Government Dietary Guidelines

Uncertain Science Leads to Questionable Public Health Policy

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Abstract

The US Department of Agriculture has issued dietary recommendations for more than a century, and during that period the health, longevity, and nutritional status of Americans improved markedly. Before the release of the first *Dietary Guidelines for Americans* (DGA) in 1980, the recommendations were based on rigorous science and simply offered general information on choosing foods and beverages to prevent deficiencies and maintain health. Yet with each subsequent version, the DGA became increasingly complex, prescriptive, and nutrient-focused (as opposed to food-based) despite an ever-increasing uncertainty and lack of credibility in the supporting evidence. This review examines the historical record of the development of the DGA and demonstrates that current recommendations were based on biased, implausible anecdotal evidence and that rigorous contrary research and the diversity of expert opinions on diet–health relationships were ignored. It concludes with an examination of the unintended negative public health consequences of founding policy on uncertain science.

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Edward Archer, Michael L. Marlow, and Richard A. Williams

The first version of *Dietary Guidelines for Americans* (DGA) was released in 1980. As required by the 1990 National Nutrition Monitoring and Related Research Act, the DGA is now jointly published every five years by the US Department of Health and Human Services (HHS) and the US Department of Agriculture (USDA).[1] In 1985, HHS and the USDA established the Dietary Guidelines Advisory Committee (DGAC). The members of this committee—nationally recognized experts in the field of nutrition and health—review and consolidate the current scientific and medical knowledge and make recommendations for the next edition of the DGA. The DGAC's mission is clearly stated: "The Dietary Guidelines for Americans encourages individuals to eat a healthful diet—one that focuses on foods and beverages that help achieve and maintain a healthy weight, promote health, and prevent chronic disease."[2] Despite the unequivocal mission of the DGAC and DGA, the historical record suggests that contrary evidence and the extreme diversity of expert opinion on diet–health relationships are consistently obscured or disregarded. Thus, we contend that the process by which the DGAC informs the DGA is unsound and that federal dietary guidance and nutrition policy are based on misinformation generated by flawed (i.e., empirically refuted) data collection protocols, weak empirical evidence, and biased review processes.

The purpose of this review is to examine the quality of the evidence used by the DGAC to inform the DGA and to review how well policymakers follow this evidence in determining policy. This paper has four sections. First, we give a history of dietary guidance. This section is

followed by a survey of the lack of validity of the empirical evidence used to inform federal nutrition guidance and policy. We then examine the evidence and unintended consequences of policies aimed at restricting sodium and fat consumption. Finally, we discuss the economic policy implications of interventions that are based on the uncertain science.

1. The Evolution of Dietary Guidance

The USDA was established by law in 1862 in part to acquire and disseminate "useful information on human nutrition."[3] The agency has published dietary recommendations since 1894.[4] Since that time, the health, longevity, and nutritional status of Americans have improved markedly. For example, in the early 20th century, nutritional diseases such as pellagra, rickets, and goiter were significant public health challenges. By the 1930s, pellagra (a disease of niacin deficiency) had claimed the lives of more than 100,000 Americans and had severely affected more than 3 million.[5] Yet by mid-century, the diseases of nutritional deficiency had been largely eradicated and the nutritional and health status of Americans was steadily improving.

From 1900 to 1980, average life expectancy at birth increased from less than 50 years to well over 70 years, and from 1950 to 1980, life expectancy at 65 increased an additional 2.5 years.[6,7] Cardiovascular diseases (CVDs), which have been the major cause of death for men and women in America since the 1920s, peaked in the 1950s and 1960s,[8,9] after which they declined for the next half-century. From 1963 to 1979, CVD mortality declined 30 percent; in 1980 alone, there were 289,000 fewer deaths than would have been the case had the death rate remained at 1963 levels.[10] These population-wide improvements were so noteworthy that the 1979 *Surgeon General's Report on Health Promotion and Disease Prevention* began with the unequivocal statement that "the health of the American people has never been better."[11(p1-1)] Advances in

nutrition, sanitation, and medicine (e.g., vaccines) were large contributors to these improvements.

The USDA recommendations during this period of significant improvements in the nutritional status and health of Americans (i.e., 1894–1977) were simple, food-based advice that provided general information on choosing foods and beverages to overcome deficiencies and maintain health. For example, the USDA "food guides," first published in 1916, established the familiar concepts of food groups (e.g., meat, milk, breads) and serving sizes.[4] Although each version of the food guides varied the number and composition of food groups, the versions shared a common element: the relatively simple and elementary information on what foods to purchase and consume to maintain health. In keeping with the quote often attributed to Margaret Mead that "people don't eat nutrition, they eat food," the information provided in the food guides was food-based (as opposed to nutrient-focused) and was easy for the lay public to understand. However, in 1977, two years before the surgeon general's report highlighting the excellent health status of the American public, the US Senate Select Committee on Nutrition and Human Needs published *Dietary Goals for the United States*[12,13] (hereafter "the McGovern report"). This report was the first widely disseminated nutrition guidance to explicitly provide detailed, quantitative, nutrient-focused dietary recommendations. This precedence is noteworthy for two reasons. First, the authoritarian approach and specificity of the McGovern report were in direct contrast to the weakness of the correlational evidence and the lack of scientific consensus on the harms and benefits of dietary change. And second, the evidence and inferences used in support of the nutrient-specific recommendations were well beyond the comprehension of individuals not directly involved in nutrition research (e.g., policymakers and the lay public).

The McGovern report began the trend toward ever-increasing complexity, nutrient-specific detail, and prescription in federal dietary guidance.[14] For example, the 1980 DGA was a short, 19-page brochure,[15] and the 1985 report of the DGAC was a mere 28 pages;[16] the 2010 DGA was 112 pages,[17] and the 2015 DGAC report was 571 pages.[18] The 2015 report was the most complex, prescriptive dietary guidance issued, and it included guidance extremely tangential to diet and nutrition (e.g., carbon footprint and global climate change).[18]

In addition to initiating the trend toward increasing complexity and volume, the McGovern report was the first document to shift the focus of federal dietary guidance away from the well-established science behind the promotion of foods to prevent nutritional deficiencies, and toward conjectures (based on weak correlational evidence gleaned from questionnaires) that avoiding specific foods and nutrients would prevent chronic, noncommunicable diseases (NCDs)—for example, CVD. This shift in focus is noteworthy because the causal nature of the relationship between diet and health with respect to the diseases of deficiency (e.g., anemia from lack of iron and blindness from lack of vitamin A) was unequivocal and based on many decades of rigorous, highly replicated evidence. In contrast, the relationship between diet and NCDs (e.g., heart disease) was (and still is) highly speculative and was based primarily on associations from methodologically suspect observational studies (e.g., the "seven countries study"[19]) and national nutritional surveillance data that were demonstrated to be physiologically implausible[20–22] and were deemed "inadmissible" as scientific evidence.[21]

The first edition of the McGovern report began with statements from Senators George McGovern (D-SD) and Charles H. Percy (R-IL), the chair and ranking minority member, respectively. Chairman McGovern stated, "Our diets have changed radically within the last 50 years, with great and often very harmful effects on our health. These dietary changes represent as

great a threat to public health as smoking."[13(p1)] Senator Percy stated, "Without government and industry commitment to good nutrition, the American people will continue to eat themselves to poor health."[13(pv)] These statements were in direct opposition to the economic, epidemiologic, and scientific data of the time.[8,23] Given the extant empirical evidence and the steady and substantial improvements in the health and nutritional status of Americans over the preceding eight decades, the statements were more alarmist political rhetoric and disease-mongering than scientific facts. Nonetheless, these scientifically inaccurate statements were matched by equally unscientific statements from the nutrition researchers who consulted with and testified before the Select Committee.[24] These consultants demonstrated a consistent bias toward the speculation that the American diet was inherently unhealthy and was the primary cause of NCDs.

