Fix Our Food: Food Reform Begins with the Dietary Guidelines

America has not always been fat. Although nearly two-thirds of the population is currently overweight or obese, the rapid rise in the prevalence of obesity began recently in our nation’s history, not long after the creation of our nation’s first dietary recommendations. While it is recognized that origins of obesity are multi-factorial and that personal choices contribute to health outcomes, the effect of the institutionalization of national dietary recommendations on the elements of our society that affect food and nutrition cannot be excluded from an examination of factors that have contributed to creating a food environment detrimental to the health of Americans.

Government nutritionists have been giving dietary advice to Americans for more than a century [1]. However, the first Dietary Guidelines for Americans, issued in 1980 by the U.S. Department of Agriculture (USDA) and the Department of Health, Education, and Welfare (HEW, now the Department of Health and Human Services), differed markedly from previous guidance. They heralded a shift in focus from recommendations for consuming certain foods in order to acquire adequate nutrition to ones regarding avoiding certain foods in order to prevent chronic disease [2]. This shift in focus has proven to be problematic as the effects of the initial Guidelines on all aspects of the food system has unfolded, as science has evolved, as the demographics of the American population has changed, and as the current understanding of the food environment has revealed increasing levels of complexity.

The Dietary Guidelines are not only different from previous government dietary recommendations, they are also significantly different from other highly-influential government policies or decisions, such as the Social Securities Act or Brown v. Board of Education of Topeka. Unlike carefully-crafted legislation or a meticulously-argued Supreme Court decision, the Dietary Guidelines and the process that creates them did not develop from the deliberate construction of a Federally-guided policy or intention. Although, as the foundation of all Federal policies and programs related to food and nutrition, they touch lives of every American daily, the Dietary Guidelines arose out of a series of political maneuvers and measures that were more reactive than proactive. As a result, the method by which the Dietary Guidelines are generated remains flawed. The current process has resulted in Guidelines that perpetuate decades-long controversy over some key Guideline recommendations, reduce the relevance of the Guidelines to many Americans and undermine their confidence in these recommendations, and fail to address the complexity of the current food system.

Part 1: History of Guidelines

In the 1970s, Americans were concerned about obesity, so concerned, in fact, that food manufacturers had fears that theirs was no longer a “growth” industry [3]. There was evidence that per capita food consumption had actually declined [4]. Data collected at the beginning of the 1970s by the National Health and Nutrition Examination Surveys (NHANES) showed that the average amount of calories consumed had gone down by about 16 calories per day at the time the first Guidelines were being created; in contrast, by the end of the next decade and ten years after the first Dietary Guidelines were released, average daily caloric intake had increased by about 250 calories per day [5].
The public’s concern with obesity and policymakers’ alarm regarding the rising cost of healthcare focused the attention of Congressional leader and former presidential candidate Senator George McGovern on the topic of nutrition, specifically the link between diet and chronic disease [6]. In 1977, frustrated with HEW’s refusal to take a firm stand on the link between diet and disease, Senator McGovern pushed to have the USDA take the lead in nutrition research and education [6]. That same year, the Senate Select Committee on Nutrition and Human Needs under his leadership released the first Dietary Goals for Americans [7]. Written by political staffers with no training in human nutrition and based on two days of testimony from doctors and scientists, these Goals attributed America’s “epidemic of killer diseases”—obesity, diabetes, heart disease, cancer, and hypertension—to an increase in “fatty and cholesterol-rich foods” and advocated Americans reduce dietary fat, saturated fat, cholesterol, salt, and sugar and increase carbohydrate consumption [8].

Aside from the obvious inconsistency that sugar is a carbohydrate, these recommendations were very controversial. At the heart of the controversy was a lack of conclusive data on which to base population-wide recommendations that would prevent future chronic disease. Some experts argued that nutrition was “a young science of enormous complexity” that had produced “no sound evidence that a change in diet will materially alter the course of the “plague of killer diseases” [9]. Critics argued that the McGovern committee proposed to change the diet of most Americans based on relatively weak evidence from correlations in population studies, animal experiments, and the committee’s opinion about which scientists they felt were closest to the scientific truth [10]. Dr. Mark Hegsted, Professor of Nutrition from Harvard School of Public Health, acknowledged the lack of scientific support for the Goals at the 1977 press conference announcing their release, but insisted that it would be irresponsible not to issue recommendations anyway: “There will undoubtedly be many people who will say we have not proven our point; we have not demonstrated that the dietary modifications we recommend will yield the dividends expected. . . . We cannot afford to temporize. We have an obligation to inform the public of the current state of knowledge and to assist the public in making the correct food choices. To do less is to avoid our responsibility” [8].

Those who supported the Dietary Goals felt the proposed radical change in the American diet presented no risk to the health of the American people [8]. In contrast, many experts recognized the possibility of far-reaching and unanticipated consequences that might arise from this change: “The evidence for assuming that benefits to be derived from the adoption of such universal dietary goals . . . is not conclusive and there is potential for harmful effects from a radical long-term dietary change as would occur through adoption of the proposed national goals” [11]. Critics expressed concern about the “economic and cultural shock implied in these radical recommendations” [9]. These goals were felt to have the “potential for undermining both the science of nutrition and nutrition education,” raising “false hopes among consumers on inadequate grounds” by promising “nutritional treatment of diseases that are not primarily nutritional” [12].

The American Society for Clinical Nutrition addressed concerns regarding the strength of the scientific evidence behind the 1977 Dietary Goals in a 1979 report reviewing and evaluating the scientific evidence to date [13]. The study found little conclusive evidence for linking the consumption of fat, saturated fat, and cholesterol to heart disease and found potential risks in
recommending a diet high in polyunsaturated fats [13]. Despite the misgivings of many scientists and nutrition experts about the wisdom of basing a one-size-fits-all dietary prescription on such preliminary and inconclusive data, congressional pressure—especially from Senator McGovern—elicited concessions from government experts that the diet recommended in the 1977 Goals was “prudent” despite the “incomplete evidence” [14]. At this point, the basic tenets of the 1977 Goals began to gather the political momentum that would allow them to persist in some form in each edition of the Dietary Guidelines, beginning with the first one issued in 1980.

As authorized in the 1977 Farm Bill, the USDA assumed the mantle of lead agency in nutrition by establishing the multi-million dollar Human Nutrition Center led by Dr. Mark Hegsted, an early supporter of the 1977 Goals [6]. Although not specifically directed to do so in the Farm Bill, the USDA in conjunction with what was to become the Department of Health and Human Services (HHS), released the first official Dietary Guidelines for Americans in 1980. These Guidelines were very similar to the 1977 Goals and established the framework for all future Dietary Guidelines with seven basic recommendations [15]:

- Eat a variety of foods
- Maintain ideal weight
- Avoid too much fat, sat fat, and cholesterol.
- Eat foods with adequate starch and fiber
- Avoid too much sugar.
- Avoid too much sodium
- If you drink alcohol, do so in moderation

That same year, the Food and Nutrition Board of the National Academy of Sciences released dietary guidance for the nation that contained a very different message. This report stated that there was no clear evidence that restricting dietary fat or cholesterol would result in health benefits for the average person and that good health could be achieved simply by maintaining a healthy weight [16, 17]. These conflicting viewpoints and the continuing controversy over the science behind Federal nutrition recommendations led the Senate Agriculture Appropriations Committee to authorize HHS, USDA, and the National Academy of Sciences’ Food and Nutrition Board to establish an advisory committee to evaluate the available scientific data and recommend possible changes to the 1980 Dietary Guidelines [18, 19]. Also that year, asserting its position as “lead agency” in nutrition, the USDA created a specific departmental agency to house and manage politically sensitive nutritional issues [18]. The Dietary Guidelines were thus institutionalized under the control of the USDA, in what would ultimately be its Center for Nutrition Policy and Promotion.

The Dietary Guidelines Advisory Committee (DGAC) made only a few minor changes to the 1980 Guidelines before releasing the second edition of the Dietary Guidelines in 1985. This edition reflects the continued lack of certainty in the science behind a diet-disease link with the acknowledgment that “we don’t know enough about nutrition to identify an ‘ideal diet’ for each individual” and qualifies the recommendations to reduce dietary fats by saying, “Some people can have diets high in saturated fats and cholesterol and still maintain desirable blood cholesterol levels. Other people, unfortunately, have high blood cholesterol levels even if they eat low-fat, low-cholesterol diets” [20]. Scientists outside the DGAC continued to point to the mixed results
from “several expensive long term intervention trials,” citing the “complexities of cholesterol metabolism, and uncertainties about long-term effects of diet” as the primary reasons for scientists’ inability to make a conclusive connection between diet and disease, especially dietary fat and heart disease [21].

Although there was still no official mandate for the creation of the Dietary Guidelines, language in a 1987 report of the House Committee on Appropriations indicated that the USDA, in conjunction with HHS, “shall reestablish a Dietary Guidelines Advisory Group on a periodic basis. This Advisory Group will review the scientific data relevant to nutritional guidance and make recommendations on appropriate changes to the Secretaries of the Departments of Agriculture and Health and Human Services” [22]. Following this directive, USDA and HHS established a second advisory committee and, in 1990, released the third edition of the Dietary Guidelines. This committee acknowledges the politicizing of the Guidelines process, conceding that “the existing Dietary Guidelines are well established as Federal nutrition policy” and recognizing the “importance of stability of the message in efforts to educate the public about nutrition and health issues [23]. The same general guidelines were reiterated, now with specific numerical limits for dietary fat and saturated fat and with references to the USDA’s Food Pyramid, which was in the process of being developed at the time. The DGAC report also confirms that “some foods that contain fat, saturated fatty acids, and cholesterol, such as meat, milk, cheese, and eggs, also contain high-quality protein and are our best sources of certain vitamins and minerals” [23], but in general, Americans began reducing their intake of high-fat versions of these foods [24].

A decade after the first Guidelines were released, America’s growing obesity crisis captured the attention of nutrition experts across the country. The 1990 National Nutrition Monitoring and Related Research Act (NNMRRA) was established in part to eliminate a redundancy in nutritional surveys undertaken by these USDA and HHS [25]. It was also hoped that a coordinated information-gathering system would help scientists figure out why, “despite growing awareness of its associated problems, and the wide availability of low calorie, and low or no-fat foods, Americans are gaining weight” [26]. This Act also made the creation of Dietary Guidelines for Americans an official task of the USDA and HHS. By convention, the agencies alternate administrative leadership beginning with HHS in this role for the 1995 Guidelines. Although the law does not bestow exclusive rights to creation of dietary advice for Americans on these two agencies, it does give them “veto power” over any guidelines other agencies may create. This clause was included at the insistence of the USDA, concerned that the focus on health at HHS might overshadow the agricultural concerns at the USDA [18].

Extensive guidance is given in NNMRRRA regarding the approval process for any dietary guidance submitted by another Federal agency; however, no other mandated framework for the creation of the Dietary Guidelines is given. There is no mandate that the Guidelines focus on the prevention of chronic disease, only the stipulation that they “shall be based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared” [25]. With the exception of previous language establishing the creation of an advisory committee to review the science and make recommendations regarding changes to the Guidelines, how this task is to be undertaken is not specified.
As a result, the process for creating the Guidelines has undergone a number of significant, agency-based changes in the past decade. As with all previous Guidelines after 1980, the 2000 edition was based on the report submitted by the DGAC. The DGAC is created under rules specified in the Federal Advisory Committee Act that call for balance in viewpoints of members of the committee, transparency in its actions, and disclosure of conflicts of interest. Prior to 2005, the text for the Dietary Guidelines was taken almost verbatim from the DGAC report, with few changes made by USDA or HHS staff. Although HHS and USDA alternated administrative lead, no staff members were indicated as contributing to the writing of the final Guidelines, prior to 2005.

