possibility of tailoring local interventions to specific community needs. Practically, it is less likely § 4205 would have been passed as an explicit floor due to strong business interests in having a uniform federal policy that capitalizes on economies of scale.[216] However, it is important to recognize the likely reduction in, or abolishment of, innovation that will result.

Because states can now only regulate smaller establishments that still retain the option to opt in to the federal scheme, there will be little, if any, incentive for states and localities to use legislative resources to enact new policies because the number of restaurants subject to new state and local regulations will be drastically reduced, and such establishments can choose to opt out by complying with § 4205. Already, in Montgomery County, Washington, county executives have decided to delay enforcement of a local menu labeling regulation, explaining that "the most prudent course of action is to proceed with enforcing the components of county law that are identical to [§ 4205]

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211. Preemption can be express or implied. Mermin, *supra* note 131. Section 4205 contains an express preemption clause. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205(b) (to be codified at 21 U.S.C. § 343(q)(5) (H)).

212. Buzbee, *supra* note 123, at 1593.

213. *Id.* at 1593–94.

214. Rutkow et al., *supra* note 206, at 773.

215. GOSTIN, *supra* note 121, at 501. An example of a community-specific solution to obesity is zoning. South Los Angeles has high rates of obesity and poverty compared to surrounding neighborhoods, so the City Council effectively banned new fast food restaurants in that area. Jennifer Medina, *In South Los Angeles, New Fast Food Spots Get A 'No, Thanks,'* N.Y. TIMES (Jan. 15, 2011), http://www.nytimes.com/2011/01/16/us/16fastfood.html?_r=3&src=twrhp&source=govdelivery.

216. For example, national franchises may produce one type of menu board, but different state or local regulations on top of a national floor might necessitate custom boards.

and delay those components of county law that the FDA will address in federal regulations."[217] The same holds true in New Jersey, where Governor Jon Corzine signed a calorie disclosure law that has not yet been implemented.[218] Health and Senior Services Department spokeswoman Donna Leusner announced "[i]nstead of confusing businesses and the public with two sets of rules, the department is trying to be business-friendly by at least waiting to see what the FDA proposes in March."[219]

Thus, the effect of § 4205 will be a reliance on a static status quo, both federally and locally, without substantial encouragement for experimentation with different policy choices. [220] Given that obesity is a complex challenge and important public health issue, such a regulatory freeze is a poor long-term strategy. Many critics argue that current anti-obesity policies are not effective,[221] so stifling innovation could lead to even more chronic illness and higher taxpayer costs. It is impossible to predict how the fight against obesity will take shape, and § 4205 engulfs an entire sphere of disclosure without leaving room to grow and change to best incorporate new research and innovative approaches to combating obesity through nutrient disclosure.

5. Section 4205 Presents Additional Inconsistencies and Implementation Challenges of Note

In addition to inconsistencies regarding businesses with under 20 establishments, silence regarding state tort lawsuits, and the potential to create a regulatory freeze, § 4205 presents other inconsistencies and implementation challenges. Namely, the FDA has been charged with promulgating regulations for and implementing § 4205 but it is not yet clear how the FDA will interpret all parts of § 4205, or how much flexibility the FDA will leave to the states and business.

a. Regulation and Enforcement

It is unclear how § 4205 will be regulated and enforced, and how

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217. Brian Hughes, *Montgomery Scales Back Menu Labeling*, WASH. EXAMINER, Dec. 22, 2010, http://washingtonexaminer.com/blogs/capital-land/2010/12/montgomery-scales-back-menu-labeling.

218. Susan K. Livio, *State Isn't Embracing New Menu Label Law*, NORTH JERSEY.COM, Jan. 20, 2011, http://www.northjersey.com/news/health/nutrition/114259754_State_isn_t_embracing_new_menu_ label_law.html.

219. *Id.* The FDA released proposed rules in April of 2011, but final rules are not expected to be implemented until 2012.

220. The status quo bias is a phenomenon where "individuals will generally oppose change." Buzbee, *supra* note 123, at 1608.