Evidence contrary to this perspective and against the necessity of sweeping government recommendations was minimized, obscured, or ignored. For a detailed exposition of the history of the reticence of nutrition researchers and federal agencies to examine or include contrary dietary evidence, see Hite et al.,[25] Ioannidis,[26] Taubes[27,28] and Teicholz.[29]

A number of researchers were consulted during the development of the McGovern report, but Dr. D. Mark Hegsted was the preeminent scholar who testified at the Select Committee's hearings.[24] Hegsted was a founding member of the Harvard School of Public Health's Nutrition Department and later became the USDA's administrator of human nutrition. He is considered by many to be the "father of the seminal 'Dietary Goals for Americans.'"[30] His opening remark in the 1977 hearings was typical of the approach taken in the report: "The diet of Americans has become increasingly rich—rich in meat, other sources of saturated fat and cholesterol . . . [and] the proportion of the total diet contributed by fatty and cholesterol-rich foods . . . has risen."[13(p3)] This portion of his opening statement is noteworthy because it directly contradicted the extant data on

the US food supply. For example, USDA economic data suggest that total calories and the availability of meat, dairy, and eggs (i.e., a crude proxy for consumption) at the time of the report were equivalent to or marginally less than the amount consumed in 1909.[23] Whole-dairy (i.e., full-fat) product consumption was lower in 1977 than in 1909, having declined steadily from 1950 to 1977.[23] Given these trends in animal product availability, one could argue that cholesterol consumption was equivalent or lower in 1977 than in 1909. The USDA evidence is clear that the availability of foods containing saturated fatty acids was marginally lower in 1977 than in 1909, not greater.[23] These data stand in direct contrast to Hegsted's statement that the American diet had "become rich—rich in meat," yet Hegsted further stated that "the risks associated with eating [our current] diet are demonstrably large."[13(p3)] This statement was in opposition to the significant and well-established health and nutritional gains by Americans over the preceding decades.

Neither McGovern's nor Hegsted's comments regarding changes in the American diet and associated health outcomes had empirical support. In fact, the vast majority of epidemiologic trends and economic data suggested that, as stated by the surgeon general's report, "the health of the American people [had] never been better."[11(p1-1)] There was little, if any, evidence that Americans were "eating themselves to poor health." In fact, the opposite position had stronger empirical support. Nevertheless, the McGovern report was published and included Hegsted's recommendations to reduce overall fat consumption and reduce (dietary) cholesterol consumption by greater than 30 percent, from 430 mg per day[23] to less than 300 mg per day.[12,13] These recommendations were sustained in all future federal dietary guidance until the Dietary Guidelines of 2015.[31]

The response to the publication of the first edition of the McGovern report was "vigorous and constructive"[12(pvii).] In reply to scientific criticisms, a "Supplemental Foreword" by Senators

Percy, Schweiker (R-PA), and Zorinsky (D-NE) was added to the second edition.[12] In that foreword, the senators expressed "serious reservations"[12(pvii)] regarding the recommendations. They explicitly stated the "lack of consensus among nutrition scientists"[12(pvii)] and presented evidence of the diversity of scientific opinion on diet–health relationships. Their three main reservations were

> (1) the question of whether advocating a specific restriction of dietary cholesterol intake to the general public is warranted at this time, (2) the question of what would be the demonstrable benefits to the individual and the general public, especially in regard to coronary heart disease, from implementing the dietary practices recommended in this report and (3) the accuracy of some of the goals and recommendations given the inadequacy of current food intake data.[12(pvii)]

The senators wrote, "The record clearly reflects extreme diversity of scientific opinion on these questions."[12(pvii)] Fearing that the "extreme diversity of scientific opinion" would be "overlooked," the senators quoted numerous expert panels from around the world that explicitly argued against dietary restrictions. For example, the Canadian Department of National Health and Welfare concluded in a National Dietary Position that "Dietary cholesterol may not be important to the great majority of people. . . . Thus, a diet restricted in cholesterol would not be necessary for the general population," and Great Britain's Department of Health and Social Security reached a similar conclusion. The senators wrote,

> It is clear that science has not progressed to the point where we can recommend to the general public that cholesterol intake be limited to a specified amount. The variances between different individuals are simply too great. A similar divergence of scientific opinion on the question of whether dietary change can help the heart illustrates that science cannot yet verify with any certainty that coronary heart disease will be prevented or delayed by the diet recommended in this report.[12(pviii)]

The senators closed their foreword with the statements,

> *The value of dietary change remains controversial and . . . science cannot at this time insure that an altered diet will provide improved protection from certain killer diseases such as heart disease and cancer.* . . . [and it is best to] inform the public not only about what is known, but also about what remains controversial regarding cholesterol, the

> benefits of dietary change, and the reliability of current food intake data.[12(pix)] (emphasis in original)

The cautionary words of Senators Percy, Schweiker, and Zorinsky were ignored, as was the senators' reluctance to risk the unintended consequences of sweeping government dietary recommendations lacking empirical support. The second edition of the McGovern report was published with the same recommendations as the first edition. Nevertheless, the senators' prescience has been confirmed by the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee*, which explicitly states, "Cholesterol is not a nutrient of concern for overconsumption."[18(p17)] This policy reversal on the restriction on dietary cholesterol validates the accuracy of the contrary evidence that was obscured four decades earlier.

Recent research suggests that the concerns raised by Senators Percy, Schweiker, and Zorinsky regarding the inadequacy of food intake data were also well founded.[20,21] Federal population-level dietary recommendations such as the DGA are based on the current nutritional consumption of the American people as captured by national surveillance data from the National Health and Nutrition Examination Survey (NHANES) What We Eat in America (WWEIA) Survey. It has been demonstrated that those data are fatally flawed,[20,21] and therefore any recommendations based on the data may be unsound.

In June 2016, Representative Andy Harris (R-MD) wrote to Robert Califf, the commissioner of the US Food and Drug Administration (FDA). Harris expressed his issue with the FDA's newly issued sodium restriction guidelines (discussed later in this paper) and concluded:

> I stand by my position that the prudent, cautious action of any public health agency is to make sure they have their science right before proceeding, in this case, with a one-size-fits-all sodium policy. If you are correct, and your assumptions are borne out in the requested review, so much the better for Americans. However, if your assumptions are wrong, the actions taken by the Agency are potentially dangerous for significant segments of the American population.[32]

The following section details the lack of validity and reliability of national nutritional surveillance and the limitations of those mechanisms for informing US dietary guidance and public health nutrition policy.

2. The Uncertain Science of US National Nutritional Surveillance

Main Points Covered in This Section

The NHANES and the WWEIA Survey together form the major component of nutritional surveillance in the United States. The surveys are conducted jointly by the USDA and Centers for Disease Control and Prevention (CDC).[33] The surveys provide the data for estimates of US dietary consumption used in the 2015 DGAC report[18] and 2015 DGA.[31]

1. In 2013, the data collected by the NHANES and the WWEIA Survey were demonstrated to be physiologically implausible and not compatible with life.[20] Those results were supported by numerous prior studies.[26,34–39]

   Note: the term physiologically implausible is defined as reported dietary intakes that are patently invalid as an estimate of actual dietary consumption when examined against the scientific understanding of human nutrient-energy physiology.[20,40] The term incompatible with life means that the survey respondent could not possibly survive on the amount of food and beverages he or she reported consuming.

