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Health and Economic Impacts of the National Menu Calorie Labeling Law in the United States

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BACKGROUND: Excess caloric intake is linked to weight gain, obesity, and related diseases, including type 2 diabetes mellitus and cardiovascular disease (CVD). Obesity incidence is rising, with nearly 3 in 4 US adults being overweight or obese. In 2018, the US federal government finalized the implementation of mandatory labeling of calorie content on all menu items across major chain restaurants nationally as a strategy to support informed consumer choice, reduce caloric intake, and potentially encourage restaurant reformulations. Yet, the potential health and economic impacts of this policy remain unclear.

METHODS AND RESULTS: We used a validated microsimulation model (CVD-PREDICT) to estimate reductions in CVD events, diabetes mellitus cases, gains in quality-adjusted life years, costs, and cost-effectiveness of the menu calorie labeling intervention, based on consumer responses alone, and further accounting for potential industry reformulation. The model incorporated nationally representative demographic and dietary data from National Health and Nutrition Examination Surveys 2009 to 2016; policy effects on consumer diets and body mass index-disease effects from published meta-analyses; and policy effects on industry reformulation, policy costs (policy administration, industry compliance, and reformulation), and health-related costs (formal and informal healthcare costs, productivity costs) from established sources or reasonable assumptions. We modeled change in calories to change in weight using an established dynamic weight-change model, assuming 50% of expected calorie reductions would translate to long-term reductions. Findings were evaluated over 5 years and a lifetime from healthcare and societal perspectives, with uncertainty incorporated in both 1-way and probabilistic sensitivity analyses. Between 2018 and 2023, implementation of the restaurant menu calorie labeling law was estimated, based on consumer response alone, to prevent 14 698 new CVD cases (including 1575 CVD deaths) and 21 522 new type 2 diabetes mellitus cases, gaining 8749 quality-adjusted life years. Over a lifetime, corresponding values were 135 781 new CVD cases (including 27 646 CVD deaths), 99 736 type 2 diabetes mellitus cases, and 367 450 quality-adjusted life years. Assuming modest restaurant item reformulation, both health and economic benefits were estimated to be about 2-fold larger than based on consumer response alone. The consumer response alone was estimated to be cost-saving by 2023, with net lifetime savings of $10.42B from a healthcare perspective and $12.71B from a societal perspective. Findings were robust in a range of sensitivity analyses.

CONCLUSIONS: Our national model suggests that the full implementation of the US calorie menu labeling law will generate significant health gains and healthcare and societal cost-savings. Industry responses to modestly reformulate menu items would provide even larger additional benefits.

Key Words: cardiovascular diseases ■ cost-benefit analysis ■ diabetes mellitus ■ menu calorie labeling ■ nutrition policy ■ obesity ■ restaurants

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WHAT IS KNOWN

- Excess caloric intake is linked to weight gain, obesity, and related diseases, such as type 2 diabetes mellitus and cardiovascular disease.
- More than one-third of US adults are obese. The estimated costs of all obesity-related conditions exceed $1.42 trillion annually. Meanwhile, over half of American adults consume foods from restaurants on a given day.
- As a strategy to support informed choice and reduce caloric intake, the US federal government finalized in 2018 the implementation of mandatory labeling of calorie contents on all menu items across major chain restaurants nationally.

WHAT THE STUDY ADDS

- Using nationally representative data and a validated microsimulation model, we found that the consumer response policy could prevent 14 698 cardiovascular disease events and 21 522 type 2 diabetes mellitus cases, gaining 8749 discounted quality-adjusted life years over 5 years; over a lifetime, corresponding values were 135 781 cardiovascular disease prevented and 99 736 type 2 diabetes mellitus averted, and 367 450 quality-adjusted life years gained. The healthcare savings were $0.26 billion over 5 years and $10.42 billion over a lifetime.
- Potential health gains and cost savings would be twice as large, accounting for modest corresponding restaurant menu reformulation, highlighting the restaurant's critical role in maximizing the health and economic benefits of the menu calorie label.

The prevalence of overweight and obesity among US adult has increased from 56% to 71% in <2 decades.[1] Poor diet is one major contributor, with Americans consuming far lower than recommended levels of healthy foods, such as fruits, vegetables, nuts, whole grains, healthy oils, and fish; and far higher levels of less healthful items such as sugary drinks, foods rich in refined starches and added sugars, and processed meats.[2] Excess caloric intake is linked to weight gain, obesity, and related cardiometabolic diseases, mainly type 2 diabetes mellitus and cardiovascular disease (CVD).[3,4] These diet and obesity-related conditions substantially shorten life expectancy, adversely affect quality of life and can result in premature death.[5,6] The corresponding economic burdens are substantial, with estimated direct and indirect costs of obesity-related conditions exceeding $1.42 trillion/y, or about 8% of US gross domestic product.[7]

