HEARING TO REVIEW THE DEVELOPMENT OF THE *2015 DIETARY GUIDELINES FOR AMERICANS*

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

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CONTENTS

*American Bakers Association; American Institute of Baking International Grain Foods Foundation; Independent Bakers Association; National Association of Wheat Growers; National Pasta Association; North American Millers' Association; Retail Bakers of America; USA Rice Federation; Wheat Foods Council.

HEARING TO REVIEW THE DEVELOPMENT OF THE *2015 DIETARY GUIDELINES FOR AMERICANS*

WEDNESDAY, OCTOBER 7, 2015

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Committee met, pursuant to call, at 8:59 a.m., in Room 1300 of the Longworth House Office Building, Hon. K. Michael Conaway [Chairman of the Committee] presiding.

Members present: Representatives Conaway, Neugebauer, Lucas, King, Rogers, Thompson, Gibbs, Austin Scott of Georgia, Crawford, DesJarlais, Gibson, Hartzler, Benishek, LaMalfa, Davis, Yoho, Allen, Rouzer, Abraham, Moolenaar, Newhouse, Kelly, Peterson, David Scott of Georgia, Costa, Walz, Fudge, McGovern, DelBene, Kuster, Nolan, Maloney, Kirkpatrick, Aguilar, Plaskett, Adams, Graham, and Ashford.

Staff present: Anne DeCesaro, Callie McAdams, Haley Graves, John Goldberg, Mary Nowak, Mollie Wilken, Scott C. Graves, Stephanie Addison, Faisal Siddiqui, Lisa Shelton, Liz Friedlander, Mary Knigge, Mike Stranz, and Nicole Scott.

OPENING STATEMENT OF HON. K. MICHAEL CONAWAY, A REPRESENTATIVE IN CONGRESS FROM TEXAS

The CHAIRMAN. Well, good morning. Let us go ahead and get started. Mr. Kelly, would you open us with a prayer, please?

Mr. KELLY. Dear Heavenly Father, we just ask that you bless this Committee. We ask that you bless this government. We ask that you bless all those who lead this great nation. Dear Lord, we just ask that everything we do honor and please you. In Jesus's name I pray, amen.

The CHAIRMAN. Thank you, Trent. This hearing of the Committee of Agriculture regarding the review of the development of the *2015 Dietary Guidelines for Americans,* will come to order. I want to thank our witnesses for being here this morning. It is no small feat to get the Secretaries of two of the most important agencies of government to come sit at the same table at the same time, and so I thank you, Secretary Vilsack, Secretary Burwell, for making this happen. We certainly appreciate it.

We are joined today by the Secretary of Agriculture and the Secretary of Health and Human Services to discuss development of an important document: The *2015 Dietary Guidelines for Americans.* It is not this Committee's intention to legislate specific recommenda-

tions or guidelines, however we will demand that the guidelines be developed in a transparent and objective manner. The DGA is not only a recommendation to the American people on how to make healthy food purchasing decisions to live a healthy lifestyle, but it also forms the basis of Federal nutrition policy, education, outreach efforts used by consumers, industry, nutrition educators, and health care professionals.

It is essential that the guidance that comes out of this process can be trusted by the American people. To achieve this, it must be based on sound, consistent, and irrefutable science. The DGA is Congressionally mandated under the National Nutrition Monitoring and Related Research Act of 1990. According to the Act, the DGA shall contain nutritional and dietary information and guidelines for the general public, shall be "based on the preponderance of the scientific and medical knowledge current at the time the report is prepared", and "shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program". Ensuring a sound development process is important because it is extremely difficult to reverse or change public policy once implemented without causing consumer confusion. At a time when consumers are already subjected to conflicting, and often contradictory, nutrition and health information, staying within the scope of the intent of the law by providing the public with science-based realistic and achievable information is more likely to improve public health outcomes.

The process of the 2015 DGA began in 2012, when Secretary Vilsack and Secretary Burwell's predecessor, Secretary Sebelius, created, and then appointed, the 15 members to the Dietary Guidelines Advisory Committee. Though this committee is not specifically authorized, it was chartered under the Federal Advisory Committee Act, which requires that the advice rendered by the Committee be "objective and accessible to the public" by formalizing the process for "establishing, operating, overseeing, and terminating" the committees. This makes the committee solely responsible to USDA and HHS, who are then responsible for continually reviewing the committee's performance and process compliance, which include activities as detailed as approving all of the meeting agendas. It is therefore the responsibility of USDA and HHS to maintain control over the scope and methods used by DGAC.

I personally weighed in with both of you, as have many of my colleagues, about our concerns with the process of developing the guidelines. I raised concerns about the committee's report shortly after its release, and called on you to extend the public comment period, which you did, and I appreciate that very much. USDA and HHS received over 29,000 public comments to the committee's report, many of which were developed by nutritionists and other experts in the study of human health. Included in their submitted comments, available for public viewing on DGA's website, were scientific studies and other evidence that observers assert had been ignored by the committee. As a result, I repeatedly requested that each and every comment be considered by USDA and HHS before the final guidelines are published.

In May the Ranking Member and I sought, in writing, details on your plan to review the more than 29,000 comments, and to make

sure that they were viewed properly. You response to us on that plan, though, was less than sufficient, so I look forward to hearing more today on this matter.

Uncertainty in the process leads to concern about whether the committee's recommendations will maintain the scientific integrity necessary to be actionable by Americans. It is my hope that as USDA and HHS review of the 2015 recommendations, that in that review they are mindful of the process failures that lie squarely between each of the recommendations. It is imperative to hear assurances from each of you that Americans were ultimately presented with the best and most reliable information for making healthy food and beverage choices.

Again, thank you, Secretary Vilsack and Secretary Burwell for being with us today, and I look forward to our conversation.

[The prepared statement of Mr. Conaway follows:]

PREPARED STATEMENT OF HON. K. MICHAEL CONAWAY, A REPRESENTATIVE IN CONGRESS FROM TEXAS

I want to welcome our distinguished witnesses to today's hearing and thank them for taking the time to be with us. We are joined by both the Secretary of Agriculture and the Secretary of Health and Human Services to discuss the development of an important document: The *2015 Dietary Guidelines for Americans* (DGA).

It is not this Committee's intention to legislate specific recommendations or guidelines; however we will demand that the guidelines be developed in a transparent and objective manner.

The DGA is not only a recommendation to the American people on how to make healthy food purchasing decisions in order to live a healthy lifestyle, but it also forms the basis of Federal nutrition policy, education, and outreach efforts used by consumers, industry, nutrition educators, and health professionals. It is essential that the guidance that comes out of this process can be trusted by the American people. To achieve this, it must be based on sound, consistent, and irrefutable science.

The DGA is Congressionally mandated under the National Nutrition Monitoring and Related Research Act of 1990. According to the Act, the DGA shall contain nutritional and dietary information and guidelines for the general public; shall be "based on the preponderance of the scientific and medical knowledge current at the time the report is prepared"; and "shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program."

Ensuring a sound development process is important because it is extremely difficult to reverse or change public policy, once implemented, without causing consumer confusion. At a time when consumers are already subjected to conflicting and often contradictory nutrition and health information, staying within scope of the intent of the law by providing the public with science-based, realistic and achievable information is more likely to contribute to improved public health outcomes.

The process for the 2015 DGA began in 2012, when Secretary Vilsack and Secretary Burwell's predecessor, Secretary Sebelius, created and then appointed fifteen members to the Dietary Guidelines Advisory Committee (DGAC). Though the DGAC is not specifically authorized, all advisory committees must be charted under the Federal Advisory Committee Act which requires that the advice rendered by the committee be "objective and accessible to the public" by formalizing the process for "establishing, operating, overseeing, and terminating" the committees. This makes the DGAC solely accountable to USDA and HHS, who are then responsible for continually reviewing the DGAC's performance and process compliance, which included activities as detailed as approving all DGAC meeting agendas. It was therefore the responsibility of USDA and HHS to maintain control over the scope and methods used by DGAC.

I have personally weighed in with you both, as have many of my colleagues, about my concerns with the process of developing the *Dietary Guidelines.* I raised concerns about the DGAC report shortly after its release and called on you to extend the public comment period, which you did.

As we are all aware of by now, USDA and HHS received over 29,000 public comments to the DGAC report, many of which were developed by nutritionists and other experts in the study of human health. Included in their submitted comments, avail-

able for public viewing on the DGA's website, were scientific studies and other evidence that observers assert had been ignored by the DGAC. As a result, I repeatedly requested that each and every comment be considered by USDA and HHS before the final *Dietary Guidelines* are published.

In May, the Ranking Member and I sought, in writing, details on your plan to review the more than 29,000 public comments because public comments do matter. Your response to us on that plan was less than sufficient so I look forward to hearing more from you today.

Uncertainty in the process leads to concern about whether the DGAC recommendations will maintain the scientific integrity necessary to be actionable by Americans. It is my hope that as USDA and HHS review the 2015 DGAC recommendations, they are mindful of the process failures that lie squarely behind each of DGAC's recommendations. It is imperative to hear assurances from USDA and HHS that Americans will ultimately be presented with the best and most reliable information for making healthy food and beverage choices.

Again, thank you Secretary Vilsack and Secretary Burwell for being here today, I look forward to our conversation.

The CHAIRMAN. Are there any opening comments from the Ranking Member?

OPENING STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Mr. PETERSON. Thank you, Mr. Chairman, and I welcome both Secretary Burwell and Secretary Vilsack to the Committee, and I look forward to your testimony. Given that USDA and HHS are still reviewing comments, we are probably getting ahead of ourselves here, but I do hope that today's testimony can shed more light on the process to establish new guidelines, and what they will actually mean for our constituents. There has been a strong reaction to the Dietary Guidelines Advisory Committee report. I have heard concerns about future sodium targets, difficulties of small schools meeting the guidelines, and what this could mean for cranberries and sugar. But these are mostly coming from those who are directly impacted, industries, schools, and the medical community. We are not really hearing from the public.

I don't think the general public is paying much attention. For those who are, I think they are very skeptical of the whole process. For example, we were once told that butter and eggs were bad for you. Now I guess they are okay. According to the *Washington Post* this morning, they were wrong on milk as well, and I don't know how much government subsidized powder we bought because of it. So people may be losing confidence in these guidelines. Given the public skepticism, maybe we should reconsider why we are doing this. Is it because it is something that we have always done? We may wish, at first look, to expand on a provision in the 2008 Farm Bill that would help us understand more about what people are actually eating, and then go from there.

I am a little concerned that we have lost sight of what we are doing, and we seem to be more focused on ideology and marketing food products than providing clear nutrition advice to the general public. But I do hope we can have a productive hearing and achieve a good outcome. I know you are going to do the best that you can breaking through all this noise, and I thank the Secretaries for appearing before us today, and I yield back.

The CHAIRMAN. I thank the gentleman. I would like to inform my colleagues that Ms. Burwell has a hard stop at 11:30. She has an

international flight to catch. And so, with that, I don't know who wants to go first. Secretary Burwell?

Secretary BURWELL. I would be happy to, yes.

The CHAIRMAN. Okay.

STATEMENT OF HON. SYLVIA M. BURWELL, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Secretary BURWELL. Good morning. Thank you, Mr. Chairman, and Ranking Member Peterson, as well as Members of the Committee, for the opportunity to discuss the *Dietary Guidelines.* I want to begin by thanking the Committee for your interest in the *Dietary Guidelines,* and for your work to support Americans, and a healthy agriculture sector.

One of the most important responsibilities that our government is entrusted with is protecting the American public, and that includes empowering them with the tools they need to make educated health decisions. Since 1980, families across the nation have looked to the Departments of Health and Human Services and Agriculture for science-based *Dietary Guidelines* to serve as a framework for nutritious eating and healthy lives. Our guidelines also help lay a foundation for preventing diet-related health conditions, like obesity, diabetes, and heart disease.

As is required by the National Nutrition Monitoring and Related Research Act, the Departments update these regulations and guidelines every 5 years. The key elements that make up a healthy lifestyle remain consistent, fruits and vegetables, grains and lean proteins, and limited amounts of saturated fats, added sugars, and sodium. We anticipate these will continue to be the building blocks of the 2015 guidelines, updated to reflect the latest research in science, as well as our current understanding of the connections between food and health. As part of our effort to rely on the best science available, we have appointed an independent Advisory Committee of nutrition and medical experts and practitioners to inform each addition. The 2015 Advisory Committee evaluated research, and considered comments from the public to develop recommendations included in its finished report.

It is important to note that the Advisory Committee report is one input into the *Dietary Guidelines.* The guidelines themselves are written and reviewed by experts at both of our Departments. In addition to the recommendations of the Advisory Committee, our Department's experts perform their own extensive review and consideration of public comments. In fact, as was mentioned, we received 29,000 written comments during the 75 day public comment period. As a result, the *2015 Dietary Guidelines* will be informed by a review of thousands of scientific papers, and decades of nutrition and medical research, as well as input from the public.

We know that the guidelines are of critical importance to many Americans. They contribute to a culture of wellness, and empower individuals to better manage their own health, help keep their families healthy, reduce the onset of disease, and reduce the amount of money that we spend on healthcare. They also provide guidance to public and private programs, and support efforts to help our nation reach its highest standard of health. At HHS, the *Dietary*

Guidelines provide a roadmap for the nutrition advice, and services that we deliver, such as chronic disease prevention efforts, food assistance programs, and educational initiatives.

HHS and USDA are working together to finalize the *2015 Dietary Guidelines,* which are expected to be completed in December of this year. Without a finished product, I am unable to comment on the final content of the forthcoming edition at this time. I expect, however, that the new guidelines will continue to emphasize the importance of healthy eating habits and individual food choices. I want to thank you again for your interest in this topic, as well as the feedback that we have received. I know many of you have specific questions and concerns, and I want to assure you that we are taking your concerns into consideration. And we are working hard to answer your questions as thoroughly as we can as we are in the process of doing the guidelines. I look forward to continuing to work together, and look forward to your questions today. Thank you.

[The prepared statement of Ms. Burwell follows:]

PREPARED STATEMENT OF HON. SYLVIA M. BURWELL, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Chairman Conaway, Ranking Member Peterson, and Members of the Committee, thank you for the opportunity to discuss the *Dietary Guidelines for Americans* (*Dietary Guidelines*).

I want to begin by thanking Members of this Committee for your interest in the *Dietary Guidelines* and, more broadly, for your work to support Americans and a healthy agricultural sector. The *Dietary Guidelines* are a critical science-based initiative drafted by experts at the Departments of Agriculture and Health and Human Services that gives Americans advice on building healthy eating patterns that can help prevent chronic diseases and promote the health and well-being of our nation. I want to emphasize that the focus of the *Dietary Guidelines* is on preventing diet-related health conditions, such as obesity, diabetes, and heart disease, rather than treating these and other diseases. The *Dietary Guidelines* are one part of a larger effort to help lower disease rates in the United States and give every American the tools they need to live healthy and productive lives.

History

The *Dietary Guidelines* are required under the 1990 National Nutrition Monitoring and Related Research Act, which directs the Departments of Health and Human Services (HHS) and Agriculture (USDA) to publish a report entitled "*Dietary Guidelines for Americans*" at least every 5 years. By law, each edition of the *Dietary Guidelines* includes "nutritional and dietary information and guidelines for the general public . . . ." The law also states that the *Dietary Guidelines* should "be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program." In our development of these Guidelines, we follow this statute to guide the scope of our work.

Historically, the Key Recommendations of the *Dietary Guidelines* have not changed substantially from one edition to the next. Elements of healthy eating patterns continue to include fruits, vegetables, grains, dairy, and protein-rich foods such as lean meats and seafood, and limit components like saturated fats, added sugars, and sodium. The guidelines provide a science-based framework for policy makers, nutrition educators, and healthcare providers to include nutrition as part of an overall prevention strategy for lowering rate of disease. The guidelines also help Americans make healthy food choices, enjoy food, and celebrate personal culture through food, all of which are important to Americans.

Development

HHS and USDA strive to develop *Dietary Guidelines* recommendations that are based on the strongest available scientific evidence and represent our current understanding of the connections between food and health. One of the ways that we achieve this goal is by appointing a Dietary Guidelines Advisory Committee (Advisory Committee). The Advisory Committee is an independent group of experts and practitioners in the fields of nutrition and medicine that is voluntary and solely ad-

visory, and although their work informs the government's work, they are not directly involved in the Departments' development of the *Dietary Guidelines.* It develops a scientific report and recommendations to inform each edition of the *Dietary Guidelines.* The use of an Advisory Committee is a best practice to ensure that the Federal Government is obtaining sound, external scientific advice to inform policy decisions. Advisory Committees have been used to inform the development of the *Dietary Guidelines* since the 1985 edition.

The 2015 Advisory Committee used state-of-the-art standards to develop its scientific recommendations to the Federal Government, which were delivered to HHS and USDA in its Advisory Report in February 2015. In addition to drawing on the expertise of the Committee members, the Advisory Committee also received both written and oral public comments over the course of its work. These comments helped ensure that the Committee discussed topics and issues of interest to the public and received evidence to consider in the scientific process.

The work of the Advisory Committee informs HHS and USDA's development of the *Dietary Guidelines;* however, the Advisory Report is only one component that the Departments consider when developing each edition of the guidelines. The Guidelines themselves are written and reviewed by the experts at our Departments and ultimately by Secretary Vilsack and me. In addition to the Advisory Committee's report, HHS and USDA consider public comments on the Advisory Report and look to Federal agencies with expertise in nutrition to review both the Advisory Report and the draft policy before Secretary Vilsack and I approve it.

We recognize that the Advisory Report addressed many issues about which nutrition and agricultural stakeholders care deeply. We received over 29,000 written comments during the 75 day public comment period on the Advisory Report, as well as 73 oral comments during a March 2015 public meeting. This demonstrates public interest and concern about information in the *Dietary Guidelines.* In response to the high level of interest and Congressional requests, HHS and USDA extended the public comment period by 30 days to accommodate a high volume of public comment submissions and ensure we were able to take the public's input into account. These comments have been fully reviewed by staff within our Departments and are being considered in the development of the *2015 Dietary Guidelines.* While all public comments are reviewed, in order to ensure the *Dietary Guidelines* are based on sound science, the Departments focus heavily on public comments that include scientific justification.

As a result, the *2015 Dietary Guidelines* will be informed by a review of thousands of scientific papers and decades of nutrition and medical research, as well as significant input from the public. The Guidelines will translate this science into succinct, food-based guidance that Americans can rely on for choosing a healthy diet.

Impact

The 2015 edition of the *Dietary Guidelines* will build on this strong scientific foundation to continue to provide guidance to help encourage more healthy food choices across our nation. As Members of this Committee know, this issue is of critical importance. We must strive, together, to prevent nutrition-related disease and improve the health of American families and communities.

The *Dietary Guidelines* are one of numerous important Federal policy initiatives that aim to help Americans reach their highest standard of health. For more than 25 years, over ½ of our adult population has been overweight or obese. Today, about ½ of all American adults have one or more preventable chronic diseases, which are attributable to several causes, including poor-quality diet and physical activity behaviors. All sectors of society play an integral part in contributing to a culture in the United States that champions wellness and empowers all people to achieve their highest standard of health. The *Dietary Guidelines* provide the framework for not only the Federal Government but also for other sectors of influence, including other policymakers, health professionals, *etc.* who can apply the Guidelines in a multitude of ways with the potential to lower nutrition-related disease rates.

At HHS, the *Dietary Guidelines for Americans* provide a roadmap for the nutrition advice and services that we deliver to the public through chronic disease prevention efforts, food assistance programs, and educational initiatives. Examples include the Older Americans Act Nutrition Services Programs and Head Start. The Guidelines are also used to inform national disease prevention and health promotion objectives related to nutrition and weight status, primarily through Healthy People 2020. CDC's prevention campaigns, NIH's lifestyle guidance, and FDA's Nutrition Facts Label regulations consider the nutrition information in the *Dietary Guidelines.* As in the past, the 2015 edition of the *Dietary Guidelines* will help focus our resources on efforts that have the greatest positive impact on health outcomes.

***Dietary Guidelines for Americans,* 2015**

HHS and USDA are working together to finalize the *2015 Dietary Guidelines,* which are expected to be completed in December of this year. We will conduct several layers of scientific review prior to preparing a draft for final approval, which has not yet occurred. As such, I am unable to comment on the final content of the forthcoming edition of the *Dietary Guidelines* at this time. However, I expect the new *Dietary Guidelines* will continue to focus on food-based recommendations that emphasize the importance of consuming a total "healthy eating pattern" over time while recognizing the importance of individual choices.

Closing

Again, thank you, Chairman Conaway, Ranking Member Peterson, and Members of the Committee for this opportunity to discuss the *Dietary Guidelines* and for your interest in this important topic. I am looking forward to continuing our partnership so that together we can ensure that every American has access to the building blocks of healthy and productive lives. I am happy to answer your questions.

The CHAIRMAN. Thank you, Secretary. Secretary Vilsack?

STATEMENT OF HON. THOMAS "TOM" J. VILSACK, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Secretary VILSACK. Thank you, Mr. Chairman, Ranking Member Peterson, and all of the Members of this Committee, I want to thank the Chairman for the opportunity to be here today, and I want to thank my colleague, Sylvia Burwell, for the extraordinary work that she and her team have done, in concert with the Department of Agriculture, in getting us to this point today.

I will tell you that I struggle with the *Dietary Guidelines,* because it is important for people to understand precisely what they are and what they are not. These guidelines are a set of recommendations based on a series of well-informed opinions that create a framework that is designed to encourage and to educate Americans about what they can do to increase their chances of preventing chronic diseases. This is not about treating disease. This is about trying to prevent chronic diseases.

As a result, the guidelines that we formulate are, and should be, restricted, by law, to nutritional and dietary information. The Advisory Committee report, which Secretary Burwell mentioned, is not the guidelines, and sometimes there is confusion about that. The report informs our work, but certainly does not, and should not, dictate it. Only HHS and USDA can, and should, write the guidelines, based on a variety of inputs. This has been an open and transparent process. Questions were posed by and to the Advisory Committee. A number of studies, indeed thousands of studies, and tens of thousands of pages of documents, were reviewed. Those reviews went through a very strict and gold standard process for determining what is the strongest, best, and most available science. Multiple public meetings took place. Information was posted on the web, and we indeed received 29,000 comments as a result of the extended comment period, of which 8,000 comments are probably considered unique.

I recognize that our process here is to determine the best available science, and, based on that, and the preponderance of that, we formulate the guidelines. I believe I have the same goal that Secretary Burwell has, which is to finish our work on time, before the end of the year, so that we can use these guidelines, as directed by Congress. So I too look forward to your comments and questions,

and this hearing is an important opportunity for us to educate folks about what these guidelines are and what they are not.

[The prepared statement of Mr. Vilsack follows:]

PREPARED STATEMENT OF HON. THOMAS "TOM" J. VILSACK, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Chairman Conaway, Ranking Member Peterson, and Members of the Committee, thank you for the opportunity to discuss the *Dietary Guidelines for Americans* with you. I know it is important to all of us that the Department of Health and Human Services (HHS) and Department of Agriculture (USDA) deliver on our Congressional mandate.

The *Dietary Guidelines* are focused on promoting health and preventing disease by providing food-based recommendations on diet and nutrition. The Guidelines form the cornerstone for all Federal nutrition programs. Over the years, they have also become an important resource for policy makers, nutrition educators, health professionals, and industry. What unites us all is the shared appreciation for the importance of nutrition in helping to prevent chronic diseases such as cardiovascular disease, high blood pressure, type 2 diabetes, diet-related cancers, and obesity—and the knowledge that too many Americans suffer from these preventable diet-related diseases.

It is important to note that the *Dietary Guidelines* are intended to prevent these diet-related conditions, not to treat them. The recommendations apply to individuals 2 years of age and older who are healthy or at increased risk of chronic disease, not those with medical conditions or special dietary needs. Dietary recommendations for specific populations that suffer from various conditions are likely to differ from those recommended by the *Dietary Guidelines.*

HHS and USDA currently are working together to develop the eighth edition of the *Dietary Guidelines,* which is scheduled to be released by the end of this calendar year.

Background

HHS and USDA have jointly published the *Dietary Guidelines* every 5 years since 1980, even before it was required by statute. The 1990 National Nutrition Monitoring and Related Research Act now directs HHS and USDA to publish the *Dietary Guidelines* at least every 5 years. The Congressional mandate states that the *Dietary Guidelines* "shall contain nutritional and dietary information and guidelines for the general public, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program." The law also requires that each edition of the *Dietary Guidelines* "shall be based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared."

Since the 1985 edition of the *Dietary Guidelines,* the Secretaries of HHS and USDA have appointed an external, independent group of experts and practitioners in the fields of nutrition and medicine to provide independent, science-based advice and recommendations to the Departments as we develop the *Dietary Guidelines.* Each Dietary Guidelines Advisory Committee is compliant with the Federal Advisory Committee Act, serves in a voluntary and advisory role only, and submits a report of scientific recommendations to the Federal Government. The Advisory Committee does not develop the *Dietary Guidelines;* that is the role of HHS and USDA, and the recommendations we receive from the Advisory Committee inform our work.

External Scientific Evidence Review Prior to HHS–USDA *Dietary Guidelines* Development

The 2015 Advisory Committee was charged with reviewing the *2010 Dietary Guidelines* and reviewing the current state of scientific evidence on nutrition and health to develop food-based recommendations of public health importance for Americans ages 2 years and older. Their recommendations were outlined in the *Scientific Report of the Dietary Guidelines Advisory Committee,* submitted to HHS and USDA in February 2015.