2. The implausible nature of the NHANES and WWEIA data was ignored in the 2015 DGAC report and 2015 DGA,[22] despite the obvious fact that dietary data that are not compatible with life cannot be representative of the current dietary consumption of the American people.

   The methods used by the NHANES and the WWEIA Survey are known as memory-based dietary data collection methods (M-BMs).

   M-BMs are considered "pseudoscientific and inadmissible" as scientific evidence[21(p911)] for five reasons: (a) M-BMs produce data that bear little relation to actual caloric or nutrient consumption (i.e., M-BM–derived data are not physiologically plausible);[21] (b) M-BMs were repeatedly empirically refuted over the past five decades;[20,35,39,41,42] (c) the errors of the dietary estimates are unknown, unknowable, and therefore nonquantifiable;[21,22] (d) M-BM protocols mimic procedures known to induce false memory and false reporting;[21] and (e) the subjective (i.e., not publicly accessible) mental phenomena (i.e., memories) from which M-BM data are generated cannot be independently observed, quantified, or falsified.[21]

3. USDA and government-funded nutrition researchers routinely manipulate implausible dietary data to create the appearance of plausibility.[21,22] Such practices include statistical and mathematical adjustments and deletion of implausible data without caveat for the biases introduced via these post hoc manipulations.

Nutritional surveillance is the systematic collection and analysis of dietary and economic data with the objective of depicting current contexts (e.g., estimating caloric intakes), detecting trends, and highlighting priorities and potential corrective measures.[43] All federal dietary guidance and nutrition policy is based on the USDA's nutritional surveillance programs. Despite the essential nature of national nutritional surveillance data, mismanagement and unscientific methodology have plagued the USDA's efforts to accurately characterize the diet of Americans.[20,44–46]

For example, in 1991, the General Accounting Office (GAO) reported that mismanagement had led to "violating key internal controls designed to safeguard the government's best interests."[44(p3)] Moreover, "methodological problems" and "lax controls over the collection and processing of the results" had led to "doubts about the quality and usefulness of the data."[44(p2)] Thus, the GAO said, it did "not recommend use of the data."[44(p4)] Three years later, a follow-up GAO report stated, "We conclude that . . . a coherent, consistent system for nutrition monitoring is not yet in place."[46(p7)] Despite the significant caveats highlighted over the past few decades by the GAO and others regarding the methodological issues associated with the use of memory-based dietary data collection methods (M-BMs; e.g., interviews, surveys, and questionnaires),[20–22,40,47] those protocols remain the predominant research tools for nutritional surveillance and government-funded epidemiologic nutrition and obesity research.[20,21,48–50]

2.1. The Empirical Refutation of US National Nutritional Surveillance Data

Since their inception, the DGA have been informed via population-level estimates of dietary consumption derived from the M-BM data from the NHANES, despite unequivocal evidence that M-BM data bear little relation to actual energy and nutrient consumption.[20,21] For clarity,

M-BMs do not objectively measure energy or nutrient intake, nor do they directly or objectively measure food and beverage consumption. The data generated from M-BM are the a priori nutrient and caloric values from various databases that are *assigned* by researchers to the participants' reports of their memories of eating and drinking behaviors. In other words, USDA researchers and other federally funded nutrition epidemiologic researchers simply assign numeric values to whatever the respondents are willing or able to recall about what they think (or want the researchers to think[51]) they consumed during the study period. Given the indirect, pseudo-quantitative nature of M-BMs and the fact that the respondents' reports of their memories are subject to intentional and unintentional distorting factors (e.g., confabulation, perceptual, encoding, and retrieval errors;[52] social desirability;[38] false memories;[53] and omissions[54–56]), it is not surprising that the vast majority of conclusions drawn from studies using these protocols failed to be supported when subjected to objective examination.[26,57]

M-BMs were first refuted empirically in the 1950s,[58] and unlike most research findings that lack reproducibility,[59] the lack of credibility of M-BM data has been replicated consistently over many decades.[20,34–41,58,6064] M-BM research reports a wide range of energy intake estimates that are not physiologically plausible; that are often incompatible with survival (i.e., too few calories); and that fail to accurately quantify the foods and nutrients consumed.[20,21,26,34–39] In that context, the term *physiologically implausible* is defined as a reported energy intake (rEI) that is patently invalid as an estimate of actual energy intake when examined against the scientific understanding of human energy physiology and minimum energy requirements.[20,40] The term *incompatible with life* means that the survey respondent could not possibly survive on the amount of food and beverages he or she reported consuming. Not all estimates of caloric consumption that are physiologically implausible will be

incompatible with life. Nevertheless, Archer et al. recently reported that "across the 39-year history of the NHANES, [self-reported energy intake] data on the majority of respondents (67.3% of women and 58.7% of men) were not physiologically plausible"[20] and that the mean rEI values for overweight and obese respondents (i.e., the majority of Americans) were incompatible with life.[20,21]

In other words, if the diets reported by the USDA in the NHANES and WWEIA studies were consumed on a daily basis, they could not support human life. For example, Archer et al. found that a bedridden, frail, elderly woman (i.e., a person with the lowest possible energy requirements) could not survive on the number of calories reported by the *average* person in the NHANES and the WWEIA Survey.[20] The reason for this finding is simple: the data collection methods used by the USDA and all other federally funded nutritional surveillance research (i.e., M-BMs) rely on both the memory and the truthfulness of the study participant, and it has been demonstrated consistently over the past century that human memory and recall are woefully inadequate for scientific data collection.[54,56] Therefore, M-BM data are fundamentally and fatally flawed and cannot be considered reliable scientific evidence.[21] Yet despite the repeated empirical refutation of M-BMs, the 2015 DGAC report states that "repeated 24-hour recalls [a form of M-BM] remain the backbone of dietary assessment and monitoring"[18(App.E-4,p3)] and requests an increase in the use of the NHANES and WWEIA M-BM.[18]

Given the empirical refutation of the NHANES and WWEIA data, the 2015 DGAC's statement (without caveat) that the NHANES and WWEIA M-BM data "provide national and group level estimates of dietary intakes of the U.S. population, on a given day"[18(p13)] is extremely misleading both to the public and to policymakers. This statement puts the USDA in violation of its own information quality guidelines (from the Data Quality Act) to "ensure that the

information they disseminate is substantively accurate, reliable, and unbiased and presented in an accurate, clear, complete, and unbiased manner."[65]

2.2. Unsupported USDA Official Testimony

The unsupported belief in the scientific credibility of the NHANES and WWEIA M-BM data was emphasized in a recent communication by a senior USDA official. The official asserted that the DGAC review process produces the "strongest, best . . . available science"[66(p8)] and the "best science . . ., best available science . . . , and least biased science"[66(p43)] and that "the *2015 Dietary Guidelines for Americans* will be grounded in the preponderance of the best available scientific evidence."[66(p10)] The official also testified to the utility and validity of the Healthy Eating Index.[66] The Healthy Eating Index estimates are also derived from the physiologically implausible NHANES and WWEIA dietary data. It should be obvious that a valid Healthy Eating Index cannot be created from dietary data that are incompatible with life. Another official expressed the notion that the DGAC food pattern analyses tell us "what [it is] actually [that] Americans are eating."[67(p43)] Clearly, those officials did not appear to appreciate the unscientific nature of the dietary data.

