# THIS ARTICLE CONTAINS 400 CALORIES: A CRITIQUE OF, AND CALL FOR EXPANSION TO, THE MENU LABELING REQUIREMENTS OF SECTION 4205 OF THE AFFORDABLE CARE ACT

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## INTRODUCTION

The extremely high cost of healthcare in the United States continues to be an exceptional burden on a significant number of citizens. Coupled with decades of increases in major health conditions and diseases, solving these massive issues appear to be insurmountable, with solutions being perpetually out of reach. However, our nation's healthcare costs are kept from rising even higher by participation in preventative healthcare measures, such as adhering to yearly primary care office visits, receiving a yearly physical and flu vaccination, and receiving regular colonoscopies and breast exams.[1] Preventative healthcare measures are designed to prevent healthcare issues from materializing or to detect early onset of a disease for targeted treatment.[2] Taking preventative healthcare measures is immensely effective.[3] Being cognizant of the nutritional makeup of the food one eats and the beverages one drinks is another means of preventing healthcare issues before they take hold. Unlike the traditional means of preventative care which require a commitment of time while trying to fit a visit into yours an overburdened primary care physician's schedule, this type of preventative care is undertaken directly by the consumer at the time of purchase.

Once in a generation, a healthcare law is passed that has the ability to significantly improve the health of Americans while potentially driving down the cost of healthcare. When such a law is passed, our leaders need to seize the opportunity to strengthen it to better assure its effectiveness. The sweeping

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1. *See* Jeffrey Hostetter et al., *Primary Care Visits Increase Utilization of Evidence-Based Preventative Health Measures*, 21 BMC FAM. PRAC. 151 (2020), https://bmcprimcare.biomedcentral.com/track/pdf/10.1186/s12875-020-01216-8.pdf [https://perma.cc/5X9G-A4Y9].

2. *See id.*

3. *See id.* The study shows evidence that preventative healthcare measures make a difference by leading to the adoption of other preventative healthcare measures; notably, patients who made one or more primary care office visits per year were 126% more likely to also receive one or more vaccinations, 122% more likely to receive a colonoscopy, and 75% more likely to receive a mammogram than those who did not average a primary care office visit per year. *Id.*

healthcare law that has received plenty of press over the past several years, the Affordable Care Act (ACA), includes section 4205, which requires restaurant chains and similar retail food establishments of twenty or more stores to supply calories for standard items on menus (onsite and online) and menu boards, along with providing a succinct explanatory statement of the significance of the calorie information on the menus and menu boards.[4] Many other types of chain establishments of twenty or more stores that sell restaurant-type food are covered under the definition of "similar retail food establishment," such as movie theatre concession stands, bowling alleys, arenas, amusement parks, sporting facilities, concert venues, and grocery stores.[5] Standard menu items are restaurant-type food sold on a regular basis.[6] The items must be "substantially the same" as is sold in at least twenty stores in the chain in order for section 4205 to apply, a definition that includes items made from a common recipe even if the items are slightly altered for regional differences.[7] This definition excludes chain restaurants that offer "one or two" of the same items, but the rule does not give a more refined definition of what is meant by "substantially the same."[8] Section 4205 also requires that written nutrition information be available for handout on request.[9]

After several years of delays, compliance with the law became a requirement in 2018.[10] With talk for decades about runaway healthcare costs in the United States and how affordable healthcare is off limits for millions of citizens, section 4205 has the potential to make a significant dent in spiraling healthcare costs over time, resulting in improvement to the health of millions of Americans, improving both our quality of life and how long we live and, hopefully, reduced healthcare premiums. By limiting section 4205 to just the largest restaurant chains and similar retail establishments, however, Congress missed a golden opportunity by excluding tens of thousands of restaurants.[11] In addition to section 4205 not

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4. Patient Protection and Affordable Care Act § 4205, 21 U.S.C. § 343(q)(5)(H).

5. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101) (see table at the top of 79 Fed. Reg. at 71,158 for a summary of what type of foods do and do not qualify as "restaurant-type food"); *see also id*. at 71,259.

6. *Id*. at 71,158. The definition of "standard menu item" excludes daily specials, special order meals, condiments, and bottles of alcohol sold from behind the counter, and temporary menu items which are defined as appearing on the menu less than sixty days per year. *Id*; *see also id*. at 71,185.

7. *Id*. at 71,173.

8. *Id*.

9. 21 U.S.C. § 343(q)(5)(H)(ii)(III).

10. *Menu Labeling Requirements*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-labeling-nutrition/menu-labeling-requirements [https://perma.cc/A9BE-8NVA] (last visited Mar. 27, 2022).

11. *Number of Restaurants in the United States From 2011 to 2018*, STATISTA (May 30, 2022), https://www.statista.com/statistics/244616/number-of-qsr-fsr-chain-independent-restaurants-in-the-us/ [https://perma.cc/X5T9-6M92] (showing that for just restaurants and not similar retail food establishments, there were 660,755 restaurants in the United States as of the spring of 2018); *Number of Restaurants in the US, 2022/2023: Statistics, Facts, and Trends*, FINS. ONLINE, https://finances

applying to chains with fewer than twenty stores,[12] it also does not apply to elementary and secondary schools,[13] or to mobile restaurants such as food trucks, train cafes, aircraft, or restaurants on ships.[14] Section 4205 also does not apply to third-party delivery services such as DoorDash, Grubhub, Uber Eats, and Postmates.[15] A major criticism of the law was the claim that it would be too costly for restaurants to implement even though it is limited to major restaurant chains.[16] This article demonstrates that even expanding the law to include more restaurants will not add significant costs to their bottom line.

Although section 4205 is seen as a nutritional breakthrough, its path to law was long and difficult. This article discusses the major objections to extending section 4205 to other restaurants and retail food establishments and why those arguments are not valid. The article also summarizes the effectiveness of menu labeling. This article concludes that section 4205 should be extended to chain restaurants and similar retail food establishments of three or more stores, chain mobile restaurants and similar retail food establishments of three or more stores[17] and all elementary and secondary schools. This article also advocates that, in addition to total calories, menus and menu boards should also include grams of

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online.com/number-of-restaurants-in-the-us/ [https://perma.cc/EA2K-RSC6] (last visited May 30, 2022) (stating that in 2018, there were roughly 308,000 restaurants that were part of a chain; however, it is not known what the numerical breakdown is between chain restaurants).

12. 21 U.S.C. § 343(q)(5)(H)(i).

13. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,169.

14. 21 CFR § 101.11 (2016). Aside from the above restrictions on types of restaurants not needing to comply with section 4205, this section further limits restaurants by defining "location" as being "a fixed position or site. *Id*.

15. *See* Joe Guszkowski, *Consumer Groups Want Menu Labeling Enforced on Delivery Apps*, Rest. Bus. (April 2, 2021), https://www.restaurantbusinessonline.com/food/consumer-groups-want-menu-labeling-enforced-delivery-apps [https://perma.cc/A2BR-DZ6A].

16. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,176; U.S. DEP'T OF HEALTH & HUM. SERVS., FDA-2011-F-0172, FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS, FINAL REGULATORY IMPACT ANALYSIS 6 (Nov. 2014), *available at* https://www.fda.gov/media/116833/download [https://perma.cc/GHL7-GVNV] [hereinafter REGULATORY IMPACT ANALYSIS].

17. *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (To be codified at 21 C.F.R. Pts. 11, 101), 128 HARV. L. REV. 2098, 2103-05 (2015) https://harvardlawreview.org/2015/05/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food-establishments/ [https://perma.cc/8RP2-DX9E] [hereinafter *Recent Regulations*]. The author determined that, from a practical standpoint, it makes no sense to limit applicability of section 4205 to stationary restaurants while excluding mobile restaurants, but the author did not make a legal argument for that conclusion. However, in analyzing the constitutionality of excluding mobile restaurants from the strictures of section 4205, the author determined that the FDA is likely in violation of the Chevron test in its interpretation of the word "location" as being a fixed position. *Id*.

carbohydrates, fats, and protein.[18] Finally, to echo the solution posited by a prior author, third-party delivery platforms that deliver food for covered establishments should be subjected to section 4205.[19]

The focus of this article is both on the application of section 4205 and on ways to make it more effective. Therefore, this article does not discuss potential issues that pertain to subgroups of the population, such as how menu labeling may affect eating disorders, or how socioeconomic issues may impact food choice. In addition, the purpose of this article is not to delve into first amendment issues that foreshadow potential legal battles. There already exists articles that delve deep into both socioeconomic and first amendment issues that may be implicated by section 4205.[20]

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18. In researching and writing this article, the author of this paper did not find another source that advocated for inclusion of all four of calories, carbohydrates, fat, and protein on menus and menu boards. The sources getting the closest are the following: James G. Hodge, Jr. et al., *Food Fight!: The Legal Debate Over the Obesity Epidemic, Food Labeling, and the Government's Involvement in What You Eat: Alternative Models to Supplement Menu Labeling*, 17 NEXUS J. OP. 79, 90 (2011/2012) (noting that ideally, total calories, fat, sodium, and sugar content should be listed on the menu and menu boards); Menu Education and Labeling Act, H.R. 3895, 110th Cong. (2007) (unenacted bill advocating for calories, fat, and sodium); King Cnty. Bd. of Health Code § 5.10.015 (2017), https://kingcounty.gov/depts/health/environmental-health/food-safety/food-business-permit/~/media/depts/health/board-of-health/documents/code/BOH-Code-Title-5.ashx [https://perma.cc/ALF3-6ZX4] (requiring total calories, grams of saturated fat, grams of carbohydrates, and milligrams of sodium be placed on the menus and menu boards of covered establishments); City of Philadelphia Health Code § 6-308 (2021), https://codelibrary.amlegal.com/codes/philadelphia/latest/philadelphia_pa/0-0-0-190383#foot-8-1 [https://perma.cc/EJ5P-B8XQ] (requiring covered establishments to post total calories, grams of fat, grams of carbohydrates, and milligrams of sodium); *Anyone's Guess*: *The Need for Nutrition Labeling at Fast-Food and Other Chain Restaurants*, CTR. FOR SCI. IN THE PUB. Int. 2 (2003), https://www.cspinet.org/sites/default/files/media/documents/resource/restaurantreport.pdf [https://perma.cc/G8XS-LNWZ] (advocating, well before section 4205 was proposed, for the inclusion of calories, fat, and sodium content be placed on menus and menu boards of covered establishments, which they thought should be chains with ten or more stores).

19. This paper argues that third-party delivery apps should be subject to section 4205 only *if* the establishment that they are delivering for is subject to the section. *But see* Guszkowski, *supra* note 15 (advocating for third-party delivery services being subjected to section 4205).

20. *E.g.*, Paul. A. Diller, *Combating Obesity With a Right to Nutrition*, 101 GEO. L.J. 969 (2013) (socioeconomic analysis to food law policy); *see also* Jessica Mantel, *Tackling the Social Determinants of Health: A Central Role for* Providers, 33 GA. ST. U. L. REV. 217 (2017) (social determinants of poor health); *Recent Regulations*, *supra* note 17 (First Amendment analysis of section 4205); Dayna B. Royal, *The Skinny on the Federal Menu-Labeling Law and Why It Should Survive A First Amendment Challenge*, 10 FIRST AMEND. L. REV. 140 (2011) (First Amendment analysis of section 4205); Michelle I. Banker, *I Saw the Sign: The New Federal Menu-Labeling Law and Lessons From Local Experience*, 65 FOOD & DRUG L. J. 901 (2010) (First Amendment analysis of section 4205).