The Advisory Committee conducted comprehensive and rigorous systematic reviews of scientific evidence on food, nutrition, and health using state-of-the-art standards to develop its Scientific Advisory Report. The Committee formulated and addressed more than 80 scientific questions using: (1) original systematic reviews conducted through USDA's Nutrition Evidence Library (NEL); (2) existing high-quality systematic reviews, meta-analyses, and reports from the scientific community; (3) data analyses; and (4) food pattern modeling analyses. These four ap-

proaches contribute to a comprehensive body of scientific evidence upon which the Federal Government can develop policy.

It is worth noting that systematic reviews were used to examine the majority of the scientific evidence in diet and health. Considered the gold standard and standard practice for more than 25 years in the medical field, systematic reviews are relied upon to inform the development of national guidelines for use by research and health professionals. The NEL, developed in consultation with leaders in the systematic review community such as the highly respected Cochrane Collaboration, involves a structured, protocol-driven approach to identify, evaluate, summarize, and synthesize peer-reviewed scientific literature as a means to answer the scientific questions specifically focused on diet and public health. Use of the NEL involves thorough searches of all peer-reviewed scientific literature contained in multiple electronic databases, and putting the results through pre-determined inclusion/exclusion criteria to focus on those that answer the scientific questions. Because the *Dietary Guidelines* focus on disease prevention, and not treatment, these reviews excluded studies that involved treating disease, such as those in which patients with an existing condition followed a therapeutic diet. Of approximately 4,000 manuscripts screened for inclusion, the 2015 Advisory Committee reviewed nearly 300 studies that met the criteria for the systematic review questions.

In addition, the Advisory Committee used existing systematic reviews from the NEL and external national and international scientific organizations to prevent duplication of efforts and to conserve Federal resources and time. All existing systematic reviews were screened by Federal staff and underwent assessment to ensure the proper quality and objectivity.

Public Participation in the Process

Public participation in the *Dietary Guidelines* scientific review process has been important and extremely valuable. HHS and USDA issued a public call for nominations of candidates for 2015 Dietary Guidelines Advisory Committee members in the fall of 2012. Following a careful and diligent process, members were appointed to the Advisory Committee by Secretary Sebelius and me. The Advisory Committee proceeded to hold seven public meetings spanning 19 months, which included an opportunity for the public to provide oral testimony. After each public meeting, the Committee's slides and videos were posted for public access on *DietaryGuidelines.gov,* along with a list of all the scientific studies discussed during the meetings and the inclusion-exclusion criteria the Committee used. Throughout this time, the public was encouraged to submit comments to the Advisory Committee on *DietaryGuidelines.gov*. These comments ensured that the Committee considered all relevant topics in preparation of the Scientific Advisory Report.

Once the Advisory Committee submitted its Scientific Advisory Report to Secretary Burwell and me in February 2015, the report was posted on *DietaryGuidelines.gov* for public review and comment. HHS and USDA extended the public comment period from 45 days to 75 days; for comparison, the public comment period to review the 2010 Advisory Report was 30 days. In addition, the public was invited to provide oral testimony to the Federal Government on the Scientific Advisory Report in March 2015.

Public comments serve as a vital resource to our Departments in drafting the *Dietary Guidelines.* In addition to the March public meeting for oral testimony, we received more than 29,000 written comments during the 75 day public comment period. Staff from both Departments have reviewed all comments submitted and posted them online at *DietaryGuidelines.gov*. To ensure the *Dietary Guidelines* are based on the totality of sound science, the Departments' focus is primarily on public comments with scientific justification.

HHS–USDA Development of the *2015 Dietary Guidelines for Americans*

In addition to the Advisory Committee's report and public comments, HHS and USDA look to Federal agencies with expertise in nutrition to review both the Scientific Advisory Report and the draft of the *Dietary Guidelines for Americans*. This ensures that the *Dietary Guidelines* are grounded in the current scientific knowledge and are compliant with existing Federal policies before Secretary Burwell and I review and approve it for release and implementation across Federal nutrition programs.

As a result of this multi-faceted process, the *2015 Dietary Guidelines for Americans* will be informed by thousands of scientific papers, decades of nutrition and medical research, public comments, and reviews by Federal experts. We will conduct several layers of review prior to preparing a draft for final approval, which has not yet occurred. However, I can assure you that the *2015 Dietary Guidelines for Americans* will be grounded in the preponderance of the best available scientific evidence,

represent our current understanding of the connections between food and health, and integrate the science into succinct, food-based guidance that Americans can rely on for choosing a healthy diet.

The *Dietary Guidelines* has been referred to as the nutrition backbone of our nation. We take this responsibility very seriously. Again, thank you, Chairman Conaway, Ranking Member Peterson, and Members of the Committee for this opportunity to discuss the *Dietary Guidelines for Americans.*

The CHAIRMAN. Well, thank you. I got ahead of myself. Let me mention that the Chairman requests that other Members submit their opening statements for the record. And I rudely failed to introduce Secretary Tom Vilsack, who is the Secretary of the Department of Agriculture, and the Honorable Sylvia Burwell, who is Secretary of Department of Health and Human Services. Two folks who needed no introduction, and I didn't introduce you, I apologize for that. The chair would remind Members that they will be recognized for questioning in order of seniority for the Members who were here at the start of the hearing. After that, Members will be recognized in order of arrival, and I appreciate the Members' understanding. And I recognize myself for 5 minutes.

Ms. Burwell, you said in your comments that the guidelines don't change substantially from one set to the next, but yet the Advisory Committee reports have gone from 57 pages in 1995 to 571 pages for this one. So I am not sure we have gotten ten times better information today than we did at that point in time.

As I mentioned in my opening statement, the oversight we are conducting today is on the development of the guidelines in sight of concern for the integrity of the process, and its resulting recommendations. The Federal Advisory Committee Act defines how Advisory Committees operate. The law puts special emphasis on open meetings, chartering, public involvement and reporting. According to statute, a Federal Advisory Committee shall, among other things, require the membership of the Advisory Committee to be fairly balanced in terms of the points of view represented and the functions to be performed, contain appropriate provisions to assure that the advice and recommendations of the Advisory Committee will not be inappropriately influenced by the appointing authority, or by special interests, but will instead be the result of Advisory Committee's independent judgment.

Despite these statutory safeguards, serious questions have been raised about the oversight of the overall DGAC process while it was ongoing. This has tended to fuel concerns that members of the commission may have been appointed in order to achieve certain policy outcomes outside the legitimate purview of the Advisory Committee. I refer specifically to an op-ed published on October 1, 2015 by former Deputy Secretary Kathleen Merrigan, who currently serves as the Executive Director of the Sustainability Institute at George Washington University. I note that Secretary Merrigan was serving as USDA Deputy Secretary during the time the DGAC was chartered and appointed. The suggestion of including sustainability and tax issues by the DGAC has been a topic of intense discussion for some time. I recognize that you both jointly published a blog yesterday acknowledging that sustainability is out of the scope of this exercise, and I hope to get some comments from you about tax issues as well. I am likewise sure you recognize that the inclusion of these issues in this process could have resulted in misguided rec-

ommendations, which would have ill effects on consumer habits and agricultural production.

The counter to potential bias in the process is the public comment period. The 75 day period was the public's first real opportunity to review the 571 page document. In your written statement, Secretary Burwell, you mentioned that USDA and HHS staff have already fully reviewed all the comments. You also mentioned that you focused most heavily on those with scientific justification. Help us understand, then, what is going on right now. What have you done with the studies, such as those evaluating low carbohydrate consumption patterns, since the review has been taking place?

Secretary BURWELL. I think there were a number issues raised, and I apologize, I could not hear your final question.

The CHAIRMAN. What have you been doing? Have you been studying the comments, and the report itself. Can you talk to us about how you have been evaluating other information, like low carbohydrate consumption patterns, as a part of that review?

Secretary BURWELL. With regard to one issue that you touched on earlier that I want to go ahead and address, you asked which was the tax issue, and the question of tax policy. I think, like our comments yesterday in the blog that Secretary Vilsack and I put out about the issue of sustainability, while we haven't received recommendations from our staff speaking to the specifics of what are in the *Dietary Guidelines,* that is a question of scope, like the sustainability question, and that is not an issue that we would address, on the tax issue, when I address that.

With regard to the process that we are now going through, and how, whether it is the carbohydrate issue, or any of the specific issues, what is happening is we received the report of the committee. Our staffs are reviewing that. At the same time, we are reviewing all of the public comments that we have received. In addition to that, we are bringing in the experts from all of our Departments to make sure that they weigh in as we do the consideration. And, for us, that includes the Food and Drug Administration, the NIH, the Centers for Disease Control, the Office of the Assistant Secretary for Health, and many others. So that is the process that we are using now, to review what we received, and to put together the guidelines.

The CHAIRMAN. Could the guidelines have things in them that weren't necessarily directly reported in the recommendations from the committee? Your own wisdom, your own thoughts, would be reflected in the guidelines as well?

Secretary BURWELL. In terms of the expert advice of our staffs that exist, with regard to the question of studies and pieces of work, it is important to reflect what Secretary Vilsack said, which is there has been a systemic literature review with regard to the studies, and that is part of keeping integrity to the process. With regard to our experts who are constantly involved in those issues, yes, they will be a part of that process.

The CHAIRMAN. Thank you. Ranking Member?

Mr. PETERSON. Thank you, Mr. Chairman. I think you both know that sodium not only provides a benefit in making products shelf stable, it also improves taste, and is an important food safety component in cheese. Studies have shown that there is insufficient evi-

dence to conclude that lowering sodium intake below 2,300 milligrams per day decreases risk of cardiovascular disease, and the Dietary Guidelines Advisory Committee agreed. So why has the committee continued to support further sodium reduction, and is this something that you will be able to address in your guidelines?

Secretary VILSACK. Well, let me take a stab at that. First of all, again, we are going to probably respond to a number of questions by pointing out these guidelines have not been formulated yet, and we can't comment on the specifics of what the guidelines will be because we haven't had an opportunity to prepare them and to review them.

Having said that, the Advisory Committee, basically, they go through a process, as Secretary Burwell indicated, of reviewing a variety of studies. There, no doubt, were studies that linked prehypertension, hypertension, to sodium consumption. They probably looked at the National Academy of Medicine studies, in terms of sodium, and they probably concluded that there was evidence relating to sodium consumption and these chronic diseases, which is why they have recommended what they have recommended.

The reality of this situation is that science changes, and we learn more information, and that is why it is important to have a process that we have in place to review what the Advisory Committee recommends, then to have public input, to get public comments, to have our own staff review studies, based on information they have accumulated during the course of the 5 year period since the last *Dietary Guidelines,* and also to refer back to the last set of guidelines, which is a foundation for this set of guidelines. So, Congressman, I can't comment specifically on why the Advisory Committee did what they did because they sort of operate independent. We don't inject ourselves into that process. But we do basically take their input into consideration, along with many, many other studies, many, many other opinions, to try to formulate the best set of guidelines and framework for the country.

Mr. PETERSON. Thank you, Secretary. I don't know if you both have seen the *Washington Post* story today? Secretary Vilsack, I guess you have seen it.

Secretary VILSACK. I have seen it, and several people were mentioned in there. I have read books by those folks in preparation for this. This is what has caused my concern about what these guidelines are and what they are not.

Mr. PETERSON. Well, my concern is that we have had these guidelines that have pushed people away from eggs, and butter, and milk, and so forth, and then they come back and say, well, we were wrong. And so my question is, for both of you, what are we going to do to make sure that doesn't happen in the future? First of all, do you agree with this, and second of all, how are we going to keep this from happening? Why are we going off on these tangents if we have a process that is so heavily vetted?

Secretary BURWELL. I would say a couple of things. First, the consistency over time for most issues has been there, and it is right to point out that, with regard to the issue specifically of dietary cholesterol, there has been a change over time.

I can think of a couple things, to answer your question. First, for the most part, things are consistent over time. Second, we need to

make sure we use the most scientific evidence we can. And there has been an evolution and change, and that does get reflected in what the Advisory Committee has given us. They no longer will do recommendations based on expert opinion. Instead, they will only do recommendations based on the science, and that is a change that will occur.

The other thing that is an important thing to reflect is that, in some cases, science does change. And in the case of our understanding of blood cholesterol *versus* dietary cholesterol, there has been an evolution in understanding of the difference of those, and what they cause. And we want to be prepared to make sure we review in a rigorous way changes that happen. There is not one simple answer to the problem that you raise, but a number of pieces of how we can work to get to a place where we have the most consistent science-based advice.

Secretary VILSACK. And let me just simply add that Congress has directed us to take a look at the preponderance of that available science, which *suggests,* which is a term that I am familiar with in the practice of law, it suggests that there may be studies on both sides of an issue. And it is important and necessary for folks to sort of weigh the studies. And one of the challenges of this is to distinguish between one single quality study that is absolutely solid *versus* a bulk of studies over time that may have a slightly different view.

And this is the challenge here, and it is a reflection of the fact that all of this is evolving. You are not going to ever have something that just basically is going to be a fact about this, because science evolves. We learn more, we understand more. And I would hope that we would be flexible enough to appreciate that, and to take that into consideration.

Mr. PETERSON. Well, I thank both of you for your observations, and you have made some points, but I just want you to understand, for my constituents, most of them don't believe this stuff anymore. You have lost your credibility with a lot of people, and they are just flat out ignoring this stuff. And so that is why I say I wonder why we are doing this. From what I am hearing from my constituents,

Secretary VILSACK. Congressman——

Mr. PETERSON.—what it is worth.

Secretary VILSACK.—can I respond to that for just a second? Here is the challenge, though. We take these guidelines, we incorporate them in our website, *choosemyplate.gov*. We have had over 290,000,000 hits on *choosemyplate.gov*. It may very well be that there are folks who are concerned about this, but I still think there is merit in it, as long as people understand what they are and what they are not. They are not a hard and fast set of rules, they are a guideline, a set of guidelines, a framework. And they are not about treating disease, they are about preventing it.

The CHAIRMAN. Thank you. Mr. Neugebauer, for 5 minutes.

Mr. NEUGEBAUER. Thank you, Mr. Chairman. I want to go back to something that the Chairman was asking, and I want to make sure that we are all on the same page here. So, taxes are off the table, as far as consideration in the guidelines, is that correct?

Secretary BURWELL. With regard to the question of whether there be a tax recommendation in our *Dietary Guidelines,* we do

not believe that that is something that is in the scope of the work that we are doing.

Mr. NEUGEBAUER. Secretary Vilsack?

Secretary VILSACK. Well, that is not within the scope. It is not dietary, it is not nutrition, and it doesn't belong in this context. There are probably many other ways in which that conversation should be taken and should be had. As is the case with sustainability, it doesn't belong here, it belongs elsewhere. And I am happy to have that conversation with folks if they are interested.

Mr. NEUGEBAUER. So both of you agree, then, sustainability and taxes are off the table, as far as these recommendations are concerned?

Secretary BURWELL. Both are important issues that we believe should have conversations, but not in the context of this document.

Mr. NEUGEBAUER. Thank you. HHS and USDA have always stated that they have looked to appoint members to the DGAC so it consists of nationally recognized experts in the fields of nutrition and health. As you know, the DGAC is subject to the Federal Advisory Committee Act, which is widely used throughout the Federal Government. This Act is designed to ensure that the various Advisory Committees formed over the years are objective and accessible to the public. The Act has formalized a process of establishing and operating and terminating these advisory bodies. For the 2015 guidelines, the HHS and the USDA began to solicit nominations for the DGAC in 2012. Once selected and appointed, the DGAC was composed of academics, including professors, epidemiologists, and even a physician-scientist.

In a departure from prior Dietary Guidelines' Advisory Committees, nutritionists and food scientists were not selected to serve on this DGAC. Understandably, questions regarding the inherent bias are being raised by the fact that no food industry scientists were included in the DGAC committee. Additionally, after the DGAC had officially disbanded, the former Advisory Committee members decided to hold a public event, acting in their capacity as DGAC members, which they were not, according to the committee's charter and Federal Advisory Committee Act.

Based on the charter, it is the DGAC's responsibility to review the science and make recommendations to your Departments, which is then developed for final recommendations for the public. It is, however, not the responsibility of the DGAC to educate the general public on the report that still needed to be considered by the HHS and USDA claiming the nutritional recommendations were based on *Dietary Guidelines.*

Secretary Burwell, what instructions were given the Advisory Committee members regarding the FACA and the Advisory Committee's disbandment?

Secretary BURWELL. With regard to the specifics of the disbandment, I can get back to you, Congressman, with regard to the direction that was given as to review the science with regard to the issues that were in front of them with regard to the *Dietary Guidelines,* and present a report about that. So, with regard to the question of disbandment, I don't know what, if any, specific direction was given, but the point that you have made, which is this is about an Advisory Committee producing a document, an independent

group of people producing a document, that then is an element in the basis of what our decisions will be on the *Dietary Guidelines,* is what their role is.

Mr. NEUGEBAUER. Well, was their role to then go out and start doing a road show on their recommendation? Is that a part of the scope of that committee?

Secretary BURWELL. With regard to what we followed, at least at the Department, and what I know about is the fact that, once we received the committee's recommendations, and those became public, that there was a public comment period. That was the part that we have both been focused on, and the 29,000 comments that have come in from the public. As well as, when we heard from you all that you asked for an extension of the public comment, Secretary Vilsack and I very quickly agreed that that was something we thought was an important thing to do. That is the——

Mr. NEUGEBAUER. Well——

Secretary BURWELL.—part of the process, in terms of public——

Mr. NEUGEBAUER.—the question here is that; first, did they follow the guidelines, and second, what steps were taken to make sure that the committee followed the law? And then, from an ethical standpoint, once you have served in your capacity on that Advisory Committee, and made your recommendations, what is your responsibility, moving forward? And one of the things we don't want is that this turn into some kind of a profitable situation on their behalf because of their participation on that Advisory Committee.

Secretary BURWELL. With regard to—these are voluntary, nonpaid. They all have to file financial disclosures on an annual basis as they go through this process, and so those are all things we want to protect against. With regard to the specific question of a press briefing, or some kind of briefing, I apologize, I am not familiar with that. As I said, we have focused on the public comments and the steps and process that we are following.

The CHAIRMAN. The gentleman's time has expired. Mr. Scott, for 5 minutes.

Mr. DAVID SCOTT of Georgia. Thank you very much, Mr. Chairman. I am very concerned that you are not using the most relevant, basic, and the best science-related information in formulating these guidelines. You certainly did not use some of the most recent peer-reviewed and published nutrition and diet-related science. It was not even considered by the Advisory Committee, and not even included in the evidence-based library to be considered by the Advisory Committee when they were finalizing the report. That is a fact.

And, Mr. Vilsack, you said you were using the best information. Your quote was we have the best informed opinions. But if you are not using the most recent peer review, that information that is there, and your committee has not even agreed to put it into the final report. So maybe you all can give me some level of confidence that your staffs and you will take into consideration the strong scientific evidence with the final policy document, even though it was not included in the evidence-based library throughout the working group process?

Secretary VILSACK. Congressman, can you be specific about which study you are talking about?

Mr. DAVID SCOTT of Georgia. I am talking about the scientific study that came out that gave evidence that certain things were very important. Let me just give you one example. Let us look at the whole issue of the involvement of sugar, and how it is not even included. Why, for example, that low calorie sweeteners are not being recommended, when the study pointed out that low calorie sweeteners could be used to lower weight, to be able to help what is called atopocity, and it is not even being used. What is wrong with low calorie sweeteners that can be used, and it is not even in the report?

Secretary VILSACK. Congressman, let me try to respond to the question as best I can. First of all, when you have a process that is every 5 years, you, obviously, are going to have to have, at some point in time, a cutoff of what information you consider, because, theoretically, the minute before we publish the guidelines, somebody could publish a study, and you would be criticizing us for not taking the latest science into consideration. So there has to be a cutoff time in terms of consideration. Having said that, over 4,000 studies were reviewed, 300 manuscripts were reviewed, and they went through a gold standard process for evaluating the appropriateness and efficiency of those studies. That it is unfair to the committee, and unfair to the process, to suggest that we are not looking at the science. We are. Number one.

Number two, as far as sugars are concerned, look, here is the problem. Our children, 15 to 17 percent of what they consume is sugar. And so, obviously, we are looking for ways in which we can reduce that. And what they were recommending and suggesting is that if you are going to have sugared drinks, if you are going to have sugar in your diet, you ought to at least look for the most nutritionally dense foods that you possibly can consume for that sugar, that you don't basically use empty calories to obtain it. So you could have something like chocolate milk *versus* a low cal drink. You would get more nutrition bang for your sugar buck, if you will, out of that process. And that is what they were suggesting.

Mr. DAVID SCOTT of Georgia. But you are familiar with that report? The Added Sugars Working Group said that moderate, and generally consistent, evidence from studies conducted in adults and children supports replacing sugar-containing sweeteners with low calorie sweeteners to reduce calorie intake, body weight, and atopocity.

So the issue simply is for both of you to be able to explain why the DGAC, the *Dietary Guidelines for America,* would then recommend that consumers not—that is the whole point. You have used this evidence, it is pointed to where it could be helpful, but then the committee recommends that the consumers not use low calorie sweeteners as a tool in the toolbox to reduce added sugars. All I am simply saying is that if this report is going to have value for the welfare of the American people, and you all say you are using the most relevant basic information, then this clearly contradicts that.

Secretary BURWELL. There are two different things. One is what the Advisory Committee has in its report, and the other is what we do in the guidelines. And the specifics of that, as we have said, are not something we received as recommendations. My understanding of what is in the committee report, with regard to the question of substitution of the drinks, is that not enough evidence exists one way or another to make a recommendation, and that that is where the committee left the issue of the specific of the substitution.

The CHAIRMAN. The gentleman's time has expired. Mike Rogers, 5 minutes.

Mr. ROGERS. Thank you, Mr. Chairman. I thank you all for being here. You have both made reference to the fact that you take these comment periods seriously, and that you consider these comments in your guideline making process. And I take you at your word. One particular area of concern to me, though, and producers in my district, is in the Dietary Guidelines Advisory Committee recommendations regarding red meat. The current DGAC report seemingly recommends that Americans consume less red meat. Will your agencies be reviewing studies submitted during the comment period that address the recommendations for red meat, both pro and con, and can you tell me more about that?

Secretary VILSACK. In terms of the issue of red meat, it is fairly clear that there is a recognition that lean meat is, and should be, part of a healthy diet. The challenge is to understand that, as Americans, if we look at the obesity epidemic that we are confronting in this country, that some of us are consuming more calories than we should. And so the recommendation is in relationship to the overall consumption of calories. And one way to reduce the overall consumption of calories is, obviously, to eat less of certain things. And in that category would be red meat, but that is by no means the only thing in that category. So I want to be clear here——

Mr. ROGERS. What I don't understand. I am sorry, Mr. Vilsack, but why would you include in that category red meat? I mean, why wouldn't you just say anything that takes you over a caloric level that is unacceptable, you shouldn't eat? Why would there be a category of things not to eat?

Secretary VILSACK. Because of the importance of having balance, in terms of what you consume, in terms of what a healthy diet consists of. Again, remember what this is. It is a set of guidelines which is designed to give you the best chance of reducing cardiovascular, cancer, and chronic diseases.

Mr. ROGERS. But wouldn't red meat be part of a——

Secretary VILSACK. It is.

Mr. ROGERS.—list of things that you should eat, as long as you eat lean?

Secretary VILSACK. It is. That is what I am saying. It is.

Mr. ROGERS. I am sorry, I thought you said that you would put it in a list of things not to eat.

Secretary VILSACK. No. Sir——

Mr. ROGERS. Okay.

Secretary VILSACK.—what I said was, if you are concerned about over-consumption of food generally, then obviously you are going to

suggest that people should eat less of something that they are eating a lot of. That is the key.

Mr. ROGERS. I agree.

Secretary VILSACK. To suggest that we are not going to have a guideline, it is fair to say, regardless of the fact the guidelines aren't fixed yet, that lean mean is going to be part of a healthy diet. There is no question about that, as far as——

Secretary BURWELL. Yes. The Advisory Committee's recommendation on this is exactly the same as 2010. So I think——

Mr. ROGERS. Yes.

Secretary BURWELL.—the Secretary's comments hold.

Mr. ROGERS. Okay.

Secretary BURWELL. The Secretary's comments are also reflected—I have Fiesta plates, those are what my mother had. Those are the plates, those colorful plates, and my mother used those. The plates that I have from my mother, and the ones I received for my wedding, they are a different size, reflecting the issue that we, as a nation, I just think that is a visible thing that people see. My mom's plates, they are smaller, the ones I have from her. The ones that I received—and this gets to the issue of the totality that we need to work on at the same time that we think about the nutritional content. So we have too much, and we have to get the right nutritional content.

And what everybody wants is an opportunity to be able to have guidelines to do that. And that is what the *choosemyplate.gov* hits are about, and everything is about. Being a mother of an 8 and a 6 year old, and your time in the grocery story, having worked for the largest grocer in the country, Wal-Mart. The average time for a working mom or dad is, like, 20 minutes. And so your ability to get in there, get it done, and try and do it in a way that is healthy for your children, you need ease in decision-making. This is step one. It is just the guidelines. How it gets translated into other things are the next steps. That is what the Secretary's comment about what this is, and what this isn't, and why we want something that is useful for working families who are just trying to get this right for themselves and their children.

Mr. ROGERS. Great. Thank you both. I yield back.

The CHAIRMAN. The gentleman yields back. Mr. Walz, for 5 minutes.

Mr. WALZ. Thank you, Mr. Chairman. And I want to thank both of you for being here, for the work you do. And, Secretary Burwell, I appreciate that last comment, too, as a father of a young son, and someone who, as I often tell my colleagues, I supervised the high school lunchroom for 20 years, so you see that side of things, and how those school lunches impact. You brought up great points here, and this is an important hearing. And articulating what this is and what this isn't is really important. Because, at the heart of this, with so much information out there, and Americans are going to try and find it, from their uncle's e-mail to them to Dr. Oz and others, they are looking for the gold standard on what makes a difference in their own lives as they search for this.