2.3. Additional Weaknesses of Evidence in the 2015 DGAC Report

Since M-BM data were first demonstrated to lack credibility six decades ago,[58] nutrition epidemiologists have used statistical and mathematical machinations and post hoc exclusions to obscure the fact that such data were not plausible. The epidemiologists altered or simply deleted the data not compatible with life. For example, Donin et al. explicitly stated the (nonrandom) removal of "176 participants with implausible energy intakes" (i.e., they simply deleted ~9

percent of their data),[68(p116)] and Mendez et al. stated that "adjusting for implausible reporting may help to reduce bias in diet–health outcome association."[69(p9)] Poslusna et al. stated, "energy adjustment seems to be a good tool for practice to decrease an influence of misreporting,"[70(pS73)] and Willett et al. advised that "calorie-adjusted intakes [i.e., implausible dietary intake data that are manipulated mathematically to appear plausible] are likely to be more appropriate with respect to public health policy. . . ."[71(p61)]

Numerous researchers have demonstrated that statistical and mathematical machinations (e.g., calorie adjustments, nonrandom deletions of data, use of ratios) distort risk ratios and invalidate conclusions because researchers cannot control for the biases induced via differential recall (e.g., the overreporting of fruit and vegetable consumption and underreporting of foods containing sugar and fat).[22,62,72,73] These data-doctoring protocols have significant negative public policy consequences because the underreporting of fatty foods in confluence with calorie adjustments and nonrandom deletions lead to the overestimation of speculated diet–health relations with respect to fat consumption.[62]

Such studies demonstrate that when data or results blatantly lack credibility, nutrition and obesity researchers simply delete or mathematically manipulate the implausible data regardless of the well-established systematic biases and nonquantifiable errors introduced into the analyses.[20–22,73,74] Nevertheless, the ubiquity of implausible data did not lead the researchers to question the appropriateness of their methods of data collection. And although studies have unequivocally shown that "calorie-adjusted intakes" and other forms of data doctoring (e.g., calorie adjustments) fail to address the systematic biases of M-BMs,[22,62,72,73] these data manipulations are still standard practice in national nutritional surveillance, government-funded nutrition and obesity research, and the development of the DGAC's report. The use of

systematically manipulated data to inform federal dietary guidance may have substantial public health policy ramifications.

2.4. Violations of Statistical Assumptions

To attempt to correct for the inadequacy of M-BM data (i.e., physiologic implausibility), researchers have developed numerous statistical manipulation protocols.[75,76] The 2015 DGAC used a method developed by the National Cancer Institute (NCI) to estimate "usual intake distributions"[18(App.E-4,p2)] even though the foundational assumptions of the method were not met. The NCI method "assumes that the 24-hour recall is an unbiased instrument for measuring usual food intake . . . and provides an unbiased measure of the amount of food consumed on a consumption day."[77] But M-BM data were repeatedly demonstrated to be systematically biased estimates of food intake and dietary composition.[20–22] For example, it is well established that myriad factors bias M-BMs (e.g., intentional misreporting, sex, body weight, social desirability, body image, exercise habits, dieting history, socioeconomic status, and fear of negative evaluations).[21,78,79] Thus, the assumptions necessary for the DGAC's statistical analyses to be valid were unequivocally violated. Therefore, the DGAC's statement that "usual intake distributions [of the US population] can be estimated based on statistical techniques"[18(App.E-4,p2)] misrepresents the evidence and is misleading to the public and to policymakers. The use of "energy adjustment"[80(p1086)] and "calibration equations"[60(p172)] leads to nonquantifiable errors, and these protocols for statistical manipulation should not be used to inform public policy aiming to improve public health.

2.5. Presentation of Correlations as Evidence of Causation

Until recently, nutrition science had a long and successful history of revealing rigorous causal relations between diet and health outcomes. For example, although the exact nutrient-specific mechanisms were not delineated until more than a century later, it was clearly established in the 18th century that diets deficient in citrus fruits caused scurvy.[81] In the early part of the 20th century, despite the correlational evidence pointing to genetic factors and infectious agents, it was established that diets chronically deficient in niacin caused pellagra.[5,82] The history of pellagra may be illuminating because the political use of the correlational evidence appears to have impeded scientific progress and harmed public health.[82,83]

Despite nutrition science's history of overcoming the inherent flaws of correlational research (e.g., bias, confounding, ecological fallacy) through the use of rigorous scientific research, in the 2015 DGAC report, the distinction between correlation and causation is obscured.[22] For example, the terms *association*, *associated*, and *relationship* are used more than 900 times in the 571-page report, yet the words *causal* and *causality* are used fewer than 30 times and are never used to define an actual causal diet–health relationship.[18] Although the descriptions of the research may be accurate, public health policy should be based on rigorous science, and observational studies that produce only correlations with descriptive information are very "low-quality evidence."[84(p407)] Nevertheless, the 2015 DGAC generated dietary recommendations to policymakers on the basis of statistical associations from physiologically implausible dietary data while ignoring established causal factors for the development of many chronic noncommunicable diseases and conditions (e.g., obesity, type 2 diabetes mellitus, [and CVD).[85–91] The DGAC's use of questionable, confounded, and clinically trivial correlations to inform dietary guidance may explain recent policy reversals on cholesterol and fat consumption.[18]

2.6. Direct Contrary Evidence to the 2015 DGAC Report

Objective measurements suggest that the nutritional status of Americans is exemplary. For example, the CDC conducts rigorous biochemical analyses on representative samples of Americans as part of national nutritional surveillance,[92,93] and in 2013, the CDC's *Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population* reported that approximately "80% of Americans (aged ≥ 6 y) were not at risk of deficiencies in *any* of the 7 vitamins" examined via serum biomarkers (i.e., vitamins A, B_6, B_{12}, C, D, E, and folate; emphasis added).[94(p938S)] Moreover, about 90 percent of women of childbearing age (i.e., 12–49 years of age) were not at risk of iron deficiency, and folate levels had increased about 50 percent since 1998.[94] The eradication of nutritional diseases and the substantial reduction in the risks of nutritional deficiencies in confluence with the recent population-level improvements since the CDC's first *National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population* a decade earlier suggest that our nation's food supply and the nutritional status of Americans have improved to a level unprecedented in human history.[92] Yet the 2015 DGAC report states that "several nutrients are underconsumed"[18(PartA,p20)] (i.e., vitamins A, C, D, E, and folate) and that for women of childbearing age (i.e., adolescent and premenopausal females), "iron also is a shortfall nutrient."[18(PartA,p2).]

Clearly more than 80 percent of Americans could not have adequate serum levels of the nutrients tested if these nutrients were "underconsumed." Therefore, there is an obvious conflict between the rigorous, objective biochemical (i.e., serum) analyses and the subjective, implausible M-BM data that the CDC and the USDA collected. Nevertheless, the DGAC failed to acknowledge the existence of the contrary data via the biochemical analyses and chose to report only the subjective, implausible, and alarmist M-BM data. This bias has significant public

health consequences because it distorts the scientific record by erroneously suggesting that Americans are at risk for nutritional deficiencies when in fact they are not.