Beginning with the 2005 Dietary Guidelines, this was no longer the case. Now, the DGAC submits its report to the agencies, but HHS and USDA staff members are responsible for the production of the Guidelines, which are no longer considered to be a scientific document whose audience is the American public, but a policy document whose audience is nutrition educators, health professionals, and policymakers [Figure 1] [27]. Why and under whose direction this change took place is unknown. When HHS was administrative lead in 2005, 26 HHS and 22 USDA staff members worked on the production of the Dietary Guidelines [28]. With the USDA at the helm, the 2010 edition was produced by 17 USDA staff members, with 6 staff members from HHS [28]. Because the text of the final Guidelines is not written by scientists chosen under the guidance of FACA rules, there is no guarantee of balance, transparency, and disclosure of conflicts of interest.

By convention, public commentary has been solicited by the DGAC with regards to the content of its report. Because, prior to 2005, the content of the DGAC Report and the text of the final Guidelines were very much the same, by commenting on the DGAC Report, the public was, in

![Figure 1: The process for development of the Dietary Guidelines beginning in 2005 [27]](image-url)
essence, commenting on the final Guidelines. Prior to 2005, a summary of those comments is contained in the DGAC Report. With the creation of the 2005 and 2010 Guidelines, the DGAC solicited public commentary which is available for viewing on USDA and HHS websites. No indication is given regarding how the commentary is used either in the DGAC Report or the final Guidelines for either year. Because the text contained in the final Guidelines is not the same as the text recommended in the DGAC Report, beginning with the 2005 Guidelines, the public is no longer commenting on the text that will be found in the final Guidelines.

Translating the DGAC Report into the Dietary Guidelines is an agency process not under FACA jurisdiction. The DGAC Report is “advisory in nature and not the actual 2010 Dietary Guidelines for Americans;” the writers of the final Guidelines document are under no statutory or regulatory obligation to adhere to its recommendations [30]. Because the scientists on the DGAC no longer provide the suggested text for the Guidelines, beginning in 2005, the Dietary Guidelines document recognizes the contributions of an “Independent Scientific Review Panel who peer reviewed the recommendations of the document to ensure they were based on a preponderance of scientific evidence” [28]. However, the activities of and purpose for the Panel are unclear. Although the Guidelines indicate that the Panel’s responsibilities pertain to the scientific accuracy of the Guidelines, the 2010 Dietary Guidelines Peer Review Charge indicates that the panel was to review the Guidelines only “for clarity and technical accuracy”[31].

In direct conflict with guidance from the Office of Management and Budget (OMB) regarding the peer-review process [32], the activities of the Panel had been withheld from the public [33, 34]. Requests submitted under the Freedom of Information Act (FOIA) asked for information regarding the process used to select the panel members, their identities, credentials and potential conflicts of interest, and the report regarding the Dietary Guidelines policy document that this panel would have generated [33, 34]. The USDA’s initial response to the FOIA stated: “there is no written or established process” for selecting panel members; furthermore, their identities must be kept secret because revealing them “would have a chilling effect on the government’s ability to attract qualified reviewers in the future” [35]. Nutrition experts questioned whether the decisions made by the “Independent Scientific Review Panel” were based on politics or science, something that could not be determined unless their identities were known [36]. Yet USDA officials felt that there was no need to disclose the names of the scientists involved as it was felt that their activities were not, in fact, influential [36].

Although the identities of the 2010 Independent Review Panel have now been made public, the actual purpose of the panel, the need for such a panel, its selection process, and the purpose for the initial secrecy surrounding its activities remain unclear. In conflict with guidance from the OMB, the response from the USDA indicates that the Panel did not, in fact, act as a peer-review panel, provide peer-review as it is commonly understood, or meet requirements for balanced viewpoints, independence, and reduction of conflicts of interest [37]. The USDA indicates that, in contrast to the activities that the Panel was credited with in the 2010 Dietary Guidelines Acknowledgements, the Panel did not act to ensure the Dietary Guidelines were based on the preponderance of scientific evidence. The USDA indicates that the panel “served only to review the concepts in the DGAC report so that it would be understandable for nutrition educators, health professionals, and policymakers,” and the “peer reviewers played no role in interpreting the science;” furthermore, reviewer’s comments were “only used when relevant and valid”
although it is unknown who was responsible for such assessments [37]. In the end, it is unclear as to how the scientific validity of the Guidelines document is guaranteed at all. Scientists familiar with the processes involved in generating government and policy reports object to these and other breaches of transparency on the part of the USDA and are calling for reform of the Dietary Guidelines process [34, 38]. The process for creating Dietary Guidelines is the result of a series of reactions to various historical and political pressures. It is not the outcome of a deliberate legislative, executive, or judicial process. When the first Dietary Guidelines were created thirty years ago, nutrition experts had only a preliminary understanding of the complexity of the food environment and its relationship to food and nutrition policy. The results of committing the nation to a single dietary approach were unknown at the time. The consequences of having this single dietary approach shaped by the two government agencies also responsible for Federal nutrition programs, education, and research was largely unanticipated. Since then, the environment in which Americans make their food choices has changed dramatically; many of these changes can be traced back to the influence of the Dietary Guidelines.

Part 2: Understanding the Influence of the Dietary Guidelines

Impact on the Social-Ecological Model

![Image of the social-ecological model of the food environment]

The 2010 Guidelines point to the Social-Ecological model as “a framework to illustrate how all elements of society combine to shape an individual’s food and physical activity choices, and ultimately one’s calorie balance and chronic disease risk” [Figure 1] [29]. While some nutrition experts assert that “a poorly distributed federal publication” could not “single-handedly change a nation’s eating habits” [39], the Dietary Guidelines play a central role in shaping every aspect of the social-ecological model that relates to food and nutrition.
Social and cultural norms. The Guidelines are meant to answer the question, “What should Americans eat to stay healthy?”[40] For most Americans, the Dietary Guidelines shape the cultural norms regarding what foods and eating patterns are considered appropriate for a healthy diet [41, 42].

Sectors of Influence.
Government: As the foundation of Federal nutrition policy, programs, and educational materials, the Dietary Guidelines affect many sectors that have an impact on our food environment, directly or indirectly. The purpose of the Dietary Guidelines is outlined by the USDA as follows [43]:

“The Dietary Guidelines allow government to speak with one voice to the public when presenting advice about proper dietary habits for healthy Americans ages two years of age and older and how to make food and physical activity choices to promote health and prevent chronic disease. All federal dietary guidance for the public is required to be consistent with the Dietary Guidelines.

The Dietary Guidelines provide the foundation for food and nutrition policy and the government's position for debating standards and international reports.

The Dietary Guidelines influence the direction of government nutrition programs, including research, labeling, and nutrition promotion. . . . Federal nutrition assistance programs such as USDA's School Meal and Food Stamp Programs, and the WIC Program (Supplemental Food Program for Women, Infants and Children) use the principles in the Dietary Guidelines as the scientific underpinning for designing benefit structures and nutrition education programs.”

Agriculture: Agricultural programs begun in the 1970s encouraged the planting of large monoculture crops such as corn, wheat, and soy [44]. Corn and soy serve a dual role in the food manufacturing system; the vegetable oil is removed for food production, and the remaining mash can be used as feed for livestock. As Americans began changing their diet to reduce meat consumption as recommended in the Dietary Guidelines, an early concern of farmers was “what will be done with the corn we produce for the cows that no one eats?” [45] The language of the 1977 Farm Bill makes it clear that one of the purposes of the nutrition research and education program within the USDA is to bolster the market for US agricultural products [46]. Over time, agricultural researchers found new uses for corn and other commodity crops, such as corn syrup and textured vegetable protein, which may be processed into a multitude of food products then marketed to consumers.

Scientific and academic community: The foundation for understanding the relationship between diet and disease begins with scientific research. Since the first Guidelines were created in 1980, the bulk of the funding for large long-term studies regarding nutrition and chronic disease has come from the USDA and HHS [6]. When large clinical trials investigating the link between diet and health are funded by these organizations, the research protocols typically follow dietary patterns that adhere to the Guidelines [47, 48].
Public health and medical system: Scientific research provides the evidence base for public health programs and healthcare practices. Dietary patterns recommended by health professionals and endorsed by health advocacy organizations, like the American Dietetic Association and the American Heart Association, typically reflect dietary approaches used in large government-funded studies [49, 50]. Multiple studies have shown improved glucose control and reduced need for insulin in patients with type 2 diabetes when carbohydrate content of the diet is lowered below the bottom limit of 45% of calories; this was the standard method for treating type 2 diabetes before the widespread use of insulin [51, 52]. This approach to treating diabetes has yet to be recommended for long-term use by the American Diabetes Association due to concerns regarding the potential effects of the fat content of such a diet on heart disease risk factors [53].

Food industry: Although food manufacturers do create food with low nutritional value, they also work to provide consumers with food that fits the definition of healthy provided by the Dietary Guidelines. Food manufacturers can use products, such as corn syrup or soy lecithin, developed through agricultural research to manipulate the fat and fiber content of food products to meet the recommendations in the Dietary Guidelines [54]. Since the first Dietary Guidelines instructed Americans to increase their intake of starches and vegetable oils, the energy available from flour and cereal products and the fats and oils added to them in processed foods has increased by more...
than 400 calories; in contrast, the energy available from less-processed foods like eggs, nuts, meat, fruits, and vegetables has increased by a total of 35 calories [Figure 2] [2]. Low-sodium, high fiber, whole wheat, and low-fat label claims are used to market products to consumers, leading nutrition experts to express concern that these foods may give the sheen of healthiness to foods that are important to the USDA’s agricultural programs and to food manufacturers, but may offer few health benefits to consumers [54].

Marketing and consumer behavior: Guidelines information regarding health and chronic disease on food packages and in marketing materials is used to educate consumers and has been shown to successfully influence their purchasing choices [55, 56]. During the past thirty years, Americans have met nearly all of the recommended dietary goals set forth by the first Dietary Guidelines [Figure 3] [5]. As Americans have increased their intake of fruits, vegetables, grains, and cereals, dietary carbohydrate intake has increased to recommend levels of 45-60% of calories from 44.3% of calories in 1980 to 50.3% in 2000 [5,24]. Total fat has decreased to recommended level of 25-35% of calories, from 36.4% of calories in 1980 to 32.8% in 2000 [5]. Saturated fat intake decreased from 12.9% of calories in 1980 to 11% in 2000, which is slightly above the recommended upper level of 10% of calories [5]. The decreases in dietary fat and saturated fat can be at least partially attributed to a decrease in egg and red meat consumption [24]. Average cholesterol intake was below the recommend level of 300 mg per day in 1990 (the earliest time period for which this is estimated), and at 278 mg per day, it continues to be below that level currently [2]. Average daily intake of added sugars has gone from 26% of calories in 1978 to 15.8% in 2010, well below the upper limit of 25% set by the 2010 Dietary Guidelines [57, 58]. Average sodium intake has decreased from 4047 mg in 1980 to 3614 mg in 2006, but is still above recommended level of 2300 mg per day [2, 59, 60].