These health and economic challenges highlight the need for cost-effective interventions to improve dietary intakes. Restaurants represent a major opportunity for such interventions. Calories consumed in restaurants have almost doubled since 1970,[8,9] while restaurant foods typically contain more calories, unhealthy fats, and added sugar and less fiber compared with food prepared at home.[10] On any given day, nearly one-third of American adults eat at a full-service restaurant, and about half at a fast-food or quick-service restaurant.[11] And, the overall nutritional quality of these meals also remains poor, with little improvement between 2003 and 2016.[11]

Food labeling can support informed consumer choice and alter dietary habits.[12,13] Consumers at restaurants tend to underestimate the calories contained in less healthy, higher-calorie options than healthier ones.[14] Food labeling can also encourage companies to reduce portion sizes or reformulate or replace their products with healthier alternatives.[12] In 2018, the US federal government finalized the implementation of mandatory labeling of calorie contents on all menu items across all chain restaurants with 20 or more locations,[15] covering ≈300 000 food retail establishments nationwide,[15,16] to support informed consumer choice, reduce caloric intake, and potentially encourage restaurant reformulations. In a regulatory impact analysis, the US Food and Drug Administration (FDA) estimated that this policy could result in a total net savings of ≈$8 billion to the healthcare system over 20 years.[10] However, this analysis did not report the potential diseases averted, cost-effectiveness of this policy, different time horizons, findings within key population subgroups with health disparities, or the potential effects of restaurant reformulation.[10] Thus, the overall potential health, economic, and equity impacts of the menu calorie labeling law remain unclear. Simulation modeling is a key analytical approach for estimating the population health and economic effects of large-scale policy changes and potential impacts on health disparities.

To address key gaps in knowledge, we used a validated microsimulation model to estimate the impact of the federal restaurant menu calorie labeling policy on cardiometabolic outcomes, costs, and relative cost-effectiveness within the overall US adult population and key population subgroups, based on expected changes in consumer caloric intake at restaurants as well as the potential additional impact of corresponding restaurant item reformulations. This investigation was performed as part of the Food Policy Review and Intervention Cost-Effectiveness Project (www.food-price.org).

METHODS

Study Overview and Simulated Population

The potential health and economic impacts of the federal restaurant menu calorie labeling policy from healthcare and societal perspectives were modeled using the validated microsimulation model–the Cardiovascular Disease Policy Model for Risk, Events, Detection, Interventions, Costs, and Trends (CVD PREDICT),[17,18] both over 5 years (2018–2023) and a cohort lifetime using a simulated nationally representative sample of US adults aged 35 to 80 years from 4 National Health and Nutrition Examination Surveys cycles (NHANES 2009–2016). Total caloric intake was derived using up to two 24-hour recalls per person as previously described.[19] Calorie intake from restaurants was estimated by the reported source of food, including categories of "restaurant with waiter/waitress", "restaurant fast food/pizza", and "restaurant no additional information." To estimate the impact of the federal menu calorie labeling policy on the entire US adult (age 35+ years) population, we included both those who do and do not consume restaurant foods in our model. To simulate a nationally representative population of 1 000 000 individuals, we sampled from NHANES with replacement, adjusting for sampling weights to account for unequal probabilities of sample selection due to complex sample design and oversampling of certain subgroups.[2] Each of these simulated individuals was followed through the microsimulation model (Figure I in the Data Supplement) with annual cycles allowing for health state transitions from one state to another until death or age 100, whichever came first. At each stage of the model transition, we incorporated model inputs from the best available sources, supplement with reasoned assumptions when data sources were incomplete, and their associated uncertainties (Table I in the Data Supplement). Each of the model inputs, structure, and outputs are described in further detail below. As recommended for economic evaluations of health interventions, results were reported according to the Consolidated Health Economic Evaluation Reporting Standards statement.[20] This modeling investigation was exempt from institutional research ethics review given published or publicly available data with de-identified personal information. The source code of the model is not publicly available.

Policy Description and Scenarios

We evaluated 2 policy scenarios, a consumer response and a consumer response + reformulation, each compared with a counterfactual base-case (status quo) scenario of no new menu calorie labeling (after 2016). We first evaluated the potential impact of the consumer response alone. The effect of the menu labeling policy on consumer calorie intake from restaurants was derived from a systematic review and meta-analysis of the effect of menu labeling interventions on consumer calorie intake,[12] which identified a 7.3% calorie reduction (95% CI, 4.4%–10.1%) with no significant heterogeneity by population or intervention characteristics (eg, population demographics or intervention duration, region, or labeled products). Consistent with these intervention studies, we assumed the time lag between policy implementation and change in calorie intake was <1 year, with the intervention effect sustained as long as the policy continues. While some of these intervention studies evaluated consumer calorie intake over a day or even longer, many evaluated the calories consumed at a single meal. We recognized that the calorie reduction in a single meal may overestimate a consumer's overall (habitual) calorie reduction, as people may partly compensate for reduced calories at one meal by increasing calories at other meals. Thus, in contrast to prior analyses of menu labeling which assumed no compensation,[21] we assumed that 50% of the reduction in calories from restaurant meals would be compensated by an increase in calories consumed outside of restaurants (ie, diminishing the policy effect size by half).