And all we have to do is look at the cost of obesity in the United States, estimated at between $150 and $200 billion per year. This is an important subject. We need to help people find the informa-

tion. They are busy, there is lots of it. And that is why the questions that are coming up from colleagues about the integrity of your suggestions, as many of us saw, and still do believe, as the gold standard on how this gets done, and valid concerns about the decisions we make here. And, in full disclosure, I have the ninth largest agricultural district in America. We produce lots of pork, lots of milk, lots of turkeys, and all those things. When we make those decisions, they have an economic impact. So the concern is valid, it is warranted, but we have a responsibility to move headlong into this to help the American public get it. So, for me, and more a statement on this, we are concerned on process, and hearing that. It is important to hear both of you articulate that, and it is important for the American public to know that they can trust these as guidelines for them, and they are going to make decisions for their own family based on them.

So maybe what I would do is just ask you, what you are hearing on this process, do you feel like the concerns you are hearing from Members on the totality of the evidence and things, are you comfortable that those are being included when you make your guidelines? You are hearing about Members talking about things that aren't included, specific commodities that aren't in that? Are you comfortable? And maybe, Secretary Burwell, start with you.

Secretary BURWELL. Yes, that we are including these comments. And whether that is the blog that we issued yesterday, we had a number of questions about that sustainability issue, or the tax issue that we tried to address here today, that we are, across the board, hearing and listening. And you can be assured that the questions that you all are asking us are the questions that we will be asking our teams as the recommendations come forward. It was mentioned cranberries, and the issue of something that has high nutrient value, and the question of how that interrelates with added sugar, and how we think about those issues. Your questions become our questions as part of this process.

And we do believe—I mean, the comments that came in, as the Secretary mentioned, there were a number of repeat—8,000 were probably singular. There were 19,000 comments on sustainability: 97 percent of those comments, so we are clear and transparent, were positive, and that we should include sustainability as part of the *Dietary Guidelines.* And I say that to make the point that we want to hear. We are going to ask the questions, and then, based on what the *Dietary Guidelines* are, and the scientific evidence, that is how we will go about making the decisions.

Secretary VILSACK. I would only add that the debate that we are having here, and the debate that is taking place outside of this room, is a reflection of people's interest in where their food comes from, how it is produced, who is producing it, who is benefiting from it. And that is a healthy debate——

Mr. WALZ. Yes.

Secretary VILSACK.—for us to have, in the right context.

Mr. WALZ. Yes.

Secretary VILSACK. It is a healthy debate for us to have in the context of developing a farm bill. It is a healthy debate for us to have in the context of conservation, in the local and regional food system effort. All of those are avenues and vehicles for having that

conversation, and we are having that conversation, and we should have that conversation. This, however, is about dietary and nutrition, and that is what we are going to focus on as we develop these guidelines.

Mr. WALZ. Well, I very much appreciate that point of view. I am not going to miss this opportunity, with my last 40 seconds, Mr. Chairman. Mr. Secretary, again, off topic, but I am going to use it. The effect of sequestration on ARC and PLC. I am going to ask, if my folks are out there, if you could help me.

Secretary VILSACK. It will be a 6.8 percent reduction——

Mr. WALZ. Okay.

Secretary VILSACK.—across the board, regardless of when they came into the FSA office, or when they basically——

Mr. WALZ. So what they are hearing is true, there will be a reduction——

Secretary VILSACK. Yes.

Mr. WALZ.—to them?

Secretary VILSACK. Unless something happens with the sequester.

Mr. WALZ. Very good. I yield back. Thank you.

The CHAIRMAN. The gentleman yields back. Mr. Gibbs, for 5 minutes.

Mr. GIBBS. Thank you, Mr. Chairman. I have to tell you, hearing the Ranking Member's, Mr. Peterson's, comments that I agree with about everything he said. Why are we doing all this, if it is really necessary. And I make the comment that there is a lot of information out there to consumers. You have the medical associations, the cancer, heart. There are all kinds out there. I am encouraged to hear you say that the process—to make sure that the tax, sustainability issues aren't part of this, because they shouldn't be.

I guess my only demand, *demand,* would be that you use common sense, and say, moderation, people out there can make a lot of decisions on their own. There is a lot of information out there, and these guidelines should just be common sense things, that if you have a weight problem, you need to lower your calorie intake. So that is just my comment. I wonder if you know how much—I won't even bother to ask how much all this process costs, but I can just imagine.

But, Secretary Vilsack, what I want to ask you, these guidelines are supposed to be guidelines. And how does that have an affect on the school lunch program? Because we have seen the school lunch program be turned on its head, and there have been all kinds of reports of certain school districts that want to get out of the program, and there are guidelines—part of that effect of determining what is happening in the school lunch program?

Secretary VILSACK. Well, the school lunch program is, obviously, focused on compliance with the Healthy Hunger Free Kids Act, which passed Congress in 2010. And in that, Congress directed us to do a better job, in terms of the quality and nutritional value of those meals. More fruits and vegetables, more whole grains, more low fat dairy, and less fat, sugar, and sodium, and we are compliant with that. And, in fact, 95 percent of school districts have been certified as following the standards. Surveys of children, surveys of school administrators, surveys of parents, and surveys of the public

all indicate strong support for what we are doing. And we are helping school districts that are struggling through a series of programs—for success, where we are seeing struggling schools linked up with succeeding schools, and we are finding a good success for that program as well.

So the *Dietary Guidelines* help to inform, as they do with some of the other nutrition programs, as they do with the Department of Defense, in developing what they are going to serve our military. These *Dietary Guidelines* help to inform the process.

Mr. GIBBS. Okay. Because I am just really concerned what is happening in the school lunch program. I am hearing issues out there that kids aren't eating, their food is going to waste. There are things, when I was a kid, that I wouldn't eat that I eat—I love to eat today, so there are different behaviors——

Secretary VILSACK. I can say a couple things about that. Number one, there are several studies, University of Connecticut, Harvard Public Health School, that suggest that food waste is not as significant as it has been reported, and, in fact, is no greater than it was prior to the new guidelines. Number two, it is a matter of time. There is some research to suggest that if kids are given more time to eat there is less food waste. And the timing of the meal, in terms of whether it is before or after recess, may also impact that.

And then, finally, I had an interesting conversation with the President of Tufts yesterday, they did away with food trays at Tufts, and what they have found is that that has reduced significantly the amount of food waste, because kids came in with a tray, and they feel like they have to fill up the tray, as opposed to a plate. And they fill up the plate, they get satisfied, they don't go back for seconds, there is less food waste. So there is a lot of opportunity here for us, as a nation, to reduce food waste, but I don't think it is a reflection, or an indication, of the new school——

Mr. GIBBS. When USDA's working on the school lunch program and stuff, is there much discussion about physical activity? That is probably—maybe more so than what they are—I—especially in kids.

Secretary VILSACK. Well, we have over 6,000 schools that have now been certified under the U.S. Healthier School Challenge, which is an effort on our part to encourage both calories in and calories out. And we reward and acknowledge school districts that are doing a good job of balancing nutrition and exercise. We also have an interesting relationship with the Dairy Association, and the NFL, on their Fuel Up to Play 60——

Mr. GIBBS. Okay.

Secretary VILSACK.—program. So there is an——

Mr. GIBBS. Okay.

Secretary VILSACK.—emphasis on exercise.

Mr. GIBBS. Secretary, your comment about sustainability, and all the comments you had, I guess my only comment would be something that gets a little weighted by certain agendas, by certain organizations, we saw this in the *waters of the United States*. We saw a lot of comments that came in, and obviously that was orchestrated, and there are agendas out there, just so you are aware of that, and some of those comments are sometimes subject to how credible they really are. I yield back.

The CHAIRMAN. The gentleman yields back. Ms. Fudge, 5 minutes.

Ms. FUDGE. Thank you very much, Mr. Chairman, and I thank you both for being here this morning. On August 24 the Center for Nutrition Policy and Promotion issued a *Federal Register* Notice asking for input as to how to better inform the public about the *2015 Dietary Guidelines.* I think that is a great idea, because so many Americans really do not understand, and are confused, about the guidelines, and the dietary patterns. So tell me how you are planning your messaging around the guidelines, and if you have any just straightforward suggestions as to how Americans can improve their eating habits?

Secretary VILSACK. Well, we take the guidelines and incorporate it into our *choosemyplate.gov* initiative, which Secretary Burwell referred to it earlier. It is an opportunity for us to visually give people an idea of what a healthy plate looks like. The *choosemyplate.gov* website, which I mentioned before, is also part of our effort to try to do outreach. We also have a super tracker program that if you are struggling with weight—I have it on my iPhone—it basically gives you daily updates on—and suggestions on how you might be able to control your weight, tips on substituting foods and so forth so that you have a healthier, balanced diet. So there are a series of ways in which we incorporate the information from the guidelines in our educational materials, which we then disseminate through a variety of mechanisms, social media, and legacy media.

Ms. FUDGE. Thank you. How many American households do you believe are at risk for food insecurity, and how can the 2015 DGA address the critical needs of our most vulnerable populations?

Secretary VILSACK. Well, I can tell you our focus has been, obviously, on children, and there are 15.8 million children who live in food insecure homes. That number is down, which is good news. We, obviously, still have work to do. There are a variety of ways in which we can provide help and assistance. Some of the obvious ways are the SNAP program, and expansion of summer feeding, weekend feeding programs during the school year. There is an opportunity for us to also work with day care facilities and child care facilities to ensure that youngsters in those facilities get decent snacks.

And we mentioned the school lunch program. Unfortunately, a lot of kids today get ½ or at least ⅓, and in some cases all of the calories they consume in schools. So, to the extent that we can do a good job of not only providing school meals, school breakfast and school lunch, but also after school snacks through our snack program, these are all a variety of ways in which we can try to provide help.

The last thing I would say is that we are also trying to find creative ways for SNAP families to extend their SNAP dollar by giving them tips on how they might be able to use fruits and vegetables effectively in recipes. We are also making access to farmers' markets more available. Over 6,200 farmers' markets today, that is a dramatic increase in the number, now have the EBT cards that allow SNAP beneficiaries to access farmer's markets.

Ms. FUDGE. Which, by the way, works very, very effectively. I have it in my district, so I thank you for that.

Last, tell me how important it is to maintain the 5 year cycle for the *Dietary Guidelines,* so that Americans really do get the benefit of the current science for diet and health.

Secretary BURWELL. I think we think that the 5 year review is a very important part of doing many of the things that we are being asked to do, which is make sure that we have the most up to date science, and make sure that we are listening to the public, because it is a formalized process that we do hear from the public, and there are those opportunities. While it is in statute, and that is a big part of why we do it, I think we would agree that it is important to have points in time where you do the work, and settle, and do the analysis, and the listening. And so I think we think that updating it on a regular basis, on a 5 year cycle, is important.

Secretary VILSACK. I agree.

Ms. FUDGE. Thank you very much, Mr. Chairman. I yield back.

The CHAIRMAN. The gentlelady yields back. Mr. Scott, 5 minutes, Austin Scott.

Mr. AUSTIN SCOTT of Georgia. Thank you, Mr. Chairman. Madam Secretary, Mr. Secretary, thank you for being here. As we talk about the reports, the credibility of the report is arguably the most important thing. It doesn't matter how much time and money went into it, if we have a credibility gap, we have a problem. There were certainly some questions about the fact that Ms. Mylett was from the private sector now. I have read her résumé: 30 years at one of the major institutions, certainly qualified in every way, shape, and form from her academic career to be there. But there are questions about the fact that she is now a member of the private sector, chairing the committee.

Historically, we have not allowed industry representatives on the panel. And I recognize that she doesn't represent, for example, the cattle industry or the corn industry, because we would believe that there would be the assumption—whether true or not, there would be the assumption that there would be bias in the opinions of people who represented a certain industry on the panel. When I see issues like tax on sodas and other things being recommended, it seems to me that ideology is taking precedence over science, and that creates a tremendous credibility gap as well.

And I would just ask, as we go forward, how do we make sure that we don't have that credibility gap in the report? Because the CDC and the others do use this information to send out recommendations to the American public. And if the Nutrition Evidence Library is not being used, how do we guarantee the credibility of the report?

Secretary BURWELL. Do you want to speak to the nutrition library——

Secretary VILSACK. Yes, go ahead.

Secretary BURWELL.—and I will speak with regard to the credibility, that is a very important element of the trust of what we have in front of us, and that is why we are having the conversation. In the places where we can provide clarity, we do, as well as providing clarity—and that is a little bit of—some of our follow-up questions about, there is a scientific approach to what documents

are included, how they are included. That is the standard of scientific research. The gold standard is used. I have checked even with our economists, had them come in and look at it.

Mr. AUSTIN SCOTT of Georgia. Can I——

Secretary BURWELL. So clearing——

Mr. AUSTIN SCOTT of Georgia.—ask you a question there? If the standard is scientific research, how do recommendations for tax on sodas get into the report?

Secretary BURWELL. It is important to reflect that in the Advisory Committee's report that there wasn't a recommendation. It was an articulation that some used policy, and so I don't think there were recommendations. They did not make recommendations. But with regard to the issue that has been raised, when we get to the *Dietary Guidelines,* how we take what we are given, that is one input, and use it will be an important part of establishing a process that people believe in.

Mr. AUSTIN SCOTT of Georgia. I am down to a minute, so I would like to hear what Secretary Vilsack has to say, but I would suggest that, when you see those things in the report, and whether it is a jump to conclusion or not, there is a belief, then, that the people on the committee entered with a bias in some way, shape, or form, and we are searching for the science to back up what they already believe to be true, instead of using the best available science. Whether it is true or not, we can debate that there is a credibility gap from those things working their way into the report.

Secretary VILSACK. Congressman, I would like just simply to, again, emphasize there is a fundamental difference between the Advisory Committee's report and the guidelines. And there is confusion out there. For some reason, people seem to think that the report equals the guidelines. It does not. It is one aspect of information that will be taken into consideration, relative to the dietary and nutrition guidelines that we have to put together, number one.

Number two, the Nutrition Evidence Library was used, and there is an extensive process that is involved in accumulating information and putting it through a filter, if you will, of——

Mr. AUSTIN SCOTT of Georgia. Secretary Vilsack, I am down to 30 seconds, but it was used for 30 percent, at least the reports, that a tremendous number of things were not taken from that library. This is a text I received from a dad yesterday, and he is saying that their school can't sell candy bars, which they used to do to help pay for a kids' trip, and that they are being told from our local school system that that comes from the Federal Government——

Secretary VILSACK. That is not——

Mr. AUSTIN SCOTT of Georgia.—that they can't sell candy bars to raise money. Is that——

Secretary VILSACK. That is not true. Folks can sell outside of school, which is what these candy deals are. Outside of school, there is no prohibition. There are exceptions and waivers that can be granted. Oftentimes it is not the Federal law that is in place. It can be a state law that is that, or it could be——

Mr. AUSTIN SCOTT of Georgia. I don't think we would have that in——

Secretary VILSACK. Well, that may be the case. Well, then folks are mistaken about that.

Mr. AUSTIN SCOTT of Georgia. Thank you, sir, for clearing that up.

The CHAIRMAN. The gentleman's time has expired. Mr. McGovern, 5 minutes.

Mr. MCGOVERN. Thank you, and, Secretary Vilsack and Secretary Burwell, thank you for being with us today, and thank you both for your respective agencies' work on the Dietary Guidelines Advisory Committee's report. I know that this is no simple undertaking, and I appreciate the fact that it takes and requires months and months of scientific analysis and consideration of thousands of stakeholder comments, and thoughtful collaboration among committee members and agency staff. And I want to say that I appreciate the process that the Advisory Committee went through. It is a solid process, one that was open, and included, as you mentioned, many opportunities for the public to weigh in.

And it is also important, to kind of put all this in perspective here, my colleagues understand, that, in this country today, one in three school-age children and adolescents is overweight or has obesity. And more than one in three American adults suffers from cardiovascular disease and diabetes. Clearly we can do better. When I look at what we are all talking about here today, this is an attempt for us to get it better. And if people aren't interested in the well-being of our citizenry, and all they are interested in is the bottom line, they should be very supportive of what you are talking about here today, because, at the end of the day, healthier people mean lower healthcare costs. So we all benefit here.

You mentioned earlier the HHS blog yesterday, where the issues of sustainability were taken off the table for inclusion in the final guidelines. And I get that is the case, and I respect your decision, but this is an important issue, and you both have acknowledged that. *Sustainability,* somehow, in this Congress is a dirty word. I don't quite get it, but it is important, and we ought to be talking about sustainability when we are talking about issues of diet and food security. And I do think that it is important that at least we start this conversation about this issue in the context of *Dietary Guidelines.*

I also appreciate that both your testimonies do a good job of emphasizing the importance of nutrition on disease prevention, and putting these recommendations into context. In Congress we ought to be focusing more on prevention as a way to reduce healthcare costs and improve overall well-being and economic productivity. We should be highlighting what the science says on good nutrition for our kids and for our families.

I have an op-ed here today that was in today's *Hill* newspaper, penned by the Presidents of the American Academy of Pediatrics and the American Medical Association. It is entitled, *Physician's Perspective, Keep Politics Out of Dietary Guidelines,* and I would like to insert that in the record. In it they talk about the importance of *Dietary Guidelines,* and the soundness of science used to inform them. The issue was raised that sometimes science changes. Everything changes. We know more today than we knew yesterday. Our research techniques have improved over the last 10, 20, 30 years. So when we learn the latest science, then we need to make the necessary adjustments.

[The information referred to is located on p. 70.]

But, as you know, some of the biggest critics of these guidelines are from industries that produce the least healthy foods, and from special interests with questionable credentials. I was reading about some billionaire from Texas who is a former Enron executive who is funding some initiatives to try to raise questions about what you are doing. I don't know what Enron knows about *Dietary Guidelines,* but, nonetheless, there are powerful special interests out there trying to raise issues of credibility, trying to question science.

And so I just would conclude by saying I encourage you to keep, first and foremost, the health and well-being of our kids and our citizenry in the forefront as you move forward. And maybe, in my last minute, can you explain to me if we all improved our diets, what would be the impact on the rates and costs of diabetes, and heart disease, and obesity? Secretary Burwell?

Secretary BURWELL. When I examined both Medicaid and Medicare costs over the 10 year period, and as a trustee, as one goes out over periods of time, both heart disease, something that we know about how to do—and diabetes are two very, very large cost drivers for us as a nation. And they are cost drivers because those are both conditions that continue over an extended period of time, and especially as we have a population that lives longer, which is a good thing.

But the idea that these are costs that are controllable—and I would also say that in my engagement with the private-sector, and CEOs of companies—and I am sure you all hear this in your districts. They talk about wellness a lot. And the reason they are so deeply focused on this issue, and want to engage with us as a Department on the issue, is because they are putting initiatives in place because they are starting to see. And I was just actually with NAM this week, the National Association of Manufacturers, and had one of the CEOs who says she has done it now for almost 10 years, and she has the analytics to show it. Those are analytics companies can make decisions on. We want to see those to see if they are worthy enough for us to make decisions on the taxpayers' money.

So it is across the board in both the public-sector spending and the private-sector spending on these health issues, and diabetes and heart disease are two of the leading costs that we have, both publicly and privately.

The CHAIRMAN. The gentleman's time has expired. I would ask my colleagues' indulgence, Secretary Burwell has a hard stop at 11:30, and, given the apparent interest everyone has in getting these, I would ask for colleagues' unanimous consent to go to 4 minutes for questioning so that we give a chance for everybody to get here to make that happen. So, without objection, we will go to 4 minutes from this point forward. So, Mr. Crawford, for 4 minutes.

Mr. CRAWFORD. Thank you, Mr. Chairman. Kind of keeping on that subject, a lot of attention has been paid to the *Dietary Guidelines,* and the fact that they are guidelines, they are not rules. Am I correct in that?

Secretary BURWELL. Yes. They are guidelines——

Mr. CRAWFORD. Okay.

Secretary BURWELL.—that then are used as a basis for programmatic and policy decisions.

Mr. CRAWFORD. Okay. So they actually are used pretty hard and fast on rulemaking, then, correct?

Secretary BURWELL. It depends on which program. So, for instance, school lunch programs in our area—the Administration for Community Living——

Mr. CRAWFORD. Yes.

Secretary BURWELL.—in terms of Meals on Wheels and those types of programs, they are used, and they are applied in different settings in different ways.

Mr. CRAWFORD. We have heard a lot of talk about the school lunch program, and it seems that—and I know that my colleague mentioned he had gotten a text just in the last few minutes, and I have gotten phone call, after phone call, after phone call once the new school lunch program was implemented fully in 2012, but there has been very little attention paid to how we roll this out and apply it rigidly to the SNAP program.

And so it seems like using the argument that, well, we can be proactive, and we can sort of help to regulate the kind of food that people eat that we can control, the Secretary mentioned Department of Defense, and meals that our soldiers, sailors, airmen, Marines receive. We mentioned the school nutrition program, meals that our students receive, but we are not talking about actively engaging in how we do a better job in administering the SNAP program with respect to the sugary drinks that are often purchased, and all the other things that are bad, according to these guidelines. So why aren't we doing a better job of actually going in and proactively engaging in rules that help us do a better job on dietary structure, as it applies to the SNAP program?

Secretary VILSACK. Well, first of all, we are trying to address through a variety of mechanisms. The farm bill provided for the Food Nutrition and Security Initiative, which is designed to provide assistance and help for SNAP families to purchase more fruits and vegetables and alike. The expansion of access to farmers' markets is also giving them that opportunity. We are looking at a—we had a data-based, research-based program at Holyoke, Massachusetts for 2 years to determine what would actually provide direction for SNAP families, in terms of purchasing nutritious food, making nutritious choices. What we found was that incentives work.

Also, there is a fairly serious technology challenge, in terms of trying to prohibit people from using SNAP for certain products.

Mr. CRAWFORD. Okay, let me stop you right there, Mr. Secretary, because I know that our travel card will deny a purchase. If you try to fill up your car on official business with your travel card, and then put a Snickers on there, it will decline that purchase.

Secretary VILSACK. Well——

Mr. CRAWFORD. So I know the technology exists that we can do a better job in administering what the SNAP card can be used for.

Secretary VILSACK. There are 300,000 different products that are sold in grocery stores across the United States.

Mr. CRAWFORD. Right. We ought to identify the ones that aren't allowed.

Secretary VILSACK. Well, here is the problem. You want to do sugared drinks? Does that include apple juice, 100 percent apple juice? Do you want to permit that?

Mr. CRAWFORD. But that is my question, why are we not addressing that——

Secretary VILSACK. Well, I am asking, do you want to exclude that? Because——

Mr. CRAWFORD. No, I am asking you because we are not marking up a bill here. I am trying to get feedback from you on why the *Dietary Guidelines* are not more rigidly utilized in the——

Secretary VILSACK. They——

Mr. CRAWFORD.—SNAP program, they are in the school nutrition program.

Secretary VILSACK. They are used in the SNAP program, in terms of providing guidance and direction to SNAP families in terms of how they can extend their SNAP dollar, where they can buy fruits and vegetables, how they might be able to use recipes.

Mr. CRAWFORD. And you mentioned incentives. What kind of incentives are being used to incentivize people to make those smarter choices?

Secretary VILSACK. Well, the Food Insecurity Initiative is providing resources to a number of groups that are providing cash incentives. So when a person goes to a farmers' market, and they buy $5 worth of tomatoes, they actually will be able to buy $10 because of the additional incentive. So they get more bang for their buck. It is also an opportunity for associations involved to provide sales, to provide promotions, to provide recipes. There are a whole series of programs. We will be happy to provide you a list of all the grants that have been made under that initiative, and what actually is being done. I think that might be helpful to you.

Mr. CRAWFORD. Thank you, I appreciate it. I yield back.

The CHAIRMAN. The gentleman's time—Mr. Aguilar, 5 minutes—4 minutes, excuse me.

Mr. AGUILAR. Thank you, Mr. Chairman, and thank you both to the Secretaries for being here. I wanted to expand a little bit on that discussion. I participated, and I mentioned it to my colleagues before, in the SNAP challenge earlier this year. And the biggest piece that struck me was there was an end in sight, when I went through this challenge, but it was the budgetary constraints on healthy eating. And, Mr. Secretary, you were just talking about those programs, and the success that you are seeing there, and I hope that we can continue to grow those programs.

And I understand that, within the *Dietary Guidelines,* both USDA and HHS also plan to release marketing materials. And, Mr. Secretary, you talked about *choosemyplate.gov* as an example, showing folks how to live on a low budget and a balanced diet. In the Advisory Committee report it is mentioned that the best food patterns of healthy living include the healthy U.S. style pattern, the healthy Mediterranean style pattern, and the healthy vegetarian pattern. Do you know approximately how much it would cost to afford each of these lifestyles per week, and could you expand a little bit on the programs that educate low-income families on healthy purchases like the food insecurity program?

Secretary VILSACK. Well, the guidelines help to inform a series of meal patterns, and it goes from the high end to the low end. And the Thrifty Food Plan basically is the plan—I don't know the specific dollar amount. Obviously, it depends on the choices that people make, Congressman. But we need to sort of dispel the myth that healthy eating necessarily has to be more expensive. And here is why people think that. If you take a portion of potato chips and a portion of broccoli, in the past, the way we judge the value of that was by looking at 100 calories' worth of potato chips, and 100 calories' worth of broccoli. Well, 100 calories' worth of potato chips would be about three potato chips. One hundred calories' worth of broccoli would probably fill ½ this room. Obviously that is going to be more expensive. But what we ought to be doing is looking at portion sizes, because people eat more than three potato chips, and they don't eat ½ a room full of broccoli.