3. Specific Policy Examples

3.1. Sodium Restriction

A fierce and often acrimonious debate surrounds policy recommendations for sodium intake.[95,96] Numerous international, governmental, and nongovernmental authorities recommend significant reductions in dietary sodium intake on the basis of observational evidence from the 1970s.[24,95] Currently, the FDA recommends drastic reductions in sodium from 3,400 mg/day to 2,300 mg/day.[97] Surprisingly, that recommendation was made without caveat despite clear evidence from the Institute of Medicine and experimental trials that the clinical significance of sodium reduction in healthy populations is trivial[98–100] and despite studies on health outcomes showing that sodium restriction to the 2,300 mg/day range in healthy populations increases the risk of death and cardiovascular disease.[101–104]

Evidence shows that the relationship of sodium to health follows the same J-shaped or U-shaped pattern as most nutrients.[105] This finding agrees with both the ancient wisdom of Paracelsus, who stated that it is "the dose that makes a thing a poison,"[106(p511)] and the basic physiologic fact that human fluid regulation can accommodate a wide range of sodium intakes without affecting blood pressure.[95,99,100] Although some researchers disagreed with this basic notion,[107] in 2011 a Cochrane report unequivocally stated that "after more than 150 RCTs [randomized control trials] and 13 population studies without an obvious signal in favor of sodium reduction, another position could be to accept that such a signal may not exist."[98] Nevertheless, despite a lack of rigorous evidence, key public figures continue to make claims

such as "Nine out of 10 US adults and children consume too much sodium, and even modest reductions in sodium intake are associated with substantial health benefits."[108(p579)]

Even though there is a plethora of contrary evidence, the CDC and DGAC have not altered their recommendations on sodium intake. The 2010 and 2015 DGAC reports,[18,109] as well as the 2010 and 2015 DGAs,[31,110] include multiple, explicit global recommendations to limit sodium. These broad statements without caveat ignore the well-established fact that there are individual differences in micronutrient metabolism. The current statements stand in contrast to the 1980 DGA, which explicitly acknowledged individual differences. For example, the 1980 DGA stated, "The major hazard of excessive sodium is for persons who have high blood pressure. Not everyone is equally susceptible."[15] Despite all the evidence against global recommendations on limiting sodium intake, the FDA recently published a draft guidance to industry that is based on the 2015–2020 *Dietary Guidelines for Americans* and *Healthy People 2020* and that advises reducing sodium intake from 3,400 mg/day to 2,300 mg/day.[97]

In May 2016, Mente et al. published a sodium excretion study of 133,118 people from more than 49 countries, splitting the population between normal and high sodium intakes.[111] Cardiovascular disease and death were shown to increase in those with low sodium intake and in individuals with hypertension consuming more than 7 g/day. The authors concluded that the only benefit from lowering sodium would be for those persons with hypertension who consume high-sodium diets (about 11 percent of the population).

Statements targeting an entire population regardless of risk (e.g., sodium reduction in the 2010 and 2015 DGAs) diminish the credibility of recommendations and may have unintended health consequences.

The recommendation that "concentrated efforts are needed to lower total sodium intakes by all Americans"[109(p128)] may be responsible for complications and deaths due to hyponatremia (i.e., low serum sodium concentrations). This condition can lead to mental confusion, seizures, and altered cognition (i.e., mental status) when serum sodium levels fall below 135 mmol/L. In extreme cases, death from hyponatremia has occurred during exercise as a result of low serum sodium concentrations combined with excessive water intake.[112,113] Blank et al. demonstrate the negative effects of general recommendations to lower sodium intake in athletes and suggest that athletes are at risk for sodium depletion (with or without hyponatremia) because of the large sodium losses they experience when they sweat in combination with attempts "to have a balanced . . . sodium reduced diet."[114(p799)] Blank et al. present a case study of an individual with "low-sodium nutrition" who repeatedly suffered the effects of sodium depletion during recreational sport activities.[114] Jeukendrup demonstrated that sodium depletion or hyponatremia (or both) have been reported in exercising individuals consuming "low sodium drinks"[115(pS91)] and by numerous other studies that report on the effects of low-sodium diets (as recommended by the DGAC[18]) and exercise in hot or humid settings.[116–118]

The extant literature is clear that those at risk of hyponatremia[113,119] are of the same demographic profile as those individuals most likely to understand and follow the recommendations in the DGA (i.e., white women of higher socioeconomic status who exercise).[120–122] Given the extant literature and clinical evidence, if a woman exercised regularly and followed the DGA 2015 (and previous guidelines) to reduce her sodium intake to less than 2,300 mg, she would possibly be at risk of death due to sodium depletion or hyponatremia (or both) if she consumed only water during training or an event. A portion of the increase in deaths attributable to hyponatremia during endurance events since 1980 no doubt reflects an absolute

increase in both the number of participants and the number of endurance events. Nonetheless, given the blanket recommendations of sodium reduction in the DGA, one can speculate that at least some of these deaths may be due to individuals ignoring their own physiologic needs in favor of following the DGA recommendations to limit sodium.

Additionally, a 2013 study demonstrates the infeasibility of meeting the 2010 DGA for sodium and potassium simultaneously.[123] Stated simply, attempts to reduce sodium consumption can result in dietary intakes that are deficient in potassium. This finding is problematic because strong evidence exists that increases in potassium may be as important in reducing hypertension as reductions in sodium.[124,125] Hence, by focusing on a single nutrient and ignoring the totality of the diet, the DGA may actually exacerbate the health problems they were intended to ameliorate.

3.2. Fat Restriction

Despite a lack of evidence supporting low-fat diets, only in 2010 did the Dietary Guidelines committee stop recommending limits on total fat. Yet the 2010 DGA still recommended reducing saturated fat. An analysis in 2013 demonstrated that the three major sources of saturated fat and calories in the diet of Americans (namely, red meat, milk, and cheese) provided more than 46 percent of the calcium, 49 percent of vitamin D, and 43 percent of vitamin B_{12}, as well as many other essential micronutrients.[126] Attempts to reduce these foods to adhere to the 2010 DGA may significantly reduce the overall quality of the American diet. As with restrictions on sodium, the focus on a single nutrient to the detriment to the overall diet may lead to negative unintended consequences.

A recent meta-analysis of available evidence, published in the *Annals of Internal Medicine*, concluded that current evidence does not clearly support the high consumption of polyunsaturated fatty acids and the low consumption of total saturated fats.[127] The authors note that although saturated fats moderately raise "bad" LDL cholesterol, apparently this effect does not lead to adverse health outcomes such as heart attacks and death. As is often the case with epidemiologic research, alterations in intermediate risk factors (e.g., LDL cholesterol) do not consistently result in concomitant alterations in "hard" outcomes (e.g., mortality). Therefore, there may be no positive effect on public health from policy recommendations based on research examining reductions in risk factors. Similarly, other intermediate proxies may have no positive effect on public health, and those proxies may engender negative outcomes.

4. The Scientific Basis for Economic Interventions

Main Points Covered in This Section

1. Policy initiatives are often based on simplistic notions, such as the idea that a reduction in caloric intake will lead to a reduction in obesity and metabolic diseases. A basic understanding of the science behind compensatory mechanisms indicates that most public policy interventions are problematic at best.
2. Researchers frequently cite government dietary recommendations for their inspiration, but suggested interventions (e.g., taxes, "nudge" approaches, and diets) are ineffective distractions from potential solutions,[128] and these interventions may have negative unintended consequences because of compensation and other physiologic processes.
3. Government dietary recommendations have perpetuated perceptions that foods can be classified into a "healthy" versus "unhealthy" dichotomy. This false dichotomy will remain as long as government recommendations are offered without sufficient scientific evidence. Consumers who are led to believe the healthy versus unhealthy dichotomy are unlikely to experience improved health.
4. Many economic studies do not even attempt to determine whether interventions exert desired effects on disease, weight, or any other measure of quality of life. Rather, the studies simply examine whether interventions elicit "healthier" eating on the basis of the (flawed) assumption that success in decreasing any form of "unhealthy" eating necessarily improves public health.