<table>
<thead>
<tr>
<th>Dietary Guidelines Goal</th>
<th>Pre-Guidelines intake</th>
<th>Current intake</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-60% of calories from carbohydrate</td>
<td>44.3%</td>
<td>50.3%</td>
<td>Met</td>
</tr>
<tr>
<td>25-35% of calories from fat</td>
<td>36.4%</td>
<td>32.8%</td>
<td>Met</td>
</tr>
<tr>
<td>&lt;10% of calories from saturated fat</td>
<td>12.9%</td>
<td>11%</td>
<td>Near goal</td>
</tr>
<tr>
<td>&lt;300 mg of cholesterol per day</td>
<td>270 mg/day</td>
<td>278 mg/day</td>
<td>Met</td>
</tr>
<tr>
<td>&lt;25% of calories from added sugars</td>
<td>26%</td>
<td>15.8%</td>
<td>Met</td>
</tr>
<tr>
<td>&lt;2300 mg of sodium per day</td>
<td>4047 mg/day</td>
<td>3614 mg/day</td>
<td>Not met</td>
</tr>
</tbody>
</table>

Figure 3: Dietary Guidelines target intake goals compared to pre-Guidelines and current intake [5]

Environmental Settings. Because the Dietary Guidelines influence the foods that manufacturers produce, they have an effect on what foods are available in the food environment and how affordable those foods are, which in turn affects consumer food choices. The effect of the Dietary Guidelines on food choices may be even more pronounced for those whose choices are circumscribed by Federal nutrition program policies. For example, meals served to children through the National School Lunch Program must meet nutritional criteria created by the USDA [61]. In addition, the USDA provides schools with surplus agricultural commodities, which the school may have processed into ready-to-serve food. This allows donated commodities to be
better utilized and gives program participants a more desirable finished product. For example, soy has been mixed into the hamburgers in school lunches since the 1970s, initially to make them cheaper; this practice continues to be endorsed as a way of lowering the fat content of a meal [4, 62].

Restaurants may also use the Dietary Guidelines recommendations to create and market meals. A McDonald’s Happy Meal with a burger, a soda, and French fries gets 10% of its calories from protein, 30% of its calories from fat, and 60% of its calories from carbohydrate, nutrient percentages that meet the levels recommended by the Dietary Guidelines. The nutrient percentage profile of lowest calorie option on the Happy Meal menu—chicken nuggets, apple juice, and apple slices with low-fat caramel sauce—is nearly identical [63].

**Individual Factors.** The recommendations in the Dietary Guidelines may have had an inadvertent effect on gene-environment interaction in some individuals. Since the first Guidelines were released, scientists have learned that when diets high in sugars, starches, and calories are consumed by a woman during pregnancy, the changes that occur in the prenatal environment may predispose the child to metabolic disorders, including obesity and diabetes, later in life [64, 65]. This may limit the effectiveness of a “calories in-calories out” paradigm in these subpopulations.

![Figure 4: Average calorie intake compared to recommended ranges](image)

**Energy Balance.** The Dietary Guidelines place the final responsibility on the individual to maintain energy balance; the 2010 Dietary Guidelines cite “poor diet and physical inactivity” as the most important contributors to our current health crisis [29]. That Americans now eat too much and exercise too little—and apparently disregard public health messages to do otherwise—has become an accepted understanding of the obesity crisis [66]. Despite this perception, the average calorie intake level is within recommended ranges set by the USDA [Figure 4] [2, 5].
While it is true that calorie intake has increased in the past 30 years (almost all of which is from an increase in sugars and starches) [Figure 5] [5], the Guidelines acknowledge that the amount that Americans now consume is not excessive, an average of 1800 per day calories for women and 2600 calories for men [29]. The Guidelines also suggest that Americans do not exercise enough, even though recent research on the subject indicates that nearly 65% of Americans achieve the recommended 150 minutes of moderate-intensity exercise or its equivalent every week; in comparison, in 1983 just over 35 percent of the adult population exercised regularly [Figure 6] [67, 68].

The primary recommendation in the Dietary Guidelines for achieving or maintaining a healthy weight is to “control total calorie intake” and “increase physical activity” [29]. However, since the early days of dietary recommendations, scientists have recognized that “calories in-calories out” is an overly simplified approach to weight loss or weight maintenance [10]. If foods are low in protein content, people will over-eat calories in order to acquire the protein they need [69]. Sufficient protein induces a strong feeling of fullness; protein-rich foods reduce calorie intake [70]. Salt needs can drive food intake, and changing the salt content of food can change eating behaviors [71]. Urinary sodium—considered a precise biological indicator of sodium consumption—has remained remarkably stable over the past forty years even as calories have gone up, suggesting that we may be eating more food yet acquiring similar amounts of sodium [72]. Other research demonstrates that dietary sugars and starches can trigger a feed-forward mechanism similar to that found in drugs of addiction [73, 74]. Calorie restriction appears to result in at least some reduction in energy expenditure [75]. At the same time, increased activity at the level recommended for weight loss frequently does not produce the amount of weight loss predicted by the energy balance paradigm, possibly to due to some type of compensation in the form of increased intake or change in metabolic rate [76, 77, 78]. Thus, the recommendations of the Dietary Guidelines can impact both the “calories in” and the “calories out” part of the energy balance equation [79, 80].

Figure 5: Change in amount and type of calories consumed by Americans from 1970 to 2000 [5]
The possibility arises that the recommendations may not be working even if many Americans are following them. In fact, a recent study shows that Americans whose diet met the criteria for “healthy” according to the 2005 Dietary Guidelines nevertheless gained weight at an average of 10 kg over 20 years [81].

**Impact on Chronic Disease**

Trends in the prevalence of chronic disease since the Guidelines were first released do not demonstrate a favorable impact of those recommendations on most diseases. Although all-cause mortality from cardiovascular disease has declined since 1980, it should be noted that this decline began in 1963, with no significant change in rate of decline since 1975 [Figure 7] [82]. Cholesterol levels and the prevalence of hypertension had been trending downward since 1980, although hypertension rates have begun to rise in the past decade [Figures 8 and 9] [83]. Some researchers attribute this general reduction in CVD risk factors and mortality to changes in dietary patterns to match the Dietary Guideline recommendations [84, 85].

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**Figure 6: Percentage of adult population according to activity levels [67]**

![Activity Level Chart]

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Figure 7: Mortality rates for CHD, stroke and non-CVD causes [82]

Figure 8: Age-adjusted prevalence of high serum cholesterol [83]
If the Dietary Guidelines are credited with improvements in cardiovascular mortality and risk factor rates, they may also be implicated in other trends in chronic disease. While trends in cardiovascular mortality and risk factors seem to be improving, trends in the prevalence of heart disease have been mixed. Coronary heart disease prevalence is increasing for blacks, but decreasing for whites [82]. A similar trend is noted with regard to acute myocardial infarction [83]. Prevalence of heart failure, stroke, diabetes, obesity, and rates of new cases of all cancers are trending upward for both races since 1980 [Figures 10, 11, 12 and 13] [83, 86, 87, 88].

The public health impact of the rapid rise in rates of obesity and diabetes since the first Dietary Guidelines were released is of tremendous concern to public health officials and policymakers [86, 87]. The cost of maintaining the nation’s health care system is a leading concern in the nation’s economic struggles; being able to reverse the current epidemics is a key factor in our nation’s future economic as well as physical health. According to a 2009 Congressional Hearing, “Obesity costs the country an estimated $147 billion a year” [89]. Type 2 diabetes alone accounts for one out of every ten health care dollars, with a cost of over $174 billion dollars a year in direct and indirect health care expenses [90]. The current health crisis affects not only our nation’s financial security, but our military security as well. Fewer young people are eligible for military service due to overweight and obesity. According to a recent report,” the military discharges more than 1,200 first-term enlistees each year because of weight problems,” at a cost of about $60 million in expenses to recruit and train replacements [91]. Finally, our most important resource—the health of our nation’s children—is at stake. A recent study shows that over 43% of publically-insured children in the US are overweight or obese [92]. Overweight and

Figure 9: Age-adjusted prevalence of hypertension [83]

1st Dietary Guidelines (1980)
Figure 10: Age-adjusted prevalence of heart failure [83]

Figure 11: Age-adjusted prevalence of stroke [83]
Figure 12: Age-adjusted prevalence of diagnosed diabetes [86]

Figure 13: Age-adjusted prevalence of BMI $\geq 25$ [87]
obese children exhibit lower self-esteem and poorer school performance than their normal-weight counterparts [93]. According to experts, unless our approach to nutrition changes, “today’s children are likely to be the first generation to live sicker lives and die younger than their parents’ generation [89].”

**Evaluation of the Dietary Guidelines**

Although there appears to be a correlation between the changes in Federal nutrition policy and the rise in obesity and diabetes, it is difficult to determine the nature of this association. The manner in which the health effects of the Dietary Guidelines of Americans are assessed reveals some significant methodological flaws. The Healthy Eating Index is a measure of diet quality as specified by Federal dietary guidance and is based on the food patterns found in the USDA’s nutrition education program [94]. This approach does not, in fact, evaluate the Dietary Guidelines for their health effects, but measures whether or not Americans follow them.

Many food-frequency questionnaires (FFQs), the tools used to capture information regarding the eating habits of Americans, may also be based on a methodological flaw. One of the earliest FFQs, the Block FFQ developed at the National Cancer Institute continues to be used today, usually with updates and modifications. The Block/NCI FFQ was designed to investigate the relationship between cancer and dietary intakes of Vitamin A, Vitamin C, total fat, and total calories [95]. It included “questions on restaurant foods, frequency and type of fat added in cooking or at the table, and the consumption of the skin on chicken or the fat on meat” [95]. This FFQ is still used by researchers to capture dietary information even if cancer is not the focus of the current study [96]. Issues with FFQs may be further complicated by the modification of existing FFQs to accommodate changes in dietary habits and available foods, as consumers respond to “the increased presence of low-fat choices in the food supply and to the use of fats in food preparation” [97]. Residual confounding may persist if low-fat dietary patterns are regularly associated with other factors related to healthy lifestyle choices, such as more education, higher socioeconomic status, increased physical activity, and limited use of alcohol and/or tobacco, thus reflecting the cultural norms regarding the health benefits of a low-fat diet [98].

The current Guidelines acknowledge that its recommendations, which have remained remarkably consistent for thirty years, “have not been specifically tested for health benefits [29].” Viewing the effect of the Dietary Guidelines through the lens of an “intention-to-treat” analysis answers “the public health question of what happens when a recommendation is made to the general public and the public decides how to implement it. The results of an intention-to-treat analysis can be quite different from the treatment effect observed when adherence is perfect” [99]. Intention-to-treat analysis disregards the question of whether or not the diet is effective if adhered to, which may or may not be the case, but simply addresses the question of what happens when people are given advice to change their diet. In evaluating the effect of the implementation of the Dietary Guidelines for Americans in this manner, it is clear that it has not had the desired effect on reducing chronic disease, and it is possible that the concerns raised in 1977 by the AMA regarding the “potential for harmful effects” have in fact been realized.
In order to address the health crisis facing the nation today, the effects of three decades worth of low-fat dietary recommendations embodied in the Dietary Guidelines must be fully and objectively evaluated. The continued focus on chronic disease prevention through nutrition recommendations provided by the two government agencies responsible for the supervision and governance of virtually every aspect of our food system has not resulted in existence of a food or healthcare environment conducive to the well-being of Americans.