When you look at portion sizes, fruits and vegetables become affordable, number one. Number two, if you look at recipes, the use of canned and frozen vegetables and fruits also is an opportunity—there are ways in which we can stretch dollars, and so part of our education initiative is to provide people with the recipes and the information that will allow them to use fruits and vegetables more effectively, to understand that it doesn't necessarily have to be more expensive.

And then also the incentive programs that we have, where we work with foundations to encourage farmers' market purchases by incenting those, the food and nutrition incentives that allow grocery stores to offer additional bonus points, if you will, for SNAP families to purchase fruits and vegetables. I mean, there are a wide variety of things. And we are also working with food banks to make sure that the areas of opportunity that they have to help struggling families also includes more healthy choices. So there are a wide variety of steps and ways in which we are attempting to make a difference.

Mr. AGUILAR. I would love to see how we can stretch to become healthier. But, I would say, it was incredibly tough, Mr. Secretary, my wife and I, $66, on the SNAP challenge, to include healthy portions and to manage our portions. I ate peanut butter and jelly every day for at least one meal because we were trying to have a couple salads for the week.

Secretary VILSACK. The SNAP program, as everyone knows, is a Supplemental Nutrition Assistance Program. It is not designed, and not engineered, and not funded to be the be-all and end-all for a family——

Mr. AGUILAR. But for countless Americans it is.

Secretary VILSACK. Well, I understand that, but that is why we work with food banks, that is why we work with foundations, that is why we work with shelters, that is why we work with other avenues. That is why we have the school lunch and school breakfast programs that are expanding. That is why we have after school efforts, why we have a summer feeding program, to try to supplement and to——

Mr. AGUILAR. And I look forward to working with you to carry out the mission of those programs——

The CHAIRMAN. The gentleman's time has expired. Mr. DesJarlais, 4 minutes.

Mr. DESJARLAIS. Thank you. Thank you both for being here. Secretary Burwell, I can count on one finger the number of times that a sitting secretary has reached out to all the Members of a Committee prior to the hearing to ask if they had any concerns, and so thank you for that. I appreciate you doing that. I know that is time consuming, but very thoughtful.

Historically, the *Dietary Guidelines for Americans* policy document, which you say will be released in December, have not made suggestions about specific ingredients of commodities, yet that hasn't prevented the Advisory Committee from taking a look at aggregate consumption by the U.S. population, and potential health risks of ingredients such as low calorie sweetener aspartame. Aspartame is one of the most widely studied food additives in the history of the FDA, and its approval came after more than a decade of review through an affirmative food additive petition. FDA has asserted, and re-asserted, the safety of aspartame, yet DGAC used a dubious process to call into question its safety, citing extremely weak science against the backdrop of decades of research that shows otherwise. And now we are calling for more research, in spite of the fact that FDA spent over a decade studying this ingredient's safety, and concluded there is no increased risk of cancer from aspartame consumption.

During your inter-agency review of the guidelines, are you consulting with the FDA on recommendations after they spent years reviewing the science?

Secretary BURWELL. Yes, FDA is a part of the process at HHS. And, with regard to the issue of the safety of aspartame—and there are basically five products that FDA has said in given contents are fine and safe. And so, yes, FDA is a part of the HHS process.

Mr. DESJARLAIS. How did the inter-agencies review ultimately impact the final recommendations?

Secretary BURWELL. The inter-agency review is an extremely important part of the process. Both the Secretary and I have indicated that the input of the Advisory Committee is something that we are reviewing, but our own experts across our Departments, not just FDA for us, but CDC and NIH as well. The whole Department is a part of this process. It comes together, reviews everything together, and that is what forms the recommendations that we will receive from our Departments collectively together.

Mr. DESJARLAIS. Okay. Additionally, DGAC recommends replacing sugared beverages with water or low fat milk only. However, for the guidelines to be effective to most Americans, we need to be able to meet them in the middle and offer guidelines that are realistic, not idealistic. In your final recommendations, how do you intend to balance dietary ideals that are realistic and achievable for most Americans?

Secretary BURWELL. With regard to that question, getting ahead of where the recommendations are from our staff, I wouldn't be able to comment on the specifics. But we do look for a balanced approach and an evidence-based approach. With regard to where we have the evidence about issues of—when we say balanced, it is also about this issue the Secretary raised of nutritional value. And so,

when you are trying to have a set number of calories, and you have to get in certain numbers of nutrition, how you can get that puzzle to fit together is an important part of what we will think about as we put together the final guideline.

Mr. DESJARLAIS. Okay. Thank you, Secretary. Secretary Vilsack, at the December meeting, before the final Advisory Committee recommendations were voted upon, the committee got in a discussion about the definitions of red *versus* lean *versus* processed meat. At the end of the discussion they decided to remove lean meat from the healthy dietary pattern, even though the scientific data in their own report was not changed, and the same, as the *2010 Dietary Guidelines,* which recognized lean meat as a nutrient-dense food, and nutrient-dense foods were encouraged to increase.

It is important for the *Dietary Guidelines* to have a strong scientific background, peer reviewed and published research to give Americans clear advice on their diets and health. Can you please give me the assurances that you have both taken into account to ensure strong scientific evidence is the foundation for the 2015 guidelines?

Secretary VILSACK. I can, and I can also suggest—it is my understanding, and maybe I am wrong about this, that the report basically is fairly consistent with the recommendation that was made in the 2010 guidelines with reference to lean meat. I would be surprised if our final conclusion is not to include that as part of a healthy diet.

Mr. DESJARLAIS. Thank you, sir.

The CHAIRMAN. Mr. Costa, 5 minutes.

Mr. COSTA. Four minutes, I got it. Thank both Secretaries for your efforts in reaching out. I do appreciate that, and to the degree that we collaborate on a greater basis, we all do a better job.

A lot of discussion this morning has been talking about the process in these guidelines, and I do appreciate your emphasizing that they are guidelines, as a part of a total work product. And I guess I would like to get your take, both of you, on how we measure success. Clearly we all believe, or I hope it is not in debate, that part of healthy Americans is a healthy diet, and it is part of preventative health care. As our mothers told us a long time ago, an ounce of prevention is worth a pound of cure. So how do we measure success in terms of the incredible changes that have been taking place in American's dietary habits over decades, and this effort to use these guidelines as a means to provide better diets so that we have healthier lifestyles? Have you thought about that in this process?

Secretary BURWELL. So——

Mr. COSTA. I mean, we are asking you the questions. How can we make this process better?

Secretary BURWELL. When we think about success, first, the guidelines themselves being a quality product. We need to start with that, and that is a lot of the conversation that we are having today, about an evidence-based and quality product. The second thing is how the guidelines get used in an appropriate fashion, in terms of people understanding what they are and——

Mr. COSTA. Do you think we are making progress along those lines?

Secretary BURWELL. I think it——

Mr. COSTA. There is a lot of advertising out there that tries to, especially among young people, skew their eating habits.

Secretary BURWELL. Yes, and so that comes to the third, which is the knowledge has to be activated so that people are acting and behaving. And those are all places where we believe that we, as a nation, can improve. And we can improve it both at a population health level, and then we improve it in the ways that we use it in the programs. And whether that is the programs at USDA, or the programs at HHS, in terms of applying them. And CDC, and its work in population health, is another place that I believe we can make progress.

Mr. COSTA. Secretary Vilsack, you have been at this for 7 years.

Secretary VILSACK. Congressman——

Mr. COSTA. How do you measure success?

Secretary VILSACK. I would only add to what Secretary Burwell said, is that one way, potentially, of looking at this is to take a look at the healthy eating index that we have, which is a 100 point system. And currently today the average American is about 57. We have seen improvement over the last couple of years. That is good, but obviously—I don't know what your mother said about 57 out of 100, but my mother wasn't satisfied with that.

Mr. COSTA. No.

Secretary VILSACK. So it is important for us——

Mr. COSTA. Not good.

Secretary VILSACK.—to continue. That is one index. That is one way of measuring. Another way is to measure whether or not we are making headway on obesity. I am pleased by the fact that, at least among young children, we are beginning to see some indication of a plateauing, and potentially maybe even a slight decline in obesity rates. That is good news. But we still have work to do.

And in terms of improving the process, I would say that this debate is healthy because it allows people to understand what these recommendations are, and what they aren't. And there is a misunderstanding between a prevention orientation, which is what these guidelines are, *versus* a treatment orientation, a lot of the criticisms often are because you aren't dealing with certain diets that would be helpful in dealing with obesity. And so maybe there is a way which we could potentially expand, or create an avenue, for that kind of treatment discussion to take place.

Mr. COSTA. Okay. I have other questions regarding GMO labeling, and biotech traits as it relates to that, and I will submit that for the record, because there is no time. I guess, just a final comment, and it is getting back to good habits. When I grew up, it was a few years ago, but 8 ounces was considered a regular thing, and a 12 ounces was really considered big. And then I remember we were all floored by 16 ounces. Today, you see 24 ounces. It is a large part of the problem, just sizes and amounts as it relates to obesity, and how we combat against obesity. That is a comment.

The CHAIRMAN. The gentleman's time has expired. Mrs. Hartzler, 4 minutes.

Mrs. HARTZLER. Thank you, Mr. Chairman. Thank you, Secretaries. I really appreciate the work that you are doing, as a former family consumer sciences teacher who taught nutrition for many years. It is very, very important, and very important to be science-

based. I am very encouraged to hear that you are going to make sure that it is that, and doesn't include sustainability, tax policies, other issues.

I wanted to focus on the Nutrition Evidence Library. We have heard much about it, with even the USDA officials describing it as the gold standard. But I have heard concerns that the Nutrition Evidence Library has ignored a large credible and growing body of peer-reviewed science on low carb diets, as it contradicts the evidence from previous guidelines. So can you elaborate on how scientific studies are added to the Nutrition Evidence Library, and what can be done to ensure that cutting edge research in nutrition science is considered?

Secretary VILSACK. Well, there are four approaches as it relates to the library. There are original systematic reviews, there are existing reports, there are new reports that are funneled in from a variety of different locations. There is a review of what the typical diet of an American might be. Food pattern modeling is also included. So there is a broad array of things that are included in this effort.

The issue of low carb diets raises the point that I just made with Representative Costa. I think that is ultimately in the context of how do you treat a particular condition, obesity, for example? It may very well be that a low carb diet, or a high protein diet, might be a way in which a physician would prescribe for an obese individual to deal with obesity. That is not what these guidelines are about. These guidelines are about preventing that circumstance to begin with.

There isn't an avenue within the guidelines today for that treatment discussion, and that is why there is a lot of confusion about all of this, and why there is a lot of angst about it, because some people are looking at the guidelines as treating all health issues, and we are looking at what the law requires us to do, and that is——

Mrs. HARTZLER. Sure.

Secretary VILSACK.—focus on dietary and nutritional guidelines relative to prevention.

Mrs. HARTZLER. Now, some people point out that 52 percent of U.S. adults are pre-diabetic, and they allege that a low carb diet helps prevent people becoming pre-diabetic, so it is actually——

Secretary VILSACK. So in that——

Mrs. HARTZLER.—would be helpful to include that.

Secretary VILSACK. So in that circumstance you have competing studies, which is why it is important to understand this is really about well-informed opinion. I wish there were scientific facts, but the reality is stuff changes, right? Stuff changes. And the key here is taking a look at the preponderance, the greater weight of the evidence, and trying to make a judgment based on the greater weight of the evidence. If you have one study on one side, and you have 15 studies on another side, the preponderance of the evidence may be on this side, with the 15 studies.

And that is a challenge, and that is why we do this every 5 years, to give an opportunity for that quality study to be further enhanced so that, 5 years from now, maybe there are 15 studies on this side, and 15 studies on this side.

Mrs. HARTZLER. In the guidelines——

Secretary VILSACK. It is an evolving process.

Mrs. HARTZLER. In the guidelines, are there any disclaimers mentioned in there that say for certain populations, this might not be true, or for certain populations this might be helpful? Do you include that, or do you just pick one and say, this is it?

Secretary VILSACK. It isn't so much that. It is a caveat that these are recommendations focused on prevention. They are guidelines. They are not saying, "You shall do this." They are recommendations and suggestions that you should do this. And that, sort of an indirect way——

Mrs. HARTZLER. Yes.

Secretary VILSACK. We obviously haven't crafted the guidelines yet, so I don't know whether or not they will be caveats as——

Mrs. HARTZLER. Yes, is there any population—I mean, there has to be differences, perhaps, for different populations——

Secretary VILSACK. Well, there are——

Mrs. HARTZLER.—the guidelines may not be one size fits all, or do you present it as everybody—this is for——

Secretary VILSACK. It is a general guideline. It is a general set of recommendations. It is—I mean, in theory, you could have 317 million different guidelines——

Mrs. HARTZLER. Yes.

Secretary VILSACK.—because we are all slightly different, in slightly different circumstances. So you have to create kind of a wide berth here, but within that wide berth, this is what we are recommending. If you are interested in a healthy diet, if you are interested in reducing the risk of diabetes and cardiovascular, this is a course that you might want to consider. Obviously, people are going to make choices and decisions based on what is best for them.

The CHAIRMAN. The gentlelady's time has expired. Ms. Plaskett, for 4 minutes.

Ms. PLASKETT. Yes, thank you, Mr. Chairman, and good morning to you both. Thank you so much for your time today. I was just looking at the volume of comments that you had received, the 29,000 comments after the report came out. Can you explain how you are going to, and will you be able to, meet the timeframe that you have for an evaluation of all of those responses to be able to issue that report, the guidelines?

Secretary BURWELL. Yes. Our staffs have gone through all of the comments. One of the things that is helpful, in a sense, is that a large percentage of them actually were form letters. So, as the Secretary reflected, only about 8,000 were individual. Not only, but that is less than 29,000——

Ms. PLASKETT. Yes.

Secretary BURWELL.—in terms of our ability to get through. And the Secretary and I are both working very hard with our teams to meet the deadline of this year.

Ms. PLASKETT. Okay, great. And I guess my other question is related to moderate alcohol intake. And, looking at the guidelines that were issued in 2010, I noted in the 2015 Committee Statement that it confirmed the conclusions from 2010. Do we think that that

is going to remain the same, or what is considered moderation? Will that change as well?

Secretary BURWELL. So, as you appropriately reflect, the Advisory Committee has the identical recommendations from the 2010 report. While we are not going to comment on specifics, it is important——

Ms. PLASKETT. Yes.

Secretary BURWELL.—to reflect that there was no change.

Ms. PLASKETT. Okay.

Secretary VILSACK. After this hearing, I may be consulting that guideline.

Secretary BURWELL. The FDA would say he meets age requirements.

Ms. PLASKETT. And that is two for males, right?

Secretary VILSACK. Good enough.

Ms. PLASKETT. Well, I just want to thank you all for the tremendous work you have done. This is really important to the American people. I am just echoing my colleagues' discussions about proportion sizes, and the need for healthy diets, particularly in communities in which there may be a dearth of fresh foods that are available to them as well.

And also, let us not forget, in terms of obesity, the thing we haven't talked about, which is not just your diet, but exercise as well, which is something that Americans have been woefully lacking for our young people for some time now. So thanks very much. I yield the balance of my——

The CHAIRMAN. The gentlelady yields back, and I don't think the Secretary—after 5 o'clock, did you? Mr. Rouzer, 4 minutes.

Ms. PLASKETT. It will be 5 o'clock somewhere.

Mr. ROUZER. Thank you, Mr. Chairman, Secretary Vilsack, Secretary Burwell. Thank you both for being here today. I appreciate it very much, because this is an incredibly important issue, and I am looking at this from a very macro perspective. We have close to a $20 trillion debt. Medicare and Medicaid, which you referenced a little earlier, is such a huge component of that debt because the vast majority of our budget is mandatory spending. Medicare and Medicaid are a huge component of mandatory spending.

And so you consider the obesity issue that we are facing, and you mentioned obesity and heart disease as two major components that drive the cost of Medicare and Medicaid. All that gets back to what we consume. And back to my time, when I was in K through 12, *versus* the schools that I go in today, when I look at the student population, I do not recall, at least, when I was growing up, the number of overweight kids that are in school that you have today.

And I visit all kinds of schools all across my district, and I would say ⅓ of them are clearly overweight. And some of them are really young, I mean exceptionally young. And some of them I know their parents, I knew their grandparents, and obesity was not an issue in the family until this generation. And so that leads me to think that clearly something has changed in our society over the last 20 years, in particular, and I look at it from the perspective of that you have different movements out there influencing public policy. In the Dietary Guideline Advisory Committee, there is the statement in there that says common characteristics of dietary patterns

associated with positive health outcomes include lower consumption of red meats.

It was mentioned earlier about caloric diet, trying to maintain a certain number of calories. Well, not all calories are the same. I would suggest, just from a common sense perspective, 2,000 calories of beef *versus* 2,000 calories of donuts are very different. Your body reacts to it very different. Your body takes the carbohydrate and turns it into sugar, and that often goes straight to the belly. Whereas consumption of protein, same calorie amount, the body treats it very differently. In fact, if you go and have a blood test done, they measure protein level in your blood, which suggests that obviously protein is a key component to a healthy lifestyle.

So my main point that I want to drive home this morning is that it is very, very important to understand that there is a difference, not all calories are the same. And, from a public policy standpoint, perhaps maybe we have gotten too smart for our own good. I recognize science has improved dramatically, but mankind has survived for many a thousand a year on red meat, whole milk. In fact, I remember growing up when there was a report that came out that said apple juice was bad for you, and then they came out and said, actually, no, we are wrong. Eggs, bacon. I remember growing up where they said, "May contribute to high cholesterol and heart disease."

I want to make sure that we get back to common sense, and that we do what is right for future generations, because—not only for the health standpoint, but that translates directly in terms of the public policy decisions we have to make as it relates to our budget.

Finishing it up here, I want to ask both of you——

The CHAIRMAN. You can't ask anything at this point. We are going to have to keep going. Ms.——

Mr. ROUZER. No problem.

The CHAIRMAN.—DelBene, 4 minutes.

Ms. DELBENE. Thank you, Mr. Chairman, and thank you both for being here and for your time today. First I wanted to ask you about dairy. As you know, it has been a distinct food group in the past, and, according to the report, dairy products contribute many essential nutrients, Vitamin D, calcium, magnesium, iron, Vitamin A, riboflavin. And yet, since 2010, one percent flavored milks haven't been allowed in schools, and we also know that dairy consumption has dropped in girls ages 4 to 8. And so I just had a couple questions: how do we continue to make sure students have access to appealing and nutritious dairy products, and do you expect that dairy would remain its own food group, going forward?

Secretary VILSACK. Well, I don't want to assume what we are going to do, in terms of the guidance, but I will tell you that one of the things that we have done is to work yogurt into the school lunch program. And we are also taking a look at the issue of milk, relative to school meals. So that is in the process, not in the context of the guidelines, but in the context of our efforts to try to encourage healthier choices at schools.

Ms. DELBENE. Yes.

Secretary VILSACK. I don't think there is any question that dairy is an important component. It is going to be recognized, and should be recognized.

Ms. DELBENE. And, kind of on a different note, given that we have regional, cultural, socioeconomic diversity throughout the country, how will the *Dietary Guidelines* meet the challenges of being relevant, accessible, achievable for all Americans, knowing that, folks have different backgrounds, cultural backgrounds, that may impact the types of foods that they are eating?

Secretary BURWELL. I think that many of the programs that the Secretary has spoken about, in terms of how you put those out, it is about having information that is simple enough that you can use it in your own cultural context, and then it is about a number of the programs, in terms of how the information moves. Not just the guidelines themselves, but then the programmatic piece that follows on. So it is the step beyond the guidelines. Having guidelines that are clear and simple enough that can be applied across context is the first step, but then it is how those guidelines are then implemented.

Secretary VILSACK. Right. Our work at USDA with Native American populations, is a good example of where we are trying to work to reflect the traditions and culture of Native Americans and Indians to make sure that their dietary choices are a wide enough range that they can meet their cultural and traditional needs.

So there is a greater sensitivity, and that is the challenge for us in the future, which is to understand those differences, and to try to figure out creative ways from recipes, and from direction and instruction, to reflect those differences without necessarily getting to a circumstance where we have to move away from the purpose of these guidelines, which is a—sort of a general recommendation.

Ms. DELBENE. Thanks. I guess it is also, then, important to understand what the messaging might be, going forward, and how different folks will understand and be able to learn about the guidelines as well.

Secretary VILSACK. Well, there will be an extensive effort at both Departments, but certainly at USDA we will be using all of the tools that we currently have, which have been pretty effective. The *choosemyplate.gov* has been one of the more effective efforts on the part of USDA. We are going to refresh that, obviously, the *choosemyplate.gov*, the super tracker, the SNAP education and nutrition information that we provide to SNAP families, the work that we will continue to do on menus with school lunch personnel. There are a variety of ways in which we can incorporate and assist folks in trying to follow these recommendations.

Ms. DELBENE. Thank you both again for being here, and I yield back, Mr. Chairman.

The CHAIRMAN. The gentlelady yields back time. I need to apologize, Mr. Rouzer. I was brusque and rude. I should have simply said your time has expired. So, David, please accept my apologies.

Mr. ROUZER. No problem, Mr. Chairman.

The CHAIRMAN. Mr. Kelly, 4 minutes.

Mr. KELLY. Thank you, Mr. Chairman. Thank you, witnesses. The *Dietary Guidelines for Americans* have been published every 5 years since 1980. We are concerned that the public at large has lost faith in the process to develop the *Dietary Guidelines,* which will ultimately decrease the adherence to them, with potentially costly effects on public health. In the military, in my service, we often say

you can have an SOP, standard operating procedure, but if your units and your soldiers don't know them and use them, you don't have an SOP. It is the same thing with guidelines.

Before coming to Congress I was a prosecutor, and I understand that two people can look at a problem and come to a different solution. And, Secretary Vilsack, during your process you talked many times about the preponderance of evidence, but as a prosecutor, I didn't get by with that standard, because the things that I was doing were so important that I had to prove beyond a reasonable doubt my case.

Because for different things and different priorities, the importance of them, sometimes we have to use a different standard of evidence, and I would say maybe a preponderance of the evidence for scientific evidence is not the right standard. Maybe it is clear and convincing evidence. Or maybe it is beyond a reasonable doubt that, when we have science, that we hold them to a standard that makes sure that the end result is something that we have a good belief that it will be viable, and it will be the right answer. Although we won't always be correct, if we raise the standard, maybe we will be correct more often.

Secretary VILSACK. Congressman——

Mr. KELLY. Further—if I can finish—there have always been disagreements about this, and there always will be, about what the science is. I just say, sometimes we may want to look at the standards. But over 1,350 percent increase in public comments, it raises some concern with me that people don't have faith in the system.

So, to both of you, I just ask you, what can we do? Because it doesn't matter how good the standards are, and it does not matter if we are doing the right things, if the public doesn't have trust that it is the right thing, we have to build that trust. And, Secretary Vilsack or Secretary Burwell, what would you do to make sure that our public believes that the standards of the guidelines that we are putting forward are the true and correct ones? Thank you.

Secretary VILSACK. Congressman, first of all, the preponderance of the evidence standard is a Congressional mandate, so we have to follow the Congressional mandate. So if you all believe that it should be a higher standard, that is obviously your call, and whatever your call is, we will follow it. Second, despite the fact that we had 29,000 comments, we have also had 290,000,000 hits on our *choosemyplate.gov* website, which would suggest to me that people are following these guidelines, they are interested in these guidelines, and they haven't necessarily lost confidence in them. So that is another data point that I think is important to take into consideration.

And I see this as a positive thing. Maybe I am looking at this wrong, but the more public input that you have, the better the decision-making can be. And we are obviously going to take all this information into consideration, as we should, and there are a variety of input focuses on all of this, and hopefully we are going to come up with the best guidelines that continue to have the faith and confidence in the American——

Secretary BURWELL. And I would just add, even as we implement the statute in preponderance, that, as you appropriately indicate,

there are different levels of evidence, and it is related to your colleague's earlier comment about aren't there different populations that are affected in different ways? And the evidence that we look at, and whether that is on the issue of sodium, and what that recommendation will be, and what we did last time, it does look at different places, where there is more evidence or less evidence. And that is something that is important to do, and we do follow statute. But we hear your point——

Mr. KELLY. Thank you.

Secretary BURWELL.—and the scientific review actually—when we get our——

Mr. KELLY. If I can just—I have 10 seconds. If I can have one further point? I just think it is just important, that the citizens want to know that we are not using science to justify ideology, that it is the other way around. Thank you, and I yield back, Mr. Chairman.

The CHAIRMAN. The gentleman's time has expired. Mr. Davis, 4 minutes.

Mr. DAVIS. Thank you, Mr. Chairman. Thank you, Secretary Burwell. It was great to speak with you last week, and thanks for being here and talking about this very important subject. Secretary Vilsack, I know you are probably going to be surprised by this, but I am not going to ask you about the school lunch today. It has been discussed already, so I will skip over that. But I do have some concerns.

My most serious concern today is what I see as a lack of evidence to show that the recommended dietary patterns proposed by the DGA have been based on any evidence on children. According to the citations in some previous advisory reports for recommendations, the recommended diet has been tested almost exclusively on middle-aged men, and women, whose nutritional needs, obviously, are very different from young people and growing children.

In particular, I am concerned because young children need certain vitamins and minerals, obviously, in order to grow and develop. We are talking about where, in previous reports, the expert report states that the recommended dietary patterns do not meet sufficiency goals for potassium, Vitamin D, Vitamin E, choline, and that Vitamin A sufficiency may be marginal. These are essential basic nutrients for growth and health in children, and as a dad of a freshman in high school, and a coach, these are things that concern me on a regular basis too.

At the same time, the DGAC appear to be deficient in their role in developing nutritional guidance to meet the basic nutritional sufficiency for children to grow and be healthy. They were expanding their review of what has been referred to as the dining out topic. Specifically, the fast food category was broadened to capture other types of dining out venues, including, like, quick serve, casual, formal restaurants, and grocery store take-out.