5. The stark reality that traditional weight-management programs are ineffective can be considered at least a partial indictment of the historical effectiveness of government dietary guidelines. A major concern is that continued misplaced belief in the efficacy of dietary guidelines will lead to more taxes, nudges, or bans as advocates recognize that their interventions do not prove successful in steering individuals toward healthier choices or improved health.

6. Greater harm to public health from more aggressive economic interventions remains a distinct possibility as long as government recommendations are offered without sufficient scientific evidence.

4.1. Human Physiology Is a Complex, Dynamic System

Misinformation generated by weak empirical evidence and by biased review processes led to a widespread illiteracy in basic human physiology and nutrition science. Such misinformation contributed to myriad myths and presumptions that pervade both popular media and the academic literature.[129] This lack of basic knowledge of human nutrition physiology and lack of understanding that the human body is a complex, dynamic system led to simplistic, ineffective interventions that redirected resources away from the actual causes of disease and ill health.[85]

Human nutrient metabolism evolved under intense selective pressures and is robust to perturbations resulting from metabolic or behavioral compensation. For example, when energy (caloric) intake is decreased (e.g., when dieting), resting metabolism slows exponentially to compensate for the loss of energy intake.[130] This decrement in resting metabolism may persist for years.[131] Nevertheless, it is a common practice in economic interventions to ignore compensation and model human nutrient energy metabolism in a simple, linear fashion and extrapolate large changes in weight from small, sustained changes in energy intake, expenditure, or both.[129,132,133] A common example of this error is the "3,500-calorie rule,"[133,134] in which a reduction in energy intake or an increment in energy expenditure of 100 calories per day over 350 days is posited to lead to a 10-pound loss of fat. This result is incorrect by an order of magnitude.[135] In 2009, an 18-month randomized,

controlled, behavioral intervention demonstrated that a reduction of 100 calories per day was associated with a weight loss of ~1 pound.[136]

The evidence is unequivocal that perturbations in energy balance (increases or decreases in energy (calorie) intake, expenditure, or both) are met with metabolic and behavioral compensatory mechanisms that dampen and can eliminate the caloric surplus or deficit over time.[137–144] In other words, it is naive and unscientific to believe that policymakers can somehow elicit changes in one aspect of behavior (e.g., eating fewer potato chips) without fostering changes in other aspects of behavior (e.g., eating more onion rings) or metabolism (i.e., a decrease in metabolic rate). Compensatory mechanisms have been demonstrated in many species,[145] including humans, and it has been known for decades that small decreases in energy intake have almost no clinically meaningful effect on body weight over time because of compensation.[133] For example, Edholm and colleagues demonstrated that even large negative changes in energy balance are compensated over the course of multiple days either behaviorally (e.g., increased energy intake or decreased physical activity) or metabolically (e.g., decreases in resting energy expenditure).[146–148] Rosenkilde et al. demonstrated that participants exercising at either 300 or 600 kilocalories per day lost the same amount of body weight over a 13-week intervention.[140] This result is indicative of substantial (i.e., ~300 kilocalories per day) metabolic and behavioral compensation. An understanding of compensatory mechanisms demonstrates that current public policy interventions are simplistic and problematic at best.

Perhaps the strongest evidence against the idea that small changes in energy balance (e.g., "nudges") will have any effect is from the bariatric surgery literature. Bariatric patients are an important group to examine for compensatory mechanisms because of their significant investments in terms of time, money, effort, and caloric restriction. Although bariatric surgery is

clinically effective for many patients,[149] weight loss failures are extremely common in a large number of patients, for whom less than 50 percent of excess weight loss is maintained at multiyear follow-ups.[150–152] The failure rate (i.e., maintenance of less than 20 percent of excess weight lost) when follow-up is at least 10 years is greater than 20 percent for morbidly obese patients and almost 35 percent for super obese patients.[153] In the morbidly obese, failure rates approach 50 percent with some procedures,[154,155] with nutritional indiscretions and physical inactivity cited as the behavioral compensatory mechanisms leading to the failure.[156,157]

4.2. Policy Initiatives Based on Uncertain Science

Many policy initiatives are based on the simplistic notion that a reduction in caloric intake will lead to a reduction in obesity and metabolic diseases. Although there is little argument that significantly reducing energy intake can be effective in the short term (<1 year), there is strong evidence that interventions that focus exclusively on "diet" inevitably fail to produce clinically significant long-term weight loss (>5 years).[158–160] If highly motivated individuals with large sunk costs and extreme changes in energy balance (e.g., bariatric patients) have significant failure rates, one must question the efficacy of small changes (e.g., nudges) at effecting clinically relevant weight loss. Importantly, individuals often exit diet-only interventions with impoverished body composition and health[161–165] and are predisposed to additional gains in weight and fat mass.[139,166–168] We contend that taxes, nudge approaches, and diet-only interventions are generally ineffective distractions from potential solutions[128] and may have negative unintended consequences because of compensation and other physiologic processes. Again, basic understanding of the science behind compensatory mechanisms indicates that most public policy interventions are problematic at best.

4.3. Guidelines Used to Rationalize Intervention

Widespread beliefs and scientific illiteracy stemming from government guidelines about what constitutes "healthy" eating have sparked a cottage industry of researchers seeking to change eating behaviors. The following goal statement in the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* suggests the legitimacy of economic policies aimed at steering individuals toward "healthier" eating.

> Align nutritional and agricultural policies with Dietary Guidelines recommendations and make broad policy changes to transform the food system so as to promote population health, including the use of economic and taxing policies to encourage the production and consumption of "healthy foods" and to reduce "unhealthy foods." For example, earmark tax revenues from sugar-sweetened beverages, snack foods, and desserts high in calories, added sugars, or sodium, and other less "healthy" foods for nutrition education initiatives and obesity prevention programs.[18(p9)]

Researchers have taken the call to arms by producing a growing body of literature on how government can help steer individuals toward following its dietary guidelines. One set of studies focuses on how close Americans are to eating within guidelines. One study, for example, examines how the food system can begin supplying food more in line with the dietary guidelines concerning the recommended number of servings designated for various foods.[169] Another study focuses more on demand by quantifying discrepancies between how Americans are eating and federal recommendations.[170] Implications for energy use, blue water footprint, and greenhouse gas emissions associated with shifting from current US food consumption patterns to those contained in the 2010 USDA Dietary Guidelines are the subject of yet another study.[171] Although nutritional status has improved, one study concludes that the United States falls short of meeting the 2010 Dietary Guidelines for Americans by a large margin in nearly every component of diet quality.[172]

Another body of literature focuses on the Dietary Guidelines as they apply to schoolchildren. One study examines how close food and beverage policies in school districts are to the 2010 Dietary Guidelines' recommendations.[173] The authors conclude that the USDA should (a) focus on stronger implementation of nutrition guidelines at the secondary level; (b) set quantifiable and attainable limits on trans fat, sodium, sugar-sweetened beverages other than regular soda, and fat content of milk; and (c) pursue policies that increase the availability of fruits, vegetables, and whole grains at all sale locations. This policy recommendation is offered despite strong evidence from other research that increasing fruit and vegetable consumption will have "no discernible effect on weight loss"[174] and that reducing sugar-sweetened-beverage consumption will have only a trivial effect on obesity.[175] The potential for the guidelines to improve student weight status is examined in another study, which focuses on the relationship between state laws on school meal nutritional content and student weight. The study finds some improvement for states that had strict meal requirements.[176]

Other studies estimate price sensitivities of demand for major commodity foods included in the Dietary Guidelines. Estimating how price changes can be combined with public education campaigns is the subject of one study that aims to guide consumers toward eating within government guidelines.[177] Not surprisingly, price changes affect the quantity consumed, depending on the type of food. Another study estimates effects of taxes on "healthy" eating, based on government guidelines that single out calories, empty calories, calorie from fat, carbohydrates, fiber, fat, cholesterol, protein, sugar, and sodium.[178] The results show that how much consumption is affected depends on how the tax is levied. Inclusive taxes (those levied at the point of production) are shown to be more effective than exclusive taxes (levied at the point of sale) in reducing "unhealthy" eating.