## I. FDA RATIONALE FOR SECTION 4205 OF ACA

Healthcare spending in the United States in 2020 was an astonishing $4.1 trillion dollars, averaging over $12,530 per person, or about 19.7% of the country's Gross Domestic Product.[21] About 30% of the growth in healthcare spending between 1987 and 2011 was because of an increase in chronic disease,[22] which can largely be attributed to excessive alcohol use, tobacco use, insufficient physical activity, and poor nutrition.[23] The U.S. Food and Drug Administration ("FDA") plays a major role in containing healthcare costs and does so through its food regulations.[24] The FDA is well aware that Americans have a major problem with obesity, leading to serious health issues costing an enormous amount of money, acknowledging such in its administrative final rule for the menu calorie requirement.[25] The FDA notes that excess body weight leads to many health, social, and psychological issues, to include "[l]ower life expectancy, elevated risk of diabetes, hypertension, stroke and other cardiovascular disease."[26] According to the National Institutes of Health and the World Health Organization, obesity leads to multiple health problems and often greatly reduces one's life expectancy.[27]

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21. *National Health Expenditure Data*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical [https://perma.cc/PE96-JH68] (last visited Mar. 27, 2022).

22. Mantel, *supra* note 20, at 220-22 (citing Kenneth E. Thorpe et al., The Role of Chronic Disease, Obesity, and Improved Treatment and Detection in Accounting for the Rise in Healthcare Spending Between 1987 and 2011, 13 APPLIED HEALTH ECON. & HEALTH POL'Y 381, 381, 384-85 (2015)) (concluding that 77.8% of the growth in healthcare costs between 1987 and 2011 were because of chronic health disease; and after allowing for population increase and the increase of healthcare costs, the authors estimated that 30% of the cost increase was directly related to an increase in chronic disease).

23. Poor Nutrition, Chronic Disease Fact Sheets, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/chronicdisease/resources/publications/factsheets/nutrition.htm [perma.cc/4BPK-TZY6] (last visited June 6, 2022).

24. *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,159 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

25. *Id.*

26. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,221 (proposed Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11, 101).

27. NIH Study Finds Extreme Obesity May Shorten Life Expectancy Up To 14 Years, Nat'l Insts. of Health (July 8, 2014), https://www.nih.gov/news-events/news-releases/nih-study-finds-extreme-obesity-may-shorten-life-expectancy-14-years [https://perma.cc/Q2UG-NSWS] (after studying over 300,000 people, doctors concluded that "[y]ears of life lost ranged from 6.5 years for participants with a BMI of 40-44.9 [above average] to 13.7 years for a BMI of 55-59.9"); *Obesity and*

The FDA identifies the following rationale for the implementation of section 4205 in its Final Rule, in sections pertaining to purpose and background.[28] First, the FDA notes that over two-thirds of U.S. adult consumers are either overweight or obese,[29] while the Centers for Disease Control and Prevention ("CDC") notes that 41.9% of adults, and 49.9% of African American adults, are obese.[30] The FDA notes that "overconsumption of calories" is a main factor in obesity and that calorie content of food is often unknown or underestimated.[31]

The cost of treating obesity is staggering. "In 1998[,] the medical costs of obesity were estimated to be as high as $78.5 billion, with roughly half financed by Medicare and Medicaid" and by 2008, that annual cost had risen to $147 billion.[32] "The estimated annual medical cost of obesity in the United States was nearly $173 billion in 2019 dollars" and "[m]edical costs for adults who had obesity were $1,861 higher than medical costs for people with healthy weight."[33] Figures from a Milken Institute study represent a high-end estimate on such costs, where it is estimated that direct healthcare spending due to obesity in 2016 was $480.7 billion and that indirect costs due to lost economic productivity was $1.24 trillion.[34] Another comprehensive study marks the middle ground for costs, estimating obesity healthcare costs to be over $340 billion.[35] Additionally, a recent voluminous study called "Direct Medical Costs of Obesity in the United States and the Most Populous States" by Cawley et al. represents the low ground costs of non-governmental studies.[36] The authors analyzed data from more than

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*Overweight*, WORLD HEALTH ORG. (June 9, 2021), https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight [https://perma.cc/WLP3-9LNP] (WHO notes that 1.9 billion people worldwide are overweight and more than 650 million are obese, and that "[r]aised BMI is a major risk factor" for certain cancers, to include breast cancer, prostate cancer, and colon cancer, as well as for cardiovascular disease, diabetes and osteoarthritis).

28. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,157-59.

29. *Id.* at 71,157.

30. *Adult Obesity Facts*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/obesity/data/adult.html [https://perma.cc/EY5E-G57W] (last visited Mar. 4, 2022).

31. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,157.

32. Eric A. Finkelstein et al., *Annual Medical Spending Attributable to Obesity: Payer-and Service-Specific Estimates*, 28 HEALTH AFFS. w822-31 (2009), *available at* https://pubmed.ncbi.nlm.nih.gov/19635784/ [https://perma.cc/E3ZS-AWAS].

33. *Adult Obesity Facts*, *supra* note 30 (citing Zachary J. Ward et al., *Association of Body Mass Index with Health Care Expenditures in United States by Age and Sex*, 16(3) Plos One e247307 (2021), *available at* https://doi.org/10.1371/journal.pone.0247307 [https://perma.cc/ZNY5-YG2B]).

34. Hugh Waters & Marlon Graf, *America's Obesity Crisis: The Health and Economic Costs of Excess Weight*, MILKEN INST. 1 (Oct. 2018), https://milkeninstitute.org/sites/default/files/ reports-pdf/Mi-Americas-Obesity-Crisis-WEB_2.pdf [https://perma.cc/35U5-4DJ3].

35. Adam Biener et al., *The Impact of Obesity on Medical Care Costs and Labor Market Outcomes in the US*, 64 CLINICAL CHEMISTRY 108, 113 (2018).

36. John Cawley et al., *Direct Medical Costs of Obesity in the United States and the Most*

63,000 respondents entered from 2001 to 2016 in the Medical Expenditure Panel Surveys (MEPS).[37] The authors found that the estimated cost of direct healthcare attributed to obesity was over $260 billion in 2016, up from approximately $124 billion in 2001.[38] To better put that total into perspective, the authors estimated that annual inpatient costs for obese patients was $1,463 compared to $375 for those of average weight.[39] The authors also determined that ambulatory care costs increased by $787 per year and prescription drugs by $917 per year.[40]

In addition to conducting research on the usefulness of nutrition labeling in crafting rules for section 4205, the FDA analyzed consumer eating habits, the nutritional makeup of food consumed away from home, and the prevalence or scarcity of nutritional information at the point of sale. The FDA noted that the average American consumes one-third of their calories from food away from home.[41] "The difference in calorie consumption between 'food away from home' and food prepared at home was greater for study participants who were overweight or obese;[42] among those individuals, the away-from-home meals had 240 more calories per meal relative to meals prepared at home."[43] Further, the FDA noted that there was not sufficient nutritional information in the vast majority of the hundreds of thousands of retail food establishments in the United States because of a lack of incentives for establishments to provide it.[44] When choosing a food or beverage to consume, the amount and type of macronutrients in the item determines the total calories: a gram of fat contains nine calories, and a gram of carbohydrate and protein contain four calories.[45] In addition, the USDA recommends that there be a balance between fats, carbohydrates, and proteins.[46] Thus, it is important to be able to view the macronutrient content of an item to identify the best food purchasing options. Food purchased away from home is generally higher in calories and fat, along with having larger portion sizes.[47] The

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*Populous States*, 27 J. MANAGED CARE & SPECIALTY PHARMACY 354 (2021), https://www.jmcp.org/doi/epdf/10.18553/jmcp.2021.20410 [https://perma.cc/GU6Q-7SRL].

37. *Id.* at 357.

38. *Id.* at 361.

39. *Id.* at 359.

40. *Id.* at 359-61.

41. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,222 (proposed Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11, 101).

42. The CDC defines an overweight person with 25 to 29.99 BMI and an obese person with BMI of 30 or more. *Id.* at 19,192.

43. *Id.* at 19,222.

44. *Id.* at 19,221.

45. *See* Lizzie Streit, *What Are Macronutrients? All You Need to Know*, HEALTHLINE (Nov. 1, 2021), https://www.healthline.com/nutrition/what-are-macronutrients#food-sources [https://perma.cc/UG5P-LX77].

46. *Id.*

47. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,221 (proposed Apr. 6, 2011) (to be codified at

FDA noted that by not providing nutritional information, consumers "may fail to make informed choices and may undervalue the future costs of excessive calorie consumption."[48]

## II. STUDY-BASED RATIONALE FOR SECTION 4205 OF ACA

The most recent food labeling studies strongly indicate positive behavioral changes associated with section 4205 requirements. These behavioral changes include a lower number of calories per purchase, a lower number of calories per new menu item offering, and a projection that a high number of cardiovascular and diabetes cases and deaths will be prevented.[49]

Two recent studies are of the most salience, as they include purchase analysis after the menu labeling requirement took effect in the United States. A 2021 study, called "Changes in the Calorie and Nutrient Content of Purchased Fast Food Meals After Calorie Menu Labeling: A Natural Experiment" by Petimar et al., collected sales data from 104 fast food restaurants "that [were] part of a fast food franchise for 3 national chains in three US states," retrieved nutritional information on all sale items from the MenuStat database, and analyzed the calorie content of purchases from 2015 to 2019, which reflected sales before and after the implementation of the menu labeling requirement in 2018; however, "[t]he franchise labeled menus in April 2017, 1 year prior to the required nationwide implementation date of May 2018[.]"[50] This sprawling study included over 331 million purchased items from over sixty-seven million transactions.[51] The analysis started in 2017 when the stores implemented a voluntary menu labeling program.[52] Results showed a decrease of fifty-four calories per purchase after the franchise voluntarily implemented the labeling program and decrease of eighty-two calories per purchase after the national menu labeling law became a requirement in 2018.[53] The authors noted that menu items in the last week of the analysis were projected to contain seventy-three fewer calories than if there were no menu labeling requirement.[54] This reduction in calories is significant over the

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21 C.F.R. pts. 11, 101) (citing M.A. McCrory et al., *Dietary Determinants of Energy Intake and Weight Regulation in Healthy Adults*, 130 J. NUTRITION 276S (2000)).

48. *Id.*

49. *See, e.g.*, Joshua Petimar et al., *Changes in the Calorie and Nutrient Content of Purchased Fast Food Meals After Calorie Menu Labeling: A Natural Experiment*, 18 PLOS MED. 1 (2021), https://doi.org/10.1371/journal.pmed.1003714 [https://perma.cc/KB6D-GQWV]; Christine Barton et al., *Millennials Passions: Food, Fashion, and Friends*, BCG (2012), https://www.bcg.com/publications/2012/consumer-insight-consumer-products-millenial-passions [https://perma.cc/P76A-YZZV].

50. Petimar et al., *supra* note 49, at 2-4.

51. *Id.* at 2.

52. *Id.* at 1.

53. *Id.* at 7.