Part 3: Challenges and Recommendations

The Controversy Continues: Building scientific integrity into the Dietary Guidelines process

When the 2010 Dietary Guidelines were released on January 31, 2011, USDA Secretary Tom Vilsack declared, “The science behind these Guidelines is unquestioned”[100]. Contrary to this statement, experts have been questioning the science behind the Guidelines since their initial release thirty years ago. For thirty years, Americans have been told to decrease dietary fat, saturated fat, cholesterol, sugar, and sodium, and increase consumption of grain and cereal products and vegetable oils in order to reduce the risk of chronic disease [15]. Significant scientific controversy exists with regard to some of the original and current assertions upon which the Dietary Guidelines recommendations are built. These can be seen generally as an ongoing uncertainty with regard to how food and diet patterns relate to chronic disease. More specifically, controversy surrounds the theories that 1) dietary fat, saturated fat, and cholesterol cause heart disease, obesity, diabetes, and cancer and should be replaced in the diet with polyunsaturated vegetable oils; 2) a diet high in carbohydrates will reduce the risk of chronic disease; and 3) excessive sodium intake is the primary variable in the etiology of hypertension, a risk factor for heart disease.

Unresolved: Dietary fat, saturated fat, and cholesterol cause chronic disease.

In the 1970s, there was no agreement regarding the relationship of diet to blood lipids and atherosclerosis. The reasons given then for the difficulty in clarifying the relationship are “the complicated nature of this disease, as well as the multitude of contributing factors and their relationships” [101]. The relationship of dietary fats to heart disease was based on the theory that dietary fat, especially saturated fat and cholesterol from animal products, raised serum cholesterol, and this led to increased risk of heart disease. However, scientists at the World Health Organization in Geneva, Switzerland concluded in 1970 that the development of heart disease could not be attributed to any one dietary factor and that the relationship of cholesterol to heart disease was still controversial [102].

Early animal studies seemed to link dietary fat to atherosclerosis, but other studies did not support this relationship [101]. Even within groups of scientists who believed there was a clear relationship between fats from animals and heart disease risk, there was disagreement on what aspects of the diet were most important. Some felt that dietary cholesterol was of less importance than overall dietary fat, while others believed that dietary cholesterol itself was the most important [101]. In population studies, “no significant dietary differences in saturated and polyunsaturated fat intake have been detected among those suffering higher versus lower rates of atherosclerotic disease” [103]. Large observational and intervention studies conducted early in
the history of the Guidelines, such as the Framingham study, Multiple Risk Factor Intervention Trial, and the National Diet-Heart Study, are frequently cited as proving that a low-fat, low-cholesterol diet reduces risk of heart disease, yet the results from these studies are weak or inconclusive with regard to the relationship between diet and the development of heart disease [21, 104, 105, 106].

Before the Dietary Guidelines were created, the role of polyunsaturated fats in the diet remained unclear as well. Some felt that PUFAs reduced cholesterol [103]; others felt that diets high in polyunsaturated fats may lead to increased cholesterol absorption, elevated serum cholesterol levels, accumulation of cholesterol in tissue, and increased lipid peroxidation [103, 107].

Twenty years later, the 2000 DGAC Report concluded that “the specific contribution of low-fat diets to low rates of chronic disease remains uncertain. Particularly germane is the question of whether a low-fat diet would benefit the American population, which is largely urban and sedentary and has a wide choice of foods.” In this same report, the language linking dietary fat to cancer was removed from the Dietary Guidelines because the matter was considered to be inconclusive [108].

More recently, studies cited by the 2010 DGAC Report demonstrate varied metabolic responses to lowered dietary saturated fat, with increases in atherogenic lipoprotein levels or triglycerides and decreases in high density lipoprotein-cholesterol observed in certain subpopulations [109, 110, 111, 112]. A large 2010 meta-analysis that found there is no substantial evidence for concluding that dietary saturated fat is associated with an increased risk of heart disease [113]. Other recent evidence confirms the common understanding of human biochemistry from the 1960s that indicates that plasma saturated fat, the presumed cause for concern, is substantially determined by dietary carbohydrate [114, 115, 116].

Unresolved: Increasing carbohydrate intake will reduce risk of chronic disease.

The first of the 1977 Dietary Goals was a recommendation that Americans increase their intake of carbohydrates; this was followed by a goal that recommended that Americans reduce their intake of sugar [8]. As the 1995 DGAC report explains however, “there is no evidence that the gut can distinguish between sugars which result from intestinal breakdown of complex carbohydrates or disaccharides originating within the intrinsic food matrix and the chemically identical, exogenous sugars added to food during processing or afterward [117].

Scientists have questioned the value of a diet high in carbohydrates since the first Dietary Guidelines were released. Experts pointed to data that suggested that increased dietary carbohydrate may result in metabolic changes associated with type 2 diabetes and heart disease [118, 119]. These concerns continued to arise throughout the development of the Guidelines. Members of the 2000 DGAC raised the concern that “consumption of high-carbohydrate diets also can produce an enhanced post-prandial response in glucose and insulin concentrations. . . . In persons with insulin resistance, this response could predispose to type 2 diabetes mellitus” [108].
Scientists continue to question the value of a low-fat, high-carbohydrate diet and have pointed to evidence that, in some cases, this type of diet may increase the risk of chronic disease. In her review of recent scientific evidence, Janet King, Chairwoman of the 2005 Dietary Guidelines Advisory Committee, cited specifically that “evidence has begun to accumulate suggesting that a lower intake of carbohydrate may be better for cardiovascular health” [120]. A report by the Institute of Medicine’s Food and Nutrition Board issued in 2005 indicates that “Compared to higher fat diets, low fat, high carbohydrate diets may modify the metabolic profile in ways that are considered to be unfavorable with respect to chronic diseases such as coronary heart disease (CHD) and diabetes” [121]. According to Dr. Frank Hu, Professor of Nutrition and Epidemiology at the Harvard School of Public Health, "The country's big low-fat message backfired. The overemphasis on reducing fat caused the consumption of carbohydrates and sugar in our diets to soar. That shift may be linked to the biggest health problems in America today" [122]. Nevertheless, the 2010 DGAC Report states unequivocally that “Healthy diets are high in carbohydrates” [2].

Unresolved: Reducing sodium intake will reduce risk of chronic disease.

In a summary of the science on sodium published prior to the release of the 1980 Dietary Guidelines, experts from the American Society of Clinical Nutrition concluded that approximately 17% of adult Americans would become hypertensive on the typical daily intake of sodium in America. They also concluded that “the advantages of prevention of hypertension by reduction of salt intake in the entire population as compared with early detection and treatment of new cases have not been clarified” [123].

More recent research shows that the controversy over the benefits of population-wide recommendations for sodium reduction continues. Harvard researchers have found that the amount of sodium consumed by Americans over the past four decades has remained relatively unchanged, while the rates of hypertension have recently increased [72], indicating that the etiology of hypertension is multi-factorial and that reductions in sodium intake may not be an effective preventive measure. A recent review of sodium reduction interventions confirms this, concluding that “intensive interventions, unsuited to primary care or population prevention programs, provide only minimal reductions in blood pressure during long-term trials” [124]. Science continues to demonstrate that the population response to salt reduction is heterogeneous in both normal and hypertensive individuals; about equal proportions experience an increase or decrease in blood pressure in response to sodium restriction [125].

Recent research demonstrates that population-wide sodium reduction may not be without risks. Scientists observed that in a 2010 comparison of healthy individuals on a low-salt diet vs. a high-salt diet, the low-salt diet was found to be significantly associated with an increase in insulin resistance, while the high-salt diet showed no negative consequences [126]. Two population studies in 2008 and 2011 found an association between reduced sodium intake and increased mortality, and a recent large-scale review of sodium reduction interventions does not support a population-wide prescription for sodium reduction [127, 128, 129].
**Recommendations:**

Reliance on dietary prescriptions with inconclusive or weak scientific support has undermined the public’s confidence in the USDA’s food guidance system [130]. Improving the process by which the Dietary Guidelines are created in order to ensure a balanced review of all available scientific evidence would be the most effective way to improve the scientific integrity and the credibility of the final document.

While the USDA and HHS have been given a mandate to create Dietary Guidelines based on current science, how this mandate is interpreted and executed is left to the discretion of those agencies. No specific statutes or rules exist to set and maintain a process and a set of standards for the creation, validation, and evaluation of either the Guidelines or the Guideline-making process. The Office of Management and Budget defines “process integrity” as including such issues as “transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement,” and adherence to defined procedures [32]. Process integrity creates consistency and completeness in the relation of the parts of a process to the whole and to the final product; it is responsive to public participation and demand for change; and it prevents undisclosed and undue influence from entrenched points of view or other special interests. Without a set of rules to govern the process, the creation of the Dietary Guidelines lacks the qualities that define process integrity.

**Selection of expert committee:** The first step in the development of any edition of the Dietary Guidelines is the selection of the DGAC, the group of scientists who review the scientific evidence and, until 2005, created the text for the Guidelines themselves. Although nominations are publicly solicited, USDA and HHS create the criteria for selecting members of the Committee, much of which is based on expertise in prevention of chronic disease; USDA and HHS Secretaries choose committee members according to these criteria [30]. This system lacks the checks and balances or meaningful participation by the public which would allow for corrective measures should the criteria for selecting experts need to be modified.

In addition, the Federal Advisory Committee Act designates that any advisory committee must be balanced according to points of view represented [131]. As with many areas of science and as the ongoing controversy regarding the Guidelines confirms, there exists a range of respected scientific viewpoints regarding the interpretation of the available literature on the relationships between nutrition and disease; the National Academy of Sciences specifically selects experts with competing points of views in order to create balance in their reports [32]. As there is currently no public window into the DGAC selection process, how this balance is achieved for the DGAC is unknown

The DGAC should be selected according to the National Academy of Sciences’ principles of balance. Experts with clinical experience should be represented equally with experts in population-based research or public health. Criteria for selection of DGAC members should reflect a complete evaluation of the effect of the Dietary Guidelines on all aspects of the food environment including health outcomes, not simply reinforce an *a priori* assumption regarding the benefits of chronic disease prevention through nutrition.
Selection of science. Currently, USDA and HHS establish the system whereby the vast literature on the science of nutrition is distilled into manageable working summaries for the DGAC. This creates a situation in which science may be excluded from the literature analysis by the framing of the research question and other exclusionary criteria [132, 133]. While population studies and clinical trials are of value, because of the possible bias built into the research surrounding nutrition after the initial Guidelines were created, other opportunities for acquiring, evaluating, and including prima facie evidence regarding diet, nutrition and health must be explored.

Translation of science into policy. Rather than have the Dietary Guidelines written solely by government employees with no mandate to adhere to the science presented in the DGAC report, scientists outside of the government should work with policymakers on the creation of the final Dietary Guidelines document to ensure that scientifically-accurate principles are represented.

Transparency of process. Rather than closed door sessions and secret panels, the workings of the DGAC and government employees involved in the writing of the Dietary Guidelines should take place under circumstances of complete transparency from start to finish.

Meaningful public involvement. Concerns raised by the public in response to recent DGAC Reports are not publicly addressed by the Dietary Guidelines Advisory Committee, USDA, HHS, or in any publicly-available report; currently, there exists no system by which the public can know how, or if, their concerns are recognized and addressed. No opportunities existed for the public to comment on the text found in the 2005 and 2010 Dietary Guidelines. Appropriate commentary periods for both the DGAC Report and the final Dietary Guidelines policy document are needed. How concerns raised by the public are addressed in the final policy document should be published in a report available to the public.