221. GOSTIN, *supra* note 121, at 501.

much variance in calorie content between what is posted on menus and what is actually in food samples will be acceptable.[222] A 2010 study by Tufts University researchers found that where calorie content of menu items was disclosed in restaurants, the actual calories varied significantly from the posted calories, and in many instances averaged 18% higher than the stated values, with some items containing over 200% more calories than stated.[223]

The FDA has not indicated if they will contract with state and local public health departments to enforce the statute, or if it will regulate restaurants and vending machines itself and in either case, where the funding will come from. The FDA should consider how to control for variation in compliance and inspection procedure. Some scholars question whether the FDA is even competent to implement and enforce menu-labeling requirements.[224] State and local health departments may be more adept, as they "likely have preexisting relationships with local restaurateurs via enforcement of other state and local food safety and health code regulations."[225] Further, state and local agencies often have greater knowledge of local problems and more direct political accountability, as well as the ability to meet diverse needs.[226]

Because the FDA has not yet indicated the enforcement structure of § 4205, states and locales may consider enacting their own menu label laws that are operationally identical to the final federal regulations.[227] A parallel law would likely give the states and localities authority necessary to enforce the disclosure requirements at a local level. The fact that § 4205 leaves some regulatory room available for state and local governments to regulate establishments with less than twenty locations shows some intent of Congress to leave some power with states and localities to police the regulatory scheme.[228]

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222. For example, California's law directs local inspectors to check menu labels requires fines for infractions. CAL. HEALTH & SAFETY CODE § 114094 (West 2009).

223. Lorien E. Urban et al., *The Accuracy of State Energy Contents of Reduced-Energy, Commercially Prepared Foods*, 110 J. OF THE AM. DIETETIC ASS'N 116, 116–23 (2010).

224. *See supra* note 156.

225. Banker, *supra* note 60, at 928. However, the FDA has administered the NLEA for almost twenty years, although the NLEA explicitly exempts restaurants. *Id.*

226. GOSTIN, *supra* note 121, at 79; ERWIN CHEMERINSKY, ENHANCING GOVERNMENT: FEDERALISM FOR THE 21ST CENTURY 123 (2008) ("[T]there are significant differences between the needs in Manhattan as compared to, say, rural Mississippi.").

227. "'Not identical to' does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations . . . [that] Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation)." 21 C.F.R. 100.1(c)(4).

228. If states and localities do not take such steps, they may face an effective vacuum of null preemption in the face of inaction. *See generally* Jonathan Remy Nash, *Null Preemption*, 85 NOTRE DAME L. REV. 1015, 1021 (2010) ("In essence, null preemption arises where two things happen: (1) the federal government establishes a "zero level" of federal regulation, and (2) the federal government preempts the states from filling the regulatory void.").

Moreover, it is unclear which, if any, individuals will have standing to bring lawsuits against restaurants for noncompliance and what such penalties might be.[229] Thus, the preemptive reach of § 4205 in the name of national uniformity may lead to implementation challenges as the FDA attempts to regulate an area that has traditionally been reserved for the states. The FDA should be sure to address these issues when releasing additional guidance documents and final rules.

b. Contextual Calorie Number on Menus

Section 4205 mandates the presentation of "a succinct statement concerning suggested daily calorie intake . . . designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided" on menu boards so consumers will be able to compare totals for individual food items to suggested daily consumption.[230] The FDA is charged with the responsibility of determining this number.[231] In proposed rules, the FDA "tentatively concludes that 2,000 calories is an appropriate reference value to include in the succinct statement," but should be presented in a way that serves to "inform consumers that individual needs vary."[232]

While presenting a contextual calorie number is a promising idea, one number is not a sufficient guide for all people. Sex, weight, activity level, and other factors all contribute to how many calories an individual should consume daily.[233] The 2010 U.S. Dietary Guidelines Report lists target calorie ranges for children and adults that range from 1000 to 3000 calories per day.[234] Accordingly, this part of § 4205 requires a more thoughtful application that accounts for discrepancies in average intake between people and also for children. Some possibilities are to present daily calorie ranges, averages for different ages, sexes, and weights, or including a different number for children.

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229. Further, there is the possibility that mislabeling could be a topic of interest for industrious litigators. Green, *supra* note 37, at 770. For example, two Kentucky women recently filed a lawsuit against Applebee's Restaurants for lying about fat and calorie content of certain menu items (which was voluntarily posted), seeking damages for consuming food that was more calorie and unhealthy than represented. Ashlee Clark, Florence Women Sue Applebee's, Weight Watchers, Sept. 7, 2009, LEXINGTON HERALD-LEADER, http://www.kentucky.com/2009/09/07/924591/florence-women-sue-applebees-weight.html#more.