54. *Id.*

course of a year if eating out just twice a week.[55]

In another study, called "Changes in Calorie Content of Menu Items at Large Chain Restaurants After Implementation of Calorie Labels" by Grummon et al., the authors also compared calorie content of menu items before and after the implementation of the national menu labeling requirement using the MenuStat database, analyzing over 35,000 items from fifty-nine chain restaurants.[56] However, unlike the Petimar study described above, this study did not analyze actual purchases; instead, this study simply analyzed the calories associated with menu items before and after the implementation of the menu labeling requirement.[57] Results show that although the average calories of items that *remained* on menus after implementation of the federal law did not decrease, but that restaurants reduced the calories on *new* menu offerings by about 113 calories per item on average, or by about 25%.[58]

Reducing the calories of new menu offerings is an example of section 4205 bringing about positive modification of restaurant behavior. This is an important component of what the new law hopes to accomplish and was acknowledged by the authors of the Grummon article as being an important intervention strategy.[59] While the Petimar study primarily showed a positive modification of purchaser behavior, the Grummon article primarily showed a positive modification of the behavior of restaurant management.

Another study of interest, called "Health and Economic Impacts of the National Menu Calorie Labeling Law in the United States" by Liu et al., created a model based on consumer data from several recent National Health and Nutrition Examination Surveys to project the health effects that the 2018 menu labeling law will have.[60] The model estimated that between 2018 and 2023, 14,698 new cases of cardiovascular disease, including 1,575 cardiovascular disease deaths, could be prevented, and 21,522 new type 2 diabetes mellitus cases would be prevented.[61] The model projected that over a lifetime, 135,781 new cases of cardiovascular disease and 99,736 new cases of type 2 diabetes mellitus could be prevented.[62] Further, "[w]ith a 5% additional calorie reduction from restaurant reformulation, estimated health gains over lifetime were 292[,]560

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55. *See* Barton et al., *supra* note 49 (stating that the average person eats out between 2.8 and 3.4 times per week); *see also* Christina A. Roberto et al,, *Rational and Evidence for Menu-Labeling Legislation*, 37 AM. J. PREV. MED. 546, 547 (2009), *available at* http://staging.peachlab.org/wp-content/uploads/2013/05/Roberto_AJPM-Menu-Label-Review.pdf [https://perma.cc/DY4J-U6J9] (the average American eats out 5.8 times per week).

56. Anna H. Grummon et al., *Changes in Calorie Content of Menu Items at Large Chain Restaurants After Implementation of Calorie Labels,* 4 JAMA NETWORK OPEN 1, 1-3 (2021).

57. *Id*.

58. *Id.* at 4.

59. *Id.* at 9.

60. Junxiu Liu et al., *Health and Economic Impacts of the National Menu Calorie Labeling Law in the United States*, 13 CIRC. CARDIOVASC. QUALITY & OUTCOMES 309, 309-11 (2020).

61. *Id.* at 309, 313.

62. *Id.*

CVD [cardiovascular disease] new cases and 221[,]345 type 2 diabetes mellitus cases averted[.]"[63] Those numbers would have huge implications on the health of the nation and the amount of healthcare money saved would be staggering.

A review of some of other recent studies that analyze the effectiveness of menu labeling support the studies above, which showed (or in one instance, model-projected) that the law has led to positive behavioral changes. A 2022 article, called "Attention Mediates Restrained Eaters' Food Consumption Intentions" by Moore et al., indicates that menu labeling would positively affect restrained eaters, which they define as eaters who "have a high concern for dieting" and who try to limit what they eat.[64] This study first identified the level of dieting restraint that each of the fifty-six participants possessed by the administration of a questionnaire.[65] Then eye tracking software was utilized to measure the amount of time each of the fifty-six participants spent viewing calorie information on menus, which was compared to the total calories of their food choices.[66] With this information, conclusions were able to be drawn between the restrained eaters and those that did not identify as being restrained eaters.[67] Participants who identified as restrained eaters had the highest menu dwell times and chose the least number of calories for lunch and dinner.[68] The authors' conclusion that providing relevant nutrition information on menus would be particularly helpful for restrained eaters is echoed by the author of this article, who has practiced restrained eating for decades and has been frustrated with the general lack of nutrition information all along the way.[69]

A 2021 article, called "U.S. Adults Noticing and Using Menu Calorie Information: Analysis of the National Cancer Institute's Health Information National Trends Survey Data" by Rising et al., assessed results from the 2018 National Cancer Institute Health Information National Trends Survey.[70] The authors found that nearly 44% of the approximately 1,400 participants noticed menu calorie information.[71] The authors noted that about three-quarters of the participants who noticed calorie information on the menus ordered less from the menu in one or more ways.[72]

A 2019 article, called "A Meta-Analysis of Food Labeling Effects on Consumer Diet Behaviors and Industry Practices" by Shangguan et al., searched

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63. *Id.* at 313.

64. Kelly Moore et al., *Attention Mediates Restrained Eaters' Food Consumption Intentions*, 96 FOOD QUALITY & PREFERENCE 1, 2 (2022).

65. *Id.* at 3.

66. *Id.* at 3-4.

67. *Id.* at 6.

68. *Id.* at 4-6.

69. *Id.* at 9.

70. Camella J. Rising et al., *U.S. Adults Noticing and Using Menu Calorie Information: Analysis of the National Cancer Institute's Health Information National Trends Survey Data*, 153 PREVENTATIVE MED. 1, 2 (2021).

71. *Id.* at 6.

72. *Id.*

for studies on the efficacy of food labeling on purchase decisions through 2014.[73] Of the sixty relevant studies that the authors identified, they noted that caloric intake was reduced by 6.6%, the ingestion of total fat decreased by 10.6%, and vegetable consumption increased by 13.5% due to food labeling.[74] As previously mentioned, another benefit to the provision of food item specific information is that it will cause some companies to provide healthier options. Additionally, it was noted that companies reduced sodium levels in their items by 8.9% and also decreased trans fat calories by 64.3%.[75]

A 2018 article, called "Calorie Labels on the Restaurant Menu: Is the Use of Weight-Control Behaviors Related to Ordering Decisions?" by Larson et al., analyzed data from the Project EAT-IV survey that was collected in 2015 and 2016.[76] The authors found that 52.7% of the 1,830 participants "noticed calorie information while purchasing a meal or snack in a restaurant within the past month."[77] Of those participants, one-half reported using the calorie information to select limited calorie choices.[78]

A 2018 article, called "Menu Labels, for Better, and Worse? Exploring Socio-Economic and Race-Ethnic Differences in Menu Label Use in a National Sample" by Feng and Fox, analyzed data of roughly 13,500 to 14,000 respondents from the National Health and Nutrition Examination Survey from 2007 to 2014 to find that people were noticing and using menu labels at a much higher rate in 2013 than in 2007.[79] The authors reported that the percentage of people noticing menu labels in fast-food restaurants increased from 19.6% to 42.2%, and increased from 16.2% to 32.4% in sit-down restaurants, from 2007 to 2013.[80] People who reported using menu labels increased from 7.8% to 18.1% in fast food restaurants, and increased from 8.3% to 13.6% in sit-down restaurants, between 2007 and 2013.[81]

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73. Siyi Shangguan et al., *A Meta-Analysis of Food Labeling Effects on Consumer Diet Behaviors and Industry Practices*, 56(2) AM. J. PREVENTIVE MED. 300 (2019).

74. *Id*. at 306; *see id.* at 300 (stating that the authors reviewed more than 6,200 articles, finding sixty studies that were relevant to their research).

75. *Id*. at 307. *But see Trans Fat*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-additives-petitions/trans-fat [https://perma.cc/KCB4-93BG] (last visited May 15, 2022) (artificial trans fats are no longer "Generally Recognized as Safe" in United States, meaning manufacturers cannot add them to foods).

76. Nicole Larson et al., *Calorie Labels on the Restaurant Menu: Is the Use of Weight-Control Behaviors Related to Ordering Decisions?*, 118 J. ACAD. NUTRITION & DIETETICS 399, 400 (2018). "Project EAT" stands for "Eating and Activity in Teens and Young Adults." *Id.* The data reported in the article is "drawn from the fourth survey wave conducted," hence the "-IV." *Id.*

77. *Id*. at 402.

78. *Id.*

79. Wenhui Feng & Ashley Fox, *Menu Labels, for Better, and Worse? Exploring Socio-Economic and Race-Ethnic Differences in Menu Label Use in a National Sample*, 128 APPETITE 223, 225 (2018).

80. *Id.*

81. *Id.*

A 2018 article, called "Higher-Calorie Menu Items Eliminated in Large Chain Restaurants" by Bleich et al., found that large chain restaurants reduced calories in their menu offerings as section 4205 of the ACA was about to be implemented in 2018.[82] After analyzing over 27,000 menu items of sixty-six of the one hundred largest restaurant chains from 2012 to 2015, the authors found that newly added menu items contained sixty fewer calories (or 12% fewer calories), items that stayed on the menu for all four years of the study contained 102 fewer calories than items that were dropped (about 18% fewer calories), and that restaurants posting menu items had fewer item calories than non-posting restaurants.[83]

Similar results were found in a 2016 article called "Macronutrient Composition of Menu Offerings in Fast Food Restaurants in the U.S." by Jarlenski et al.[84] The authors analyzed 11,737 menu items from thirty-seven fast food restaurants from 2012 to 2014 and found that new food menu items in 2014 had fifty-two fewer calories than 2012 food items and new beverage items had thirty-six fewer calories than 2012 beverage items.[85] The authors simply attributed the decline in calories as part of the general trend that restaurants are employing,[86] perhaps because these restaurants were anticipating that these changes would soon be necessitated by the implementation of section 4205, as the Bleich study of sixty-six of the largest chain restaurants noted.[87] These recent studies dovetail nicely with a prior summary of recent studies that this author has previously published.[88]

Studies from other countries have shown that menu labeling is effective. Results in Ontario, Canada are similar to those found in studies conducted in the United States. A 2018 study, called "A Quasi-Experimental Study of a Mandatory Calorie-Labelling Policy in Restaurants: Impact on Use of Nutrition Information Among Youth and Young Adults in Canada" by Goodman et al., focused on the efficacy of the new Ontario calorie inclusion requirement on menus and menu

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82. Sara N. Bleich et al., *Higher-Calorie Menu Items Eliminated in Large Chain Restaurants*, 54 AM. J. PREVENTATIVE MED. 214, 214 (2018).

83. *Id.* at 214-16.

84. Marian P. Jarlenski et al., *Macronutrient Composition of Menu Offerings in Fast Food Restaurants in the U.S.*, 51 AM. J. PREVENTIVE MED. e91, e94 (2016).

85. *Id.* at e91, e94 (of note is that the reduction of calories in the new food items was largely via a drop in unsaturated fats, and the reduction in new beverage items was largely via a drop in saturated fats).

86. *Id.* at e96.