Elimination of conflicts of interest. As noted above, the Guidelines shape many aspects of our food system. The Federal agencies that are responsible for overseeing food production, consumer nutrition education, and food, nutrition, and agricultural research are the same ones in charge of creating Dietary Guidelines. The potential for conflicts of interest between these concerns cannot be denied. For example, the “Wheat and Wheat Foods Research and Nutrition Act” directs the USDA to carry out “a programmed effort of research and nutrition education” into wheat on the grounds that “[a]dditional research on the optimal use of wheat products can improve the American diet” [46]. This is an a priori assumption (what if there is no “optimal” use of wheat products in improving the American diet?) that may misdirect nutrition research and education, yet it is part of the USDA’s mandate.

Members of the DGAC may have conflicts of interest as well, especially with regard to their own contribution to the literature on diet and disease. At least one member of the DGAC committee has served on that committee multiple times. In this case, the member served in successive DGACs as the chair of the subcommittee on fluid and electrolytes responsible for making sodium intake recommendations [2, 134]. In addition to serving on these two DGAC subcommittees, this member also served as the chair of the Institute of Medicine committee responsible for determining dietary intake levels for water, salt, and potassium in order to maintain health and reduce chronic disease risk [135]. While the expertise of this member is no doubt valuable in multiple settings, such a situation places the member in the untenable position
of having to re-evaluate the standards of his own work. While this may not be a conventional issue of “conflict of interest,” it is nevertheless one to be avoided by not placing experts with a single perspective on a nutrition issue in charge of multiple policy-making and report-generating processes.

The creation of the “Independent Scientific Review Panel” does not follow OMB guidance regarding transparency, balance, and independence, and conflicts of interest [32]. In 2010, two members of the Panel also served as members of the DGAC, whose work the Panel is ostensibly assessing in its review of the Dietary Guidelines [35].

While each of these issues may be addressed piecemeal, the most effective way to resolve issues regarding the scientific integrity and credibility of the Dietary Guidelines would be to remove the process for their creation from the USDA and HHS and establish a new process for the creation of all Federal food and nutrition policies in a deliberate, consistent, and transparent manner.

One Diet Does Not Fit All: Making the Dietary Guidelines relevant in a diverse and changing world.

In 1977, the Dietary Goals acknowledged that “genetic and other individual differences mean that these guidelines may not be applicable to all” [8]. However, this qualification has been muted in future Dietary Guidelines. Prior to 1980, the primary focus of Federal nutritional guidance was the provision of essential nutrition, not the prevention of chronic disease. Although it is clear that good nutrition plays an important role in long-term health, when the first Guidelines were created the particular dietary pattern that would be optimal for achieving lifelong health was unclear; that is still the case today. Early critics of the Guidelines felt that the scientific model that was used to address nutrient deficiencies did not apply to chronic diseases such as heart disease and cancer [136]. Scientists thirty years later express similar concerns, adding that “nutrient-based metrics [of current recommendations] are hampered by imprecise definitions and inconsistent usage,” and “few individuals can accurately gauge daily consumption of calories, fats, cholesterol, fiber, or salt” [54]. However, current Guideline recommendations urge Americans to track food and calorie intake as means of achieving a healthy diet [29].

The early science that appeared to demonstrate reduced risk of heart disease and other chronic disease was primarily established in cohorts of Caucasian males [16, 103]. The same recommendations are applied thirty years later, frequently through Federal nutrition programs, to a population that is often much younger or older, predominantly female, and ethnically diverse. The dietary framework upon which these Federal nutrition programs operate, i.e. a selection of foods chosen for their value in reducing the risk of chronic disease, is based on research that may not validly apply to these subpopulations; foods provided by these programs may be inappropriate for the maintenance of good health in these groups. Despite adherence to healthy eating patterns as determined by the USDA Food Pyramid, studies have shown that African American children remain at higher risk for development of diabetes and prediabetic conditions, and that African American adults gain weight at a faster pace than their Caucasian counterparts [Figure 14] [81, 137].
An increased understanding of population variations in response to different dietary factors precludes an insistence on a single dietary approach as appropriate for all Americans [51]. While reducing dietary fat can reduce low-density lipoprotein (LDL) cholesterol for some, for other portions of the population, it can also result in decreased LDL particle size, a more atherogenic lipid profile [138]. When dietary fat is reduced, it is often replaced with carbohydrate. Individuals who may be more susceptible to dyslipidemia related to this dietary change include those with higher fasting insulin concentrations and higher body weight [139].

The Guidelines, by their own admission, have changed very little in thirty years. But America has changed significantly, and, in fact, nutritional needs vary with age and life stage, genetic makeup, lifestyle, disease state, hormone levels, and gender. The underlying assumption of the blanket recommendations put forth by the Dietary Guidelines is that the nutritional requirements for the prevention of chronic disease are a one-size-fits-all approach for everyone over the age of 2, with minimal regard for within or between person variations. In the end, however, the prevention of chronic disease through manipulation of diet remains inconclusive and may be highly variable from one subpopulation to the next. On the other hand, what nutrients are essential to all human diets is well elucidated and, to a large extent, non-controversial. Restoring the relevance of the Dietary guidelines calls for a return to policies that focus on the provision of essential nutrients in order to provide appropriate and adequate nourishment, thus establishing the basis for good health for all Americans, rather than focusing on controversial and inconclusive methods to prevent chronic disease that may apply to only a portion of the population.

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Figure 14: Adjusted 20-year mean weight change according to low or high Diet Quality Index (DQI) scores [81]
**Recommendation:**

Ultimately, there is little evidence one particular dietary approach can be expected to prevent chronic disease across a diverse population. The Guideline-making process must shift its focus from chronic disease prevention to the provision of essential nutrition, and include in its evaluation measures of the impact of the Dietary Guidelines terms on both the acquisition of essential nutrition as well as on specific health outcomes of Americans from all demographic groups.

**Healthy Food Comes from a Healthy Food System: Creating a comprehensive approach to food and nutrition through the Dietary Guidelines**

The current Guidelines fail to address the complexity of the current food system. The food environment, eating patterns, and health outcomes of Americans are affected by concerns including but not limited to: protection of the environment, the humane treatment of animals, workers rights, women’s rights, soil conservation, global hunger, food safety, genetic modification of our food supply, health claims on food packaging, support for small and medium-sized farms and producers, and the regulation of agricultural monopolies. There is a current recognition that the present food system is a “disaster” when viewed from health outcomes standpoint [140]. Some changes in our food system can be directly or indirectly related to the how the Dietary Guidelines have influenced, and been influenced by, nutrition research and education, food production, and agricultural policies. In order to reform the food system in America and improve the health of Americans, the process that creates the Dietary Guidelines must include more perspectives and expertise than those which are housed in the Center for Nutrition Policy and Promotion in the USDA and the Office for Disease Prevention and Health Promotion in HHS.

The current food system reform movement calls for greater accessibility to “healthy” foods, but this call relies on a definition of “healthy” provided by the Dietary Guidelines, which influenced the creation of the food system that needs reform [141,142]. The current Dietary Guidelines help to keep the current food system in place, where relatively few foods in the marketplace can be considered truly nutritious and even fewer reflect the local food system [143]. Scientists working in the field of sustainable agriculture have cited “current federal agricultural policy and influences on policy-making” as one of the barriers to widespread reform of the current food system [143]. The Collaborative Initiatives at Massachusetts Institute of Technology produced a report advocating for a more unified approach to the food- and nutrition-related problems facing our nation, summarizing their recommendations as follows: “There are many barriers to transforming the current food system into one that prioritizes health, while also promoting ecological sustainability and economic development. The existing food production, processing, transportation, and retail infrastructure is based on a model that emphasizes maximizing quantity of food, not quality. In order to change this, entrenched economic and political interests will have to be overcome, and an entirely new food infrastructure will have to be developed” [144].
The top three food commodities supported by the government are corn, wheat, and soybeans, which provide the raw materials for processed foods, such as corn syrup, vegetable oils, and flour [145]. In current and past Dietary Guidelines, grain and cereal products, vegetable oils, and plant-based protein foods (such as soy) are emphasized as important foods to consume in order to prevent chronic disease [2]. With overall trends keeping prices for commodity crops low and production high, growth in the food manufacturing and production sector comes from changes in the food price spread. The food price spread is the difference between the retail price and the farm share, or the money the farmer receives. This spread represents charges for processing and marketing. When consumers shift their purchases from less to more processed foods, unless prices increase, farm share decreases. Farm share remained stable from 1960 to 1980 at about 40% of each dollar spent on food; from 1980 to today, farm share declined rapidly to 19% [Figure 15] [146]. As consumers adopted eating patterns recommended in the Dietary Guidelines, a much larger share of their food dollar went to increased processing and marketing and the labor costs associated with these activities. Currently, the farm value share of beef, whole milk, and butter, are 46% or higher; the farm value share of cereals, flour, and margarine are 21% or lower [Figure 16] [147]. Since Americans consume fewer of the products that generate a higher farm share value and more of the products that generate a lower farm share value, farmers overall receive less of each dollar spent on food in America. Creating a more “democratic, socially and economically just, and environmentally sustainable” food system that supports farmers and provides nutritious food to consumers begins with reforming the Dietary Guidelines process [143].
Recommendation:

In light of this situation, it is time to chart a new course for food and nutrition policy in America. The future Guideline-making process should be one that:

- ensures that the health of all Americans is the first priority in the creation of Dietary Guidelines and nutritional policy
- focuses on the provision of adequate nutrition rather than the prevention of chronic disease
- is completely transparent, subject to evaluation and accountability, and encourages and is responsive to meaningful public participation in all aspects of development of the Guidelines
- incorporates a recursive system of evaluation of the Guidelines based on a comprehensive and objective review of available science and clinical experience, the provision of adequate nutrition, improvements in targeted health outcomes of Americans, and changes in the food industry and the eating patterns of Americans
- works to reduce or eliminate conflicts of interests between this priority and the interests of industry and agriculture so that agricultural and industry capabilities enhance the
production and distribution of foods that promote the consumer health outcomes set forth in the evaluation process

- addresses the complexity of the current food system with the understanding that the quality of the food environment, eating and activity patterns, and health is affected by concerns including but not limited to: protection of the environment, the humane treatment of animals, workers rights, soil conservation, global hunger, food safety, genetic modification of the food supply, health claims on food packaging, food advertisement and marketing, support for small and medium-sized farms and producers, and the regulation of agricultural monopolies

Fulfillment of these objectives could be accomplished in a number of ways; transferring leadership to HHS seems an obvious choice. However, the Food and Drug Administration arm of HHS is responsible for oversight of health claims on food packaging, which may also raise questions regarding the relationship between industry and policymakers. This agency also has its own research arm, the National Institute of Health, which houses many offices involved in investigating the science behind its own policies and educating the public accordingly. This may introduce potential concerns that research agendas would be manipulated to fulfill policy priorities or goals, or to maintain consistency in messaging rather than accuracy in science. In addition, this agency does not have the capabilities to conduct a comprehensive overview of the effects of food and nutrition policies on areas that go beyond that of human health.