And, given today's busy lifestyle, and really, when you look at restaurants, they have offered a lot more healthy choice than what we saw just a decade ago. And, with that, I am kind of disappointed, and others are disappointed, that restaurants seem to be singled out, even though they are doing their best to offer healthier options to customers, and that concerns me. And I just

find it difficult to understand that location in which we would eat, without any other consideration, automatically impacts the quality or nutritional value of the food served. And I certainly understand that some restaurants may serve better food than others, but that is the consumer that can make that final decision on that too.

So, Secretary Burwell, wouldn't you agree that the nutrient content of food is more important than where the food is purchased, and that, rather than directing people away from dining out, maybe we should focus on helping to educate them on their nutritional choices?

Secretary BURWELL. So, with regard to the issue of children, and the amount of research and evidence that we have in that space, even as we are preparing to complete where we are now, the conversation—my team actually brought up the issue of children yesterday, as we look to making sure we have appropriate evidence for a number of the things that you are talking about for the next set. Because, what you are appropriately reflecting is the research doesn't exist because it is on older, so we need to get started on that now. So with regard to the issue of, do we need to understand this better, we don't have the facts yet. We don't have a science base, but if we start now, we will for the next.

With regard to the question——

Mr. DAVIS. Great.

Secretary BURWELL.—the dining out——

Mr. DAVIS. And I appreciate that.

Secretary BURWELL.—the dining out question, right now 30 percent of your calories, for Americans, are consumed outside the home. And with regard to how we think about making sure that——

Mr. DAVIS. What percentage?

Secretary BURWELL. Thirty percent. So when that is happening, what we need to focus on, with regard to this issue, is making sure people have appropriate information. That is what we want to do, is make sure that people have appropriate information to make the choices. As you reflect, it is up to people to make their own choices in that context. And that is where we touch on that issue. And, again, always separating the Advisory Committee's work with the work that we are doing.

Mr. DAVIS. Well, thank you again both. My time has expired.

The CHAIRMAN. The gentleman's time has expired. Mr. Benishek, 4 minutes.

Mr. BENISHEK. Thank you, Mr. Chairman. Thank you both for being here today. I want to follow up on a few of the thoughts that Representative Hartzler had. As a physician, I have been involved in peer-reviewed science in my training, and in my career, and I am a little bit concerned about some of the things you guys have said here. You brought up the fact that the AMA brought out that 52 percent of Americans are pre-diabetic, or diabetic, and yet, the dietary recommendations, as I understand it, are not really appropriate for that. There are too much carbohydrates. These people have a carbohydrate intolerance, and there are more carbohydrates in the diet that you are recommending than is really appropriate for that. And you mentioned that this would be a treatment, but

this is really not a treatment. This is a preventative problem, and I think that you have to address that more.

Those are my comments, but one of the questions that I had is, how are the studies taken, how do you determine what studies to base your science on? I have evidence that this evidence library included some trials, while excluding several other larger trials, some of which were funded by the NIH. I don't know why all the studies aren't included in the data. How does that not lead me to believe that there is a pre-determined result that has been looked for?

Secretary VILSACK. Well, the process starts with a series of questions that are formulated, and then information is accumulated, and it goes through a process of evaluation.

Mr. BENISHEK. Is the NIH involved in this process?

Secretary VILSACK. Well, it is involved in the sense that the NIH helps to fund studies that——

Mr. BENISHEK. I know, but I mean they are not involved as interagency review of how the studies are picked?

Secretary BURWELL. I think there are two different processes. There are three. One is the library of materials that people use, and that is housed at USDA. I think the second is——

Mr. BENISHEK. So is stuff excluded from that library? Who makes the choice of what goes in the library?

Secretary VILSACK. Well, there is a process that the folks at the National——

Mr. BENISHEK. That is what I am asking. Is the NIH involved in that process? I mean, I am just surprised that NIH funded studies, some of which were larger than the studies that you rely on for your data, contradictory studies, funded by the NIH, are not included in the data. So I am just kind of wondering why.

Secretary VILSACK. If you can give me specific——

Mr. BENISHEK. Well, yes, I can do that.

Secretary VILSACK. Yes, I will be able to provide you a specific answer as to why that particular study, or series of studies, were not included, or perhaps they were, and we are having a——

Mr. BENISHEK. Well, my understanding is they are not. That is——

Secretary VILSACK. Well——

Mr. BENISHEK.—why I am concerned, because that is leading to my question, and some of your comments suggested that diabetes, and pre-diabetes, and obesity are major problems in this country. And, because of the cut down on the fat portion of the diet, we are recommending more carbohydrates. Well, this is a—that is exactly the problem that pre-diabetics and diabetics have, is not being able to respond to carbohydrates. So, I mean, for the majority of the people, 52 percent of the people being pre-diabetic, this is the wrong diet to recommend.

So when you say it is a general diet, well, that is great, but then shouldn't it be the caveats that Mrs. Hartzler mentioned? This is pretty serious stuff here, somebody else mentioned, when we were kids, people aren't as fat back when we were kids, and we are eating more fat. And, frankly, it is not an exercise thing, as far as I can see, because I am experienced with it. If you eat a lot, you can exercise it all off. You have to get it right.

The CHAIRMAN. The gentleman's time has expired.

Mr. BENISHEK. I am sorry. I did go on, but——

Secretary VILSACK. Mr. Chairman, if I could just have 30 seconds. I would say that the NEL website will provide you the information as to why certain studies weren't selected, but if you get us specific information, Congressman, we will be happy to provide you specific answers to specific studies.

The CHAIRMAN. All right. Mr. Allen, for 4 minutes.

Mr. ALLEN. Yes, and I will just follow up on that question, as far as the NEL was concerned, and as far as the Dietary Guidelines Advisory Committee did not use the NEL for more than 70 percent of their research questions, why was the NEL not used in these guidelines?

Secretary BURWELL. For certain issues, like food pattern analysis, that they needed to do to understand what we actually are eating, an issue that has been brought up a number of times in this hearing, that is not information that would be available there, and they need to turn to other sources for that information to understand what is it actually Americans are eating? The sources for that are different. I think there were some other issues.

The reason it is not all there is if the question—if that is not where the source of information can come from, there are certain data analytics, and there are also places where systemic reviews have already been done on the issues, and while they do their own systemic review, they at least consider the other systemic reviews. And so I don't think those are counted in that percentage. But, Secretary, since that is housed at——

Secretary VILSACK. Well, the only other thing I would say is that the review process goes through a series of mechanisms to try to provide an understanding of what the best science is, the best available science is, and the least biased science is. And it is a series of things, the Cochran Collaboration, the Academy of Nutrition and Dietetics, the Aging for Healthcare Research and Quality, the Data Quality—all consistent with the Data Quality Act. So that is the other parameter that we have to work under, is that the Congress has given us direction, under the Data Quality Act, as to how this is to be managed.

Mr. ALLEN. Well, the NEL is basically science-based. There is very little ideology there. They go by exact science. And I didn't quite understand why you—still don't understand why you are not using them as a—more of a resource in these guidelines.

Secretary VILSACK. They are used——

Secretary BURWELL. Extensively.

Mr. ALLEN. Extensively.

Secretary BURWELL. It is only when a question can't be answered—one of the issues is certain of the data analytics around what everyone is eating right now are different sources, is my understanding of why the Advisory Committee didn't use it. That is the kind of——

Mr. ALLEN. So they didn't have the information on more than 70 percent of the research?

Secretary BURWELL. I think there are a number of other places that the Advisory Committee has to turn to other things, and they do that.

Mr. ALLEN. Regarding sodium, obviously, there are some of us that retain fluid, and there are others who do not retain fluid. Sodium, back in my athletic career, I took salt pills, and I had a hard time retaining fluid. Of course, now it is the opposite, I am on a low sodium diet. All this stuff is very personal. It depends strictly on your DNA, and that sort of thing. In my opinion, it is very dangerous to set forth guidelines when everybody has a different DNA, and at different ages you have different requirements. And, of course, we already talked about it doesn't apply necessarily as much to children.

And the mistrust here is that this one size fits all thing. Because, folks are getting a lot of bad information in our SNAP program. They are really not getting good information, and then the consequences are this epidemic of diabetes that we have, particularly in Georgia, with folks who do not know how their diet works, and how it fits. Is there any way to get this more locally based, rather than Washington top down?

Secretary BURWELL. We want to get it to the place where it is useful, and I think that is a big part of the conversation. With regard to the issues like sodium, we do take care to not put something—a standard that—it is the standard for everyone, not the standard for individuals. And then, this is about how one implements, in terms of—if it is the standard—but if you have a certain disease condition, then we need to figure out how we, in a public health setting, and other settings, can provide the right information for you. Because the IOM has said 2,300 milligrams of salt, but perhaps right now, for you, in your current state, that is not actually accurate.

Mr. ALLEN. Yes. I am less than 1,000. And I yield back, Mr. Chairman.

The CHAIRMAN. The gentleman's time has expired.

Secretary BURWELL. So we have to make sure, even though we set at 2,300, that we can have a forum in which we can communicate, so you know where to turn, together with your physician.

The CHAIRMAN. Mr. Moolenaar, for 4 minutes.

Mr. MOOLENAAR. Thank you, Mr. Chairman, and Secretary Vilsack, and Secretary Burwell. Thank you for being with us, and my apologies for my voice. It still hasn't gotten better since yesterday. I wanted to mention just a couple of themes that I have heard, especially you, Secretary Vilsack, stating today is that you don't want to assume what we will do with the guidelines. You don't want to pre-determine what the outcome will be. Is that a fair assessment?

Secretary VILSACK. The process hasn't been completed yet.

Mr. MOOLENAAR. Okay. And then one of the other themes I heard you say was that the more public input you have, the better decisions we will have. Is that a fair statement?

Secretary VILSACK. Yes.

Mr. MOOLENAAR. Okay. Well, one of the concerns I have about the process that you are currently following, my understanding is you have the *Dietary Guidelines* that are based on the expert report from the Advisory Committee, and then that is translated by you and your staff into—or your Department into actual guidelines. Is that——

Secretary VILSACK. That is one aspect of it, Congressman. It is not the only thing that we rely on or look at. It is one piece of a large puzzle.

Mr. MOOLENAAR. Okay. Well, the concern is, and I know that we have had a comment period to date, and it seems that right now the process only allows for the American people to comment after the committee releases its report, but does not allow for public comment after USDA and HHS release the final *Dietary Guidelines.* And I appreciate that you did extend the 60 day public comment period by an additional 15 days following the release of the report this spring, but, as you can tell from the hearing today, there is still considerable criticism of the report.

And there is a provision in the Fiscal Year 2016 agricultural appropriations legislation that, if enacted, requires a 90 day comment period after the *Dietary Guidelines* are formally released. And this process seems more in line with the Administrative Procedures Act, which long pre-dates the current process you are using for the *Dietary Guidelines.* And considering the fact that more than 29,000 comments were submitted on this report, while only 2,000 were received on the 2010 report, it really shows that there is a great deal of interest in this by the public, and it seems to me that the public should have a final opportunity to comment on this report before it is finalized. And I guess my question is would you agree to give the American people another comment period, given the fact that the 2015 committee report generated the most comments in the history of the guidelines?

Secretary VILSACK. Well, first of all, I would point out that there were a number of places where the public could have input in this process before even the public comment period. As the dietary advisory group was meeting, there were a series of public meetings, opportunities for people to have input, and the like. There has also been continued opportunity to have input in the process. The challenge I have, Congressman, is when does the process—you have to have a finality to it. You have to have a stopping point to it, and—in order for us to be able to factor into the various other decisions we have to make that are in some places based on the guidelines. So I am concerned about how long you extend this process.

Mr. MOOLENAAR. Well, yes, but——

Secretary VILSACK. And the last thing I would say is the public does have a way of commenting on this, and that is that they could decide not to follow them. They could decide to be critical of them once they are proposed. So, I mean, there is an ongoing debate and conversation about this.

Mr. MOOLENAAR. I guess——

Secretary VILSACK. It never ends.

Mr. MOOLENAAR.—my concern is, right from the start you made the comment, and I appreciated it, that you didn't want to prejudge what the guidelines will be. It is not a complete process. You are taking in feedback now. But the reality is that once you publish those guidelines, those are the guidelines, and there is no avenue for the public to have input on that. And I think that is——

Secretary VILSACK. Well, I would disagree with that, in the sense that there have already been several places where they have had input, and they can continue to have input. They continue to re-

spond to the 2010 guidelines, which are part of the foundation and the information that we take into consideration. So it is an ongoing education process. I don't think it ever stops. Now, there may not be a formalized period of time, but it never stops.

Mr. MOOLENAAR. Well——

The CHAIRMAN. The gentleman's time has expired.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. King, 4 minutes.

Mr. KING. Thank you, Mr. Chairman. Thanks to the witnesses for testifying today. A few questions still come to mind, after all this discussion that we have had here. And the first one that I have is that when I look at data on the students that are overweight or obese, have we had any evidence that of which direction their weight has gone? I ask first Ms. Burwell. Do we have any indication on whether this program is reducing the obesity of our children in school, or whether it might be working against us?

Secretary BURWELL. So with regard to the specifics of programs in schools, I would——

Mr. KING. The lunch program, yes.

Secretary BURWELL.—defer to my colleague, Secretary Vilsack, in terms of those programs. What we do know is that in younger children we are starting to see overarching across the board, not just from a programmatic school base, but we are starting to see the numbers go in the right direction. With regard to the specifics of school programs, I would defer——

Mr. KING. Well——

Secretary BURWELL.—to Secretary Vilsack.

Mr. KING. And I was actually prepared to redirect that question after your response, so thanks for pointing that out. I would say this information, Mr. Secretary, according to the Centers for Disease Control, we saw the obesity rate of high school students by nine percent in the 4 years prior to the Healthy and Hunger Free Kids Act's implementation, and, in the 4 years after, that the obesity rate increased by 16 percent. Have you seen any data like that from the Centers for Disease Control, and does that cause you to wonder what the result of that might be?

Secretary VILSACK. Congressman, I would be happy to take a look at that information to better understand it, but there is no question in my mind this is not a situation where we are going to see fundamental change in a year. It is going to be a generational process. And I am convinced that, from a generational process, we are going to see progress. And Secretary Burwell's correct, that we have begun to see progress, particularly among younger children.

Mr. KING. Let me just ask you another one. This data says the opposite. It says the obesity rate of high school students had reduced by—we just picked the 4 years since it has been implemented and went to the 4 years prior, so it was the longest period of time that we could have that would have balance, 4 years before, 4 years after. In the 4 years before, obesity rates went down nine percent, according to CDC, and the 4 years after obesity rates for high school students went up 16 percent, according to the CDC.

Now, I don't know how to explain that, because what I am getting back from my constituents, and across this country, is more and more complaints about not enough food for these kids. And I

would ask, Mr. Secretary, we are all very well aware of those complaints, especially as this was implemented in the fall of 2014. Now we are well into the school year of 2015. Are those complaints going up or down, in comparison to the year earlier?

Secretary VILSACK. They have gone down. In fact, some school districts that left the program have come back into the program.

Mr. KING. Well, I am glad to hear that, and how is that program doing in Rhode Island that was spawned by the waste, and do you have any measure on the waste of the food that has been—the program in Rhode Island that I am referring to is aptly named—it is at North Smithfield, Rhode Island, where they are feeding 3,000 pigs with the waste from the school, essentially an industry that is created. And I still get a lot of complaints on hungry kids.

Secretary VILSACK. So——

Mr. KING. I am concerned. Is there any question, and then is there evidence that our students, K through 12, are getting overweight because of school lunch program, or are they eating that food somewhere else that is making them overweight? Was there ever any evidence that indicated it came from the school lunch?

Secretary VILSACK. Congressman, in terms of food waste, there is the Rudd study at the University of Connecticut. There is the Harvard Public Health school study. There is a study at Berkeley, University of California Berkeley, suggesting that kids are eating more fruits and vegetables, no more food waste, and, in fact, are eating more of their entrées than before. So I don't think there is documentary evidence. There may be anecdotal evidence from school to school, and we are, obviously, focused on the food waste issue. I am sorry, the—your second question?

Mr. KING. Were they ever getting overweight on school lunch? Was there ever any evidence prior to 2010?

Secretary VILSACK. Well, that is sort of an interesting question. It could be answered yes and no. Yes, because it was part of the overall caloric intake that a young person was taking, and if they were taking more calories than they should, then everything that they ate in that particular day, in a sense, contributed. But if you are asking whether or not the number of calories consumed in a school meal, if we fit it within the standard, it shouldn't contribute to obesity.

Mr. KING. Either before after——

Secretary VILSACK. Especially——

Mr. KING.—2010?

Secretary VILSACK. Especially if we are reducing the fat, sodium, and sugar, as we are.

Mr. KING. I am out of time, I regret. Thank you, Secretaries.

The CHAIRMAN. The gentleman's time has expired.

Secretary VILSACK. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Newhouse, for 4 minutes.

Mr. NEWHOUSE. Thank you, Mr. Chairman, and thank you, Mr. Secretary, and Madam Secretary, for being here with us this morning. I appreciate your time. I have a couple observations, but also some requests, and a question or two, and I will try to get through in 4 minutes. I have spoken with a lot of impacted constituents, and also through my own review. It seems clear that this Dietary Guidelines Advisory Committee went outside the scope of their

mandate in developing the recommendations for the report, including policy recommendations from taxes to local restaurant zoning, to food labeling, and sustainability policy. According to the underlying statute, that was the sole product of this committee back in 1990, each such report shall contain nutritional and dietary information and guidelines for the general public.

Secretary Vilsack, back in March, the *Wall Street Journal* reported you saying, "I read the actual law, and what I read was that our job ultimately is to formulate dietary and nutrition guidelines, and I emphasize dietary and nutrition because that is what the law says. It is my responsibility to follow the law." Sustainable diets are an appropriate debate to have, you said, however there are forums and places for that to take place. And I was pleased to hear your comments, but what concerns me is the lack of evidence to suggest that neither of the agencies exercised any effort to instruct the Advisory Committee on their scope, or mandate.

When you, Secretary Vilsack, and Secretary Burwell, your predecessor established the committee, you did so under the Federal Advisory Committee Act. This Act is designed to ensure that advice by the various Advisory Committees formed over the years is objective, and accessible to the public. The Act has formalized a process for establishing, operating, overseeing, and terminating these advisory bodies across government. The DGAC members are not full time employees, and rely very heavily on agency staff to carry out their duties.

To be clear, when I review portions of the report, such as the Advisory Committee's conflict statements on encouraging lower meat consumption, but then higher meat consumption for the Mediterranean diet, or when I can see the Advisory Committee's recommendations on added sugars *versus* natural sugar, or use a lower scientific threshold than groups like the Institute of Medicine have used to reach their conclusions, I worry greatly about the process, and the guidance and oversight that they have been given.

So it would be helpful for you to provide the Committee evidence in writing to confirm that your agencies did, in fact, make attempts to oversee the Advisory Committee once it became clear they were delving to areas of public policy. In response I would like to see evidence that your agencies provided instructions to the committee during their assembly to ensure they were staying focused on the right guidance, and not straying into policy matters outside their scope or mandate. And, likewise, I would like to receive documented evidence of the instructions agencies provided to the committee on the public law to help them understand their report must be based on the preponderance of scientific and medical knowledge that is current at the time of publication.

And, finally, I would like to welcome your comments on any advice you could give future secretaries as to future Advisory Committees, and how they could stay focused on their charter, and produce a recommendation that really stays coloring with in the lines. So I would appreciate a response. Thank you.

Secretary VILSACK. We will certainly provide a response to your questions, Congressman, as we are bound to do, and would be happy to do that in writing.

My advice to future secretaries will be to continue the process of educating people about what these recommendations are and what they are not, and the distinction between the report and the guidelines. There seems to—again, I have said this several times today, there seems to be a misunderstanding upon some folks that the report equals the guidelines, and that is not the case. The report is one aspect of our consideration, one aspect of the data, or the information, that is used to formulate these guidelines.

And, to me, this debate has been helpful, I hope, in getting a better understanding of precisely what the recommendations are. And the discussion we have had today is also healthy, as it relates to what is the purpose of these guidelines? Is it focused on prevention, or is it focused on treatment, or should it be focused on both? I think that is a healthy discussion.

The CHAIRMAN. The gentleman's time has expired. Mr. Thompson, 4 minutes.

Mr. THOMPSON. Thank you, Mr. Chairman. Thank you, both Secretaries. I really, really appreciate you being here. My first question actually is very specific. It is an area I care a lot about. So my question is, why do Americans, especially children over the age of 4, continue to fall short of the *Dietary Guidelines*' recommended servings of milk, and its nine essential nutrients and vitamins, and what can we do to remove policies that are hindering milk consumption, or promote policies that could enhance milk consumption?

Secretary VILSACK. We can, basically we are taking a look at those issues right now, Congressman, and that is the goal here, is that, as we learn more, as we understand more, as we re-learn lessons of long ago, that is obviously going to change the direction and focus. That is the whole purpose, and the whole reason why we do this every 5 years, is it is an evolving process.

Mr. THOMPSON. Yes.

Secretary VILSACK. And as our information evolves, our policies will evolve. And we are taking a look at the issue of milk, and taking a look at ways in which milk can be introduced into diets in a variety of different ways, dairy products.

Mr. THOMPSON. And we worked together on that, and I appreciate those efforts. I want to know, how much of a factor do you think that it is that we publish these guidelines once every 5 years, and as you said, 5 minutes before you are ready to publish it, there is new evidence that probably is contrary to what you are publishing. And I am assuming, correct me if I am wrong, that the rate of research within nutrition is significant. Which is a really good thing, so the fact is, as soon as you publish these guidelines, to some extent they are inaccurate, and the longer they are there until the next 5 years, the more inaccurate they are. But when you publish them, doesn't that influence the markets?

I would argue—I would think, I am not going to argue, but I would think that when it comes to milk, the fact that at one point the guidelines discouraged milk took all the flavor out of it, because somehow fat was bad for you. And I know the science today shows contrary to that. But you take the fat, you take the taste out, and that somehow these guidelines that we do every 5 years, that are never really totally accurate, and increasingly more inaccurate to-

wards the end of the 5 years, increases the impacts on the ag commodity markets.

My question for you, given the fact that these were under—I may be wrong—President Carter, so it would be late 1970s when it was originated, are Americans healthier or less healthy since the guidelines have been published, and therefore, are these, in some way, haven't these guidelines somewhat failed? We are talking about increasing obesity. The Pentagon is more concerned than ever about having access to kids that would be able to serve in the military. Have these guidelines really been successful, given disease, and chronic illnesses, and conditions? And that is not to be a criticism, because my second question is, then, how do we use these in a way that they could be successful? Because they don't seem like they are accomplishing the objective, as you two have very well articulated today.

Secretary BURWELL. So we do want to—and I think the issue of obesity is one that has a number of different elements. And the physical activity guidelines, which are something that Congress mandated——

Mr. THOMPSON. As a former rehabilitation guy, I am all in on that. I agree, yes.

Secretary BURWELL. So that is another piece that I think that we need to focus on, and we need to make sure that these things are being used. I think you are right to reflect. The question is, what is the critical path issue, and what is the counterfactual? That is the other thing that we all can't answer. We are on the wrong trajectory, but would the——

Mr. THOMPSON. Yes.

Secretary BURWELL.—trajectory have been worse, and then second——

Mr. THOMPSON. Sure. Well——

Secretary BURWELL.—what is the——

Mr. THOMPSON.—let me make a suggestion, and get a response in the few seconds I have left. It seems like once every 5 years this doesn't work because it changes. And, in fact, it can negatively impact ag commodities, which is irresponsible, to tell people not to eat certain things when the next round of research says that you want to eat more of it. Shouldn't we do something, in this day and age, with technology that would just share the best research with folks? A place where people can go to get the best possible information in terms of eating, and knowing that that changes all the time? Once every 5 years, I don't think this is effective. Sorry, Chairman.

Secretary VILSACK. Honestly, this discussion suggests that there is some extraordinarily bright line on science, that over here there is the real science, and then over here, there is not the real—the science is evolving. It is——

Mr. THOMPSON. That is my point.

Secretary VILSACK. And so——

Mr. THOMPSON. That is what science does.

Secretary VILSACK. It does. So you have to have general guidelines that provide some parameters.

Mr. THOMPSON. Well, do we have static guidelines once every 5 years, or do we have——

Secretary VILSACK. Well, you could theoretically go through this process every year, but I don't know that that would be particularly helpful.

Mr. THOMPSON. No.

Secretary VILSACK. I think a 5 year period is good. Obviously, it gets better informed. And this issue of obesity is far more complex than just simply saying, because we have these guidelines, that somehow we have become an obese nation. It has to do with the fact that an average kid spends 7 hours in front of a screen every day. I mean, that is part of it, right? It is portion size, that is part of it. It is a variety of factors. I suppose if every American followed the guidelines it might be a different situation. But we don't.

The CHAIRMAN. The gentleman's time has expired.

Secretary VILSACK. Doesn't mean we shouldn't have them.

Mr. THOMPSON. Yes.

The CHAIRMAN. Mr. LaMalfa, for 4 minutes.

Mr. LAMALFA. Thank you, Mr. Chairman, and both Secretaries, thank you for being here today. Ms. Burwell, let me follow up on what Mr. Thompson was saying on that as well, we have been hearing, ever since I was a kid, eggs are bad, so my grandparents had a lot of powdered eggs, because of their age, and factors like that. And it turns out eggs are okay later. Then you hear beef, red meat, and then we have high protein diets are supposed to help you lose weight. Somebody I was talking to just over the weekend, a constituent, they lost weight, but they are staying away from fruit, because fruit has sugar in it. Well, I mean, how are people supposed to really know when the ideals are changing all the time, the guidelines?