87. Bleich et al., *supra* note 82, at 214. Since Section 4205 had "several delays," it is likely that restaurants felt the changes were imminent as far back as 2013 and 2014, even though its implementation was delayed. *See id.*

88. *See* Patrick Meyer, *The Crazy Maze of Food Labeling and Food Claims Laws*, 92 ST. JOHN'S L. REV. 233, 252-58 (2018). Aside from summarizing studies on prior recent studies on the effectiveness of food labeling, the article critiques the role of the FDA in providing consumers with accurate and relevant food label information, identifies impediments in the pursuit of its mission, and offers solutions to those impediments. *Id.*

boards as compared to a voluntary program in British Columbia where calorie and sodium information was made available on request and to three other provinces with no such policy (the control group).[89] Of the nearly 4,000 participants, those from Ontario noticed the menu nutrition information significantly more than those from both British Columbia and the control group, and the information influenced their purchasing decisions significantly more.[90] Between wave one and wave two of the study, the percentage of Ontario participants who noticed the calorie totals on the menus jumped 25.1% compared to the British Columbia participants who jumped 1.6% and the control group participants who jumped 6.5%.[91] The percent of participants who were significantly influenced by the nutrition information increased by 12.9% in the Ontario group as opposed to 2.2% in the British Columbia group and 2% in the control group.[92] The authors concluded that their findings suggest that a mandatory policy is effective in promoting healthy food choices and that voluntary policies that depend on consumers asking for nutrition information are of little or no value.[93]

A United Kingdom study from 2019, called "Differences in Energy and Nutritional Content of Menu Items Served by Popular UK Chain Restaurants With Versus Without Voluntary Menu Labelling: A Cross-Sectional Study" by Theis & Adams, found that popular U.K. restaurants that voluntarily provided menu labeling information served items with 60% less salt and 45% less fat than those that did not provide nutritional information on their menus.[94] This study analyzed over 9,600 web-based menu items from ninety-seven popular U.K. chain restaurants—forty-two restaurants that included nutritional information on their websites and fifty-five that did not provide nutritional information on their websites.[95] In line with the conclusions of prior studies summarized above, the authors suggested that a compulsory menu labeling law could prompt restaurants to offer healthier fare.[96]

Another U.K. study, called "The Influence of Calorie and Physical Activity Labelling on Snack and Beverage Choices" by Masic et al., found that using a label that showed either the number of calories in an item or how long it would take to walk off the calories of the item significantly increased the selection of

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89. Samantha Goodman et al., *A Quasi-Experimental Study of a Mandatory Calorie-Labelling Policy in Restaurants: Impact on Use of Nutrition Information Among Youth and Young Adults in Canada*, 116 PREVENTIVE MED. 166, 166-67 (2018).

90. *Id.* at 167-68.

91. *Id.* at 167.

92. *Id.* at 168.

93. *Id.* at 171.

94. Dolly R. Z. Theis & Jean Adams, *Differences in Energy and Nutritional Content of Menu Items Served by Popular UK Chain Restaurants With Versus Without Voluntary Menu Labelling: A Cross-Sectional Study*, 14 PLOS ONE 1, 1 (2019), https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0222773&type=printable [https://perma.cc/JJ8K-AQ8B].

95. *Id.* at 4-5.

96. *Id.* at 1, 12.

lower calorie items as compared to having no label.[97] This finding suggests that providing more than just total calories on menus and menu boards can be a more effective health strategy, further supporting adding additional nutrition information on menus and menu boards.

A study in Australia, called "What Types of Nutrition Menu Labelling Lead Consumers to Select Less Energy-Dense Fast Food? An Experimental Study" by Morley et al., focused on an experiment in which researchers gave nearly 1,300 fast food-eating respondents a menu with one of several options: no kilojoule labeling of any kind, kilojoule labeling, kilojoules plus percentage of recommended daily intake, kilojoules and traffic light colors (green equals "go," which signals a healthiest choice, amber equals "OK," and red equals "stop," which symbolizes a least-healthy choice), and kilojoules with both traffic light colors and recommended daily intake.[98] Respondents who were given the menu with kilojoule totals or kilojoule totals plus the traffic light colors chose 490 and 500 fewer kilojoules, respectively, per meal than respondents who had no such information on their menus.[99] The authors concluded that this reduction of kilojoule intake could lead to nearly four fewer pounds being gained in a year if the consumer ate fast food at least twice a week (a category that over one-third of the Australian population falls within).[100] The inferences drawn from this experiment further support adding additional nutrition information on menus and menu boards.

Slightly older studies on the effectiveness of providing nutritional information found that the vast majority of consumers do view the information, especially for unfamiliar products.[101] These studies strongly suggest that the absence of nutritional information results in an underestimation of how many calories are consumed.[102] One of those studies found that, on average, the 193 participants underestimated calories of "less-healthful" food items by a whopping 642 calories, grams of fat by 44 grams, and saturated fat by 15 grams.[103] The

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97. Una Masic et al., *The Influence of Calorie and Physical Activity Labelling on Snack and Beverage Choices*, 112 APPETITE 52, 52-53, 55 (2017). The study also noted, however, that having combined calorie and exercise information may be a form of "information overload" and less effective than simply providing either calories *or* exercise labels. *Id*.

98. Belinda Morley et al., *What Types of Nutrition Menu Labelling Lead Consumers to Select Less Energy-Dense Fast Food? An Experimental Study*, 67 APPETITE 8, 8-9 (2013); *see also* Gavin Van De Walle, *What's the Difference Between Kcal and Calories?*, HEALTHLINE (Mar. 8, 2021), https://www.healthline.com/nutrition/kcal-vs-calories [https://perma.cc/PU3R-LS7T].

99. *Id*. at 11.

100. *Id*. at 14.

101. *See* Meyer, *supra* note 88, at 252.

102. *Id.* at 253; *see also* Bryan Bollinger et al., *Calorie Posting in Chain Restaurants,* 3 AM. ECON. J.: ECON. POL'Y 91, 117 (2011) (authors found of the 792 survey participants in Seattle and San Francisco, "for purchased food the average error of respondents in Seattle (San Francisco) in December was an underestimate of 20.2 (61.6) calories" and that "76.2% (76.9%) of respondents in Seattle (San Francisco) underestimate their purchased food calories.").

103. Scot Burton et al., *Attacking the Obesity Epidemic: The Potential Health Benefits of*

authors noted that participants made healthier choices when nutrition information was provided.[104] The authors also noted that if a consumer ate out once per week and consumed 600 extra calories each time, he or she could gain approximately nine pounds per year.[105] Studies suggest that even those consumers who do not consider themselves to be health-conscious benefit from the provision of nutritional information.[106]

The FDA states that section 4205 allows consumers to make better-informed dietary choices by giving them calorie information.[107] The FDA further concludes that making nutritional information available helps consumers accurately determine how the items that they purchase (or are scrutinizing for purchase) coincide with their daily caloric and nutritional needs.[108]

## III. CRITICISMS OF SECTION 4205

### *A. Criticisms Other Than Implementation Costs & FDA Responses*

As part of the administrative process, the FDA published the proposed rule for menu labeling, which explains the particularity of the rule and asks for public comments.[109] These comments were summarized and responded to in the final rule, which is published in the *Federal Register*.[110] The FDA received about 900 submissions of comments from consumers, consumer groups, federal and state government, industry, trade associations, and others.[111] The FDA noted that most comments supported the proposed rule for nutrition labeling of menu items.[112] Comments that did not support the rule included the typical government overreach argument; concern over potential enforcement issues; disagreement with the FDA's definitions of key terms in the rule; mention of practical issues

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*Providing Nutrition Information in Restaurants*, 96 AM. J. PUB. HEALTH 1669, 1670-71 (2006), https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.2004.054973 [https://perma.cc/8XNK-RRP3].

104. *Id.* at 1674.

105. *Id.*

106. Meyer, *supra* note 88, at 253.

107. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,220 (proposed Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11, 101)

108. *Id.*

109. *See* 5 U.S.C. § 553(c) (the rulemaking process, among other things, requires that citizens be given a chance to comment on the proposed rule); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192 (proposed Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11, 101).

110. *See generally* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,160-251 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

111. *Id.* at 71,160.

112. *Id.*

with providing large menus near some restaurant drive-through windows; concern that menu changes may be onerous for restaurants if further additions to the labeling requirement are instituted; arguments that alcohol should be included in the menu labeling requirement (alcohol originally was not included in the proposed rule); mention of the need to develop a system verifying the accuracy of calorie information from restaurants; opinions on the location of and font size of menu calorie information; opinions regarding the rule for calorie totals for combination meals; comments on the verbiage and placement of the explanatory statement; and opinions on which nutrients should be part of the required nutrition handout-on-request, on the form of such a handout, and on the calorie and nutritional substantiation requirements.[113] The focus of this Section III.A. is on the comments and responses deemed to be most relevant or substantial to this article, except for comments on implementation and subsequent compliance costs. The cost of complying with section 4205 will be discussed in Section III.B.

Comments on government overreach took the following forms: the government should not tell us what to eat, listing calories will cause or exacerbate eating disorders, general comments that menu labeling will not work, providing calorie information will negate the intended positive effective of section 4205 by causing information overload to consumers, and finally, a claim that most fast food restaurants already provide nutritional information.[114] The FDA devised a strong response, stating that the rule does not actually require consumers to eat any specific item, and that the rule provides consumers with the opportunity to make health-conscious decisions through its consistency and by providing critical access to health information at the point of sale, where such information is most effective.[115] The FDA highlighted the significance of the rule, noting that food purchased and consumed outside of the home amounts to about one-half of consumer food dollars and about one third of food calories.[116] The FDA commented on how the required succinct statement of daily calorie needs compliments the specific calorie information provided for each menu/menu board item.[117] Finally, the FDA responded to the claim that most fast food restaurants already provide adequate nutritional information, suggesting that the third piece to the rule, providing nutrition information for handout on request, insures that all covered restaurants include substantial nutritional information on the handout, whereas many restaurants either did not provide such a handout or provided incomplete information therein.[118]

There were several comments on the FDA definition of "restaurant or similar retail food establishments."[119] These comments ranged from urging the FDA to include other types of companies that serve food, such as movie theatres, to the

113. *See id.* at 71,160-251 (summary of *Final Rule* comments which this author synthesized).
114. *Id.* at 71,160.
115. *Id.* at 71,160-61.
116. *Id.* at 71,161.
117. *Id.*
118. *Id.*
119. *Id.* at 71,162.

exclusion of movie theatres, bowling alleys, airlines, trains, and hotels.[120] In response, the FDA revised its definition of "restaurant or similar retail food establishments" to: "a retail establishment that offers for sale restaurant-type food."[121] The FDA defines "restaurant-type food" as being the sale of "food most like food offered for sale in restaurants."[122] The FDA gives several examples of restaurant-type food in its final rule, noting that food purchased for immediate consumption, food bought at a drive-through, pizza purchased in-store, in a grocery store or convenience store (ready-to-eat), pizza purchased via delivery, buffet food and food from a salad bar, self-service foods, food at a deli counter, and other food offered for individual sale.[123] The definition of "restaurant or similar retail food establishments" that sells "food most like the food offered for sale in restaurants" means that a whole list of establishments are covered by section 4205 (as long as they meet the other criteria of section 4205):

> bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues (such as amusement parks, bowling alleys, and movie theaters), food service vendors (*e.g.*, ice cream shops and mall cookie counters), food take-out and/or delivery establishments (such as pizza take-out and delivery establishments), grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants.[124]

Chain restaurants of twenty or more locations must include calorie information for "substantially the same menu items."[125] Several comments focused on the admittedly vague definition of that phrase. Comments on the vagueness of this definition were that it would mean that if 51% or more of items are similar then the rule would be triggered (if all other criteria are met), and that the definition is unclear as to whether similar items that have regional recipe variations would count.[126] As mentioned in the introduction, the final rule does not clarify the high-end of what constitutes "substantially the same." The FDA only provides one example on the very low-end of what would not meet the definition while inserting the unhelpful phrase "offering for sale a significant proportion of menu items" into the definition.[127] This author sees no difference between the words "substantially" and "significant" without more clarification by the FDA. Both terms are vague as to providing a solid percentage and basically mean "considerable" or "noteworthy." A reasonable person could consider 25%

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120. *Id.* at 71,165.