Research has also been aimed at gaining a better understanding of the underlying nature of consumers' response to price changes for "healthy" and "unhealthy" foods. Defining *healthy eating* as that described by the DGA, one study concludes that not only do consumers exhibit asymmetric patterns of demand sensitivity to price changes for both healthy and unhealthy food, but they do so in opposite and undesirable directions.[179] Specifically, demand sensitivity for healthy food is greater for a price increase than for a price decrease, whereas the pattern is reversed for unhealthy food. The authors conducted experiments that indicated that "fear appeals" attenuated some of the undesirable asymmetry of demand sensitivity for unhealthy and healthy foods. Specifically, the authors included the following insert as one method of implementing a fear appeal designed to help guide consumers toward foods defined by the study to be healthier.

Fear Appeal

> Eating Can Be a Dangerous Experience . . .
>
> Did you know that an overwhelming majority of Americans' diets do not meet Federal Food Guide Pyramid recommendations? The unhealthy diets of a majority of Americans result in more deaths each year than smoking, drug-use, and firearms combined and [are] one of the two leading causes of premature death in the United States (American Medical Association).
>
> Such a diet contributes to four of the six leading causes of death:
>
> - Heart disease
> - Diabetes
> - Stroke
> - Many cancers (colon, prostate, mouth, throat, esophagus, lung, stomach)
>
> Please follow the USDA's nutritional guidelines for healthy eating.[179(p134)]

Not all studies cite dietary recommendations as their inspiration, but their proposed taxes and subsidies are aimed at steering people toward "healthier" choices consistent with government guidelines. Proponents often target so-called junk foods such as soda or snacks.[180] For example, one study concludes that a soda tax of one penny per ounce could prevent as many

as 26,000 premature deaths over 10 years.[180] This tax on what the authors term "liquid candy" is claimed to yield $13 billion in tax revenues while avoiding $17 billion in medical costs associated with obesity, diabetes, and cardiovascular disease. Other authors find considerably different effects.[181] The author of yet another study concludes that a 30 percent rebate on various "healthy" foods would remove only a small fraction of the gap between people's actual eating behaviors and what the dietary guidelines recommend—a result that leads the author to conclude that the subsidy would exert limited beneficial effects on weight management, disease prevention, and health-related quality of life.[182]

Nudge proposals advocated by behavioral economists are also gaining traction in the policy arena.[183] Nudges are aimed at helping steer individuals—who are often believed to be irrational—toward "healthier" eating.[184] Thaler and Sunstein, for example, argue, "It would be quite fantastic to suggest that everyone is choosing the right diet, or a diet that is preferable to what might be produced with a few nudges."[184(p7)] One study in this area found that placing "junk food" in the back of the school cafeteria is a powerful nudge because it considerably reduces consumption of such food.[185] Food labeling is also often believed to nudge individuals to make "healthier" choices because they become better informed about the caloric, fat, salt, and other content of foods they consume. Eating-behavior researchers have also argued that small changes in choice architecture (e.g., changing sizes of utensils, bowls, and plates) allow people to "effortlessly control their consumption and lose weight in a way that does not necessitate the discipline of dieting."[186(p472–473)]

On the more extreme side of intervention, one author proposes a broad template for regulation of our food environments that mirrors regulation of the environment, food safety, alcohol, tobacco, and building codes.[187] Proposals include (1) standardizing portion sizes with

only single-portion units allowed; (2) banning certain foods in locations not dedicated to food (e.g., sodas sold in hardware stores) and allowing drive-up windows to be open only during designated meal periods (i.e., breakfast, lunch, and dinner); and (3) raising government counter-advertising to overturn industry marketing of "unhealthy" foods. Deborah A. Cohen speculates that our future will include encoded ID cards that are personalized with our unique energy requirements, telling restaurants what each of us may consume.[187]

4.4. Is the "Healthy" versus "Unhealthy" Dichotomy Unhealthy?

Government dietary recommendations have perpetuated perceptions that foods can be classified into a "healthy" versus "unhealthy" dichotomy. Previous discussion has argued that this will be a false dichotomy as long as government recommendations are offered without sufficient scientific evidence. For example, the US government promoted the notion that obesity and heart disease are linked to the consumption of fats, but in 1992, the USDA introduced the Food Guide Pyramid. According to the Pyramid, the majority of calories (up to 11 servings per day) should come from complex carbohydrates—primarily breads, cereals, rice, pasta, potatoes, and other starches—whereas meats, fish, eggs, and other protein sources are relegated to 2 to 3 servings per day and fats are to be eaten sparingly. It has been speculated recently that the US government inadvertently fostered dietary changes that contributed to our growing weight problem and diabetes prevalence through its emphasis on limiting consumption of eggs, butter, milk, and meat while bulking up on carbohydrate-rich foods such as pasta, bread, fruit, and potatoes.[29] Meanwhile, recent Gallup polls demonstrate that most individuals remain committed to avoiding fat in their diets, with nearly twice as many Americans saying they actively avoid fat in their diet (56 percent) as those who say they actively avoid carbohydrates (29 percent).[188]

Undeterred, the federal government continues to promote the "healthy" versus "unhealthy" dichotomy, as is evident in a 2015 report evaluating research on food policies to reduce obesity and diabetes.[189] The report included the following list of ways of "Limiting the Availability of Unhealthy Food":

- Taxes
- Agricultural policies
- International trade policies
- Prohibition or regulation of unhealthy foods
- Regulation of advertising and marketing
- Industry self-regulation
- Zoning laws

Note that the report did not define what makes various foods unhealthy or healthy, presumably because this distinction is assumed to be obvious or because it can be understood by simply reading the government dietary guidelines.

Studies indicate that consumers may react to this false dichotomy in unintended ways. One study finds that the mere presence of a "healthy" food option vicariously fulfills nutrition goals and provides consumers with a license to indulge, thus exerting ambiguous effects on overall diets.[190] Psychologists also report *negative calorie illusion*, whereby adding a "healthy" option to weight-conscious individuals' "unhealthy" meals decreases their perception of the meals' calorie content. For example, weight-conscious participants estimated that a hamburger alone contains 734 calories but that the same hamburger contains only 619 calories when accompanied by celery sticks.[191] Studies also suggest that restaurants claiming to serve "healthy" foods may steer diners to underestimate the caloric density of their foods. Additionally, studies

suggest that diners are more likely to purchase higher-calorie side dishes at restaurants that claim to serve "healthy" foods than at restaurants not making such claims.[192]

Economic interventions themselves may also legitimize the "healthy" versus "unhealthy" dichotomy in the minds of the public. For example, taxes on soda may signal to consumers that soft drinks are unhealthy in much the same way that educational campaigns in print or radio media remind the public to avoid or limit soda consumption. The nontaxed status of fruit juices and milk may confer a "health halo" on those drinks, similar to the effect of low-sugar or low-fat health claims.[193,194] Consumers may interpret such health claims to mean that a food item is healthy and consequently can be consumed in larger quantities. However, many fruit juices contain as much sugar as sodas, so hikes in consumption of fruit juice may actually increase consumers' caloric intake.