So, I guess following up on the 5 year thought, is it good to have a hard and fast 5 year timeline of changing the *Dietary Guidelines,* or should it be less frequent, more frequent, or does it need to be even more—kind of change what you know to change, and have the—and leave the rest alone? What do you think of that?

Secretary BURWELL. I think that the Congress, in making a choice on 5 years, probably made a good choice. And the reason for that is, while we heard from some of your colleagues about extending the period—I think that this took 18 months for the Advisory Committee to do its work, then you had an additional 75 days of the period of comment for us to receive comments on that, and then you have the period for us to review and get it out. And so when you add that up, and you think about that timetable, if you tried to shrink that, the question is, would you have relevant——

Mr. LAMALFA. Well, I guess what I am looking at is maybe you have most of the guidelines are going to be consistent for a long time. When you have school books, for example, it seems like they throw out the whole school book. You are buying a new one where maybe most of that math lesson is fine, so maybe you are just changing the elements in there, since it is electronic, and not doing something every 5 years.

So let me follow that up with should there be a legislative change that we should produce that would help this process?

Secretary BURWELL. I don't know that there should, and actually, we are like the school books, in that most of this is consistent. You reflected on, in terms of where there are changes, the things that

there are key recommendations on have been relatively consistent over the period since the 1980s, in terms of the importance of fruits and vegetables, the importance of a balanced approach that provides nutrition that is fewer calories than the nation currently consumes.

In several select areas, it is fair to appropriately reflect the science has changed, but the dominant picture is a very similar picture over the periods of time. And so I also think it is important to distinguish between the *Dietary Guidelines* and what is happening in our popular culture with regard to different diets that are proposed by different people in different ways. Distinguishing that is also an important element, and this gets to what are the guidelines, and what are they not?

Mr. LAMALFA. Certainly, there is a lot of overlap, a lot of different messages being sent. The *Dietary Guidelines,* though, they can be seen by people as confusing, or difficult to follow. Do you think the *2015 Guidelines* will be more straightforward, giving people a little more straightforward ideas of how to follow this pattern for what they need? Is the 2015 going to be an improvement over that?

Secretary BURWELL. We will, obviously, work to make things as simple as we can. But the real way that people interact with these things is actually in their implementation in programs. And whether that is the topic we have talked about in school lunch, or another topic we haven't touched as much on, which is the labeling issues. And that is how most people interact with what the *Dietary Guidelines* are, in terms of how they get their advice about what they are going to eat, and that sort of thing.

Mr. LAMALFA. Well, let me ask, then, since most of the efforts say to follow or be consistent with the guidelines, what does follow the DGA mean to you, Madam Secretary?

Secretary BURWELL. What it means to me is that there are these guidelines, and when we apply those from a perspective of the Federal Government to certain of our programs, that they are the basis that we think about promoting the programs. And whether that is our Meals on Wheels program, or, as we think about our Million Hearts initiative at CDC to try and reduce by a million the number of people with heart attacks, that an important element of that is understanding what the *Dietary Guidelines* say.

Mr. LAMALFA. Thank you. You have had a very difficult job the last year or so, so thanks for coming.

The CHAIRMAN. The gentleman's time has——

Secretary BURWELL. Thank you.

The CHAIRMAN.—expired. And before we adjourn, David Scott, any comments you have from the Ranking Member?

Mr. DAVID SCOTT of Georgia. Yes. Well, thank you very much, Mr. Chairman. First thing I want to say is how much we appreciate both of you Cabinet officials coming before us at the same time. That is a rarity, and we really appreciate it.

Agriculture is indeed our most important industry. It is the food we eat, it is the water we drink. It is our survival. And you do get the feeling from this Committee of how important this is. And I hope that what we have discussed today, that you all will take back in the manner and the spirit in which we have given it, be-

cause this is the single most important industry in the world, our agriculture. My hope is that you will take back and understand—even go back and review a bit.

Secretary Vilsack, you hit the nail on the head when you stated that they sit there before the screen. That is exactly right. When you and I were coming along, folks would say, Daddy or Mama, can I go out to the playground? That is a phrase we don't even hear now. I am going upstairs, or I am going downstairs, I am going in the room, and get on the Internet, sit before that screen hour after hour. And that is why it is so important now that we use our science to make up for that.

And that is why I hope that you will take my suggestions to go back, and look, and make sure we are using the strong scientific evidence. And if there are things like the low calorie sweeteners, where the study has already shown that it will lower obesity, go back and review, and explain why you don't use that. Or maybe you go back and you look at, and you say, you know what, I think we can use this and make a difference. And that is why, Mr. Chairman, this has been an extraordinary and very important hearing, and I thank you for calling it.

The CHAIRMAN. Well, I thank the gentleman. I also want to thank our witnesses. This is a big deal, to get both of you at the table at the same time. I appreciate that. The emphasis today was on the process, and restoring trust.

And, Ms. Burwell, your testimony said that the guidelines don't change much from issue to issue. Is that a bias that, if I am a scientist, and I have a body of work that comes to certain conclusions, and I am going to be hard bent to change my conclusion against new evidence? That is going to be an issue that is there. Hopefully the next time you will be asked are the guidelines themselves contributing to the problem? For example, the emphasis on carbohydrates over the last 20 years, and the impact that has had on these issues that we are talking about, whether it is obesity, or diabetes, or other things. Do we have anybody who is going to live these guidelines for 5 years so we could see what it did to them? I know you guys try to gather that information, because the guidelines are important. They are voluntary for me. I am going to go have lunch here in a little bit, and I will decide for myself. They are not voluntary, though, when they get woven into school lunch programs, and SNAP, and everything else. They become the law of the land in many instances, so it is important that we get these right.

And I appreciate both of your comments this morning about limiting the criticisms about sustainability and taxes. You laid those to rest. Thank you so very much for that, for the emphasis on staying within the scope that was supposed to be there. I appreciate that. And I really also appreciate your work on trying to clarify that these are guidelines, and that the report was one thing. You have work to be done between now and December to make that happen. The idea that perhaps a proposed rule might have some value. I understand time and that getting it finished is an important process as well. I appreciate that both of you came today, and the comments that were made from my colleagues.

Under the rules of the Committee, the record of today's hearing will remain open for 10 calendar days to receive additional material and supplementary written responses from the witnesses to any questions posed by a Member. This hearing of the Committee on Agriculture is adjourned.

[Whereupon, at 11:25 a.m., the Committee was adjourned.]

[Material submitted for inclusion in the record follows:]

SUBMITTED ARTICLE BY HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

THE WASHINGTON POST

Wonkblog

For decades, the government steered millions away from whole milk. Was that wrong?

By Peter Whoriskey October 6

The United States Government once considered butter and margarine as one of seven food groups to consume daily. Look back at other advice that unfortunately is no longer a part of the USDA's *Dietary Guidelines.* (Jayne W. Orenstein/*The Washington Post*)

Video hyperlink: *http://wapo.st/1VEwNVl.*

U.S. *Dietary Guidelines* have long recommended that people steer clear of whole milk, and for decades, Americans have obeyed. Whole milk sales shrunk. It was banned from school lunch programs. Purchases of low-fat dairy climbed.

"Replace whole milk and full-fat milk products with fat-free or low-fat choices," says the *Dietary Guidelines for Americans,* the Federal Government's influential advice book, citing the role of dairy fat in heart disease.

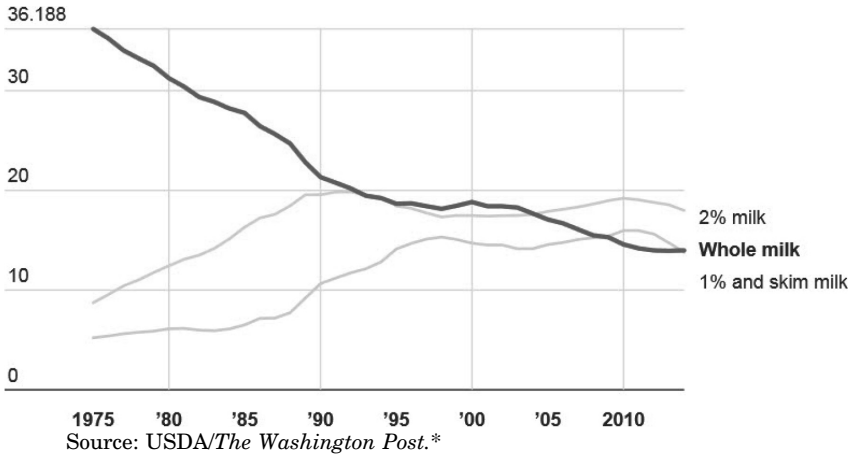
Whether this massive shift in eating habits has made anyone healthier is an open question among scientists, however. In fact, research published in recent years indicates that the opposite might be true: millions might have been better off had they stuck with whole milk.

Scientists who tallied diet and health records for several thousand patients over 10 years found, for example, that contrary to the government advice, people who consumed more milk fat had *lower* incidence of heart disease.

By warning people against full-fat dairy foods, the United States is "losing a huge opportunity for the prevention of disease," said Marcia Otto, an assistant professor of epidemiology at the University of Texas and the lead author of large studies published in 2012 and 2013, which were funded by government and academic institutions, not the industry. "What we have learned over the last decade is that certain foods that are high in fat seem to be beneficial."

Over Decades, Consumers Spurned Whole Milk

For decades, public health authorities have advised Americans to switch away from whole milk, and they have obeyed. The chart shows sales of milk in millions of pounds.



Source: USDA/*The Washington Post.**

This year, as the "*Dietary Guidelines for Americans*" undergoes one of its periodic updates, the Federal bureaucrats writing them must confront what may be the most controversial and weighty question in all of nutrition: does the consumption of so-called saturated fats—the ones characteristic of meat and dairy products—contribute to heart disease?

It is, without doubt, an important question. Heart disease is the leading cause of mortality in the United States, and the Federal Government has long blamed saturated fats.

[**Whole milk is okay. Butter and eggs too. What's next—bacon?** (*https://www.washingtonpost.com/news/speaking-of-science/wp/2015/10/07/whole-milk-is-okay-butter-and-eggs-too-whats-next-bacon/*)].

But the idea that spurning saturated fat will, by itself, make people healthier has never been fully proven, and in recent years repeated clinical trials and large-scale observational studies have produced evidence to the contrary.

After all the decades of research, it is possible that the key lesson on fats is two-fold. Cutting saturated fats from diets, and replacing them with carbohydrates, as is often done, likely will not reduce heart disease risk. But cutting saturated fats and replacing them with unsaturated fats—the type of fats characteristic of fish, nuts and vegetable oils—might.

This shift in understanding has led to accusations that the *Dietary Guidelines* harmed those people who for years avoided fats—as instructed—and loaded up excessively on the carbohydrates in foods such as breads, cookies and cakes that were marketed as "low fat."

It also has raised questions about the scientific foundations of the government's diet advice: To what extent did the Federal Government, and the diet scientists they relied upon, go wrong? When the evidence is incomplete on a dietary question, should the government refrain from making recommendations?

The dietary science has drawn the skepticism of some on Capitol Hill. On Wednesday, a House Committee will air concerns regarding the evidence for the guidelines with Agriculture Secretary Tom Vilsack and Health and Human Services Secretary Sylvia Burwell.

[**Read: Could 95 percent of the world's people be wrong about salt?** (*http://www.washingtonpost.com/news/wonkblog/wp/2015/05/26/could-95-percent-of-the-worlds-people-be-wrong-about-salt/*)].

The *Dietary Guidelines* have stepped back slightly from their blanket advice to reduce saturated fats, adding the caveat that saturated fats ought to be replaced with unsaturated fats. But Dariush Mozaffarian, a cardiologist, epidemiologist, and dean of the Friedman School of Nutrition Science & Policy at Tufts University said that in his view the *Dietary Guidelines* have yet to retreat far enough from the idea that

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* **Editor's note:** this is an interactive graphic that was embed in the article. To access the interactive functionality go to *http://www.washingtonpost.com/news/wonkblog/wp/2015/10/06/for-decades-the-government-steered-millions-away-from-whole-milk-was-that-wrong/*.

saturated fat is a dietary evil, and their suspicion of whole milk is a good example. Judging a particular food solely on how much fat it contains, he said, can too easily blind people to its other benefits.

"If we are going to make recommendations to the public about what to eat, we should be pretty darn sure they're right and won't cause harm," Mozaffarian said. "There's no evidence that the reduction of saturated fats should be a priority."

Some, including representatives of the American Heart Association, disagree. In their view, the evidence for the dangers of saturated fats arises from these two ideas: Consuming saturated fats raises levels of so-called "bad" cholesterol in the blood, and higher levels of "bad" cholesterol, in turn, raise risks of heart disease.

[**Related—USDA: We will not steer people away from meat to protect the environment** (*https://www.washingtonpost.com/news/wonkblog/wp/2015/10/06/usda-we-will-not-steer-people-away-from-meat-to-protect-the-environment/*)].

In support of their position, they point to the trials of statin drugs, which show that the drugs lower "bad" cholesterol levels and lower risks of heart disease.

There is a "mountain of evidence" explaining how consumption of saturated fats raises the risk of heart disease, said Penny Kris-Etherton, a Nutrition Professor at Penn State University and a former member of the Dietary Guidelines Advisory Committee.

How We Die

Heart disease is the leading cause of death in the U.S. and health authorities have long blamed its prevalence, at least in part, on our consumption of fatty foods.

The Case Against Saturated Fats Begins

Over the long tortured course of fat research, it certainly seemed at times that there was strong evidence in the case against saturated fats.

The history of the fat warning is usually traced to the work of Ancel Keys, a scientist at the University of Minnesota, whose study of heart disease in the 1950s startled the medical world.

Keys examined fat consumption and rates of heart disease in various countries. In places where people eat lots of fat, he found high levels of heart disease. One of his famous charts, from 1953, showed that in the United States, where close to 40 percent of the diet came from fat, people suffered a disproportionate number of heart disease deaths. People in Japan and Italy, by contrast, consumed less fat and died of heart disease less often.

Degenerative Heart Disease

1948–49, Men

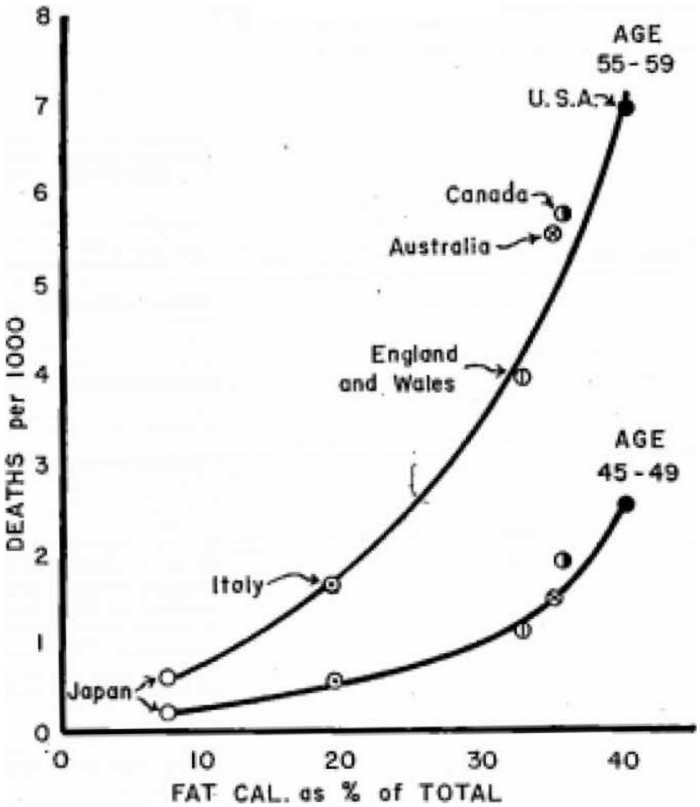

FIG. 2. Mortality from degenerative heart disease (Categories 93 and 94 in the Revision of 1938, categories 420 and 422 in the Revision of 1948, International List. National vital statistics from official sources. Fat calories as percentage of total calories calculated from national food balance data for 1949 supplied by the Nutrition Division, Food and Agriculture Organization of the United Nations.

In 1953, scientist Ancel Keys linked national fat consumption to heart disease.

From the Keys, A., *Atherosclerosis: A problem in newer public health.* 1953. JOURNAL OF MOUNT SINAI HOSPITAL 20: 118–39.

In 1953, scientist Ancel Keys linked national fat consumption to heart disease.

To Keys, the data offered proof that Americans could improve their health by reducing the fats in their diets.

"It is now abundantly clear that degenerative heart disease is not an inevitable consequence of aging," he wrote in the 1953 medical journal article.

More evidence was coming. In the 1960s, several clinical trials—from Oslo, Los Angeles, Finland, London and Minnesota—put his suspicion to the test. Three of the five suggested that he was right.

The Oslo study, for example, studied 412 men who'd previously had a heart attack. Half were given a special diet that was low in saturated fat; the other half was allowed to eat their usual diet, which was richer in saturated and trans fats. The special diet seemed to work: After 5 years, 64 subjects on the special diet had a relapse of heart disease, while of those eating their regular diet, 90 people did.

Public health authorities, including those in the United States, were soon recommending that people reduce their consumption of saturated fats—meat, eggs and dairy—as a means of lowering heart disease risks.

The idea became a part of U.S. official advice in 1977, when the U.S. Dietary Goals, a forerunner of the *Dietary Guidelines,* embraced the position.

How a Hypothesis Became Dogma

But even as a Senate committee was developing the Dietary Goals, some experts were lamenting that the case against saturated fats, though thinly supported, was being presented as if it were a sure thing.

"The vibrant certainty of scientists claiming to be authorities on these matters is disturbing," George V. Mann, a biochemist at Vanderbilt's medical school wrote in the *New England Journal of Medicine.*

Ambitious scientists and food companies, he said, had "transformed [a] fragile hypothesis into treatment dogma."

Indeed, the subsequent 40 years of science have proven that, if nothing else, the warning against saturated fats was simplistic.

By itself, cutting saturated fats appears to do little to reduce heart disease. Several evidence reviews—essentially summing up years of research—have found no link.

"There is no significant evidence for concluding that dietary saturated fat is associated with an increased risk of coronary heart disease," said one published in 2010 in the *American Journal of Clinical Nutrition.*

"Current evidence does not clearly support" guidelines linking saturated fat and heart disease, according to a review of experiments and observational studies published in the *Annals of Internal Medicine.*

"Saturated fats are not associated" with mortality, heart disease, strokes or type 2 diabetes, a major review in the *British Medical Journal* reported in July.

One of the most noted experiments on fats was the Women's Health Initiative, which involved more than 48,000 older women. Some had counseling to eat less fat and more vegetables and fruits; others continued, more or less, with their normal diets. Subjects in the diet group cut their saturated fat intake from 13 percent of their diet to ten percent, as well as their consumption of other fats. Their levels of "bad" cholesterol dropped. Yet when it came to heart disease, researchers found no significant difference between the two groups.

To many critics, the trouble with the fat warning was not merely academic.

The "campaign to reduce fat in the diet has had some pretty disastrous consequences," Walter Willett, dean of the nutrition department at the Harvard School of Public Health has said. "With more fat-free products than ever, Americans got fatter."

Best-sellers such as "Good Calories, Bad Calories" by Gary Taubes and "Big Fat Surprise" by Nina Teicholz went further in their critique of the government position.

"There's a large body of scientific literature to show that a high-carb diet, as recommended by the *Dietary Guidelines for Americans,* provokes a number of heart-disease risk factors," said Teicholz, whose critique of the guidelines appears in a recent issue of the *British Medical Journal.*

The Case Weakens

For the bureaucrats writing the forthcoming *Dietary Guidelines,* the shifting evidence against saturated fats may be a lesson, experts said: there were weaknesses in each of the three lines of evidence used.

First, there were those studies by Keys showing that a country's fat consumption was linked to its rate of heart disease. After Keys' paper appeared, scientists began adding other countries to his graph, and when they did, the pattern suggesting a link between fat consumption and heart disease became less distinct.

More importantly, by the very nature of his research, Keys' data could only show that saturated fat consumption was *associated* with heart disease, not that consuming saturated fat *caused* heart disease. That's because his study was "observational"—that is, it was based on merely observing subjects rather than randomly assigning them to high-fat and low-fat diets. It was possible, in other words, that some unaccounted factor caused the varying rates of heart disease.

The second line of evidence in the case against saturated fats came from those controlled experiments in the 1960s—in Oslo, Finland and Los Angeles. These suggested that subjects who consumed less saturated fat suffered less from heart disease.

As further scientific review showed, none of the experiments was perfectly designed to assess the danger of saturated fats, and the results in some cases were modest. Moreover, the diets showing a benefit were not just low in saturated fats, they were also high in unsaturated fats—the ones common in fish, nuts and vegetable oil.

Indeed, these trials, along with more recent studies, have led many scientists to conclude that merely cutting back on saturated fats provides no benefit, but replacing them with unsaturated fats does. By contrast, cutting back on saturated fats and eating breads and cookies instead won't help.

"We have strong evidence that replacing saturated fats with carbohydrates has no effect on cardiovascular disease," said Alice Lichtenstein, a Tufts University nutritionist who served this year on the Dietary Guidelines advisory panel.

No More "Blanket Recommendations"

Even so, the advisory panel has continued to tout the benefits of limiting saturated fat to ten percent of the diet, and of swapping whole milk for fat-free.

In doing so, the panel is relying on the third piece of the argument against saturated fats, which is that two-step chain of logic: that saturated fats raise the levels of "bad" cholesterol in the blood, and that higher levels of "bad" cholesterol in turn raise the risks of heart disease.

Scientists generally agree on the premises of that argument. The trouble, according to critics, is that connecting the two and drawing the conclusion that saturated fats lead to heart disease is a vast oversimplification, for a handful of reasons.

First, while consumption of saturated fats tends to raise levels of "bad" cholesterol in the blood, they also tend to raise the levels of "good" cholesterol levels, too, and that may have compensating effects.

Second, saturated fatty acids come in chains of carbon of varying lengths, and each one differs in its effects on heart disease risks. Some molecules appear to raise the amount of "bad" cholesterol in the bloodstream, while other longer chains appear to have no appreciable effect.

And it gets even more complicated. It turns out that "bad" cholesterol comes in two forms. One consists of particles that are smaller and denser and these appear to be strongly linked to heart disease; the other type of "bad" cholesterol consists of lighter, fluffier particles that appear to have lesser effects on heart disease. Saturated fats do raise the levels of "bad" cholesterol, but seem to produce mainly the lighter, fluffier and less dangerous particles.

As a result of such complexity, as well as the ways in which food sources vary in their health effects, "blanket recommendations to reduce total saturated fats may not be appropriate," according to the most recent *Annual Review of Nutrition,* an academic publication that provides summaries of the latest research.

So What About Whole Milk?

While nutrition advice is often presented in terms of "macronutrients"—fats, proteins, carbohydrates—foods may be more than the sum of their scientific parts.

Milk is a good example.

Repeated research on milk, not funded by the industry but by public institutions, has provided evidence that the fats in milk are, for some reason, different.

In 2013, New Zealand researchers led by Jocelyne R. Benatar collected the results of nine randomized controlled trials on dairy products. In tallying the tests on 702 subjects, researchers could detect no significant connection between consuming more dairy fat and levels of "bad" cholesterol. (Four of the nine studies included in the tally were funded by the industry. Those results were consistent with those of the trials funded by government entities.)

The same year, Otto and Mozaffarian, then both at the Harvard School of Public Health, conducted another study on the effects of milk. Their study sought to address a key weakness in the previous research.

One of the flaws of nutrition studies is that they rely on people to accurately recall what they've eaten over the course of a year. Those recollections are vulnerable to inaccuracy, especially for dairy fats which can be found in small amounts in many different foods. This inaccuracy may be one of the reasons studies have yielded contrary results on the link between milk and heart disease.

To improve estimates, Otto and Mozaffarian used a blood sample for each of more than 2,800 U.S. adults. Using the blood sample, they could detect how much dairy fats each had consumed. And over the 8 year follow up period, those who had consumed the most dairy fat were far less likely to develop heart disease compared to those who had consumed the least.

The advocates of whole milk allow that it has more calories than its low fat cousins, and for some, that might be reason to avoid it. But the traditional case against whole milk—based on the risk of heart disease—has frayed enough now that many argue the *Dietary Guidelines* should yield to the new findings.

"There is no scientific basis for current dietary advice regarding dairy," Benatar said. "Fears [about whole milk] are not supported by evidence. The message that

it is okay to have whole fat food, including whole fat milk, is slowly seeping into consciousness. But there is always a lag between evidence and changes in attitude."

Peter Whoriskey is a staff writer for *The Washington Post* handling investigations of financial and economic topics. You can email him at *peter.whoriskey@washpost.com*.

SUBMITTED REPORT BY HON. VICKY HARTZLER, A REPRESENTATIVE IN CONGRESS FROM MISSOURI

Scientific Integrity in Policymaking

A White Paper authored by Joanne L. Slavin, Ph.D., R.D.

Executive Summary

A scientific white paper was commissioned by a coalition of food and agriculture trade associations to examine the use of scientific research in U.S. food and nutrition policymaking efforts, including the *Dietary Guidelines for Americans* (DGA). The white paper, authored by Joanne Slavin, Ph.D., R.D., was published in *Nutrition Journal* (*Attachment*). Following is an executive summary of the white paper's main findings and recommendations.

Rationale

The current Administration, Federal agencies and regulators are increasingly looking to policy and systems-change interventions to improve public health in America. The process by which Federal agencies and policymakers consult scientific research in developing proposed regulations and policies varies and greatly impacts the nature of the ultimate recommendations. Because of the profound effect that many of these policies have on consumers, the food environment, Federal nutrition assistance programs and subsequent policy and regulatory recommendations, it is imperative that only the strongest, best available evidence is used to inform and set policy.