121. *Id.* at 71,164.

122. *Id.* at 71,169.

123. *Id.* at 71,158 (see table at the top of the page for examples of both foods that would and would not normally be classified as restaurant-type food).

124. *Id.* at 71,164.

125. *Id.* at 71,166.

126. *Id.* at 71,172-73.

127. *Id.* at 71,173. The only clarifying example used was that if a chain had just one or two similar items, those items would not meet the definition of "substantially similar." *Id*.

or 33% of similar items to be considerable. The FDA did somewhat help matters by refining the proposed rule so that it allows for slight variations in the recipe of items between stores to reflect regional tastes, regional availability of ingredients, or to allow for special and/or regional dietary practices such as for Kosher foods.[128] This addition to the rule now makes it more likely that regional variations to recipes for similar menu items in chain restaurants are considered to be "substantially the same menu item."[129] But variations could be so substantial that it causes confusion as to the applicability of section 4205. A high-end example of the meaning of "substantially similar" would be useful for national chains or regional chains that span several states. For instance, if two stores from a chain are located in a northern state and somewhere in the deep south, it is conceivable that these stores will offer several items where the recipes are dissimilar enough that it not clear whether they are substantially similar. An example would be helpful to all national chain restaurants in determining if the items they offer that have several recipe variations by region would lead to being deemed "substantially similar" or not. Or perhaps each store offers several different items because of regional custom. In that case, an example would be useful to determine a high-end percentage of different items that would need to exist in order to shield chains from section 4205 compliance.

Some comments noted that since the requirements of section 4205 can be amended at any time, it is onerous to restaurants, since menu boards would have to be changed with each amendment.[130] This is a valid concern, if nothing else in the context of uniform compliance. The law is complicated and does not lend itself to constant change. There is no indication that the FDA intends to tweak section 4205.[131] With all of the comments and responses that the FDA has fielded and provided, it is assumed that they are well aware of the likely result of continually changing the law.[132] For that reason, the FDA should not often change the required information that is to be displayed on menu boards.

Many of the comments disagreed with the portion of the proposed rule that excluded alcohol from the requirements of section 4205, wanting the FDA to require that alcoholic beverages be included in the final rule.[133] These comments included noting that alcohol was not listed in the types of foods that Congress specifically exempted from the requirements of section 4205, that the FDA has the authority to regulate alcohol labeling anyway, and that alcohol needs to be covered as a public health concern considering alcohol comprises a substantial amount of calories in the average diet.[134] The FDA reversed its stand and agreed that section 4205 will apply to alcoholic beverages.[135] In response to comments

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128. *Id.* at 71,173.
129. *Id.*
130. *Id.* at 71,180.
131. *Id.*
132. *Id.*
133. *Id.* at 71,186.
134. *Id.*
135. *Id.*

concerning the costliness of listing calories for all of the many brands of alcohol that small breweries may sell, the FDA noted that one of the means to satisfy the rule's "significant flexibility" in justifying the "reasonable basis" for nutritional disclosures is to use the USDA National Nutrient Database for Standard Reference, which includes calorie and other nutrient totals for alcohol.[136]

Section 4205 requires that total calories, fat calories, saturated fat, cholesterol, sodium, carbohydrates, complex carbohydrates, sugars, fiber, and protein be included on the nutrition handout.[137] There were several comments about various aspects of the handout.[138] The FDA declined to make the changes that most of the comments asked for, which included the requirement that supporting references for nutrition values listed on the handout be given to consumers upon request,[139] that only one type of trans-fat (industrial trans-fat) be listed on the handout,[140] that font size specifications be required for all handout information,[141] and that nutrition information helpful to individuals battling obesity and diabetes be highlighted on the handout (a request for comment that the FDA had specifically asked for).[142] The FDA's rejection of most of the comments was uneventful. The FDA did, however, note that highlighting nutritional information to help those battling obesity would not negatively showcase a food, although it ultimately determined that it would not require such highlighting.[143] Aside from changing section 4205 to cover alcohol, the FDA made other changes based on comments.[144] These changes include providing a list of abbreviations for nutritional information required to be included in the handout[145] and permitting covered establishments to include micronutrients in the handout.[146]

There were several comments related to general enforcement of section 4205 and also specifically to the substantiation and accuracy of calorie and other nutrition information.[147] In addressing a comment that stated it is not clear exactly who would be liable for noncompliance, the FDA stated that those exhibiting "authority and supervisory responsibility" over the offending restaurant or similar retail food establishment may be held liable via the larger Act that section 4205 is part of, the Federal Food, Drug & Cosmetic Act ("FD&C Act").[148] The FDA

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136. *Id*. at 71,187-88.

137. 21 U.S.C. § 343(q)(1)(C)-(D).

138. *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,214-18.

139. *Id*. at 71,214.

140. *Id*.

141. *Id*. at 71,215.

142. *Id*.

143. *Id*.

144. *See id*. at 71,212-13.

145. *Id*.

146. *Id*. at 71,213.

147. *Id*. at 71,161.

148. *Id*. (the comment questions whether the franchisor of an offending restaurant would be held

cited the case *United States v. Park* as controlling precedent.[149] *Park* held that those who exhibit authority and a supervisory responsibility have a duty to fix violations and even to proactively prevent violations of the FD&C Act.[150] Other comments related to enforcement issues lobbied for a defined protocol for ensuring the accuracy of nutrition information, random testing, annual testing with results made public and with either retests or penalties imposed on violators, that warning letters be issued, that a tiered penalty structure be implemented, and that the FDA preapprove menus.[151] The FDA rejected nearly all of these comments, noting that there are several suggested means of verifying the accuracy of nutritional information in the rule (an often-used FDA response), that it does not keep a public file on any testing it currently does and will not start doing so, and that penalties are already noted in the FD&C Act.[152] The FDA noted that the FD&C Act did not require preapproval of menus, nor does the FDA have the personnel to preapprove menus.[153] The FDA did, however, expect to issue guidance documents for the industry and stated that it expects to employ a tiered approach to enforcement.[154] This approach is already used to enforce the FD&C Act for which section 4205 is a part of, and could involve the issuance of warning letters, seizure, injunction, and criminal prosecution (both misdemeanor and felony).[155] The FDA notes that the form of the enforcement action depends on "the nature of the violation and the public health concern, Agency policy, previous history of violations by the firm, and other factors."[156]

In response to comments expressing concern that violations may innocently occur at the time nutrition information has changed, such as when a different supplier provides items or the restaurant may have changed the recipe of an ingredient, the FDA noted this eventuality but declined to allow leeway in enforcing the law.[157] Instead, the FDA suggested that covered establishments

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liable under the theory of vicarious liability, especially of the franchisor controls what items are offered for sale at the restaurant).

149. *Id.* (citing United States v. Park, 421 U.S. 658, 659 (1978)).

150. *Park*, 421 U.S. at 659 (citing United States v. Dotterweich, 320 U.S. 277 (1943)).

151. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,241-43.

152. *Id.* at 71,242-43.

153. *Id.* at 71,243.

154. *Id.* at 71,242.

155. *Types of Enforcement Actions*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions [https://perma.cc/NK7X-B82Z] (last visited Aug. 27, 2022). The FDA website notes the following: warning letters require a response to violations of the FD&C Act; seizures are effectuated for violations that pose a health harm to the public; misdemeanor charges do not require the proof of intent and result in either fines of up to $500,000 or imprisonment for up to one year; felony convictions can result in either imprisonment up to three years or fines of up to $500,000, and further, a felony conviction may be a second conviction or based on an original case of fraud. *Id.*

156. *Id.*

157. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar

update the menus and menu boards with the new nutrition information directly before introducing the item that has the changed nutrition information.[158]

In response to comments about what entity will enforce section 4205, the FDA gave three options that it is already using to enforce the provisions of the FD&C Act: 1) a state may pass mirror legislation and then enforce the law on its behalf, 2) the FDA may work with state officers to conduct investigations, 3) a state may bring a civil action according to the Act.[159] Regarding the accuracy of calories, the FDA noted that there must be a reasonable basis for such information.[160] In addition to the USDA National Nutrient Database for Standard Reference that was previously mentioned, the FDA lists "nutrient databases, cookbooks, laboratory analyses, and other reasonable means" as being means for determining total calories.[161]

### *B. Cost of Implementing Section 4205*

This section addresses perhaps the most focused-on and critical aspect of section 4205, that of how much it will cost establishments to implement and maintain compliance with the law. In this section, this author will show just how few restaurants are now subject to the provisions of section 4205. Then, specific costs will be discussed from the proposed rule, final rule, and final regulatory impact analysis for section 4205.

The U.S. restaurant industry is undeniably big business. U.S. restaurants grossed $799 billion in 2021.[162] In light of those high gross profit numbers, however, seven in ten restaurants are "single-unit operations"[163] and currently do not need to comply with the menu nutrition requirements of the section 4205 of the ACA, which applies to chains of twenty or more restaurants or similar retail food establishments.[164] And a portion of the remaining 30% of chain restaurants may not need to comply with section 4205 if they have fewer than twenty restaurants because of the twenty-restaurant threshold. In addition, mobile restaurant chains and schools are also excluded from coverage, which is discussed in Part IV of this paper, *infra*.[165] These omissions leave a gaping hole in the protections that section 4205 is intended to provide.

It is useful to summarize official analyses of the costs of implementing and

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Retail Food Establishments, 79 Fed. Reg. at 71,243.

158. *Id.*

159. *Id.* at 71,244.

160. *Id.* at 71,178, 71,188.

161. *Id.* at 71,229.

162. *National Statistics*, NAT'L REST. ASS'N, https://restaurant.org/research-and-media/research/industry-statistics/national-statistics/ [https://perma.cc/97HK-F7PQ] (last visited Apr. 17, 2022).

163. *Id.*

164. 21 U.S.C. § 343(q)(5)(H).

165. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,169, 71,171.

maintaining the section 4205 requirements to see how the costs have developed over time. The proposed rule that introduced section 4205 in 2011 estimated the initial costs of implementation at $1,100 per covered establishment, ranging from an average of $1,000 for full service chain restaurants to $1,800 for "limited service eating establishments," which most likely have more than one menu board or display.[166] In the proposed rule, the FDA noted that costs will depend on the means in which restaurants acquire nutritional information and on the sophistication of menu design.[167] As a matter of comparison, non-government estimates projected the cost to individual restaurants to be between $1,600 to $4,700 per year to change the menus.[168]

The rest of this section consists of both industry-wide costs of compliance with section 4205 and the average cost of compliance per restaurant/similar retail food establishment. Industry-wide costs will show the scope of the current law, providing more context. At the time that the proposed rule was published, the FDA estimated that industry costs would range from $34.9 million to $130.1 million.[169] By law, the FDA offered several cost option projections in the proposed rule that allowed for various changed scenarios.[170] The industry-wide cost estimates for the larger scope option in the proposed rule was between $39.9 million and $145.8 million.[171] The scope of establishment types subject to the proposed rule was broadened in the final rule.[172] The final rule, published on December 1, 2014, lists the total industry cost of complying with section 4205 to be $141 million.[173] That total is slightly higher than the original estimate published in the proposed rule, which was calculated before compliance with section 4205 was expanded to include more eating establishments but in line with the option therein that allowed for such an expansion.[174]

As part of the executive order directives and legislation requiring agencies to

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166. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,222-23 (proposed Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11, 101).