To assess the additional impact of potential restaurant item reformulation as a response to the menu calorie label, we estimated a response corresponding to the total net reduction in caloric contents of restaurant meals over the simulated period, based on empirical evidence of the impact of FDA's labeling policies related to sodium and added sugar on food industry reformulations[22–25] and expert opinion (Text I in the Data Supplement). Given absence of strong empirical data, we evaluated a modest 5% net calorie reduction in restaurant meals due to reformulations as a result of the policy. We assumed this reformulation effect would occur in a staged manner from the first year through year 5 of the intervention (ie, 1% per year × 5 years), with no additional reformulation thereafter (see Text IV in the Data Supplement for details on assumptions and calculations).

Effects of Calorie Intake Changes on Cardiometabolic Risk

The effects of calorie intake on cardiometabolic end points were modeled through weight change. The changes in body weight resulting from calorie reduction were determined from prior energy balance models which consider dynamic energy imbalance process over time as well as physiological adaptations to weight change.[26–29] A detailed description and evaluation of the methods are presented in the supplement (Text II in the Data Supplement). In brief, the model conservatively estimates that each 55 kcal/day caloric reduction leads to an average 1 pound weight loss within 1 year, with no further weight changes thereafter. Given no available data to support a differential effect by baseline body mass index (BMI) or weight status, we applied this relationship to the overall population. Our methods for reviewing and synthesizing the evidence to estimate the effect sizes for associations of BMI change with cardiometabolic risk, including validity analyses to assess potential bias, have been reported.[5,30,31] Based on the best available evidence, the clinical end points associated with BMI change included coronary heart disease (CHD), stroke, and type 2 diabetes mellitus (Table II in the Data Supplement).

Microsimulation Model Structure and Outputs

CVD-PREDICT is a validated microsimulation dynamic model, coded in C++, which simulates and quantifies the effects of policies on cardiometabolic outcomes including CHD, stroke, and type 2 diabetes mellitus.[17,18] A detailed description of the model and validation can be found in the Data Supplement (Text III in the Data Supplement). Based on NHANES as described above, the model was populated with representative American adults aged 35+ years and their corresponding information on age, sex, age, systolic blood pressure, total cholesterol, high-density lipoprotein (HDL) cholesterol, BMI, smoking status, diabetes mellitus status, and dietary habits. Additional model parameters include validated CHD and stroke risk equations and case-fatality risks based on a calibrated Framingham-based risk function as well as validated empirical historical disease trends. CVD risk factors and subsequent estimated CVD incidence and mortality and diabetes mellitus incidence were extrapolated and updated using age and time trends from NHANES. At any given time-point, a simulated individual could only be in one health state, with the probability of experiencing subsequent events based on individual characteristics and cardiometabolic risk factors including changes in the relative risks corresponding to the policy scenarios. The microsimulation process showing all potential disease states and transitions are illustrated in Figure I in the Data Supplement.

Model outputs included total CVD cases, CVD deaths, and diabetes mellitus cases at 5 years and cohort lifetime. Specific outcomes included deaths from CHD or stroke, nonfatal events including myocardial infarction, stroke, angina, resuscitated cardiac arrest, and type 2 diabetes mellitus, quality-adjusted life years (QALYs), and event-associated healthcare costs (see below). Outputs were estimated for both the overall adult population and stratified by age (35–54, 55–74, and 75–80 years), sex (male and female), race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, and others), education (<high school, high school graduate or GED, some college, college graduate or above), income (poverty-to-income ratio ≤1.3 and poverty-to-income ratio >1.3), and BMI (underweight or normal weight: BMI ≤24.9 kg/m^2, overweight: BMI 25.0–29.9 kg/m^2, obese: BMI ≥30 kg/m^2) to investigate potential population heterogeneity in health and economic impacts of this menu labeling policy. Children and young adults below age 35 years were not included in the model due to relatively low absolute rates of CVD and type 2 diabetes mellitus as well as insufficiently established disease risk equations at these ages.

Policy and Health-Related Costs

The policy costs of the FDA menu calorie labeling rule included government administration, industry compliance, and reformulation costs, as applicable. Government costs to administer, reinforce, and evaluate the policy were derived from the FDAs budget reports[32] and nutrition review project report[33] (Table III in the Data Supplement). Industry costs to redesign and reprint menus to comply with the labeling provisions were estimated using FDA's regulatory impact analysis.[34] Since we lacked source material specific to our menu calorie labeling policy, we estimated industry reformulation costs based on industry reformulation estimates from a recent analysis of added sugar labeling policy for packaged foods[13] (Text IV in the Data Supplement). We assumed that the industry reformulation costs for the federal menu calorie labeling policy were of the same magnitude (relative to the scale of the total annual sales in the restaurant industry) as the estimated industry reformulation costs for added sugar labeling (relative to the scale of total annual sales in the relevant packaged food categories), based on a reformulation cost model developed by the Research Triangle Institute.[35]