It is therefore suggested that an Office of Food and Nutrition Policy (similar to the Office of Science and Technology Policy) be created by the passage of an Executive Order. The primary responsibility of this office will be the creation of the Dietary Guidelines for Americans. The organization of this office will be designed to bring fair and balanced oversight to the Dietary Guideline process, while taking into consideration the impact of the guidelines on the various aspects of the nation’s welfare, from personal health to economic stability – both currently threatened by obesity, diabetes, and the runaway healthcare costs associated with these two conditions. Members of this office will include representatives from both inside and outside the federal government and should include representatives from the government agencies whose activities bear on food and nutrition policies.

Part 4: Time for Change

It is time to acknowledge the fact that true recovery in America—in the health care system, the economy, the environment and the military—must begin with reforming the nutrition policies that influence and shape the total food environment. Reforming these policies creates opportunities for researching and developing nutrition programs around other approaches to a healthy diet besides the one found in the current Dietary Guidelines. This in turn creates the opportunity for other nutrition-based therapies that do not fit the current Dietary Guidelines to be used to address health issues such as obesity and diabetes. Reforming these policies creates new, expanded markets and products for producers and consumers interested in participating in a food system that utilizes sustainable agricultural practices and supports the work of small and medium-sized family-based farm operations. Reforming these policies presents the opportunity to improve the quality of food and the quality of life for all Americans.
Reforming the Dietary Guidelines process will initiate a chain of events that will lead to overall improvements in all elements of the system that affect food and nutrition choices of Americans, as well as their health outcomes. Removing the Dietary Guidelines process from the agencies that may have conflicts of interest with regard to the conducting and funding of nutrition- and food-related research would begin to open up opportunities for research into dietary patterns that may not adhere to the Guidelines or the principles of prevention of chronic disease upon which they are based. Successful dietary approaches investigated through research or admitted as evidence into the food and nutrition policy discussion through other channels may then become the basis for healthcare programs and protocols. The results of these applications may then provide further information for improving public health through novel interventions not based on current Dietary Guidelines nutrition paradigms.

As the focus of the Dietary Guidelines is shifted from prevention of chronic disease to provision of adequate nutrition, consumer education and industry response can be expected to change as well. Concerns regarding the fat, saturated fat, and cholesterol levels of whole foods would be replaced with a food-based plan for acquiring adequate nutrition. The current push for the removal of health claims regarding chronic disease outcomes from product packages would be given momentum as the scientific basis for those claims will no longer be considered valid for population-wide application [148]. Both of these changes would assist in effort to “encourage the public to eat whole or minimally processed foods and to read the ingredients list on processed foods” [148]. This can be expected to affect consumer behavior and buying habits. As consumers learn eating patterns that provide them with adequate nutrition, physiological-based drivers of appetite may shift consumption levels. Consumers may have the confidence to purchase fewer processed foods and more whole or minimally-processed foods, supporting a shift from food quantity to food quality. This shift would in turn support the goal of diversifying and localizing food production to promote environmental sustainability and economic development within local food communities. Highly-processed foods created from monoculture crops would no longer be the basis for either dietary guidance or for the food system as a whole.

The Dietary Guidelines can be considered perhaps the most influential health-related pronouncements in the world. They provide all Americans—from consumers to manufacturers to scientists to funders—with a single, specific definition for what is and is not considered to be “healthy” food. The reality is that there is no single answer to the question, “What should Americans eat to stay healthy?” and there is little evidence that one particular dietary approach will consistently prevent chronic disease across a diverse population. With a reformed Dietary Guideline process, scientists, nutrition experts, and policymakers can provide Americans with the information needed to meet essential nutritional needs and the guidance to help each individual find his or her own path to good health. The time has come to reform the Guideline-making process to a fair, transparent, consistent system that will provide Americans with a more complete and accurate picture of a healthy diet. It is time to create Guidelines that will work for all Americans.
References:


Hite, A – Fix Our Food 34


Appendix 1: March 28, 2011 FOIA Request

From: Adele Hite [mailto:ahhite@email.unc.edu]
Sent: Monday, March 28, 2011 10:44 PM
To: 'foia@fns.usda.gov'
Subject: Re: Peer-Review Process for 2010 Dietary Guidelines

Dear Ms. Weatherly,

I am requesting the names of the eight scientists chosen to review the 2010 Dietary Guidelines in the peer-review process outlined in the documents attached. I requested this information from Ms. Carole Davis in the Center for Nutrition Policy and Promotion and received a reply from Mr. John Webster informing me that this information would not be released. (Please see correspondence below.)

I am also requesting additional information regarding the process by which these eight individuals were chosen. Mr. Webster refers to “we” in his correspondence, but does not indicate to whom he refers nor how the process for choosing these peer-reviewers was undertaken i.e. what agency official(s) made this decision, what other USDA and HHS agencies and which officials in these agencies were consulted, what individuals may also have been nominated for this process, how the final eight scientists were chosen, and by whom. I’m afraid that I do not have any additional information regarding this issue other than what is provided on the attached documents and correspondence below. The approximate timing of the review is 10/22/2010 to 11/05/2010.

The USDA CNPP has been admirably and vocally transparent with regard to the process leading up to the guidelines. However, as the Dietary Guidelines are policy document that “contains findings or conclusions that represent the official position of the Federal government,” and as this document carries a tremendous amount of influence in terms of policy implications, research direction, and food industry guidance, it is important that transparency apply to the entire process.

Please let me know what fees apply. I can be contacted at this email or by phone at 919-493-4076.

Regards,
Adele Hite

From: Webster, John [mailto:John.Webster@cnpp.usda.gov]
Sent: Monday, March 28, 2011 4:42 PM
To: ahhite@email.unc.edu
Cc: Webster, John
Subject: Re: CNPP Website information Quality

Dear Ms. Hite,
Your email of Mar. 21 to Ms. Davis (below) seeking information about the peer-review process for the 2010 DGA policy document has been forwarded to this office for response.

As a matter of background on the quality of information peer-review about which you have an interest, unlike rulemaking, there is no requirement that a nutrition education policy document, such as the Dietary Guidelines for Americans (DGA), be peer-reviewed. However, as the lead agency in the development of the DGA, we chose to use peer-reviewers so as to provide an additional level of assurance to ourselves, the public, and other policy makers, that we had accurately translated the science provided by the 2010 Dietary Guidelines Advisory Committee in its report. Moreover, because the process of seeking comments on the accuracy of translating the science is pre-decisional, we cannot disclose the names of the members who served as peer-reviewers for the 2010 Dietary Guidelines.

Further, there is a practical reason for not disclosing the peer-reviewers that, I am sure, resonates with someone like you in academia. When we requested a review from peer-reviewers, there was never any mention or understanding that they would be subject to requests from the media or the public, or would have to defend their comments and opinions in any way. We, along with other governmental and non-governmental organizations, believe that revealing the identities of peer-reviewers would have a chilling effect on our ability to attract qualified reviewers in the future to serve in this voluntary, non-compensated role. This is the same reasoning that leading scientific and medical journals do not release the names of their peer-reviewers.

Having explained the circumstances, what we can tell you is that, before any potential reviewers were asked if they would be interested in serving, we sought input from other USDA and HHS agencies. Persons were identified to serve based on their knowledge and understanding of dietary guidance and nutrition education. Seven of the peer-reviewers are with universities; two of them served on the 2010 Dietary Guidelines Advisory Committee; two others served on previous committees; with exception of one research scientists, none are government employees; none are food industry employees, and all have Ph.D. degrees and are recognized experts in their field of research.

As a graduate student, your interest in the process leading up to the development of the Dietary Guidelines is appreciated. We hope that this adequately responds to your request.

Best regards,
John S. Webster
Director
Public and Governmental Affairs
USDA Center for Nutrition Policy and Promotion
(703) 305-7600
john.webster@cnpp.usda.gov

From: Adele Hite [mailto:ahhite@email.unc.edu]
Sent: Monday, March 21, 2011 3:16 PM
To: Davis, Carole  
Subject: CNPP Website information Quality  

Dear Ms. Davis,

I am researching the process behind the creation of the 2010 Dietary Guidelines. I understand that after the Guidelines were created, they underwent a peer-review process as indicated in the Dietary Guidelines Peer Review Plan. The slide show provided by the CNPP indicates the following: “The peer review for compliance with the Quality of Information Act consisted of an independent review by eight scientists from academic institutions, USDA, and HHS and included two members of the Advisory Committee. The purpose of the review was to ensure that the science in the DGAC Report was accurately translated into the plain language of the policy document.” I have not been able to ascertain who the eight scientists mentioned above were and how they were chosen. I would greatly appreciate your assistance in obtaining this information.

Regards,
Adele Hite

MPH/RD and Doctoral Student in Nutrition Epidemiology
Department of Nutrition
Gillings School of Global Public Health
UNC-Chapel Hill, NC  27599
Appendix 2: September 26, 2011 FOIA Request

John S. Webster, Director
Office of Public and Governmental Affairs
Freedom of Information Act Officer
USDA Center for Nutrition Policy and Promotion

September 26, 2011

Dear Mr. Webster:

In my initial Freedom of Information Act (FOIA) request of March 2011 to the Center for Nutrition Policy and Promotion (CNPP), I asked for the names of the eight scientists chosen to review the 2010 Dietary Guidelines for Americans as members of the USDA Independent Scientific Review Panel (the “Panel”) and for information surrounding the creation of this Panel.1 My request was denied on April 10, 2011.2 The membership of the Panel, the process for its creation, and its work remain withheld from the public. I am refiling my FIOA request below. The approximate timing of events in question is 06/05/10 to 01/31/11.

As required under the “Final Information Quality Bulletin for Peer Review” (the “Bulletin”) from the Office of Management and Budget (OMB), published in the Federal Register on January 14, 2005, the peer review process for government documents that may yield influential scientific information is to be undertaken with both scientific integrity and process integrity.3

According to the Bulletin:

“Scientific integrity,” in the context of peer review, refers to such issues as “expertise and balance of the panel members; the identification of the scientific issues and clarity of the charge to the panel; the quality, focus, and depth of the discussion of the issues by the panel; the rationale and supportability of the panel’s findings; and the accuracy and clarity of the panel report.” “Process integrity” includes such issues as “transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement,” and adherence to defined procedures [emphasis mine].4

With regard to transparency, the Bulletin indicates that:

The agency—or entity managing the peer review—shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions. The peer review report shall either (a) include a verbatim copy of each reviewer’s comments (either with or without specific attribution) or (b) represent the views of the group as a whole, including any disparate and dissenting views. The agency shall disclose the names of the reviewers and the organizational affiliations in the report. Reviewers shall be notified in advance regarding the extent of disclosure and attribution

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1 Appendix 1.
2 Appendix 2.
planned by the agency. The agency shall disseminate the final peer review report on the agency’s website along with all materials related to the peer review (any charge statement, the peer review report, and any agency response). The peer review report shall be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action.5

Executive Direction Regarding Transparency and Openness

In his Memorandum dated January 21, 2009, President Obama indicated that FOIA “should be administered with a clear presumption: In the face of doubt, openness prevails.”6 The attached response from the CNPP regarding my initial request indicates a disregard for the intent and the letter of FOIA and the presumption of openness requested by President Obama. Furthermore, in withholding information regarding the Panel and its work, CNPP has disregarded both the intent and the letter of the guidance provided in the OMB Bulletin, as the process used by CNPP to form the Panel lacks both scientific and process integrity.