167. *Id.* at 19,223. For instance, it would cost quite a lot more to have a laboratory test the nutritional value of a food than to find the value from a cookbook or a free online database. *Id.*

168. J. Patrick Doyle, *On Menu Regulations, Government Must Do Better*, THE HILL (Aug. 15, 2011, 4:25 PM), http://www.thehill.com/blogs/congress-blog/politics/176887-on-menu-regulations-government-must-do-better [https://perma.cc/8V7R-V32J].

169. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,222-23 (see Table 5a).

170. *Id.* at 19,223-24 (see Table 5b).

171. *Id.* (see Table 5b, Option 3).

172. *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,162-76 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

173. *Id.* at 71,244 ("using the most current (2013) Implicit Price Deflator for the Gross Domestic Product").

174. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,223-24.

assess all costs and benefits of proposed regulations,[175] the FDA conducted an exhaustive cost and benefit summary of section 4205.[176] This final regulatory impact analysis is separate from the proposed rule and final rule. The final regulatory impact analysis was conducted three and a half years after the proposed rule's estimated costs,[177] and it is what is cited to for most of the remainder of this section.

The potential of section 4205 to positively affect healthcare costs by providing consumers with nutrition information in restaurants and similar retail food establishments is quite high. There is a lot at stake with astronomical healthcare costs being the norm. Section 4205 should help reign in ever-spiraling healthcare costs for the nation's consumers by providing menu information not previously offered, which would, in theory, lower the high costs of healthcare insurance premiums. In the final regulatory impact analysis, the FDA estimates the overall stream of benefits from section 4205 will be between $3.74 to $10.38 billion over twenty years.[178]

Costs of compliance with section 4205 are broken down best in the final regulatory impact analysis. These costs include redesigning and reprinting menus, redoing menu boards, staff training, and determining the nutritional value of food.[179]

The analysis estimates that menu printing costs for handout menus will average "between $1 and $3 per copy," although it could vary from a few cents to several dollars per copy.[180] However, it must be noted that menus have historically been printed multiple times per year; thus, there should be minimal additional printing costs incurred by adding nutrition information to menus.[181] A 2004 survey, called "Availability of Nutrition Information from Chain Restaurants in the United States" by Wootan and Osborn, concluded that the expense associated with reprinting menus and with editing menu boards, which are altered several times per year, was "feasible both financially and logistically for chain restaurants."[182] Finally, once nutrition requirements have been determined and menus printed, they would not have to be reprinted until new nutrition information is added, such as when a new menu item is introduced.[183]

The FDA estimates that the cost of redesigning menu boards, which consists

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175. Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993); Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (Jan. 18, 2011); The Regulatory Flexibility Act of 1980, 5 U.S.C. §§ 601-612; Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, 109 Stat. 48 (codified as amended in scattered sections of 2 U.S.C.).

176. REGULATORY IMPACT ANALYSIS, *supra* note 16, at 29-104.

177. *See id*. at 1. The assessment was published in November 2014. *Id*.

178. *Id*. at 9 (assuming a discount rate of 7%).

179. *Id*. at 33.

180. *Id*. at 47.

181. *See* Margo G. Wootan & Melissa Osborn, *Availability of Nutrition Information From Chain Restaurants in the United States*, 30 AM. J. PREV. MED. 266, 267 (2006).

182. *Id*.

183. *Id*.

of "design and administrative costs," will range from "$2,402 to $5,011 per label, with a mean of $3,706" per restaurant, snack bar, or cafeteria chain (for all of the stores in the chain, not per each store).[184] Although the cost of replacing menu boards will vary by type of menu board, the FDA estimates that, on average, it will cost each restaurant $591 per menu board.[185] If the average chain establishment has three menu boards, that equates to $1,773.[186] The FDA noted that "[e]stablishments that are part of larger chains with more displays and more sophisticated ordering technology estimate that the cost may range between $1,500 and $2,500 per establishment."[187] However, it must be noted, that menu boards are already routinely edited by restaurants.[188]

The FDA estimates that there would need to be initial staff training on providing nutritional information to customers and that such training would average between four to eight hours for restaurant and grocery store managers, the parties responsible for compliance with section 4205; and between ten and thirty minutes of training for all other restaurant and grocery store employees needing to be trained.[189] The estimated costs are between $100 to $200 per manager, and up to about $7 for all other restaurant employees and $7.50 for all other grocery store employees.[190] The FDA estimates that recurring costs for managers will be one-half of initial training costs based on a 50% turnover rate in managers.[191] The FDA estimates that recurring training costs for non-managers will be the same as initial training costs, based on a 100% turnover rate for non-management staff.[192]

As previously mentioned, restaurants and similar retail food establishments have choices available to them in order to determine nutritional values.[193] The FDA issued a regulation stating that restaurants must have a reasonable basis to justify nutrition information.[194] To determine the reasonable basis, covered establishments may use nutrition databases, cookbooks, laboratory analysis, and nutrition facts labels of existing products.[195] The final regulatory impact analysis of section 4205 lists the average costs of those choices that may be used to establish a reasonable basis for nutrition information.[196] However, it is worth noting that many of the large chains have had much nutrition information

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184. REGULATORY IMPACT ANALYSIS, *supra* note 16, at 47.
185. *Id.* at 48-49 ($550 per board equipment and $41 for labor).
186. *Id.*
187. *Id.* at 48.
188. Wootan & Osborn, *supra* note 181, at 267.
189. REGULATORY IMPACT ANALYSIS, *supra* note 16, at 54-56.
190. *Id.* at 55-56.
191. *Id.* at 59.
192. *Id.*
193. *See supra* text accompanying note 152.
194. 21 C.F.R. § 101.11(c)(1).
195. *Id.*; *see* REGULATORY IMPACT ANALYSIS, *supra* note 16, at 28.
196. REGULATORY IMPACT ANALYSIS, *supra* note 16, at 35.

available to consumers for years.[197] One study noted that by 2004, 54% of the 400 largest chain restaurants already provided some form of nutritional information for standard menu items, a roughly 50% increase since 1994.[198] Additionally, 82% of those offering nutrition information did so for most of their menu items.[199] The final regulatory impact analysis estimated, however, that the smaller restaurant chains would more likely have less nutrition information than what the largest chains have.[200] An additional consideration when calculating the potential cost of food nutrition analysis is that many food items are delivered to restaurants as finished products, either in packaged or in an unpackaged form; and as such, may already have the nutrition information available to consumers.[201] In both instances, little or no expense would be incurred since the establishment already has the required nutrition information.

As a result of so many variables, it is difficult to project the cost of item nutrition analysis. Nonetheless, the FDA estimates that nutrition analysis directly from a lab costs about $650 per food item, and per-item estimates for database nutrition analysis costs range from $280 to just over $1,000.[202] At least one company offers nutrition analysis information on ten items for a flat $49.[203] Instead, companies may access compiled nutrition analysis from a database, which costs between $25 to $100 per food item.[204] Finally, new companies have emerged that will test the nutrient content of food samples, which will serve to bring testing costs down as more restaurants utilize these companies.[205] Digital signage companies have also stepped up to offer their services to restaurants.[206]

## IV. SOLUTIONS

When one considers how to best improve section 4205 so it reaches its full potential as a major healthcare improvement tool, several prevalent factors surface. First, what restaurants and similar retail food establishments should be subject to the requirements of section 4205? Next, what nutrition information should be included on the menu and menu boards to truly effectuate the purpose of section 4205? Finally, the cost factor in today's marketplace must be studied and considered.

One of this author's solutions is for section 4205 to apply to chain restaurants

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197. *See* Wootan & Osborn, *supra* note 181, at 267.

198. *Id.*

199. *Id.*

200. REGULATORY IMPACT ANALYSIS, *supra* note 16, at 34; *see also* Wootan & Osborn, *supra* note 181 (finding that the percentage of chains that had nutrition information decreased as the chain size decreased).

201. REGULATORY IMPACT ANALYSIS, *supra* note 16, at 35.

202. *Id*. at 35-36.

203. *Id*. at 36.

204. *Id*.

205. *See supra* Part IV.

206. *Id.*

and similar retail food establishments of three or more stores and not just chains of twenty stores or more. This sentiment was echoed in a comment in the final rule for section 4205, noting that perhaps the limit for not having to be subject to the regulation would be for only those restaurants that have "a very small seating capacity."[207] This author believes that the comment goes too far, disproportionately negatively affecting the most vulnerable restaurants. This author's solution of excluding non-chain restaurants means that no stand-alone restaurants will need to comply with the regulation. It is these restaurants that struggle to establish themselves in their first few years, and the addition of even nominal amounts of extra costs could be the difference between staying open and closing. According to the National Restaurant Association, seven in ten restaurants are stand-alone.[208] There are widely varying estimates as to the percentage of new restaurants that close in the first year, with approximations ranging from 17%[209] to 60%.[210] Any percent between those numbers surely places new restaurants at risk. Thus, it is prudent to err on the side of caution and exclude stand-alone restaurants from the coverage of section 4205. The decision to become a chain restaurant is one that undoubtedly requires careful consideration of all costs. As it is likely difficult to project how adding that second store will affect the bottom line, and again out of an abundance of caution, chains with just two stores should be excluded from the requirements of section 4205. In this way, chains with just two stores can focus on becoming firmly established without having to factor additional costs into the mix. Once a chain expands from two to three stores, it is presumed to be financially established

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207. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,174 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

208. *National Statistics*, *supra* note 162.

209. *See* Tian Luo & Philip B. Stark, *Only the Bad Die Young: Restaurant Mortality in the Western US*, RESEARCHGATE (Oct. 2014), https://www.researchgate.net/publication/267695784_Only_the_Bad_Die_Young_Restaurant_Mortality_in_the_Western_US [https://perma.cc/2TME-N8PX] (finding that Bureau of Labor Statistics census from 1992 to 2011 showed a first-year restaurant failure rate of 17%); *see also* Caroline Price, *What is the Restaurant Failure Rate*, TOAST, https://pos.toasttab.com/blog/on-the-line/restaurant-failure-rate [https://perma.cc/RJ27-NSEJ] (last visited Apr. 17, 2022) (citing to the National Restaurant Association's estimate that the first-year restaurant failure rate is 30%

210. *See* Jarrett Bellini, *The No. 1 Thing to Consider Before Opening a Restaurant*, CNBC (July 6, 2016, 11:20 AM) https://www.cnbc.com/2016/01/20/heres-the-real-reason-why-most-restaurants-fail.html [https://perma.cc/J9UP-DAS2] (claiming that first-year failure rate of new restaurants is 60%); *see also* Restro Gyaan, *Top 10 Reasons Why Restaurants Fail Within the First Year Of Operations*, THE REST. TIMES, https://www.posist.com/restaurant-times/restro-gyaan/top-10-reasons-why-restaurants-fail.html [https://perma.cc/6TU4-HLQX] (last visited Apr. 17, 2022) (also claiming a 60% first-year failure rate); Matthew Krimmel, *Why Do Restaurants Fail? Restaurant Failure Rate Statistics and Facts*, BINWISE, https://home.binwise.com/blog/restaurant-failure-rate [https://perma.cc/HV3F-DMBW] (last visited Apr. 17, 2022) (also estimating a 60% first-year failure rate).

unless there was serious error in assessing revenue and expenses associated with the expansion, which is unlikely after previously being successful in expanding to two stores. The presumption, therefore, is that chains will have figured it out with the first expansion. Thus, the requirements of section 4205 should easily be met by chains of three or more stores. However, even small chain restaurants should not be overburdened with additional costs; therefore, financially viable alternatives to incurring the costs of section 4205 must be explored, which will be addressed later in this Part.