Health-related costs included both formal (medical) and informal care as well as productivity costs related to CVD (CHD and stroke) and type 2 diabetes mellitus (Table I in the Data Supplement). Formal healthcare costs included costs incurred during various conditions, including acute and chronic disease states, surgical procedures, screening, treatments, and side effects. Informal healthcare costs including costs of patients' time for travel and waiting were estimated from the Bureau of Labor Statistics.[36] Productivity costs were derived using age-specific average annual earnings based on the Current Population Survey.[37]

Cost-Effectiveness Analyses

In accordance with recommendations from the US Second Panel on Cost-Effectiveness in Health and Medicine,[38] we conducted analyses from 2 perspectives: (1) healthcare and (2) societal. The healthcare perspective incorporated policy implementation costs and direct healthcare costs, and the societal perspective further incorporated costs associated with informal care and lost productivity. For the scenario including restaurant reformulation, the industry cost of reformulation was further added in both healthcare and societal perspectives. All costs were inflated to constant 2018 US dollars using the Consumer Price Index,[39] and all costs and QALYs discounted annually by 3%. Net costs were calculated as policy costs minus health-related cost-savings from reduced cardiometabolic diseases. Incremental cost-effectiveness ratios were calculated as the net change in costs (policy implementation minus status quo) divided by the net change in QALYs. Willingness-to-pay thresholds were evaluated at \$150 000 and \$50 000 per QALY, consistent with the American Heart Association/American College of Cardiology recommendations.[40]

Sensitivity and Uncertainty Analysis

Probabilistic sensitivity analyses jointly incorporated the uncertainty distributions of multiple parameters, including the policy effect on consumer response, the policy effect on restaurant reformulation, the relationship between changes in calories and changes in weight, the associations of changes in BMI with risk of CHD, stroke, and type 2 diabetes mellitus, the individual CVD risk estimated in the Framingham-based risk function, policy implementation costs, formal and informal care costs, and utility weights (Table I in the Data Supplement). Drawing from the uncertainty distributions of each of these inputs, 1000 simulations were run over a cohort lifetime with 95% uncertainty intervals based on the 2.5th and 97.5th percentiles of the 1000 simulations. To identify the threshold percentage change in consumer compensation that would render the policy cost-effective or cost-saving, we performed 1-way sensitivity analyses allowing the compensation to vary in steps between 25% and 99% (almost no effect). We also assessed the year after the start of the intervention in which the labeling policy could become cost-effective or cost-saving.

RESULTS

Population Characteristics

Among US adults aged 35 to 80 years at baseline, more than half (61%) consumed foods from restaurants (Table 1). The likelihood of restaurant food con-

Table 1. Restaurant Food Consumption Among US Adults Aged 35–80 Years by Population Characteristics*

Characteristics	No. of Participants	Any Use of the Restaurants†	
		No. of Participants	Weighted % (95% CI)‡
Overall	15 274	8825	61 (60–63)
Number of US adult represented (age 35–80 y)	163.7 million	100.4 million	
Age in years			
35–54	7074	4625	67 (65–68)
55–74	6132	3297	59 (56–61)
75–80	2068	903	46 (42–49)
Sex			
Female	7879	4495	59 (57–61)
Male	7395	4330	64 (62–66)
Race/ethnicity			
Non-Hispanic white	6565	3893	63 (61–65)
Non-Hispanic black	3242	1917	60 (57–63)
Hispanic	3843	2134	57 (54–60)
Others	1624	881	55 (51–59)
Educational level§			
<High school	4009	1941	52 (49–55)
High school or some college	7613	4544	61 (60–63)
≥4 y of college	3652	2340	66 (64–69)
Ratio of family income to poverty level§			
<1.3	4728	2375	52 (49–55)
≥1.3	10 546	6450	64 (62–65)
Body mass index§			
Underweight/normal weight	3857	2050	55 (53–58)
Overweight	5177	2973	63 (60–65)
Obese	6240	3802	64 (62–66)

*The modeled sample was drawn from all American adult participants aged 35–80 y old in combined cycles of the 2009–2016 National Health and Nutrition Examination Survey, incorporating sampling, and survey weights to be representative of the national population.

†Restaurant consumers refer to those who consumed meals at one of more of 3 sources, including restaurant with waiter/waitress, restaurant fast food/pizza, and restaurant no additional information.

‡Data weighted to be nationally representative.

§Missing values of 0.1% (n=17) for educational level, 8.9% for family income, and 1.1% for body mass index were imputed using the survey-weighted chain method.

sumption decreased with age, including 67% (95% CI, 65%–68%) of adults aged 35 to 54 years compared with 46% (42%–49%) of adults aged 75 or older. Men (64% [62%–66%]) were also more likely to consume restaurant foods than women (59% [57%–61%]); as were non-Hispanic white adults (63% [61%–65%]) compared with other Americans including multiracial (55% [51%–59%]). Restaurant food consumption was higher among adults with 4 or more years of college education (66% [64%–69%]) compared with those with less than a high school education (52% [49%–55%]). A similar trend was observed based on family income. For BMI, people who were overweight or obese were more likely to consume restaurant foods than people who were underweight or normal weight.