The Attorney General underscores President Obama’s commitment to openness and transparency in the Federal government in his memorandum dated March 19, 2009, which indicates that “an agency should not withhold information simply because it may do so legally.”7 CNPP indicates in its denial of my original FOIA request that subjecting the policy document in question to the peer-review process is a strictly voluntary act, as “there is no requirement that the Guidelines be peer-reviewed.”8 CNPP also indicates that, as this is a voluntary undertaking, “there is no written or established process for selecting peer-reviewers for the Dietary Guidelines.”9 Finally, CNPP indicates that it nevertheless chose to use peer reviewers, “so as to provide an additional level of assurance to the public, the government, and policy makers, that the draft Guidelines had accurately conveyed the science provided in the report of the Dietary Guidelines Advisory Committee.”10 To my knowledge, neither OMB nor FOIA make exceptions for peer-review processes that are undertaken voluntarily by an agency. Furthermore, if CNPP is sincere in its desire to provide an additional level of assurance to all concerned regarding the accuracy of the science in the Dietary Guidelines, it would seem reasonable that CNPP would wish to comply with both OMB and FOIA requirements regarding transparency and integrity, whether or not the process towards which the FOIA request and the OMB guidelines are directed has been required by law.

I am refiling my original FOIA request with the inclusion of the following. Pursuant to the above-referenced Bulletin and FOIA, I am requesting:

1) The names of the reviewers on the Panel and their organizational affiliations
2) The final peer review report created by the Panel which must either (a) include a verbatim copy of each reviewer’s comments or (b) represent the views of the group as a whole, including disparate and dissenting views

5 Ibid. p. 38.
8 Appendix 2
9 Ibid.
10 Ibid.
3) CNPP response to the peer-review report and documentation indicating how the peer review report was used by CNPP
4) Documentation indicating how CNPP met National Academy of Science (NAS) standards with regard to balance of the Panel membership
5) Disclosure of any real or potential conflicts of interest on the part of the reviewers
6) Additional documentation related to Peer Review Planning, as indicated in the Bulletin
7) A list of all USDA and HHS staff members and administration who contributed to the decision-making process surrounding the formation of this Panel
8) Emails and memoranda that reflect any activities pertaining to:
   a. the decision-making process undertaken in formation of the Panel, including the determination to “use peer-reviewers so as to provide an additional level of assurance to the public, the government, and policy makers, that the draft Guidelines had accurately conveyed the science provided in the report of the Dietary Guidelines Advisory Committee”11
   b. choosing the members of Panel, including “input sought from other USDA and HHS agencies”12
   c. use of the Panel commentary in the final 2010 Dietary Guidelines
   d. CNPP response to public commentary on the Dietary Guidelines Advisory Committee Report that preceded the writing of the 2010 Dietary Guidelines and the formation of the Panel
   e. documentation of the role of the public commentary and CNPP response referred to in 8(d) in the peer review process undertaken by the Panel
   f. documentation of the role of the public commentary and CNPP response referred to in 8(d) in the creation of the 2010 Dietary Guidelines
   g. decision-making surrounding the final report of the Panel, the lack of opportunity for public commentary to the report of the Panel, and the withholding of information regarding the Panel from public record

Violations of the Final Information Quality Bulletin for Peer Review
The Bulletin clearly outlines the process for peer-review that is to be undertaken when government agencies disseminate scientific information. In its lack of transparency in the creation and operation of the Panel, CNPP is deliberately operating outside of the peer-review process indicated in the Bulletin. Violations of the guidance provided in the Bulletin are as follows:

Section I: Definition
In the USDA Peer Review plan for the 2010 Dietary Guidelines, this document is designated as “Influential Scientific Information” rather than “Highly Influential Scientific Assessment.”13 This designation is inappropriate and inaccurate. In the “Charge to 2010 Dietary Guidelines for Americans OMB Quality of Information Act Peer Reviewers,” CNPP indicates: “The Dietary Guidelines for Americans form the basis of Federal nutrition policy, nutrition education, and nutrition promotion programs for the general public” and “provide the foundation for USDA’s

11 Ibid.
12 Ibid.
Furthermore, the Dietary Guidelines also influence industry trends, consumer choices, research protocols, and distribution of grant monies. These Dietary Guidelines, in fact, provide all Americans—from consumers to manufacturers to scientists to funders—with a singular definition for what is and is not considered to be “healthy” food. This qualifies the Guidelines as a “Highly Influential Scientific Assessment” bound to even higher standards of integrity and transparency. However, even the lower standards required by the designation of “Influential Scientific Information” have been disregarded as follows.

Section II: Peer Review of Influential Scientific Information

According the Bulletin, “The National Academy of Public Administration suggests that the intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decision.” As the Dietary Guidelines form the basis for all Federal nutrition policy, nutrition education, nutrition promotion programs for the general public, and provide the foundation for USDA’s food assistance programs, the level of peer review required to provide accuracy and to ensure public trust is significant. Yet CNPP fails to maintain the integrity of the peer review process on multiple counts:

Scope of the Review

The scope of the review, as indicated in CNPP’s Peer Review Charge is inadequate because it does not address several activities that the Panel was later credited with having performed. In the Peer Review Charge, CNPP asks the Panel to review the 2010 Dietary Guidelines for Americans "for clarity and technical accuracy." Absent from the Peer Review Charge is a request to review the scientific accuracy of the document.

However, in the Acknowledgements of the 2010 Dietary Guidelines for Americans, CNPP states “the members of the Independent Scientific Review Panel, who peer reviewed the recommendations of the document to ensure they were based on the preponderance of the scientific evidence [emphasis mine].”

Similarly, in a publicly-available slide deck created by CNPP, CNPP indicates that the purpose of the Panel’s peer review “was to ensure that the science in the DGAC Report was accurately translated into the plain language of the policy document [emphasis mine].” This activity, however, was not part of the Peer Review Charge.

The Charge also states that “the Departments considered numerous public comments on the Report [of the Dietary Guidelines Advisory Committee],” yet how the Departments used these comments, and how the Panel was to use them, is unknown. Concerns raised by the public in response to the Report are not publicly addressed by either the Dietary Guidelines Advisory Committee Report which did not undergo peer review, not in response the 2010 Dietary Guidelines for Americans, the document that underwent peer review by the Panel.

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15 Appendix 3, p. 12.
16 Appendix 7.
19 Appendix 7. These comments were made in response to the Dietary Guidelines Advisory Committee Report which did not undergo peer review, not in response the 2010 Dietary Guidelines for Americans, the document that underwent peer review by the Panel.
Committee, CNPP, or in any publicly-available report created by the Panel. Furthermore, this public commentary is not directed at the 2010 Dietary Guidelines that underwent peer review by the Panel as the commentary precedes its creation, and it is not in response to the report created by the Panel as no such report is made public (see Public Participation below).

Selection of Reviewers
The process for the selection of reviewers is inappropriate and inadequate. The names of reviewers and how they are selected is withheld from the public and therefore unknown. Expertise, balance, independence, and real or potential conflicts of interest cannot be determined or assessed. The public was not permitted to be involved in recommending members of the Panel, as suggested by OMB Quality of Information Act. A diversity of scientific perspective and independence from competing or vested interests is necessary for a peer-review panel to make balanced judgments regarding the more controversial aspects of nutrition and diet-disease relationships. How this is achieved for this Panel is unknown, and the public cannot be assured of the Panel’s freedom from bias.

Disclosure and Attribution: Anonymous versus Indentified
The level of disclosure and attribution is inappropriate and inadequate. The Bulletin clearly states that “When peer review of government reports is considered, the case for transparency is stronger, particularly when the report addresses an issue with significant ramifications for the public and private sectors.” As the Dietary Guidelines have significant ramifications for both public and private sectors, a high level of transparency is indicated.

“The public may not have confidence in the peer review process when the names and affiliations of the peer reviewers are unknown. Without access to the comments of the reviewers, the public is incapable of determining whether the government has seriously considered the comments of reviewers and made appropriate revisions.” Comments by Panel members, their identities and affiliations, their commentary, and the consideration of this commentary by CNPP are all withheld, undermining the confidence of the public in the Federal government’s ability to dispense accurate scientific information regarding nutrition without being unduly influenced by special interests or political and economic considerations.

Public Participation
The level of public participation allowed in the peer review process is inappropriate and inadequate as there was none. No public commentary period on the document undergoing review (the 2010 Dietary Guidelines for Americans) was permitted either before or after the peer review process. The public was allowed to comment on the Dietary Guidelines Advisory Committee Report that preceded the creation of the 2010 Dietary Guidelines and the formation of the Panel, but concerns raised in this public commentary are not publicly addressed by CNPP in any manner.

Disposition of Reviewer Comments:
The disposition of reviewer comments is inappropriate and inadequate. The Bulletin states that “The credibility of the final scientific report is likely to be enhanced if the public understand how

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20 Appendix 3, p. 20.
21 Ibid. p. 20.
the agency addressed the specific concerns raised by the peer reviewers.”

However, concerns raised by reviewers and how CNPP addresses those concerns are not made public and are not known.

**Inadmissible Freedom of Information Act Exemptions and Exclusions**

CNPP cites in its denial of my original FOIA request the exemption that “email correspondence between and among staff within USDA and HHS in which names of potential peer-reviewers are discussed, along with a list of the selected peer-reviewers, emails, and letters sent to peer-reviewers, and a compilation of peer-review comments” is predecisional and deliberative. As CNPP is operating outside the guidance of peer-review as indicated in the Bulletin, this exemption does not apply. In order for documents to be predecisional and deliberative with regard to a specific process outcome, i.e. the formation of the Panel, the process itself must be within the scope of government procedure. The application of such an exemption would apply solely to peer-review panels which are procedurally formed in the first place. If the Panel had in fact been formed in accordance to policy, there is no question that compilation of peer-review comments, the Panel report, and the membership of the panel would be considered post-decisional with regard to the actions of CNPP administration and staff, and no exemption under FOIA would apply. Additional emails and memorandum surrounding the activities of CNPP with regard to the Panel are requested because, in fact, the Panel was formed outside of policy guidelines and as a result, these activities should become part of the public record.

CNPP also cites concerns that revealing the identities of the panel members “would have a chilling effect on our ability to attract qualified reviewers in the future to serve in this voluntary, non-compensated role.” Exemptions regarding “chilling effects” are not granted under FOIA. On the contrary, the scientists I queried indicated that they would consider selection to the Panel an honor, assuming the Panel was duly created following appropriate procedures. The following scientists have indicated their willingness to openly serve on the Panel in the future as needed:

Aaron Blaisdell, PhD - Associate Professor, Department of Psychology, UCLA Brain Research Institute, University of California at Los Angeles

Dian Dooley, PhD - Department of Human Nutrition, Food and Animal Sciences, University of Hawaii, Manoa (retired)

Ronald W. Dudek, PhD – Professor and Director of Graduate Studies, Department of Anatomy and Cell Biology, Brody School of Medicine, East Carolina University

Loren Cordain, PhD – Professor, Department of Health and Exercise Science, College of Applied Human Science, Colorado State University

Christopher Gardner, PhD - Director of Nutrition Studies at the Stanford Prevention Research Center and an Associate Professor of Medicine at Stanford University

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22 Ibid. p. 22.