White Paper Objectives

1. Describe the current U.S. food and nutrition policy environment.
2. Examine how science is used in Federal food and nutrition policymaking efforts, using the *Dietary Guidelines for Americans* (DGA) as an example.
3. Describe strong *versus* weak science as well as what types of studies are most appropriate for use in policymaking.
4. Discuss the potential effects and consequences of making policy recommendations in the absence of scientific consensus or agreement.
5. Make recommendations to support the present and ongoing development of science-based policy likely to positively impact public health.

Barriers to Setting Evidence-Based Policy

- Scientific studies are used by all agencies to set nutrition policy. Yet, consistent guidelines for how to identify, evaluate, and translate research into policy recommendations do not exist. This can lead to national dietary guidance based on research studies with varying degrees of methodological strength and applicability.
- Nutrition is a constantly evolving science and much of our available knowledge and thus dietary recommendations are based on observational data or research that is of a weaker quality. It is critical that study methodology is carefully considered and applied to our interpretation of nutrition science. Limitations of such data are often underappreciated by nutrition scientists and policymakers.
- The DGA serve as the cornerstone for all Federal nutrition education and program activities, including but not limited to nutrition labeling campaigns, *Healthy People* objectives, and nutrition assistance programs including the Supplemental Nutrition Assistance Program (SNAP) and the National School Lunch Program (NSLP). The Dietary Guidelines Advisory Committee (DGAC) is the review committee responsible for formulating and publishing recommendations that lead to the development of the DGA policy document.
    - The nutrition and health topics investigated, as well as the evidence review, interpretation, and grading processes are at the discretion of DGAC members.
    - Final DGAC recommendations will be provided to the Secretaries of the Department of Health and Human Services and USDA by the end of 2014/early

2015. The content of the ultimate DGA policy document is at the discretion of both agencies.

- It is extremely difficult to reverse or change public policy, once enacted, without causing consumer confusion. Inaccurate and conflicting dietary guidance messages are detrimental to consumer understanding of nutrition and the ability to build healthy diets. At a time when consumers are already subjected to an overabundance of nutrition and health information, providing the public with science-based, realistic and achievable information is more likely to contribute to improved public health outcomes.

Recommendations

- It is imperative that food and nutrition policies reflect, and do not get ahead of the strongest available scientific evidence. It is unlikely we will ever have RCT data available to answer most nutrition questions, but we should rely on our strongest designs. We must demand stronger scientific standards from appointed committee members who serve on authoritative IOM and DGAC panels.
- A universal system that grades evidence quality would help achieve consistency in science interpretation and use across all nutrition policies and regulations. Grading schemes should be vetted and approved by authoritative bodies, so that findings and recommendations are supported across a wide array of credible groups.
- Food and nutrition policy must be a cooperative effort of scientists from universities, the government, commodity groups and food companies. Dietary guidance that is produced in such a collaborative system will more likely be translatable and realistic for the general public.
- When policy recommendations are developed by committees, such as the DGAC, those committees should be comprised of a balanced and well-rounded set of perspectives and expertise. A scientific nutrition committee should not only include experts in nutrition, biochemistry, physiology, epidemiology and statistics, but also food science, food production and processing, food policy and behavior. This would ensure that the ultimate recommendations adequately reflect our entire food system and food environment.
- Policies should reflect what is practical and likely to have the greatest impact on the general population. Simple, flexible and straightforward messages that are rooted in the best available evidence are likely to be most effective.

Joanne Slavin is a Professor in the Department of Food Science and Nutrition at the University of Minnesota, St. Paul. She is a Science Communicator for the Institute of Food Technologists and served as a member of the 2010 Dietary Guidelines Advisory Committee (DGAC).

ATTACHMENT

Slavin NUTRITION JOURNAL (2015) 14:15 *

The Challenges of Nutrition Policymaking

DOI 10.1186/s12937–015–0001–8
Review, Open Access
Joanne L. Slavin

Abstract

In my over 3 decades of work in the field of food and nutrition, I have participated in many efforts that seek new policy initiatives in the hopes that these programs can curb rates of obesity and chronic disease and help consumers make healthier dietary choices. Because of the profound effect that many of these policies have on consumers, the food environment, Federal nutrition assistance programs and subsequent policy and regulatory recommendations, it is imperative that only the strongest, best available evidence is used to set policy. This review evaluates methods by which current nutrition policies use scientific research as well as provides rec-

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ommendations for how best to ensure future nutrition policies are truly science-based and likely to have a meaningful impact on public health. Specifically, this review will:

- Describe the current food and nutrition policy environment in the U.S.
- Examine how science is used in Federal food and nutrition policymaking efforts, using the *Dietary Guidelines for Americans* (DGA) as an example.
- Describe strong *versus* weak science as well as what types of studies are most appropriate for use in policymaking.
- Discuss the potential effects and consequences of making policy recommendations in the absence of scientific consensus or agreement.
- Make recommendations to support the present and ongoing development of science-based policy likely to positively impact public health.

Keywords: Dietary guidance, Nutrition policy, Evidence based review, Sodium, Added sugars

Introduction

The U.S. food and nutrition policy and regulatory environment is highly active. The current Administration, Federal agencies and regulators are increasingly looking to policy and systems-change interventions to improve public health in America. For example, within the last 5 years, Federal and state/local governments have instituted significant changes to the school food environment [1], proposed state and local initiatives to tax and/or ban certain foods and beverages [2], and published proposed rules to significantly change nutrition labeling regulations [3]. Additionally, the 2015 Dietary Guidelines Advisory Committee (DGAC) [4] is presently meeting and will issue the 2015 DGAC report in the coming year.

The process by which Federal agencies and policymakers consult scientific research in developing proposed regulations and policies varies, and greatly impacts the nature of the ultimate recommendations. An investigation into this process would yield important understanding about how science is used to set policy and what impact this process is likely to have on consumers.

Review

How Science Is Used in Policymaking

Science is used by all agencies to set nutrition policy. Yet, guidelines for how to identify, evaluate, and translate scientific research into policy recommendations vary among agencies. Policymakers generally rely on published research and consensus reports by scientific authorities and government bodies; however the manner in which research findings and report conclusions are interpreted and applied can differ from one initiative to the next. Government agencies have outlined their approach for evaluation of scientific studies to be used in decision-making. For example, NIH uses the AHRQ system [5] and FDA has an accepted system of systematic review for health claims [6]. Because there is not a universally accepted evidence-grading scheme, conclusions are based on research studies with varying degrees of methodological strength and applicability. The fact that nutrition research produces constantly evolving scientific findings further complicates the development of objective, evidence-based policy recommendations.

One example of a U.S. scientific authority with significant influence is the Institute of Medicine (IOM). The IOM is one of the premier authoritative bodies that conducts health-related research and promulgates health and nutrition recommendations for policymaking purposes. IOM reports are frequently commissioned by government agencies for topics where policy and/or regulatory interest exists but research gaps remain. Some recent examples include sodium [7] and front-of-package labeling [8]. Once IOM recommendations are published, they are often used as scientific basis for proposed regulations and nutrition guidance. IOM recommendations aim to reflect our most current scientific understanding and usually precede the actual setting of policy to ensure any action is evidence-based. However, the IOM is challenged to keep pace with advances in our understanding of nutrition.

For example, the IOM completes the Dietary Reference Intake (DRI) reports, which are considered the most reliable sources of nutrient recommendations—they inform the very basis of our current nutrition understanding. The DRIs are summarized in the 2006 volume [9] and are an update to the Dietary Recommended Allowances (RDA) that have been published since 1941. While DRI reports for certain nutrients have been updated recently (vitamin D and calcium were updated in 2011), other DRI reports have not been updated since 1997–1998. This means that the body of research that has been completed for a number of nutrients within the last 15+ years is not accounted for in our current IOM DRI report conclusions.

Researchers and policymakers also rely heavily on the National Health and Nutrition Examination Survey (NHANES), an ongoing group of studies designed to assess the health and nutritional status of adults and children in the United States. These studies are based on self-reporting; they consist of 24 hour dietary recalls completed through individual surveys. NHANES also collects biological data and anthropometrical data with mobile units. NHANES information is a valuable resource on changes in nutrient intake and health status of a cross-sectional group of U.S. consumers.

Critics suggest the data are flawed because of biases that accompany self-reporting measures [10]. As one might expect, survey respondents have a tendency to under-report their caloric intake or over-report the amount of more nutritious foods they consume and under-report the amount of less nutritious foods they consume. Archer, *et al.* [11] reported that 67% of women and 59% of men who participated in NHANES provided caloric intake responses that were not physiologically plausible. They calculated physiologically credible energy intake values as the ratio of reported energy intake to estimated basal metabolic rate and subtracted estimated total energy expenditure to create disparity values. The greatest mean disparity values were −716 kcal/day and −856 kcal/day for obese men and women, respectively. The limitations of our nutritional data are generally not acknowledged in scientific reports or consensus statements. And yet, NHANES is cited by virtually every government agency involved in health and nutrition as an accurate representation of Americans' eating habits.

These examples raise important questions about the data that U.S. nutrition policymakers have available to them. How confident can we be that Federal dietary guidance is evidence-based when our foundational measures are outdated and significantly limited? What controls can be put in place to ensure that policies and regulations are likely to have demonstrated, positive public health impact?

The Dietary Guidelines Advisory Committee

Another highly influential scientific authority is the Dietary Guidelines Advisory Committee (DGAC), the appointed review committee responsible for formulating and publishing (in the form of a comprehensive report) an evidence-based review that provides scientific support for the *Dietary Guidelines for Americans* (DGA) policy document. The DGA are statutorily mandated (Section 301 of Public Law 101–445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III)) and are a collaborative effort between the Department of Health and Human Services (HHS) and Department of Agriculture (USDA); the DGA have been published every 5 years since 1980. The DGA aim to provide "sound advice for making food and physical activity choices that promote good health, a healthy weight, and help prevent disease for Americans ages 2 years and over, including Americans at increased risk of chronic disease" [12]. DGA recommendations serve as the cornerstone for all Federal nutrition education and program activities, including but not limited to nutrition labeling campaigns by the Food and Drug Administration (FDA) and USDA Food Safety and Inspection Service (FSIS), the Office of Disease Prevention and Health Promotion (ODPHP) *Healthy People* objectives, and USDA Food and Nutrition Service nutrition assistance programs including the Supplemental Nutrition Assistance Program (SNAP) and the National School Lunch Program (NSLP). As a result, DGA reach and impact are extensive.

The 2015 DGA process is underway, with the current DGAC holding meetings to share their evidence review process and findings with the general public. According to the 2015 DGAC charter, the Committee's official responsibilities are to "examine the current *Dietary Guidelines for Americans,* take into consideration new scientific evidence and current resource documents, and then develop a report to be submitted to the Secretaries that outlines its science-based recommendations and rationale which will serve as a basis for developing the eighth edition of *Dietary Guidelines for Americans*" [12].

The DGAC is governed by Federal Advisory Committee Act (FACA) guidelines and an official charter and charge [13]. While the freedom exists to explore food and nutrition topics that the DGAC deems important and scientifically relevant, the charge explicitly states that "DGAC responsibilities include providing authorship for this report; however, responsibilities do not include translating the recommendations into policy or into communication and outreach documents or programs" [13]. In other words, DGAC recommendations should be scientific in nature and not indicative of policy direction.

The DGAC Evidence Review Process

The DGAC process to identify, review, and evaluate available nutrition research for a variety of topics is complex and time-intensive. Typically, DGAC members are

divided into subcommittees to address specific research areas based on topic importance and DGAC member expertise. In 2010, the DGAC consisted of thirteen scientists with expertise in nutrition, physical activity, food behavior and nutrition through the lifecycle. There were eight subcommittees focusing on the following dietary issues: (1) alcohol; (2) carbohydrate; (3) energy balance and weight maintenance; (4) fatty acids and cholesterol; (5) food safety and technology; (6) nutrient adequacy; (7) protein; and, (8) sodium, potassium and water. As a member of the 2010 DGAC, the author of this paper served as chair of the carbohydrate and protein subcommittees and also as a member of the energy balance and the nutrient adequacy subcommittees.

The 2015 DGAC is organized somewhat differently, with fourteen scientists serving on five subcommittees: (1) Food and Nutrient Intakes, and Health: (2) Current Status and Trends; Dietary Patterns, Foods and Nutrients, and Health Outcomes; (3) Diet and Physical Activity Behavior Change; (4) Food and Physical Activity Environments; and (5) Food Sustainability and Safety. There are separate working groups for sodium, added sugar, saturated fat and physical activity. The 2015 Committee is also using expert consultants to inform its evidence reviews.

One of the first steps in the DGAC evidence review process is to develop research questions regarding the relationship between diet and health outcomes, including disease risk or health benefits (*e.g.,* what is the relationship between dietary fiber intake and specific health outcomes). These questions should reflect the research gaps identified by the previous DGAC, as well as areas of nutrition where there is new, influential evidence since the previous edition of the DGA. Once the research questions have been agreed upon, the DGAC, in concert with USDA Nutrition Evidence Library (NEL) staff, gathers the relevant available studies.

The research studies are then closely examined and evaluated based on strength of study design as well as relevance of outcomes. In past years, the DGAC used the NEL evidence-based review process [14], a strict hierarchy of evidence and rigorous grading process. For each question addressed in the 2010 evidence-based report, the DGAC developed precise search criteria, inclusion and exclusion criteria for all of the studies, including the range of dates searched, and made this information available on the USDA DGA portal [14]. Such detailed process and transparency in the NEL evidence-based approach minimizes bias and therefore adds credibility to the findings. However, the scientific review method ultimately used by the DGAC is at the Committee's discretion—for example, at the time of this paper's completion, the 2015 DGAC has decided to use the NEL process to answer some research questions, but not others. This permitted subjectivity and variability increases the potential for less rigorous studies to be used to inform DGAC recommendations.

Once the DGAC has determined which studies to examine for each research question, evidence conclusion statements are written. Within the NEL system, the conclusions drawn can be deemed as strong, moderate, limited, or lacking data to support them. There may also be strong evidence of no relationship. For example, strong evidence was found of no relationship between glycemic index and disease outcomes in the 2010 DGAC review [15]. Agreeing on the strength of the relationship is always difficult, as for each question, different types of studies with a variety of outcomes have been published. A closer examination of study methodology will help further illustrate this point.

The DGAC process is transparent and open to input from scientists and consumers. The 2015 DGAC will hold seven public meetings with public comments accepted throughout the process. Although the final DGAC report is not released, the committee regularly updates their progress on reviewing scientific questions at the public meetings.

Research Methodology: What Makes a Strong ***vs.*** *Weak Study*

The evidence-based medicine (EBM) hierarchy ranks research design in the following order of strength (from highest to lowest): systematic reviews of randomized-controlled trials (RCT), RCT, prospective cohort studies, case control studies, cross-sectional studies, case series/case reports and editorials/expert opinions. RCT are the strongest study designs for determining cause and effect between a dietary exposure and a health outcome [16]. Following RCT are prospective cohort studies, where a group or cohort of subjects is studied over time. Food frequency instruments are often used to collect dietary information before any diagnosis of disease, making these studies more reliable than cross-sectional studies where diet and outcome measures are assessed simultaneously. Historically, in the case of DGAC reviews, no case-control studies, animal research, or *in vitro* studies have been considered due to their relative weakness and because their findings cannot prove cause and effect in humans. Typically cross-sectional studies are only included in DGAC reviews if no stronger prospective studies are available.

Following this reasoning, food and nutrition policies would be best served if only the strongest types of evidence—perhaps RCT alone—informed their development. However, this is an unrealistic ideal as not all diet and health outcome relationships can be practically or ethically evaluated using RCT. For example, it is difficult to carry out blind food treatments in dietary studies (subjects know they are consuming an apple *versus* apple juice). However, such trials can work with nutrients, as nutrients can be added to food or drinks without the knowledge of the participants or investigators (the double-blind mechanism).

Further, all RCT data are not created equal. RCT generally use biomarkers as outcome measures rather than disease incidence due to the length of time it takes healthy people to manifest disease symptoms. Biomarker data can be extrapolated to infer relationships regarding population health without adequately accounting for weaknesses in the relationship between the biomarker and the disease state. Ultimately, this can result in a strong study methodology being misapplied and used to make assumptions that are not actually supported by the research. For example, RCT are clear that sodium intake or excretion is directly related to blood pressure, yet prospective cohort studies show that too low sodium intakes actually increase risk of cardiovascular disease (CVD). Thus, at low levels of sodium consumption, blood pressure does not account for all of the CVD risks. Biomarker data fail to tell the complete story.

In reality, many dietary recommendations are supported by evidence primarily from observational data, particularly those from prospective, cohort studies. Nutrition scientists and policymakers often under-appreciate limitations of such data. Some of the limitations of observational evidence for diet-disease relationships include imprecise exposure measures, collinearity among dietary exposures, displacement/substitution effects, healthy/unhealthy consumer bias, and residual confounding. Maki, *et al.* [16] recommend greater caution in making dietary recommendations for which RCT evidence of clinical event reduction after dietary intervention is not available.

For these reasons and because nutrition science is complex and changeable, it is critical that study methodology is carefully considered and applied to our interpretation of nutrition science. Ideally, observational data would be validated by stronger research methods before being used to inform policy. While observational research may be valuable to our understanding of nutrition and health, its limitations must be acknowledged. Consider the 2015 DGAC investigation into sustainable dietary patterns. This field of research is arguably in its infancy—in fact, there is no scientific consensus for even a definition of sustainability [17]. Any sustainability-related recommendations in the 2015 DGAC report should be preliminary at best, recognizing the need for additional, rigorous research to validate initial findings. Without these underlying studies in place, it would be premature for HHS and USDA to use sustainability recommendations to inform nutrition guidance in the 2015 DGA policy document.

Consequences of Non-Evidence-Based Policy

We don't have to travel very far back in time to witness examples of dietary guidance recommendations that were made prematurely and are now challenged as more research is introduced. Our understanding of fats has evolved considerably, with dietary recommendations now emphasizing healthy consumption of monounsaturated and polyunsaturated fats, proving that healthier dietary patterns include, rather than exclude, foods higher in fat content.

More recently, it could be argued that the 2010 DGA sodium intake recommendation was made in the absence of scientific consensus. The policy document recommends that individuals over 51 years old, African Americans or those with hypertension, diabetes, or chronic kidney disease reduce their daily sodium intake to 1,500 milligrams. This applies to about ½ the U.S. population, including children and the majority of adults.

Since then, the IOM published its *Sodium Intake in Populations: Assessment of Evidence* report. Findings stated that recent studies "support current efforts to reduce excessive sodium intake in order to lower risk of heart disease and stroke. However, the evidence on health outcomes is not consistent with efforts that encourage lowering of dietary sodium in the general population to 1,500 mg/day. Further research may shed more light on the association between lower—1,500 to 2,300 mg—levels of sodium and health outcomes" [7].

The 2010 DGA recommendations are now inconsistent with our most recent scientific understanding of sodium and health. As noted, this conflict could have been avoided if the DGA policy document had withheld such extreme guidance until more rigorous studies were fielded, reviewed, and published. Recent papers in the *New*

England Journal of Medicine cast further doubt on our low sodium recommendations for the general public [18].

The sodium example is important because of the aforementioned impact of DGA recommendations on other food and nutrition policies. The *Final Rule for the Nutrition Standards in the National School Lunch and School Breakfast Programs* [1] states that schools must "reduce the sodium content of meals gradually over a 10 year period through two intermediate sodium targets of 2 and 4 years post implementation". Now that schools have begun to implement the new regulations, these severe sodium reductions are proving difficult, costly, and may reduce student participation rates [19]. These consequences are especially concerning considering the underlying recommendation may not accurately reflect the current evidence base.

Inaccurate and conflicting dietary guidance messages are also detrimental to consumers' understanding of nutrition and their ability to build healthy diets. At a time when consumers are already subjected to an over-abundance of nutrition and health information, government agencies should be held accountable for developing policies and regulations that are rooted in strong science, and are realistic and achievable for the majority of the population. In the case of sodium, not only is there insufficient evidence to link highly restrictive sodium intakes to improved health outcomes, but encouraging the general public to reduce intakes from the estimated current average of 3,400 mg/day to 1,500 mg/day is self-defeating and unachievable [20].

Another example can be seen in the use of the 2010 DGAC review to support the FDA proposal to mandate added sugars labeling on the Nutrition Facts panel [3]. Added sugars have become the current nutrition "watch out", believed by some to uniquely contribute to obesity and other adverse health outcomes. However, the majority of scientific evidence shows that all sugars (added or intrinsic) provide 4 kcalories/gram just like any other digestible carbohydrate and are no more likely to cause weight gain or negative health outcomes than other calorie sources [21]. In fact, even the proposed rule acknowledges this fact:

> "U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease. Specifically, although it is recognized that sugar-sweetened beverages increase adiposity (body fat) in children (Ref. 30), neither the 2010 DGA nor the IOM macronutrient report concluded that added sugars consumption from all dietary sources, in itself, increases obesity. In fact, the 2010 DGA states that added sugars do not contribute to weight gain more than any other source of calories . . ." [3].

FDA states that the basis for this proposed labeling requirement is the 2010 DGA recommendation to reduce intakes of added sugars to assist consumers in maintaining healthy dietary practices. The DGA rationale is that lower intakes of added sugars will result in decreased calorie intakes and increased nutrient density of individual diets, not reduced risk of adverse health outcomes. Specifically, the 2010 DGAC energy balance subcommittee investigated sugar-sweetened beverage intakes and found that "strong evidence shows that children who consume more sugar-sweetened beverages have greater adiposity (body fat) compared to those with a lower intake" [15]. However, a closer look at the evidence review shows that only 12 of the 19 studies (which included crosssectional studies) found a positive association between sugar-sweetened beverage intakes and adiposity in all or a subsample of population studies. It is difficult to see how the subcommittee concluded this to be "strong" evidence.

Furthermore, it is unclear why FDA proposed mandatory added sugars labeling in the absence of consumer research to demonstrate whether the change will in fact influence consumer understanding and purchasing behavior. The proposed rules even preceded the agency's own study. Existing consumer research suggests that consumers already find aspects of the current nutrition label confusing [22]. In addition, public misunderstanding about added sugars abounds. Some consumers believe added sugars do cause unique adverse health outcomes compared to other sugars and even contain more calories that intrinsic sugars [22]. Even if the intention behind the proposed rule is to steer consumers away from purchasing non-nutrient dense foods and beverages that contain added sugars, current available research suggests they will do this for the wrong reasons. This proposal stands to perpetuate misleading beliefs about nutrition and lead to more consumer confusion.

It is extremely difficult to reverse or change public policy, once enacted, without causing consumer confusion. There are few mechanisms available to regulators and policymakers to make adjustments that reflect new science and understanding. Furthermore, nutrition policy recommendations, once adopted, appear frequently in the media and online. Reversing consumer misunderstanding about nutrition is an in-

credibly difficult task; providing the public with accurate, realistic and achievable information first would go a long way in improving our understanding of nutrition and health, and ultimately contributing to improved public health outcomes.

Conclusions

It is imperative that food and nutrition policies reflect, and do not get ahead of the strongest available scientific evidence. It is unlikely we will ever have RCT data available to answer most nutrition questions, but we should rely on our strongest designs, including prospective cohort studies. We should not accept cross-sectional studies as influential drivers of policy development. We must demand stronger scientific standards from our appointed committee members who serve on advisory IOM and DGAC panels.

A transparent system that grades evidence quality would help achieve consistency in science interpretation and use across nutrition policies and regulations. Grading schemes should be vetted and discussed by experts across the wide expertise needed in dietary guidance, including nutritionists, dietitians, food scientists, physicians, applied economists, and food processors so that findings and recommendations could be supported across a wide array of credible groups. This would also help ensure that the dietary guidance messages consumers are receiving are factual and consistent.

When policy recommendations are developed by committees, such as the DGAC, those committees should be comprised of a balanced and well-rounded set of perspectives and expertise. Ideally a scientific nutrition committee would not only include experts in nutrition, biochemistry, physiology, epidemiology and statistics, but also food science, food production and processing, food policy and behavior. This combination of skills would ensure that the ultimate recommendations adequately reflect our entire food system and food environment.

Scientists who understand how we "learn" about nutrition must be included, even if they have worked on research supported by commodity groups or food companies. The IOM process considers bias of individual committee members and whether they have taken such strong public stands on issues that it is not possible for them to move to another position based on the deliberations of the committee. Any linkages to the food industry are criticized, yet there seems to be little concern about committee members who are closely linked to professional groups, such as American Heart Association or other advocacy groups. Improvements to our food system and public health can only be realized if we work together, respecting the strengths of all parties. Nutrition advice that is produced in such a collaborative system will more likely be translatable and realistic for the general public.

Policies should reflect what is practical and likely to have the most impact on the general population. Simple, flexible and straightforward messages that are rooted in the best available evidence are likely to be most effective. For example, the majority of Americans are unlikely to be interested in or able to prioritize building sustainable diets, shop at farmers markets, or avoid processed foods, which provide nutrition and convenience for individuals with less access to full-service grocery stores and fresh produce.

I would finally suggest that the U.S. Government consider elongating the DGA publication schedule. The DRI reports and nutrition labeling regulations are not updated every 5 years; instead they are reexamined when there is a sufficient level of new research to warrant a change. Without new science to review, the DGAC may choose to focus on fads and trends instead of updating the scientific data for the core areas of dietary guidance. As every DGAC wants to be bold and set new direction, nutrition science would support that first we must do no harm with our dietary guidance. Moderation and variety must be kept front and center, as well as an appreciation that a teenage active boy may need two or three times more calories than an elderly man or young child. A suggestion that all Americans should reduce sodium intakes is not sound and is potentially dangerous. Targeting certain foods and beverages, including chocolate milk, processed meats, added sugars, and even the noble potato as villains in the nutrition wars is not a science-based strategy and may need to be countered on the political front if appointed scientific review committees continue to take this approach.