Policy Effects on Calorie Consumption

At baseline among all US adults, the mean calorie intake from restaurants was 399 kcal/d (384–415), and the median intake was 245 kcal/d (224–264). Among those who consumed restaurant meals, the mean and median calorie intakes were 651 kcal/day (634–668) and 524 kcal/day (506–542), respectively. Compared with the base-case scenario, the menu labeling policy was projected to reduce median total calorie consumption from restaurants by 19 calories and 44 calories per day, respectively, based on the consumer response, and consumer response + reformulation scenarios (Figure 1).

Health Outcomes

At 5 years, the consumer response policy, compared with a status quo scenario, was estimated to prevent or postpone 14 698 fatal and nonfatal CVD events and 21 522 type 2 diabetes mellitus cases; overall gaining 8749 discounted QALYs (Table 2). Over a lifetime (mean simulated follow-up 28.4 years), corresponding values were 135 781 CVD new cases (including 27 646 CVD deaths) and 99 736 type 2 diabetes mellitus cases averted; and 367 450 discounted QALYs gained. Incorporating uncertainties in key model inputs, the consumer response policy was estimated to save a median of 135 606 (95% uncertainty interval: 63 512–179 175) fatal and nonfatal CVD events, 98 511 (18 372–137 540) type 2 diabetes mellitus cases, and gain 367 450 (244 966–489 933) QALYs.

With a 5% additional calorie reduction from restaurant reformulation, estimated health gains over lifetime were 292 560 CVD new cases and 221 345 type 2 diabetes mellitus cases averted, and 787 392 discounted QALYs gained (Table IV in the Data Supplement).

Costs and Cost-Effectiveness

At 5 years, the consumer response was estimated to save $0.90B in formal healthcare costs, $1.0M in informal healthcare costs, and $0.17B in productivity costs. From a healthcare perspective (excluding informal care and productivity costs) and accounting for the government policy implementation and restaurant compliance cost of $0.64B, this policy was cost-saving (dominant) at 5 years, saving $0.26B in total net costs (Table 2). From a societal perspective (including infor-

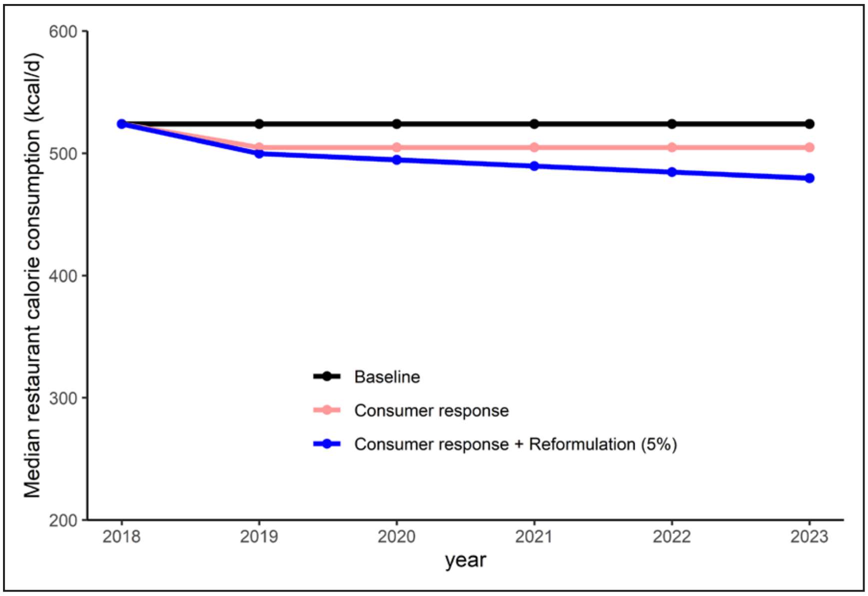

Figure 1. Median US restaurant calorie consumption among adults aged 35–80 y under the baseline projection and modeled scenarios in main analyses.

mal care and productivity cost), the total net savings were \$0.43B. Over a cohort lifetime, this policy was estimated to produce much larger healthcare savings and net cost-savings, with a net saving of \$10.42B from the healthcare and \$12.71B from the societal perspective. With a 5% additional calorie reduction from restaurant reformulation, estimated net cost-savings were \$14.11B from the healthcare perspective and \$18.68B from the societal perspective over lifetime (Table IV in the Data Supplement).