23 Appendix 2.

24 Ibid.
Robert Lustig, MD - Professor of Clinical Pediatrics, in the Division of Endocrinology Director of the Weight Assessment for Teen and Child Health (WATCH) Program at University of California, San Francisco

Michael Meguid, MD, PhD - Professor Emeritus, Surgery/Neuroscience/Physiology, Department of Surgery, Upstate Medical University (The State University of New York), Syracuse

Dariush Mozaffarian, MD, DrPH - Co-Director, Program in Cardiovascular Epidemiology Associate Professor of Medicine and Epidemiology, Division of Cardiovascular Medicine, Brigham and Women's Hospital and Harvard Medical School, Department of Epidemiology, Harvard School of Public Health

Alan Titchenal, PhD - Department of Human Nutrition, Food and Animal Sciences, University of Hawaii, Manoa

Daisy Zamora, PhD - Program on Integrative Medicine, Department of Physical Medicine and Rehabilitation, School of Medicine, University of North Carolina at Chapel Hill

The purpose of peer review is to assure scientific accuracy of a document. The scientists whom I queried regarding this matter feel that, instead, CNPP has undermined the principles of scientific debate and dialogue through egregious violation of Federal guidance surrounding the peer review process. Dr. Henry Blackburn, Professor Emeritus at the University of Minnesota School of Public Health, whose expertise in nutrition and cardiovascular disease spans five decades, has in the past served on several government boards and committees reviewing nutritional evidence and policy. In regard to the creation and use of the Panel by CNPP, Dr. Blackburn states that “The process should be completely transparent and the composition of the panel public.”

I could not agree more. I appreciate your assistance in making this so.

Sincerely,
Adele Hite
MPH/RD and Doctoral Student, Nutrition Epidemiology
Gillings School of Global Public Health, Department of Nutrition
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7461
ahhite@live.email.edu
919-817-9355

cc:
The Honorable Eric Holder
Attorney General of the United States

The Honorable Kathleen Sibelius
Secretary of the U.S. Department of Health and Human Services

25 Blackburn, H. Email correspondence. April 20, 2011
The Honorable Tom Vilsack  
U.S. Department of Agriculture  

Dr. Howard Koh, Assistant Secretary for Health  
U.S Department of Health and Human Services  

Dr. Rajen Anand  
Executive Director USDA Center for Nutrition Policy and Promotion  

Dr. Robert Post  
Deputy Director USDA Center for Nutrition Policy and Promotion  

Mr. Jacob Lew  
Director of the Office of Management and Budget  

Ms. Melanie Ann Pustay  
Director of the U.S. Department of Justice Office of Information Policy  

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Appendix 3: Response from USDA to March 28, 2011 FOIA request

Ms. Adele Hite
MPHI/RD and Doctoral Student in Nutrition Epidemiology
Department of Nutrition
Gillings School of Global Public Health
UNC-Chapel Hill, NC 27599

Dear Ms. Hite:

This is a follow-up response to your Freedom of Information Act request of March 28, 2011 in which you requested the names of the eight scientists chosen to review the draft 2010 Dietary Guidelines along with information describing the process by which these individuals were selected.

We have reviewed our files, both manual and electronic, and are attaching copies of information on Information Quality Guidelines which may be found on the USDA Center for Nutrition Policy and Promotion website, http://www.cnpp.usda.gov/InformationQuality.htm, along with the Peer Review Plan, and the Charge to the 2010 Dietary Guidelines for Americans OMB Quality of Information Act Peer Reviewers, some of which you may already have.

Beyond the Quality of Information Guidelines, there is no written or established process for selecting peer-reviewers for the Dietary Guidelines as there is no requirement that the Guidelines be peer-reviewed. Therefore, we cannot provide documents which do not exist that describe a peer-review process. Unlike rulemaking, there is no requirement that a nutrition education policy document be peer-reviewed. Since, however, the Center for Nutrition Policy and Promotion was the lead Federal agency in the development of the 2010 Guidelines, Center leadership, in consultation with HHS, chose to use peer-reviewers so as to provide an additional level of assurance to the public, the government, and policy makers, that the draft Guidelines had accurately conveyed the science provided in the report of the Dietary Guidelines Advisory Committee.

We are withholding e-mail correspondence between and among staff within USDA and HHS in which the names of potential peer-reviewers are discussed, along with a list of
the selected peer-reviewers, e-mails and letters sent to peer-reviewers, and a compilation of peer-review comments. This information is being withheld on the basis that it is pre-decisional and deliberative as provided for in the Freedom of Information Act.

There is a practical reason for not disclosing the names of the peer-reviewers as well as those also being considered. When the Center requested that the draft document be peer-reviewed by experts before being finalized, there was never any mention or understanding that the reviewers would be subject to requests from the media or the public, or would have to defend their comments and opinions in any way. We, along with other governmental and non-governmental organizations, believe that revealing the identities of peer-reviewers would have a chilling effect on the government’s ability to attract qualified reviewers in the future to serve in this voluntary, non-compensated role. This is the same reasoning that leading scientific and medical journals do not release the names of their peer-reviewers.

Having explained these circumstances, what we can tell you is that before any potential reviewers were asked if they would be interested in serving, the Center sought input from other USDA and HHS agencies. Persons were identified to serve based solely on their knowledge and understanding of dietary guidance and nutrition education. Seven of the peer-reviewers are with universities; two of them served on the 2010 Dietary Guidelines Advisory Committee; two others served on previous advisory committees; with exception of one research scientist, none are employees of the Federal government; none are food industry employees, and all have Ph.D. degrees and are recognized experts in their fields of research.

Should, however, you wish to appeal from this decision, the Freedom of Information Act provides for such relief. You may address your appeal to Dr. Rajen Anand, Executive Director, USDA Center for Nutrition Policy and Promotion, 3101 Park Center Drive, Suite 1034, Alexandria, VA 22302.

Thank you for your understanding and appreciation of our position with regard to your request.

Sincerely,

Director
Office of Public and Governmental Affairs
Freedom of Information Act Officer
USDA Center for Nutrition Policy and Promotion
November 22, 2011

Ms. Adele Hite
MPH/RD and Doctoral Student in Nutrition Epidemiology
Department of Nutrition
Gillings School of Global Public Health
UNC-Chapel Hill, NC 27599

Dear Ms. Hite:

This is in further response to your Freedom of Information Act request of September 26, 2011, in which you requested the names of the eight peer reviewers chosen to review the final draft of the 2010 Dietary Guidelines for Americans along with the membership of the peer reviewers and the process by which these individuals were selected. As we have stated, these reviewers participated voluntarily to help us ensure that we used plain language to transmit the Dietary Guidelines Advisory Committee’s (DGAC) report in the policy document.

As you may know, we are required to complete a peer review report to the Office of Management and Budget by the end of 2011, which would be accompanied by a list of reviewers’ names and affiliations, as well as a compilation of their comments. Enclosed you will find a copy of the reviewers’ names and affiliations along with a 33-page table of comments of the reviews and our response to each comment. This information will be posted on our website, www.dietaryguidelines.gov.
We have been reluctant to provide the names of the peer reviewers before the report is submitted for the concern that these people would be unfairly subjected to questions from the general public on the scientific aspects of the DGAC report when, in fact, they had no role whatsoever in creating or interpreting the science.

After our staff had drafted the Dietary Guidelines policy document, these peer reviewers served only to review adherence to the concepts in the DGAC report so that it would be understandable for nutrition educators, health professionals, and policymakers, to whom the policy is intended for application. The peer reviewers played no role in interpreting the science or in influencing the direction of the Policy Document which will be evident in their comments. The selection of these reviewers was merely for their knowledge in nutrition communication and dietary guidance so they could tell us if the complex science was expressed in understandable terms. Dr. Robert Post, Deputy Director of the USDA Center for Nutrition Policy and Promotion and Rear Admiral Penelope Slade Sawyer, HHS Office of Disease Prevention and Health Promotion made the final selections.

It is worth noting that while we referred to the peer reviewers as a “panel,” the term is misleading. Panels usually work collaboratively and provide consensus opinion as implied in your request. However, that was not the case with this group of reviewers. These reviewers worked independently. In fact, to this day they have not been informed of the names of the other reviewers. So, there was no final consensus report from the “panel,” only individual comments which are enclosed.

In response to your question about how CNPP met National Academy of Science (NAS) standards with regard to the balance of the panel membership, the reviewers were not selected to operate in a way that would require a balance of views to promote consensus. The nature of the reviewers’ charge was only for their individual opinions on whether we adhered to the scientific concepts of the DGAC report. Based on our personal knowledge of the reviewers’ backgrounds, there were no conflicts of interest. All reviewers’ comments were given consideration and only used when relevant and valid.

With regard to your question about responding to public comments on the DGAC report, there was no indication in the Federal Register that we would respond to comments. The intent was only to solicit comments to gain insight into public opinion and consumer perceptions in preparation of the subsequent Policy Document. The voluntarily initiated peer review of a final draft Policy Document for clarity and technical accuracy did not lend itself to a public comment period because of the many opportunities for public comment that were provided in the earlier review of the science, particularly during the 20-month evidence review and analysis phase.
I anticipate that this letter adequately addresses your concerns and provides closure on this matter.

Sincerely,

[Redacted]
Director
Office of Public and Governmental Affairs
Freedom of Information Act Officer
USDA Center for Nutrition Policy and Promotion
## Appendix 5: Nutrition Information – McDonald’s Happy Meals

![McDonald's Logo]

### Nutrition Information for McDonald’s Happy Meals

We provide a nutrition analysis of our kids meals to help you choose foods that best meet your child’s nutrition needs. Our goal is to provide you with the information you need to make sensible decisions about balance, variety and moderation for you and your family.

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*This list is effective 03-28-2011

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1. The values represent the sodium derived from ingredients plus water. Sodium content of the water is based on the value listed for municipal water in the USDA National Nutrient Database. The actual amount of sodium may be higher or lower depending upon the sodium content of the water where the beverage is dispensed.

2. Note: Nutrient contributions from individual components may not equal the total due to federal rounding regulations. Percent Daily Values (DV) and RDIs are based on unrounded values.

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The nutrition information on this website is derived from testing conducted in accredited laboratories, published resources, or from information provided from McDonald’s suppliers. The nutrition information is based on standard product formulations and serving sizes. All nutrition information is based on average values for ingredients from McDonald’s suppliers throughout the U.S. and is rounded to meet current US FDA NLEA guidelines. Variation in serving sizes, preparation techniques, product testing and sources of supply, as well as regional and seasonal differences may affect the nutrition values for each product. In addition, product formulations change periodically. You should expect some variation in the nutrient content of the products purchased in our restaurants. None of our products is certified as vegetarian. This information is correct as of January 2007, unless stated otherwise.

EQUAL®® Calorie Sweetener is a registered trademark of Merisant Company

SPLENDA®® No Calorie Sweetener is the registered trademark of McNeil Nutritional, LLC.
### Happy Meals with Cheeseburger

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<th>Trans Fat (g)</th>
<th>Cholesterol (mg)</th>
<th>Sodium (mg)</th>
<th>Carbohydrates (g)</th>
<th>Dietary Fiber (g)</th>
<th>Sugars (g)</th>
<th>Protein (g)</th>
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<th>Iron (mg)</th>
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This list is effective 03-20-2011

### Happy Meals with Hamburger

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This list is effective 03-28-2011
Appendix 6: Farm Share Data from USDA/ERS

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<td>Fats and oils (2009)</td>
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<td>Margarine (2009)</td>
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For a market basket of food bought in food stores in a base period, currently 1982-84. The retail price index is derived from data from the U.S. Department of Labor, Bureau of Labor Statistics. Farm value is based on prices farmers received for commodities. The spread between the retail price and farm value represents charge for processing and marketing.

Food price spreads can increase—even if food prices do not—when consumers shift their purchases from less to more processed foods.