230. Pub. L. No. 111-148, H.R. 3590, 111th Cong. § 4205 (to be codified at 21 U.S.C. § 343(q)(5)(H).

231. *Id.*

232. *Proposed Rules, supra* note 79.

233. 7 U.S. DEPT. OF AGRICULTURE & U.S. DEPT. OF HEALTH AND HUMAN SERVICES. DIETARY GUIDELINES FOR AMERICANS 26 (2010).

234. *Id.*

IV. MENU OF RECOMMENDATIONS

Section 4205 is a progressive policy rightly aimed at preventing and reducing obesity, but the passage of § 4205 may have been premature and incorrectly designed. Given the range of implementation inconsistencies, challenges, and potential consequences discussed in Parts I through III, it is vital for policymakers to reconsider the language and interpretation of § 4205, particularly following the FDA's issuance of final regulations.

A. *Rewrite § 4205 as a Uniform National Floor*

The strongest approach to preserving state influence that fosters experimentalism and tailors innovation to community needs would be to rewrite § 4205 as a uniform national floor, instead of ceiling. The purpose of uniformity underlying the current federal law does not sufficiently justify the displacement of state and local authority in combating the obesity epidemic. As a floor, § 4205 would serve as a minimum standard for nutrient disclosure for establishments with more than twenty locations, but would not preempt states and localities from enacting additional regulations. States and localities could enact their own requirements in addition to § 4205's minimum rules.

To change § 4205 into a floor, 21 U.S.C.S. § 343-1 would require amendment. § 343-1(a)(3) would have to be amended to remove § 343(h), which is the menu labeling section. Such an amendment to § 343-1(a) might read as follows:

> [n]o 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 that requires less disclosure for the labeling of food of the type required by section 403(h). States or political subdivisions of a State may, however, enact requirements in addition to those required by 403(h). Establishments not covered by 403(h) may still voluntarily comply with the requirements of 403(h), but are not excluded from any additional state or local requirements.

Further, the amended law could incorporate language from the MEAL Act: "[n]othing in this clause precludes a State or political subdivision of a State from requiring that a restaurant or similar food establishment provide nutrition information in addition to that required under this clause."[235]

Ideally, rewriting § 4205 as a floor would result in a shift from

235. S 2784; HR 3895.

command and control regulation to cooperative federalism where states and localities have the flexibility to adapt laws to new scientific evidence and practices regarding obesity control and nutrient disclosure. This solution is more effective than simply stripping away § 4205 altogether because a minimum standard will mandate some disclosure in states that would not otherwise pass such laws; this solution may also encourage supplementary state innovation and empirical research.[236] While businesses would have to concede a degree of uniformity unless they choose to adopt the strictest local requirements and implemented them nationally, the public health implications of fostering experimentalism in the sphere of disclosure will likely outweigh any negative impacts on businesses. Floor preemption preserves state roles and permits mutual learning,[237] providing a better chance of success and meeting long-term public health obesity reduction goals as calorie disclosure and other interventions become better understood with additional research.

Specifically, a floor preemption scheme would address many of the problems and inconsistencies outlined in Section III. For instance, states and localities would be able to more effectively combat obesity and promote health by requiring additional disclosure of food composition on menus, such as sodium and trans-fat content.[238] Small businesses would be more likely to bear equal responsibility for America's weight crisis because they would not be able to opt in to § 4205 to avoid stricter regulation, and the chances of encountering a regulatory freeze would be dramatically reduced. Further, states would have more control over enforcement and compliance, without having to wait for the FDA to decide on final regulations or an enforcement structure. Moreover, states would be able to control the presentation of a contextual calorie number, and could elect to present multiple numbers that more accurately reflect different calorie needs of the local population.[239] Ultimately, public health challenges are constantly evolving; it is not possible to predict what the next great public health problem may be and we do not want to keep the laboratories of democracy from being able to solve it.

Alternatively, policymakers could consider modifying § 4205, instead of completely rewriting it, to include restaurants and vending machines with less than 20 locations, such as establishments with 15 or more locations (which many state and local laws do).[240] While it is

236. *See supra* text accompanying note 1334.
237. Buzbee, *supra* note 123, at 1586.
238. Pomeranz, *supra* note 53.
239. *See supra* note 235.
240. *See, e.g.*, N.Y. HEALTH CODE LAW § 81.50 (2008).

possible that such an approach could further decrease incentives for states to propose new regulations for small chains and local restaurants, public health officials would have to consider that potential tradeoff compared to including more restaurants in the disclosure requirements, and thus informing more consumers.