Population Subgroups

Health and economic benefits were evident in all population subgroups examined, including by age, sex, race/ethnicity, education, income, and weight (Table 3). Benefits per million adults were larger among younger versus older Americans, males versus females, Hispanics and Blacks versus other race/ethnicities, those with high school or some college education versus higher education, lower versus higher-income Americans, and obese versus lower weight Americans. For example, based on the consumer response, the menu labeling policy was estimated to prevent 916 CVD events per million Hispanic adults versus 739 CVD events per million white adults. Cost-effectiveness findings were also robust by subgroups. Consistent with the main findings, net cost-savings in each subgroup were even larger from the societal perspective.

Sensitivity Analyses

Over a cohort lifetime, the consumer response scenario had a probability of 100% being cost-saving (1000 out of 1000 simulations; Figure 2), assuming 50% of the calorie reduction from restaurants was compensated with increased consumption elsewhere and no industry reformulation. In additional 1-way sensitivity analyses varying the consumer calorie compensation, if compensation were as low as 25% (ie, 75% of the menu labeling effect in restaurants was transmitted to habitual intake), a total of 524928 QALYs would be gained, with net lifetime cost-savings of \$16.0B from the healthcare perspective and \$19.16B from the societal perspective (Table V in the Data Supplement). The menu labeling policy still produced net lifetime cost-savings even if compensation were as high as 90% and was cost-effective even if compensation was higher. Finally, evaluating the likelihood of cost-effectiveness in each of the first 5 years, the menu labeling intervention was estimated to be cost-effective by year 2, highly cost-effective by year 3, and cost-saving by year 4 (Table VI in the Data Supplement).

DISCUSSION

Using nationally representative data, our microsimulation study suggests that the consumer response to the US federal menu calorie labeling policy could generate substantial health gains among US adults and produce net cost-savings under both healthcare and societal perspectives. Over 5 years, ≈14 700 CVD and ≈21 500 diabetes mellitus cases were estimated to be prevented, with net societal savings of \$0.43B; while over a lifetime, ≈135 800 CVD and 99 700 diabetes mellitus could be prevented, with net societal savings of \$12.71B. If the policy also stimulates restaurants to partly reformulate their menu items and further reduce consumer calories from restaurant foods by an additional 5%, health gains and cost-savings were even larger, with net societal cost-savings of \$18.68B over lifetime. Health gains were seen in all strata of the population evaluated, without evidence that this policy would increase

Table 2. Estimated Health Gains, Costs, and Cost-Effectiveness of the US Federal Menu Calorie Labeling Law Over 5 Years (2018–2023) and lifetime*

	5 y	Lifetime
Simulated years	4.86	28.40
Average change in calories, kcal	−15.60	−15.60
Average change in BMI, kg/m²	−0.04	−0.04
Cases averted		
CVD cases	14 698	135 781
Diabetes mellitus cases	21 522	99 736
CVD deaths	1575	27 646
QALYs gained	8749	367 450
Change in health-related costs ($billion)†		
Formal healthcare costs	−0.90	−11.87
Informal healthcare costs	−0.001	−0.009
Productivity costs	−0.17	−2.27
Change in policy-related costs ($billion)‡		
Government administrative costs	0.01	0.02
Industry compliance costs	0.63	1.43
Industry reformulation costs	0	0
Total net costs ($billion), by perspective§		
Healthcare	−0.26	−10.42
Societal	−0.43	−12.71
Incremental cost-effective ratio ($/QALY), by perspective‖		
Healthcare	Cost-saving	Cost-saving
Societal	Cost-saving	Cost-saving

ACC indicates American College of Cardiology; AHA, American Heart Association; BMI, body mass index; CVD, cardiovascular disease; and QALY, quality-adjusted life year.

*Health outcomes and costs were evaluated among US adults aged 35–80 y at baseline (n=175 million) and followed until death or age 100, whichever first. All costs were inflated to constant 2018 US dollars using the Bureau of Labor Statistics' Consumer Price Index. Costs and QALYs were discounted at 3% annually. Menu calorie labeling was estimated to reduce average calories consumed by consumers in restaurant meals by 7.3%, based on a meta-analysis of menu labeling interventions. Our model further conservatively assumed that 50% of this reduction in calories from restaurant meals would be compensated by an increase in calories consumed outside of restaurants (ie, diminishing the policy effect size by half).

†Formal healthcare costs for acute and chronic CVD states included costs of surgical procedures, screening costs, and drug costs; and for diabetes mellitus cases, costs of institutional care, outpatient care, outpatient medications, and supplies. Informal healthcare costs included patient travel and waiting time costs. We conservatively excluded other informal healthcare cost such as unpaid caregiving costs. Productivity costs included costs resulting from loss in productivity.

‡Detailed policy-related costs available in Table III in the Data Supplement.

§The healthcare perspective included policy costs and medical costs; the societal perspective further incorporated informal healthcare costs and productivity costs. Net costs were calculated as policy costs minus health-related costs reduced from CVD events and diabetes mellitus cases.