As noted before, section 4205 applies to restaurants that are "part of a chain with 20 or more locations[.]"[211] In the final rule, the FDA defined "location," noting that it meant being in "a fixed position or site."[212] By excluding mobile restaurants, such as food trucks, jets, trains, and ships, the FDA has left out tens of thousands of restaurants from the section 4205 requirements. The FDA did so by relying on dictionary definitions of the word "location."[213] Such definitions included "a position or site occupied," "a tract of land designated for a purpose," and "a place where something is or could be located."[214] The FDA used a long-standing, traditional definition of the word location, likely stemming from thousands of years ago as folks struggled to draw accurate maps of the world, long before societal mobility was a thought, and certainly before the proliferation of restaurants and jet, ship, and rail travel.[215] The concept of location has evolved greatly since then with the ease of mobility being as it currently is. Even so, it is not unreasonable to interpret those traditionally relied-on definitions to apply to mobile restaurants. One can include mobile restaurants in the definition of a "site occupied," as a site, such as the food car inside of a train, is certainly occupied by at least the restaurant staff when the train is in motion.[216] Similarly, mobile restaurants can be included in the definition of "a place where something is . . . located."[217] A mobile restaurant is every bit a place, or an establishment, as is a restaurant in a fixed location. To argue otherwise is to argue against the existence of the mobile restaurant. The only difference is that a one restaurant is stationary and the other is in motion. The FDA did not seem to appropriately consider anything besides the narrowest of dictionary interpretations to its definition of "location."

At least one author believes that the FDA made a legally questionable decision by excluding mobile restaurants from the requirements of section

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211. 21 U.S.C. § 343(q)(5)(H)(i).

212. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,171 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

213. *Id*.

214. *Id*.

215. *See* F. Lukermann, *The Concept of Location in Classical Geography*, 51 ANNALS OF THE ASS'N OF AM. GEOGRAPHERS 194, 205-07 (1961).

216. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,171.

217. *Id.*

4205.[218] In summarizing section 4205 in 2015 (the final rule was originally published in 2014 and originally had a late 2015 start date), the author opined that the FDA's arbitrary nature of the definition of the word "location" would at least fail the second step of the *Chevron* deference test.[219] Under *Chevron*, courts must look to legislation to determine if the term in question is already defined, and if the term has not been defined by Congress, then the agency may interpret it under the confines of "a permissible construction of the statute."[220] In terms of the word "location," it is assumed that the FDA determined that it had not been legislatively defined, and thus the FDA defined it the final rule.[221] If an agency's definition is challenged, courts assess whether the definition is a "permissible construction of the statute."[222] The author concludes, as I have, that the FDA erred by limiting the definition of location to a fixed place, which they succinctly noted as being at odds with the purpose of section 4205.[223] As the author notes, the FDA's definition of location as being confined to a fixed place "focuses on a statutorily irrelevant factor—whether a location can move—to undermine the statute's purpose, which is to provide consumers with nutrition information when they order restaurant-type food."[224]

The FDA specifically excluded elementary and secondary schools in its final rule for menu labeling requirements of section 4205 when it added to the proposed rule definition of "restaurant or similar retail food establishment" the additional phrase "except if it is a school as defined in 7 CFR 210.2 or 220.2."[225] In doing so, the FDA noted that Congress has not defined the phrase "similar retail food establishment" in either section 4205 or in the sprawling FD&C Act, which was the first law to require nutritional labeling of food (portions of which the ACA amended).[226] Thus, the FDA felt compelled to look to major legislation specific to schools—specifically, legislation pertaining to school lunch and school breakfast programs.[227] The FDA concluded that it is "reasonable to interpret the

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218. *Recent Regulations*, *supra* note 17, at 2101-02 (author was not advocating a solution but instead was assessing the legality of section 4205 and ultimately determined that the FDA is likely in violation of both the "permissible construction" prong of the *Chevron* test and the Administrative Procedure Act's notice and comment provision).

219. *Id*. at 2103-04. The *Chevron* test became law in the case Chevron, U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837 (1984).

220. *Chevron*, 467 U.S. at 842-43.

221. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,171.

222. *Chevron*, 467 U.S. at 843.

223. *Recent Regulations*, *supra* note 17, at 2104.

224. *Id.* The author also argued that, by only providing the new definition of location in the Final Rule, the FDA violated the notice and comment provision of the Administrative Procedures Act since the FDA did not give consumers an opportunity to comment on the change. *Id.* at 2101.

225. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,162, 71,169.

226. *Id*. at 71,169.

227. *Id*.

term 'restaurant or similar retail food establishment' to not include schools" without giving specific reasons.[228] This is a curious decision considering agencies are given broad powers in the normal course of promulgating regulations under *Chevron*,[229] and considering Congress has targeted school lunch and breakfast programs with legislation.[230] The fact that section 4205 does not apply to schools is problematic both from the context of the sheer number of children who eat in primary and secondary schools and because it is precisely the age where the introduction of nutrition information would be the most useful. This is an age where good habits can be easily formed. It is also the age group that advertisers pummel with messages of "fast food, sugary drinks, candy, and unhealthy snacks," spending roughly $14 billion per year on such advertising efforts.[231] The federal government recognizes that reaching school-age children is desirable. The CDC states that schools "can help shape lifelong healthy eating behaviors."[232] The CDC also notes that it is precisely in schools that students should be targeted, admitting that students consume "as much as half their daily calories at school."[233] In addition, the CDC recommends that schools promote healthy food choices.[234] Further, a December 2021 estimate showed that approximately $200 billion dollars of stimulus money directed at schools has yet to be allocated.[235] Thus, there is a public acknowledgment of the importance of providing healthy choice information in schools, and there is remaining stimulus money to fund it.

Another major hole in the coverage of section 4205 is that it does not apply to the burgeoning third-party delivery services sector. To echo at least one author who previously came to this conclusion, section 4205 should apply to third-party delivery services that are delivering food and beverages for covered

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228. *Id*.

229. Chevron, U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837, 843-44 (1984) (stating that an agency whose expertise allows it to promulgate legislation is given wide berth to interpret that legislation).

230. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. at 71,169.

231. *See Food Marketing to Children*, STATE OF CHILDHOOD OBESITY, https://stateofchildhoodobesity.org/policy/food-marketing-to-children/ [https://perma.cc/957G-G4T7] (last visited May 17, 2022) ("Food, beverage and restaurant companies spend almost $14 billion per year on advertising, more than 80% of which promotes fast food, sugary drinks, candy, and unhealthy snacks" and, in 2016, children saw an average of 11 to 12 such advertisements per day).

232. *School Nutrition*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/healthyschools/nutrition/schoolnutrition.htm [https://perma.cc/L4LS-TVVV] (last visited Apr. 3, 2022).

233. *Id.*

234. *Id.*

235. Nate Rattner & Jacob Pramuk, *The U.S. Has Spent Most of Its Covid Relief Funding, But There Are Still Billions Left To Dole Out*, CNBC (Dec. 9, 2021, 3:41 PM), https://www.cnbc.com/2021/12/09/covid-relief-bills-us-has-spent-most-of-coronavirus-aid-money.html [https://perma.cc/GJP4-MJZS].

establishments.[236] It is estimated that the online third-party delivery service industry generates over $26 billion per year with 31% of Americans using such services twice per week.[237] With the popularity of these delivery services even before the pandemic and the exponential increase of popularity during the pandemic, this is another large gap in the establishments subject to section 4205.

At the heart of section 4205 is that total calories must be included on menus and menu boards, as this is literally where consumers look to make purchases. This author proposes to walk the fine line between not having enough relevant nutrition information on the menu and menu boards and having too much information thereon. It is proposed here that in addition to total calories, menus and menu boards should also include grams of carbohydrates, fats, and protein. Although not ideal from the perspective of consumers needing to watch their sodium and sugar intake, this information would be closer to what the FDA requires on the nutrition facts panel of packaged goods, which is familiar to consumers, while acknowledging that only so much can be added to the menus and menu boards.[238] At the least, this information would allow consumers to determine the percentage makeup of carbohydrates, fats, and proteins in an item as a baseline level of nutritional information. If there is too much of one macronutrient, the consumer has the choice to select a different item that better fits his/her desired percentage. The provision of total calories along with grams of fats, carbohydrates, and proteins give a much more complete picture than providing just total calories, giving consumers more control over what they decide to eat. This gives nutrition-conscious consumers a good start at determining if a food meets their nutrition criteria and could prompt them to secure the nutrition handout for more detailed information on, say, the type of carbohydrates and fats and the amount of salt and added sugars that are in the food. This amount of information on menus and menu boards is similar to the amount of information that some studies found led to more healthy item selection.[239] Thus, it would not be too much information to have on menus and menu boards.

So why require more information on menus and menu boards given that

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236. *See* Guszkowski, *supra* note 15.

237. *20 Food Delivery and Online Ordering Statistics for 2021*, FUNDERA (Sept. 6, 2021), https://www.fundera.com/resources/food-delivery-statistics [https://perma.cc/8XX6-E636].

238. *See* 21 U.S.C. § 343(q)(5)(C).

239. *See, e.g.*, KING CNTY. BD. OF HEALTH CODE § 5.10.015, *supra* note 18 (the law requires total calories, grams of saturated fat, grams of carbohydrates, and milligrams of sodium be placed on the menus and menu boards of covered establishments); CITY OF PHILADELPHIA HEALTH CODE § 6-30, *supra* note 18 (the law requires covered establishments to post total calories, grams of fat, grams of carbohydrates, and milligrams of sodium); Masic et al., *supra* note 97, at 55 (calorie and minutes required to burn off the calories by walking were included with items, and this information was statistically significant in healthy food and beverage selection over providing no information or providing just total calories); Morley, *supra* note 98, at 9-11 (provision of calorie totals plus a traffic light color representing the healthfulness of the food or beverage on a menu board resulted in the selection of 500 fewer kilojoules per meal).

plenty of nutrition information is already required in the handout-on-request document? After all, section 4205 requires that total calories, fat calories, saturated fat, cholesterol, sodium, carbohydrates, complex carbohydrates, sugars, fiber, and protein calories be on the handout.[240] The answer is borne out of necessity because of consumer behavior. Customers seldomly ask for the handout. Findings in studies vary between 0.1%[241] and 3.1%[242] customers accessed calorie information that is accessible on-premise other than on the menus or menu boards. It may be because, unlike information on a menu and menu board, the handout is not necessarily available at the direct point of purchase. On a menu, the calorie information is included in the same place as the item. Customers can zero in on their selection and the calorie information is right there. The same goes for a menu board. But customers need not view the nutrition handout when ordering from the counter, even if the handouts are within reach. It's an extra step in the ordering process that, for reasons of convenience or because focus is elsewhere, does not often get taken. Basically, the nutrition handout is not in the consumer's face, and that is a problem. This is the same logic that the FDA used when disagreeing with comments pertaining to its final rule in which the commenter lobbied for having total calorie information on just the menu board of choice.[243] The FDA noted that the requirement for including total calories must be on writings in which consumers may select their items to purchase "at the time the consumer is viewing the writing . . . regardless of whether . . . the writing is not the menu used most often by consumers."[244] It is better to expand the nutrition information that is on the menu and menu boards where consumers will be able to view the information when selecting items to purchase, and the FDA has stated so in no uncertain terms.