Consumers led to believe the "healthy" versus "unhealthy" dichotomy are unlikely to experience improved health. One reason is that the dichotomy is a product of flawed research, as previously discussed. Another reason is that it is unclear what substitutions are made when consumers are steered away from "unhealthy" foods. This concern is consistent with the previous discussion of the basic science of compensatory mechanisms and with the economic literature showing that policy interventions usually do not work as intended. For example, although soda tax hikes were shown to decrease soda consumption among children, no change in total caloric intake occurred; children instead increased their consumption of other high-calorie beverages.[195] Another study documents how tax hikes on various foods steer consumers into purchasing a wide array (23 categories) of other food and beverages.[196] A field study finds that a soda tax led to an initial drop in consumption that was followed by a return to original consumption levels, but the tax also led some consumers to switch to beer.[197]

Use of the "healthy" versus "unhealthy" dichotomy is so pervasive that researchers often do not find it necessary to offer definitions of terms to readers. Consider, for example, a recent review of the economic literature on how prices interact with food consumption. As this excerpt shows, the review makes ample use of the terms *healthy*, *less healthy*, and *healthier*:

> The growing evidence base assessed herein indicates that changes in the relative prices of less healthy and healthier foods and beverages can significantly change consumption patterns and may have significant impacts on weight outcomes at the population level, particularly among populations most at risk for obesity and its consequences. Raising the prices of less healthy options by taxing them has the added benefit of generating considerable revenues that can be used to support costly programmes and other interventions aimed at improving diets, increasing activity and reducing obesity, including subsidies for healthier foods and beverages.[198(p128)]

4.5. Uncertain Science Produces Uncertain Outcomes

So far, economic interventions have not achieved their goal of steering consumers away from "unhealthy" foods and toward "healthy" foods, at least using the definitions researchers believe are consistent with the (flawed) federal dietary guidelines. Children increased their consumption of other high-calorie beverages in ways that completely offset decreased soda consumption. A recent study using scanner data at grocery stores looked at the effect of two tax events on soft-drink consumption: a 5.5 percent sales tax on soft drinks imposed by the state of Maine in 1991 and a 5 percent sales tax on soft drinks levied in Ohio in 2003. The authors concluded that neither sales tax had a statistically significant effect on the consumption of soft drinks.[199]

Food label interventions are also ineffective in achieving their goal of healthier eating. A study of New York City's 2008 law requiring restaurant chains to post calorie counts found that although 28 percent of patrons said the information influenced their choices, researchers could not detect a change in calories purchased after the law was enacted.[200] Finkelstein et al. reached a similar conclusion in a study of a mandatory menu-labeling regulation in King

County, Washington, that required restaurant chains with 15 or more locations to disclose calorie information.[201]

Just as the studies attempting to identify relationships between diet and disease are flawed, so too are the research efforts that underlie nutrition policy interventions. Many economic studies do not even attempt to determine whether interventions exert desired effects on disease, weight, or any other measure of quality of life. Rather, the studies simply examine whether interventions elicit "healthier" eating on the basis of the (flawed) assumption that success in decreasing any form of "unhealthy" eating necessarily improves public health. Yet, as demonstrated in this paper, the current dietary guidance is not the product of strong, rigorous scientific research. Moreover, studies that singularly focus on decrements in "unhealthy" food consumption often overlook the overall changes in food choices (e.g., substitutions) that individuals may make following economic interventions. That means that we simply do not know, by any measure, whether these interventions are successful in improving public health.

A major concern is that continued misplaced belief in the efficacy of dietary guidelines will lead to more taxes, nudges, or bans as advocates recognize that their initial interventions were unsuccessful in steering people toward "healthier" choices or improving health. Consider, for example, the following conclusion from a recent follow-up study to the mandated displaying of calorie information in fast-food restaurants in New York City. The study found that consumers exposed to menu labeling immediately after the mandate took effect in 2008 and at three points in 2013–2014 did not significantly change the levels of calories or other nutrients they purchased or the frequency of their visits to fast-food restaurants.[202] It concluded,

> Menu labeling at fast-food chain restaurants, which the Affordable Care Act requires to be implemented nationwide in 2016, remains an unproven strategy for improving the nutritional quality of consumer food choices at the population level. Additional policy

> efforts that go beyond labeling and possibly alter labeling to increase its impact must be considered.[202(p1900)]

Greater harm to public health from more aggressive economic interventions remains a distinct possibility, especially when advocates do not realize that the dietary guidelines they use to rationalize their interventions may themselves be public health hazards.

4.6. Necessary Evidence, Knowledge, and Understanding Are Lacking

As we have noted, the research necessary to inform sound public nutrition policy decisions requires an understanding of the complex, interdependent relationships between policy, idiosyncratic physiologic and behavioral compensatory mechanisms, and the food environment (e.g., industry, cultural factors). For the most part, the data necessary for this understanding simply do not exist. As we have documented, valid scientific evidence of dietary intake is lacking for both the general population and at-risk subpopulations. This fact, in confluence with the heterogeneous nature of intake, risk, and compensatory mechanisms, should cast doubt that general recommendations are likely to be successful at improving public health.

To make recommendations, one must acknowledge that all foods and beverages may have both positive and negative effects that differ depending on myriad factors for which evidence is lacking. For example, an individual's nutrient partitioning (i.e., the metabolic fate of consumed foods and beverages) depends on current patterns of consumption, food preparation practices, physical activity levels, body composition, inherited predispositions, and current disease status. Furthermore, knowledge of compensatory behavioral mechanisms, such as substitutions, and of physiologic compensations, such as increases or decreases in energy expenditure, is necessary. If a policy involves changes in behavior by industry, companies may strategically respond in ways that frustrate the goals of the policy. In some cases, consumers and

producers will have behavioral changes with unintended consequences that may or may not be knowable a priori or ex ante. In short, government decision makers currently do not have the knowledge necessary to make decisions involving all these very complex parameters. Therefore, the best policy course often may be to exercise humility and do nothing.

Conclusion

This paper documents the problematic nature of the current US dietary guidance that informs public health interventions and nutrition policy. Since the inception of the *Dietary Goals for the United States* in 1977,[12] contrary scientific evidence and the extreme diversity of expert opinion on diet–health relationships have been ignored, and unsound science has often informed nutrition recommendations and economic policies. Misinformation generated by weak or refuted empirical evidence and biased review processes led to widespread illiteracy in basic human physiology and nutrition science. This illiteracy contributed to myriad myths and presumptions that pervade both the popular media and academic literature and underpin many policy initiatives.

Researchers have produced a growing body of literature on how government can help steer individuals toward its dietary guidelines, despite a lack of empirical support for those recommendations or an understanding of the potential unintended consequences. Because of metabolic and behavioral compensations, economic interventions such as taxes, subsidies, and nudges are extremely unlikely to lead to significant positive public health changes. Many economic studies do not attempt to determine whether interventions exert desired effects on disease, weight, or any other measure of quality of life, but rather examine whether interventions promote "healthier" eating behaviors as defined by government guidelines. Yet the dietary guidelines are not the product of rigorous scientific research, despite their status as conventional

wisdom. Simplistic, ineffective interventions that redirect resources away from the actual causes of disease and ill health are one unintended adverse consequence of the government's pursuit of dietary advice. We hope that future government reports acknowledge that empirically supported dietary guidance and economic policies aimed at improving public health require valid scientific data and examination.

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