‖Incremental cost-effectiveness ratios were calculated as the net change in costs divided by the net change in QALYs. Incremental cost-effectiveness ratios thresholds were evaluated at $150 000/QALY and $50 000/QALY according to ACC/AHA guidelines.

diet-related health disparities and some evidence that it could potentially narrow health disparities across certain subgroups. These novel findings provide support for the ongoing full implementation of the federal menu calorie labeling policy.

While the effect on consumer intakes of the recently implemented federal policy has not been reported, several analyses have assessed the effect of similar state or local regulations. These suggest that providing nutrition information at restaurants can help consumers make lower-calorie choices and also spur reformulation of existing food items and introduction of new items.[41–43] Importantly, we did not assume that such improvements would be fully passed on to usual diets, as consumers are likely to partly compensate for reduced calories at one meal with increased intake at another. Complementary multilevel interventions could also increase the impact of menu labeling alone. For example, a New York State Department of Health iChoose600 Media Campaign in 2011[44] to educate consumers on strategies for ordering meals under 600 calories at restaurants with posted calorie information found that such a campaign can enhance the effectiveness of posted calorie labels by helping consumers to notice and use the posted calorie information.[45]

To our knowledge, this is the first study to evaluate the potential health impacts, costs, cost-effectiveness, and effects in population subgroups of the federal restaurant menu calorie labeling law. Resulting from provisions in the Patient Protection and Affordable Care Act of 2010, the FDA's menu labeling final rule came into effect on May 7, 2018, requiring calorie information be displayed in chain restaurants, supermarkets, convenience stores, and similar retail food establishments with 20 or more locations nationwide and that additional nutrition information including total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein be made available for standard menu items. An analysis conducted from May to December 2017, before full implementation, found early compliance of 79% among the 90 largest US chain restaurants.[46] The FDA has stated it will work cooperatively with relevant restaurants to achieve high levels of compliance with the law.[10] Our findings support the potential health and economic benefits of full implementation of and compliance with the federal menu calorie labeling law.

Using a microsimulation model in children, Gortmaker et al[21] estimated the potential impact of restaurant menu labeling on childhood obesity. The policy was projected to reduce cases of childhood obesity by 41 015 and be cost saving ($4.67B savings) over 10 years between 2015 and 2025. Compared with our approach, this model used the estimate for calorie reduction derived from an older study, did not assume calorie compensation outside of restaurant intake, used a prior and less conservative model of the relationship between calorie change and weight change, did not model cases of diabetes mellitus or CVD prevented, and did not assess the potential additional impact of restaurant reformulations.

Table 3. Lifetime Estimated Health Gains, Costs, and Cost-Effectiveness of Federal Restaurant Label Law, by Age, Sex, Race, Education, and Income*

Menu Calorie Label	Cases Averted			Incremental QALYs	Incremental Cost ($M), by Perspective†		ICER ($/QALY), by Perspective†	
	Total CVD	Diabetes Mellitus	CVD Deaths		Healthcare	Societal	Healthcare	Societal
Age groups								
35–54 y	84847	74880	12156	202596	–$7664	–$8888	Saving	Saving
55–74 y	33508	20863	6674	105371	–$1942	–$2364	Saving	Saving
75+ y	3719	1208	805	8766	–$45	–$69	Saving	Saving
Sex								
Men	80565	59979	14486	228732	–$6206	–$8074	Saving	Saving
Women	50275	42332	9297	126364	–$3889	–$4524	Saving	Saving
Race/ethnicity								
Non-Hispanic white	55578	44974	11356	135373	–$4314	–$4994	Saving	Saving
Non-Hispanic black	32423	25181	6202	81707	–$2529	–$3200	Saving	Saving
Hispanic	40327	29585	7000	101257	–$3073	–$3737	Saving	Saving
Other races	14065	10028	2381	33488	–$1024	–$1192	Saving	Saving
Education								
<High school	29577	21999	6522	82667	–$2040	–$2547	Saving	Saving
High school or some college	71253	48491	12123	165705	–$5319	–$6371	Saving	Saving
College graduate	30373	27236	6861	83673	–$2489	–$3035	Saving	Saving
Poverty-to-income ratio								
<1.3	38402	26594	6012	97494	–$2789	–3387	Saving	Saving
≥1.3	99067	74783	23196	289950	–$7316	–9133	Saving	Saving
Body mass index								
Normal weight	24081	22402	4021	61859	–$1924	–$2279	Saving	Saving
Overweight	42879	38431	8777	124544	–$3759	–$4534	Saving	Saving
Obese	68982	44463	13082	185859	–$4662	–$5881	Saving	Saving

CVD indicates cardiovascular disease; ICERs, incremental cost-effectiveness ratio; and QALY, quality-adjusted life year.

*Outcomes were evaluated among American adults aged 35–80 y at baseline. The distribution of the population in each subgroup was derived from the survey-weighted percentages among adult participants in the National Health and Nutrition Examination Survey 2009–2016 (Table 1).