Unfortunately, it seems unlikely that Congress will rewrite or materially modify § 4205 in the immediate future because of the attention that was recently given to the issue and Congress's long agenda in other areas of regulation, such as healthcare reform. While state suits contesting the constitutionality of sections of the ACA may change the law, § 4205 is not one of the highly contested sections of the ACA, and it unlikely that the ACA in its entirety will be struck down. Additionally, as menu labeling becomes ubiquitous and nutrient composition databases and software for labeling become more available, estimation of calorie content in menu offerings will become less onerous and will not always require direct chemical analysis, thus reducing costs of calorie content calculation.[241] Congress should be prepared to revisit § 4205 as technology develops.

B. *Considerations For § 4205 in its Existing Form*

Given the political and procedural difficulties inherent to changing § 4205 in the near future, it is important for agencies and policymakers at all levels of government to be prepared to work with § 4205 in its existing form. First, the FDA should use its agency power to immediately clarify uncertainties in § 4205, and implement the statute with broad latitude in an effort to preserve as much state innovation as possible that still preserve § 4205's statutory goals. For instance, the FDA should consider a wide definition for covered entities that includes more businesses, such as movie theaters and sports parks, whose primary business interests are not serving food, thus making nutritional information more widely available.[242]

Second, the FDA should liberally grant preemption exemption petitions as discussed in Part III.[243] In addition to granting petitions to localities that previously enacted menu labeling regulations before the passage of the ACA, the FDA should consider granting additional prospective exemptions in order to foster a degree of controlled,

241. Richard A. Williams et al., *Counting Calories: Report of the Working Group on Obesity*, Office of Scientific Analysis and Support, Center for Food Safety and Applied Nutrition, In support of the Obesity Working Group, FDA (Dec. 2003), http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081998.htm (last visited Jan. 4, 2001).

242. For instance, a large popcorn from Regal Cinemas is 1200 calories. Sarah Gilbert, Movie Theatres Not Happy with Popcorn Calorie Report, WALLET POP, Mar. 30, 2011, http://www.walletpop.com/2011/03/30/movie-theaters-not-happy-with-popcorn-calorie-report/.

243. *See* 21 U.S.C. § 343-1(b) (2010).

permissive experimentation. The Code of Federal Regulations describes the requirements and process for obtaining an exemption, providing that states and localities may apply for an exemption "where a State requirement has been preempted."[244] This language could be construed as not only applying to nutrition labeling legislation that was enacted *before* passage of the ACA, but also to legislation enacted *after* passage of the ACA. In that case, state and localities could try to request exemptions for regulations that were proposed but not implemented prior to the enactment of the ACA. Of course, granting any such exemptions would effectively read out the express preemption clause in § 4205, but this may be an area where the FDA has some latitude to permit certain localities to experiment with additional regulations. Further, the FDA should consider granting future exemption petitions for states and localities that have not yet enacted their own laws, in order to continue to promote experimentalism and innovation tailored to meet community needs. For example, the FDA could more liberally grant exemptions in communities with specific health problems that could be targeted with additional disclosure rules, such as sodium disclosure on menus in localities where high blood pressure is prevalent, evaluated against a rational basis review standard.

C. *State and Private Options for Obesity Reduction Outside of § 4205*

Private actors and government agencies should promote and fund anti-obesity and healthy living campaigns in order to avoid a frozen initial effort at combating obesity through consumer choice at restaurants. For instance, campaigns targeting certain populations who may not understand how to interpret calorie postings and contextual calorie numbers could be useful. Other campaigns could raise awareness regarding the ability of customers to request pamphlets with fat, sodium content, and other disclosures at restaurants covered under § 4205.

As discussed in Part II, federal law does not preclude state and local requirements regarding warning or safety statements. However, federal law does not allow states and localities to require restaurants to make health claims (*e.g.*, "low in sodium"), and if restaurants choose to make such claims, the NLEA requires them to comply with FDA regulations.[245] Thus, it is still possible for lawmakers or agencies to provide a mandate for the dissemination of additional health information at restaurants that do not make health claims about

244. 21 C.F.R. 100.1.

245. Rutkow et al., *supra* note 206, at 780–81.

particular items.[246] For example, lawmakers could consider requiring restaurants and other establishments to post signs about the benefits of healthy eating, and what to consume as part of a healthy diet. In addition, the NLEA contains an exception that allows localities to enact laws that regulate restaurants' ability to regulate claims about nutrients the FDA finds to be "associated with [an] increased disease or health-related condition risk," such as cholesterol and saturated fat.[247] Localities could promulgate requirements that are responsive to community needs; for example, in areas that are plagued with hypertension, lawmakers could require food establishments to hang signs or provide information about sodium reduction.