Although the evidence provided in Section III.B. shows that the cost of providing calorie information on menus is not significant for chain restaurants and similar retail food establishments, there are ways to bring down the costs even further. A great start would be to target some remaining COVID-19 stimulus money to defray the costs of complying with section 4205. This money could be spent directly on menu labeling costs, such as on food testing payments to food

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240. 21 U.S.C. § 343(q)(1)(C)-(D).

241. Christina A. Roberto et al., *An Observational Study of Consumers' Accessing of Nutrition Information in Chain Restaurants*, 99 AM. J. PUB. HEALTH 820, 921 (2009) (only 0.1% of 4,311 patrons accessed nutrition information provided for them before ordering).

242. Notice of Public Hearing, DEP'T OF HEALTH & MENTAL HYGIENE, Notice of Intention to Repeal & Reeanact § 81.50 of the New York City Health Code, https://www1.nyc.gov/assets/doh/downloads/pdf/public/notice-intention-hc-art81-50-1007.pdf [https://perma.cc/NY7V-NU2D] (last visited May 23, 2022) (3.1% of roughly 10,000 customers viewed nutrition information provided in-store; however, Subway patrons were excluded from the calculation because of the unusual way they provided the information to customers).

243. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,176-77 (Dec. 1, 2014) (to be codified at 21 C.F.R. pts. 11, 101).

244. *Id.* at 71,177.

labs to determine accurate calorie content or on independent food analysts or nutritionists. Or the money could be spent on the hiring of such positions either within a restaurant or for a position that is shared among several restaurants. In December 2021, the estimate of how much of the most recent COVID-19 stimulus money was left to obligate was approximately $500 billion.[245] Much of the money is for healthcare and schools.[246] That same estimate showed that over $100 billion is specifically for healthcare, and it has not been obligated.[247] A menu labeling effort is very much a healthcare endeavor and current stimulus money allocations should be able to be used for this purpose.

There is always the possibility that more stimulus money could be approved for this worthy endeavor, as we have already seen six relief bills passed into law.[248] In fact, there is currently more stimulus money being legislated.[249] One piece of legislation, at the time the author is writing this article, is H.R. 3807, which passed the U.S. House of Representatives and, if passed by the Senate, would allocate $60 billion dollars to the Restaurant Revitalization Fund.[250] The purpose of the Restaurant Revitalization Fund is to help restaurants and similar food and beverage establishments navigate the pandemic.[251] Congress could clarify that money spent on digital menu boards and relevant software are covered expenses. Such verbiage arguably already exists in this and other stimulus laws. H.R. 3807 includes three provisions that could cover the cost of digital menu boards and menu board software: one provision that covers operating expenses, one covers expenses required under law pertaining to social distance measures, and another provision covers expenditures for worker protection.[252] An argument can be made that providing digital menu boards and related software (and even ordering kiosks and the like) prevents much unnecessary close contact between restaurant staff and customers by avoiding the menu exchange (and, for kiosks

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245. Rattner & Pramuk, *supra* note 235; *see also* Alicia Parlapiano et al., *Where $5 Trillion in Pandemic Stimulus Money Went*, N.Y. TIMES (Mar. 11, 2022), https://www.nytimes.com/interactive/2022/03/11/us/how-covid-stimulus-money-was-spent.html [https://perma.cc/CF4H-N2F8] (data provided by the Committee for a Responsible Federal Budget, which maintains a comprehensive COVID Money Tracker website at https://www.covidmoneytracker.org/ [https://perma.cc/9Z64-8HP3]).

246. Rattner & Pramuk, *supra* note 235.

247. *Id.*

248. *Id.* (among other things, this article gives a good summary of the six pandemic relief bills); *see also* Parlapiano et al., *supra* note 245 (giving a nice summary of the pandemic relief bills and analyzing the effectiveness of each).

249. *See* Rattner & Pramuk, *supra* note 235.

250. Restaurant Revitalization Fund Replenishment Act of 2021, H.R. 3807, 117th Cong. (2022), *available at* https://www.congress.gov/bill/117th-congress/house-bill/3807/text?r=2&s=1 [https://perma.cc/5XQ3-S6EG]. This bill, which amends the American Rescue Plan Act of 2021, passed the U.S. House of Representatives on a 223-207 vote April 7, 2022, and is currently awaiting deliberation in the Senate. *Id.*

251. *Id.*

252. *Id.* at § 3(b)(4)(G), (K), (M).

and ordering tablets, the closeness required in taking orders). There is also a catchall provision giving the Administrator of the Small Business Administration discretion to deem an expense as being essential.[253] One could also argue that it is essential to reduce the number of close contacts between restaurant worker and customer.

The Paycheck Protection Program includes two provisions similar to what is found in H.R. 3807 mentioned above.[254] One provision states that "'covered operations expenditure' means a payment for any business software or cloud computing service that facilitates business operations, product or service delivery, the processing, payment, or tracking of payroll expenses, human resources, sales and billing functions, or accounting or tracking of supplies, inventory, records and expenses" are covered and another provision states that "worker protection expenditures" are covered.[255] Such an expense should be able to meet the operation costs criterion.

Additionally, Senate Bill 2675 was introduced on August 7, 2021.[256] If passed, it will provide nearly an additional $50 billion to the Restaurant Revitalization Fund.[257] In addition, money allocated to certain sectors of the economy remains unclaimed because of a lack of demand.[258] For instance, in some cases not all of the money was ultimately needed for what it was spent for, such as money for enhanced unemployment benefits, which most states have stopped providing, or money for restarting in-person schooling, which largely went unspent.[259] Such money would be returned to the general pot if not allocated by a certain time.[260]

It appears that the FDA did not fully consider or envision the development of the industries relevant to section 4205 compliance when computing likely compliance costs. Companies that sell digital signage tout the ease and quickness of updating the menu board, as well as low initial costs.[261] Companies tout startup

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253. *Id.* at § 3(b)(4)(N).

254. *See* Consolidated Appropriations Act of 2021, Pub. L. No. 116-260, § 304, 134 Stat. 1182, 1993-96 (2020),

255. *Id.* § 304(b)(2), 134 Stat. at 1994, 1996.

256. Continuing Emergency Support for Restaurants Act, S. 2675, 117th Cong. (2021).

257. *Id.* § 2 (raising provided funds from $28.6 billion to $76 billion).

258. Rattner & Pramuk, *supra* note 235.

259. *Id.*

260. *Id.*

261. *See, e.g.*, *Digital Menu Boards for Restaurants*, DOPUBLICITY, https://www.dopublicity.com/Digital-Menu-Boards.aspx [https://perma.cc/LHM6-XKLR] (last visited Mar. 27, 2022); *Powerful Digital Signage and Content*, SPECTRIO, https://www.spectrio.com/solutions/digital-signage/ [https://perma.cc/C6HH-MSZ5] (last visited Mar. 27, 2022); *Restaurants, Cafés and Bars*, YODECK, https://www.yodeck.com/solutions/digital-menu-boards/ [https://perma.cc/72E6-V4VY] (last visited Mar. 27, 2022); *Mood:Restaurant Digital Signage*, MOOD:MEDIA, https://us.moodmedia.com/ecampaign/restaurant-digital-signage/ [https://perma.cc/EB7J-S54P] (last visited Mar. 27, 2022); *Digital Menu Board*, VOOLSY SCREEN, https://www.voolsyscreen.com/industries/digital-menu-boards-solutions [https://perma.cc/B3B4-J8RD] (last visited Mar. 27, 2022).

costs of $249–$399 or plans as low as $7.99–$10 per month per digital sign.[262] There are also extremely inexpensive label printers that can be used to provide labeling for salad bars and beverage areas.[263] There are also companies that specialize in providing online nutrition information for foods and beverages.[264] These companies provide nutrition analysis for restaurants for as little as $88 per month.[265]

Not only will the above solutions make it easy and very affordable for restaurants currently subject to the provisions of section 4205 to provide calorie information to consumers, but it will easily allow for even small restaurant chains, as well as schools and mobile restaurants, to comply with section 4205.

## CONCLUSION

The extremely high cost of healthcare in the United States is an exceptional burden on a significant number of citizens and has been so for decades. The average health of consumers has trended downward for decades.[266] Any modest and fairly inexpensive attempt to contain or even lower healthcare costs while providing more relevant nutritional information for consumers should be seriously considered. Section 4205 is not too expensive to implement.[267]

The government should require that section 4205 of the ACA be extended to chain restaurants and similar retail food establishments of three or more stores, chain mobile restaurants and similar retail food establishments of three or more stores, and all elementary and secondary schools. In addition to total calories, menus and menu boards should also include grams of carbohydrates, fats, and protein. Finally, this author agrees with a prior author that third-party delivery platforms who deliver food for covered establishments should be subjected to section 4205.

The government should defray costs associated with restaurants providing such information with stimulus money, which will make it more affordable for all chain restaurants and similar retail food establishments of three or more stores, especially small chains, and create jobs for food analysts and nutritionists.

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262. DOPUBLICITY, *supra* note 261; *Pricing*, YODECK, https://www.yodeck.com/pricing/ [https://perma.cc/DP8E-GKRX] (last visited Mar. 27, 2022); *Easy Pricing for Easy Digital Signage*, VOOLSY SCREEN, https://www.voolsyscreen.com/pricing [https://perma.cc/W7EQ-S58J] (last visited Mar. 27, 2022).

263. *See, e.g.*, *Enhance Your Buffets and Make All the Personalized Cards You Need*, EDIKIO, https://www.edikio.com/edikio-guest [https://perma.cc/DU9B-K7E3] (last visited Mar. 27, 2022) (one example of a label printer marketed to restaurants).

264. *See, e.g.*, MENUCALC, https://menucalc.com/ [https://perma.cc/6UU2-2V4A] (last visited Mar. 27, 2022).

265. *Id.*

266. *See* Peter A. Muennig et al., *America's Declining Well-Being, Health, and Life Expectancy: Not Just a White Problem*, 108 AM. J. PUB. HEALTH 1626 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6221922/ [https://perma.cc/8GE7-S2BC].

267. *See supra* Section IV.B.

Stimulus money can be used to invest in digital menu boards, to pay testing companies to evaluate the nutrition content of restaurant food, or to pay for database access to existing nutrition information. Even without stimulus money, costs associated with digital menu boards is now inexpensive and should be within easy grasp of restaurants to afford. Finally, the government should encourage the creation of more companies to test foods and offer reasonable cost nutrition information that several restaurants can share. Stand-alone restaurants, similar retail food establishments, and chains of three or more stores are often in a struggle to become established, and they would not be negatively affected as they are excluded from this solution.

It took a long time for section 4205 to become effective. Like its parent law, the ACA, section 4205 has the potential to bring about significantly positive once-in-a-generation healthcare reform. The opportunity to greatly increase the health of U.S. consumers and to drive down outrageously high health care costs is a gift not to be ignored. Incorporating the proposals for improving section 4205 mentioned in this article will help the law reach its lofty potential.