†Incremental net costs and ICERs were evaluated from 2 perspectives. All costs were inflated to constant 2018 US dollars using the Bureau of Labor Statistics' Consumer Price Index. Costs and QALYs were discounted at 3% annually. The healthcare perspective includes policy costs and medical costs; the societal perspective further incorporates informal healthcare costs and productivity costs. See Table 2 footnotes and the Methods for further details.

Our investigation has several strengths. We used a validated microsimulation model populated with a nationally representative sample of US adults age 35+ years, increasing validity and generalizability of our estimates. We evaluated the impact of parameter uncertainty in probabilistic sensitivity analyses as well as specific 1-way sensitivity analyses, demonstrating robustness of findings. Potential effects of the menu labeling policy on consumer behavior and restaurant reformulation were separately evaluated, while further incorporating consumer compensation outside of restaurant eating occasions, providing a range of plausible findings. The effects of calorie reductions on weight were estimated using best available dynamic energy models, which are more conservative than a 1:1 translation of calorie reduction to body weight. We used declining BMI-disease relative risks with age, which provides a more conservative model estimate of disease effects. Both 5-year and lifetime health impacts, costs, and cost-effectiveness were evaluated, providing results across different potential time periods of interest, and from both healthcare and societal perspectives.

Potential limitations should be considered. Our modeling results cannot prove the health and cost impacts of the implementation of the federal restaurant menu calorie labeling law. Although dietary information was collected with the standardized and computerized Automated Multiple Pass Method, energy intake based on self-reported 24-hour recalls may be underreported. We did not incorporate potential effects of calorie labeling on the compositional (nutritional) quality of meals selected by consumers or reformulated by restaurants, given insufficient data to make such estimations. NHANES does not include information to separate intakes from chain restaurants versus individual proprietors. However, based on outlet data, about 40% of all

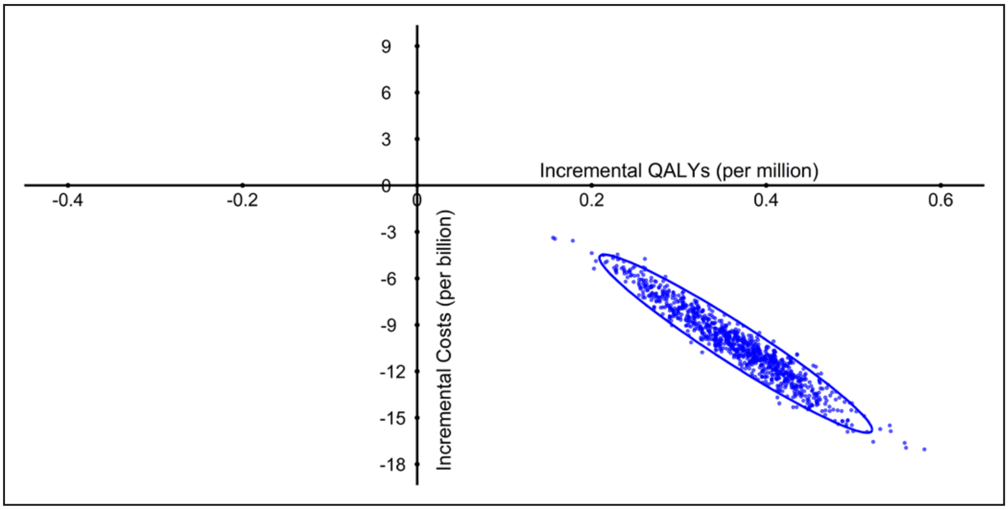

Figure 2. Lifetime cost-effectiveness of menu calorie labeling policy (consumer response).
Incremental cost-effectiveness ratios (ICERs) were calculated as the net change in costs divided by the net change in quality-adjusted life years (QALYs), compared with a base scenario of usual care. Values are shown from a healthcare perspective. This policy has much larger cost-savings from a societal perspective (not shown; see text).

US restaurants are chain restaurants, and overall sales and calories consumed in these chain restaurants are likely to be higher than in nonchain restaurants on average.[47] In addition, although not covered by the mandate, some independent restaurants have nevertheless decided to provide calorie counts on their standard menus.[48] The potential effect on restaurant reformulations was imputed from other labeling interventions, and our findings support the need for future research to directly investigate restaurant industry responses to the menu calorie labeling law. Effects of calorie menu labeling may vary in any individual, and, as with any medical or public health intervention, our findings should be considered as an estimate of the average population effect, which may be larger or smaller depending on individual variation such as based on awareness, knowledge, activity, adiposity, genetics, or other factors. We did not incorporate potential health gains in children, adolescents, or younger adults; or for other diseases affected by obesity, which could lead to substantial underestimation of the overall long-term health gains and cost-savings.

In conclusion, our nationally representative microsimulation model suggests that, based on consumer responses alone, the full implementation of the US calorie menu labeling law will generate significant health gains and cost-savings from both healthcare and societal perspectives. Industry responses to modestly reformulate menu items could provide even larger additional benefits.

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