Grants promoting state and local development of new policies for single restaurants or very small chains not covered by § 4205 would be useful to prevent an effective regulatory freeze.[248] For many single unit businesses or small chains, even the moderate cost of calculating nutrients in menu items may be prohibitive and prevent restaurants that would like to voluntarily display such information from doing so. For example, some localities are paying for nutrition information calculations for small, local restaurants that will not fall under the jurisdiction of § 4205.[249] Further, more research should be done continually to analyze the impact and effectiveness of § 4205 and to develop suggestions for implementation, enforcement, and improvement.[250]

Finally, courts should be mindful of not blocking common law tort suits, to the extent the law allows this. As discussed in Part III, retention of common law liability can serve as a safety valve and prompt improvements in federal law. Accordingly, § 4205 should not be read as a federal disclosure regime that in turn insulates businesses from potential state common law tort suits. State tort law can function as a

246. The Center for Science in the Public Interest has petitioned the FDA to require warning labels on containers of carbonated drinks that state that drinking non-diet soft drinks may contribute to weight gain and thus increase risks of chronic illness. Rothenberg, *supra* note 9, at 195.

247. 21 U.S.C. § 343(r)(2)(B).

248. For example, the Burgerville chain prints "the total calories of your order on the receipt, as well as information on fat, fiber and carbohydrate content." Katherine Hobson, *Here's Your Burger and Your Change, and By The Way, That's 1,213 Calories*, WALL ST. J. HEALTH BLOG (May 18, 2010), http://blogs.wsj.com/health/2010/05/18/heres-your-change-and-by-the-way-thats-1213-calories.

249. *See* Charity Vogel, *Initiative Will Put Nutrition Facts on Local Menus: Program Aims to Improve Health of Region's Diners*, BUFFALO NEWS (Nov. 8, 2010), http://www.buffalonews.com/city/article245402.ece (200 locally owned restaurants in Erie County, New York will be given access to a program called Menu-Calc through a state grant in an effort to make restaurants healthier for consumers by supplying nutrition information for certain food items).

250. For an additional discussion of innovative approaches to combating obesity, see Pomeranz et al., *supra* note 186, at 185.

feedback loop, which is particularly important given the ceiling preemption function of § 4205.[251] Many advocates argue that apart from of the outcome of the lawsuits, such suits and future threats of lawsuits are a tool of social reform that have compelled the food industry to market healthier foods.[252] Furthermore, preemption of tort lawsuits would shift the burden of compensation for injuries from the responsible parties to the victim, taxpayers, and society in general.[253] Accordingly, regardless of the merits and consequences of tort litigation, § 4205 should not be read to preempt state common law tort suits, which are ultimately questions for the state judicial system.

CONCLUSION

Obesity is a significant, costly and growing public health problem that demands a multi-layered government response. The law is a powerful tool for influencing behavior and having a meaningful impact on the public's health. As one approach to combating the obesity epidemic, a federal uniform standard of menu labeling is a positive step, although it is a contested policy, with mixed empirical results at the local level to date. Given the ever-changing landscape of American health, it is vital not to suppress experimentalism and innovation. As with many public health challenges, menu labeling policy poses a tradeoff. On one hand, a federal uniform standard will impact a greater number of people but does not encourage states to find more successful solutions. Conversely, a patchwork approach without any federal standard or floor may not widely address the disclosure issue, and would leave some areas without requirements of any sort.

Ideally, § 4205 should be re-written as a national floor that allows states to experiment with new disclosure requirements, or at least be interpreted broadly by the FDA and courts, with a sound understanding of the benefits of state and local regulation and input. Finally, it is important to remember that a multitude of factors contribute to the obesity epidemic, and menu labeling alone may not be effective. Ultimately, more research needs to be done to understand the public health impacts of menu labeling, and further investigate new and innovative approaches to trimming America's waistline.

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251. Buzbee, *supra* note 123, at 1583.

252. Rothenberg, *supra* note 9, at 203.

253. William Funk et al., *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety*, CENTER FOR PROGRESSIVE REFORM (Sept. 2007), http://www.progressiveregulation.org/articles/Truth_Torts_704.pdf.