As described by Schneeman [6], science is necessary for developing effective food regulation and policy, but it is not sufficient. The interface between nutrition and public health must include food science and agriculture. Food technology can help all consumers, including those of lower socioeconomic status, have access to safe, nutritious foods that science has found to be linked to improved health outcomes.

Abbreviations

HHS: Department of Health and Human Services; USDA: Department of Agriculture; DGAC: Dietary Guidelines Advisory Committee; DGA: *Dietary Guidelines for Americans;* DRI: Dietary reference intakes; EBM: Evidence-based medicine; FACA: Federal Advisory Committee Act; FDA: Food and Drug Administration; IOM: Institute of Medicine; LDL: Low-density lipoprotein; NHANES: National Health and Nutrition Examination Survey; NSLP: National School Lunch Program; ODPHP: Office of Disease Prevention and Health Promotion; RCT: Randomized-controlled trials; SNAP: Supplemental Nutrition Assistance Program; FSIS: USDA Food Safety and Inspection Service; NEL: USDA Nutrition Evidence Library.

Competing Interests

In the past 5 years Dr. Slavin has received research grants from Minnesota Beef Council, Minnesota Cultivated Wild Rice Council, Novartis Consumer Health, USA Rice, Nestle Nutrition, Tate and Lyle, General Mills, Inc., USA Pears and American Pulse Association. In the past 5 years Dr. Slavin has received speaking fees from food companies and commodity groups with interests in processed foods, dairy products, meat, pulses, fruits, vegetables, fiber, grains, and carbohydrates. Dr. Slavin has participated in scientific panels and advisory boards that are funded by food companies, ingredient companies, commodity groups, scientific societies, and trade groups. She holds a third interest in the Slavin Sisters LLC, a 119 acre farm in Southern Wisconsin.

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SUBMITTED ARTICLE BY HON. JAMES P. MCGOVERN, A REPRESENTATIVE IN CONGRESS FROM MASSACHUSETTS

THE HILL

October 07, 2015, 06:30 a.m.

***Physician Perspective: Keep Politics Out of** Dietary Guidelines*

By Sandra G. Hassink, M.D., F.A.A.P. and Steven J. Stack, M.D.

The process by which the Federal Government provides the best available dietary advice to millions of Americans is under attack on Capitol Hill. As physicians and leaders of professional medical organizations, we are compelled to speak out.

Physicians routinely provide patients with guidance on how to stay healthy. We rely on the best available scientific evidence to make these recommendations, and fortunately, we have had the *Dietary Guidelines for Americans* to turn to. Unfortunately, that could all change; there are unprecedented attacks taking place in Congress right now that threaten the scientific integrity of the guidelines.

Every 5 years, the guidelines are updated and published as America's authority for nutrition advice. Important legislation, the *Healthy, Hunger-Free Kids Act of 2010,* called for school meals to conform to these guidelines, which makes sense: since children typically consume up to ½ of their daily calories in school, we have an obligation to ensure those meals are healthy and nutritious.

At a time when nearly one in three school-age children and adolescents is overweight or has obesity and more than one in three American adults suffer from cardiovascular disease and diabetes, science, not politics, should drive the Federal Government's efforts to revise the guidelines. And indeed, the guidelines themselves are informed by an expert committee made up of scientists, doctors and nutritionists who are nominated by their peers and selected by the Federal Government after a rigorous vetting process. They evaluate the evidence and provide independent advice to the U.S. Government in the form of *Dietary Guidelines.*

This process takes years, and is intentionally removed from the political process. And yet, it is currently under threat on Capitol Hill: Language pending in multiple spending bills would hinder the Federal Government's ability to provide the best available advice to millions of children and adults on healthy diets and lifestyles. If enacted, efforts to reduce consumption of added sugars in order to lower the risk of cardiovascular disease, type 2 diabetes and dental caries would be stymied. Interventions to reduce screen time and increase physical activity in children and adults would be disrupted.

What's more, the language would limit dietary information or guidelines that can be included in the *2015 Dietary Guidelines for Americans* only to those with a "strong" evidence rating, which means it is completely free from study design concerns or disagreements between findings. As any nutrition scientist or dietician will tell you, nutrition research is exceptionally difficult to perform. Meals are so complex and varied that establishing an individual's true pattern requires meticulous diet tracking; population-level data is easier to obtain but less specific. In addition, there is an unlimited amount of factors that influence health, including physical activity, chemical exposure, and co-morbid health issues. A "strong" rating is only given if virtually every study on a topic agrees. As this rarely happens in science, the *Dietary Guidelines for Americans* have historically relied on both strong and moderate evidence to make key recommendations.

Our patients deserve nutrition guidance that is free of political interference. The *2015 Dietary Guidelines for Americans* will play a crucial role in the lives of millions of children and adults. Nutrition and physical activity are integral to a healthy population, and it's essential that doctors are able to continue to advise our patients based on what the evidence recommends. Congress should support, not derail, what the science shows and keep the politics out of the guidelines.

Hassink, is president of the American Academy of Pediatrics. Stack is president of the American Medical Association.

SUBMITTED STATEMENTS BY HON. MICHELLE LUJAN GRISHAM, A REPRESENTATIVE IN CONGRESS FROM NEW MEXICO

STATEMENT OF ACADEMY OF NUTRITION AND DIETETICS; AMERICAN ACADEMY OF PEDIATRICS; AMERICAN COLLEGE OF CARDIOLOGY; AMERICAN DENTAL ASSOCIATION; AMERICAN MEDICAL ASSOCIATION

As the science leaders of the Academy of Nutrition and Dietetics, American Academy of Pediatrics, American College of Cardiology, American Dental Association and

the American Medical Association, we are writing to clear up possible misunderstandings regarding scientific evidence and the *2015 Dietary Guidelines for Americans*.

We are concerned that the proposed language in the House's Departments of Agriculture, Rural Development, Food and Drug Administration and Related Agencies (section 734) and Departments of Labor, Health and Human Services and Education and Related Agencies, (section 232) Fiscal Year 2016 Appropriations Bills is an overreach regarding the intention of evidence-based science.

> (1) ***Each revision to any nutritional or dietary information or guideline contained in the 2010 edition of the*** *Dietary Guidelines for Americans* ***and any new nutritional or dietary information or guideline to be included in the eighth edition of the*** *Dietary Guidelines for Americans*—
>
> > (A) ***shall be based on scientific evidence that has been rated "Grade I: Strong" by the grading rubric developed by the Nutrition Evidence Library of the Department of Agriculture;***

The Academy of Nutrition and Dietetics' Evidence Analysis Library was established in 2004. The Nutrition Evidence Library was launched in July 2008 by the Department of Agriculture's Center for Nutrition Policy and Promotion and **mirrors the Academy's EAL but specializes in systematic reviews to inform Federal nutrition-related policies and programs.** The NEL conducts systematic reviews on food and nutrition-related topics by using a rigorous, transparent and reproducible methodology to support Federal nutrition policies and programs.

This process includes developing a specific research question on diet and health, developing a corresponding search plan for literature review designed to answer the research question, extracting data from existing literature as directed by the search plan, developing a conclusion statement to answer the question and grading the strength of evidence supporting the conclusion. A conclusion can be graded Strong, Moderate, Limited or Grade Not Assignable.

The strong rating is reserved for bodies of evidence completely free from study design concerns or disagreements between findings. The nature of science and statistics is such that a small number of contrary findings is expected and a preponderance of evidence can overcome limitations of individual studies. Therefore, recommendations with a moderate rating, which indicates a sizable body of well-designed research with which the committee had no more than minor doubts, are more than sufficient to inform the *Dietary Guidelines for Americans*.

The exclusion of recommendations with a moderate rating would strike several uncontested truths from the record available to USDA, including the relationships between sugar and cavities and between a sedentary lifestyle and obesity. Additionally, the current language would bar USDA and HHS from supporting two recommendations derived from emerging science that are vital to the health of Americans: the use of school-based nutrition and exercise programs to prevent obesity and the reduction of added sugar intake to prevent heart disease. Obesity and heart disease are deadly and costly burdens to the nation and Americans deserve access to the knowledge of every effective tool to combat them.

Nutrition focused systematic reviews, unlike pharmaceutical research, use a plethora of methodology, not just randomize clinical trials. The reason for a paucity of randomized clinical trials in nutrition literature is multifactorial but basically people must eat to survive and thus pure control groups are difficult. Fortunately, many new research methods are becoming acceptable to study key research questions relating to the health of the public. Unfortunately, many of these have yet to be utilized to fill the current large gaps in human nutrition research. Currently, the published food and nutrition research, which has been funded by the government, foundation and industry is a mixture of clinical trials, observational trials and cohort and case studies the latter of which do not receive as high of a grade value as randomized clinical trials. Thus, if the United States is to continue to guide the American population on healthy eating choices to prevent disease and have optimal health we must accept conclusion statements that are less than Grade 1 while futuristically funding rigorously designed food and nutrition studies in a variety of populations to fill the prevalent nutrition research gaps.

The DGAC's scientific conclusions and HHS/USDA's final development of the *Dietary Guidelines* use more than one question or source of evidence, such as NEL systematic reviews. The DGAC considered seven questions examining the relationship between dietary patterns and health outcomes, including cancer, type 2 diabetes and cardiovascular disease. The DGAC also reviewed evidence using a process known as

food pattern modeling to describe the combination of foods and drinks a person should consume to meet nutrient needs and the impact on chronic disease. The final *Dietary Guidelines* consider all this information.

Nutrition is an evolving science and a lack of evidence or limited evidence for one specific question does not mean that there is not strong evidence to support guidance. DGA recommendations have historically been made drawing upon both "Strong" and "Moderate" strength evidence. The *Dietary Guidelines* are developed based on the preponderance of the strongest available evidence. Limited or Moderate evidence for one health outcome could greatly limit the ability to provide guidance on dietary patterns when the evidence may be Strong for other health outcomes. Using the cutoff of "Strong" will significantly limit the ability to develop recommendations across the *Dietary Guidelines.*

The *2010 Dietary Guidelines for Americans* were based on the strongest evidence available, not just the evidence that was identified as Grade 1: Strong. Making a change for 2015 would create an inconsistency between recommendations in the 2010 DGAs, some of which are supported by "Moderate" evidence.

We ask that the House's Departments of Agriculture, Rural Development, Food and Drug Administration and Related Agencies (section 734) and Departments of Labor, Health and Human Services and Education and Related Agencies, (section 232) Fiscal Year 2016 Appropriations Bills not be included in the final spending package for Fiscal Year 2016.

We would be glad to discuss this request further. Please feel free to connect Alison Steiber, Ph.D., R.D.N., Chief Science Officer for the Academy of Nutrition and Dietetics, with your questions. (*asteiber@eatright.org*).

Thank you for your consideration.

Respectfully,

Academy of Nutrition and Dietetics;
American Academy of Pediatrics;
American College of Cardiology;
American Dental Association;
American Medical Association.

STATEMENT OF ACADEMY OF NUTRITION AND DIETETICS; AMERICAN SOCIETY FOR NUTRITION

As the food and nutrition leaders representing the of the Academy of Nutrition and Dietetics and the American Society for Nutrition, we ask for your support of the *2015 Dietary Guidelines* process to continue without interference by Congress. We are concerned that the proposed language in the House's Departments of Agriculture, Rural Development, Food and Drug Administration and Related Agencies (section 734) and Departments of Labor, Health and Human Services and Education and Related Agencies,(section 232) Fiscal Year 2016 Appropriations Bills will halt the progress of this important nutrition policy that could improve public health.

The *Dietary Guidelines for Americans* are founded in evidence-based science and should be insulated as much as possible from political influences. The Nutrition Evidence Library (NEL) was launched in July 2008 by the Department of Agriculture's Center for Nutrition Policy and Promotion. The NEL was built as an outgrowth from **the Academy of Nutrition and Dietetics' Evidence Analysis Library (EAL), developed in 2004.** The NEL **mirrors the Academy's EAL but specializes in systematic reviews to inform Federal nutrition-related policies and programs.** The NEL conducts systematic reviews on food and nutrition-related topics by using a rigorous, transparent and reproducible methodology to support Federal nutrition policies and programs. **This process includes:**

- **Developing specific research questions on diet and health.**
- **Developing corresponding search plans for literature review designed to answer the research questions.**
- **Extracting data from existing literature as directed by the search plans.**
- **Developing conclusion statements to answer each question and grading the strength of evidence supporting the conclusion.**

A conclusion can be graded Strong, Moderate, Limited or Grade Not Assignable. The Strong rating is reserved for bodies of evidence completely free from study design concerns or disagreements between findings, which is rare. Science and statistics expect a small number of contrary findings

and it is the "preponderance of evidence" that can overcome limitations of individual studies. As a result, recommendations with a Moderate rating, which indicates a sizable body of well-designed research with which the Dietary Guidelines Advisory Committee (DGAC) had no more than minor doubts, are more than sufficient to develop the *Dietary Guidelines for Americans.* The exclusion of recommendations with a Moderate rating would eliminate several uncontested truths from the record available to USDA and HHS and interfere with helping Americans consume a healthy diet.

Nutrition-focused systematic reviews draw on several types of methodologies, not just randomized clinical trials. The reason for this lack of randomized clinical trials in nutrition is multi-faceted, but, most important, people must eat to survive and pure control groups are ethically difficult. Large clinical trials are also very costly and take many years to complete. Fortunately, new research methods are becoming acceptable to study key research questions relating to the health of the population, which will hopefully enhance nutrition related research. Currently, the published food and nutrition research, which has been funded by government, foundations and industry, is a mixture of randomized controlled trials and observational studies which include prospective cohort and case-control studies. The NEL and the DGAC utilized only randomized controlled trials and prospective cohorts and did not consider results from case-control studies due to the potential for bias or weaker designs such as case reports or ecological studies. If we are to continue to guide the American population on healthy eating choices to prevent disease and have optimal health, we must accept recommendations that are rated less than Strong. The DGAC's scientific conclusions and HHS/USDA's final development of the *Dietary Guidelines* use more than one question or source of evidence, such as NEL systematic reviews. The DGAC also conducted *de novo* data analysis using data from our national nutrition surveillance system (the National Health and Nutrition Examination Survey, NHANES) and reviewed evidence using a process known as food pattern modeling, which is used to describe the combination of foods and drinks a person should consume to meet nutrient needs without exceeding calorie intake to maximize health benefits and reduce risk of diet-related chronic disease. The final *Dietary Guidelines for Americans* will consider all this information.

Nutrition, like all sciences, evolves with new research and information. A lack of evidence or limited evidence for one specific question does not mean that there is not strong evidence to support guidance. The *Dietary Guidelines* will continue to be developed on the preponderance of the strongest available evidence available at the time. Limited or Moderate evidence for one health outcome could greatly limit the ability to provide guidance on dietary patterns when the evidence may be Strong for other health outcomes. Using the cutoff of "Strong" will significantly limit the ability to develop recommendations across the *Dietary Guidelines* and could therefore undermine advances in improving public health.

We ask that the House's Departments of Agriculture, Rural Development, Food and Drug Administration and Related Agencies (section 734) and Departments of Labor, Health and Human Services and Education and Related Agencies, (section 232) Fiscal Year 2016 Appropriations Bills not be included in the final spending package for Fiscal Year 2016 based on their current language regarding the *Dietary Guidelines for Americans.*

We would be glad to discuss this request further. Please feel free to connect Alison Steiber Ph.D., R.D.N., Chief Science Officer of the Academy of Nutrition and Dietetics, at *asteiber@eatright.org* or Mary Pat Raimondi, Vice President at *mraimondi@eatright.org* with your questions.

Thank you for your consideration.

Respectfully,

Academy of Nutrition and Dietetics;
American Society for Nutrition.

SUBMITTED STATEMENT BY EDWARD ARCHER, PH.D., M.S., NIH/NIDDK RESEARCH FELLOW, NUTRITION OBESITY RESEARCH CENTER, UNIVERSITY OF ALABAMA AT BIRMINGHAM

Thank you Chairman Conaway, Ranking Member Peterson, and Members of the Committee for the opportunity to submit this statement for the record to the Committee on Agriculture, United States House of Representatives. My name is Dr. Edward Archer and I am currently an NIH/NIDDK Research Fellow at the Nutrition

Obesity Research Center, University of Alabama at Birmingham. I hold multiple graduate degrees including a Doctorate and two Masters of Science degrees with extensive training in physiology, psychology, nutrition, exercise science, and epidemiology. I have conducted extensive research, lectured, and published scientific papers in peer-reviewed journals regarding obesity, nutrition, and physical activity, particularly as they relate to the *Dietary Guidelines* published jointly by the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA). My *curriculum vitae* is attached.[1]

I am submitting this Statement for the Record because my research and a recent scientific paper of mine published in the July 2015 issue of Mayo Clinical Proceedings directly address the subject matter of this hearing, namely, the biased, unscientific methods used by USDA and HHS to collect the dietary data that have informed dietary and nutritional guidelines over the past 40 years. My paper, entitled *The Inadmissibility of What We Eat in America and NHANES Dietary Data* in NUTRITION AND OBESITY RESEARCH and the *Scientific Formulation of National Dietary Guidelines,*[2] outlines the lack of valid scientific evidence for and consequent confusion in Federal dietary guidance.

As this paper explains, "[t]he Scientific Report of the 2015 Dietary Guidelines Advisory Committee was primarily informed by memory-based dietary assessment methods (M–BMs) (*e.g.,* interviews and surveys). The reliance on M–BMs to inform dietary policy continues despite decades of unequivocal evidence that M–BM data bear little relation to actual energy and nutrient consumption. Data from M–BMs are defended as valid and valuable despite no empirical support and no examination of the foundational assumptions regarding the validity of human memory and retrospective recall in dietary assessment. ***We assert that uncritical faith in the validity and value of M–BMs has wasted substantial resources and constitutes the greatest impediment to scientific progress in obesity and nutrition research.***"[3]

The evidence is conclusive in this regard: "M–BMs are fundamentally and fatally flawed owing to well-established scientific facts and analytic truths."[4] This is so for the following reasons:

- M–BM produce data that are "***physiologically implausible***" and often "***incompatible with life.***"[5]
- "[T]he assumption that human memory can provide accurate or precise reproductions of past ingestive behavior ***is indisputably false.***"[6]
- "[T]he subjective (*i.e.,* not publicly accessible) mental phenomena (*i.e.,* memories) from which M–BM data are derived cannot be independently observed, quantified, or falsified; as such, ***these data are pseudoscientific and inadmissible in scientific research.***"[7]
- "Given the overwhelming evidence in support of our position, we conclude that ***M–BM data cannot be used to inform national*** *Dietary Guidelines* ***and that the continued funding of M–BMs constitutes an unscientific and major misuse of research resources.***"[8]

The results of the research reported in my paper demonstrate that the dietary data collected by the USDA and HHS via the National Health and Nutrition Examination Survey (NHANES) and analyzed by the 2015 Dietary Guidelines Advisory Committee (DGAC) were derived from fatally flawed, unscientific methods. As such, the USDA and HHS data are meaningless numbers, not scientific evidence.

This finding is critical because, as Chairman Conaway correctly stated, dietary guidance should be "*based on sound, consistent and irrefutable science.*"[9] I assert

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[1] *Exhibit A.**

* **Editor's note:** this document is retained in Committee file.

[2] *Exhibit B* (Edward Archer, Ph.D.; Gregory Pavela, Ph.D.; and, Carl J. Lavie, M.D., *The Inadmissibility of What We Eat in America and NHANES Dietary Data* in NUTRITION AND OBESITY RESEARCH and the *Scientific Formulation of National Dietary Guidelines,* MAYO CLIN. PROC., 90(7): 911–926 (July 2015), also available at *http://dx.doi.org/10.1016/j.mayocp.2015.04.009* (last accessed Oct. 19, 2015).

[3] *Id.* at 911 (emphasis added).

[4] *Id.*

[5] *Id.* at 914 (emphasis added). "Incompatible with life" means the survey respondent could notsurvive on the amount of food and beverages he or she reported consuming.

[6] *Id.* at 911 (emphasis added).

[7] *Id.* (emphasis added).

[8] *Id.* (emphasis added).

[9] Chairman K. Michael Conaway, U.S. House of Rep. Comm. on Agric., Full Committee—*Public Hearing:* ***2015 Dietary Guidelines for Americans*** (Oct. 7, 2015), Videotape at 00.01.05–

that because the NHANES dietary data are "***incompatible with life***"[10] and are therefore not representative of what Americans actually eat, it is clear that **these data are unequivocally not** "*sound, consistent and irrefutable science.*"[11]

Importantly, the testimony and written statements of The Honorable Tom Vilsack, Secretary, United States Department of Agriculture, and The Honorable Sylvia Burwell, Secretary, United States Department of Health and Human Services, do not bear up under scientific review. For example, Secretary Burwell's testimony that food pattern analyses allowed the DGAC to understand "*what is it actually Americans are eating . . .*"[12] ***is patently false.*** All food pattern analyses in the DGAC report were based on dietary data that are "*incompatible with life.*"[13] Food pattern analyses based on physiologically implausible data cannot be representative of "*what is it actually Americans are eating.*"[14]

Secretary Vilsack testified "*we should take a look at the Healthy Eating Index.*"[15] The Healthy Eating Index estimates are derived from the physiologically implausible NHANES dietary data. It should be obvious that a valid Healthy Eating Index cannot be created from dietary data that are "*incompatible with life.*"[16]

Secretary Vilsack also testified the DGAC review process produces the "*strongest, best . . . available science*"[17] and the "*best science . . . best available science . . . and least biased science*"[18] and wrote "*the 2015 Dietary Guidelines for Americans will be grounded in the preponderance of the best available scientific evidence.*"[19] **These statements are patently false.** Data from scientific papers demonstrating the implausible nature of both M–BM and the NHANES dietary data[20] were excluded from the 2015 DGAC's report, and have been excluded from all previous DGAC reports. **The decades-long exclusion of contrary data is in violation of the Data Quality Act,**[21] **and is indicative of the bias and scientific misconduct (*i.e.*, omission of data) of the DGAC.**

Sincerely,

EDWARD ARCHER, PH.D., M.S.

EXHIBIT A*

EXHIBIT B

***The Inadmissibility of What We Eat in America and NHANES Dietary Data in Nutrition and Obesity Research and the Scientific Formulation of National** Dietary Guidelines*

MAYO CLINIC PROCEEDINGS

Article in PressSpecial Article

Mayo Clin Proc. n XXX 2015;nn(n):1–16 n http://dx.doi.org/10.1016/j.mayocp.2015.04.009 ■ *www.mayoclinicproceedings.org* ■ 2015 Mayo Foundation for Medical Education and Research.*

00.01.08 (emphasis added) ("**Hearing Videotape**"), available at *https://www.youtube.com/watch?v=x6DNns4oFao&feature=youtu.be* (last accessed Oct. 19, 2015).

[10] *Ex. B* at 914 (emphasis added).

[11] *See supra* note 9.

[12] Hon. Sylvia Burwell, Sec'y, U.S. Dep't of Health & Human Servs., Hearing Videotape at01.52.34–01.52.36 (emphasis added).

[13] *Ex. B* at 914 (emphasis added).

[14] *See supra* note 12.

[15] Hon. Tom Vilsack, Sec'y, U.S. Dep't of Agric., Hearing Videotape at 01.21.32–01.21.34(emphasis added).

[16] *Ex. B* at 914 (emphasis added).

[17] *See supra* note 15 at 00.12.26–00.12.30 (emphasis added).

[18] *Id.* at 01.53.12–01.53.17 (emphasis added).

[19] Statement by Thomas J. Vilsack, Sec'y of Agric., U.S. House of Rep. Committee on Agric.(Oct. 7, 2015) at 5.

[20] *See, e.g., Exhibit C* (Archer E., Hand G.A., Blair S.N., *Validity of U.S. Nutritional Surveillance: National Health and Nutrition Examination Survey Caloric Energy Intake Data, 1971–2010,* PLOS ONE (2013), at 8(10):e76632), available at *http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0076632* (last accessed Oct. 19, 2015).

[21] Pub. L. No. 106–554, H.R. 5658 (Treasury and Gen. Gov't Appropriation Act for Fiscal Year 2001, § 515 Appendix C, 114 Stat. 2763A–153 (2000) (effective Oct. 1, 2002).

*The document referred to is retained in Committee file.

*From the Office of Energetics, Nutrition Obesity Research Center, University of Alabama at Birmingham, Birmingham (E.A., G.P.); and Department of Cardiovascular Diseases, John

Continued

Edward Archer, Ph.D.; Gregory Pavela, Ph.D.; and Carl J. Lavie, M.D.

Abstract

The *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* was primarily informed by memory-based dietary assessment methods (M–BMs) (*e.g.,* interviews and surveys). The reliance on M–BMs to inform dietary policy continues despite decades of unequivocal evidence that M–BM data bear little relation to actual energy and nutrient consumption. Data from M–BMs are defended as valid and valuable despite no empirical support and no examination of the foundational assumptions regarding the validity of human memory and retrospective recall in dietary assessment. We assert that uncritical faith in the validity and value of M–BMs has wasted substantial resources and constitutes the greatest impediment to scientific progress in obesity and nutrition research. Herein, we present evidence that M–BMs are fundamentally and fatally flawed owing to well-established scientific facts and analytic truths. First, the assumption that human memory can provide accurate or precise reproductions of past ingestive behavior is indisputably false. Second, M–BMs require participants to submit to protocols that mimic procedures known to induce false recall. Third, the subjective (*i.e.,* not publicly accessible) mental phenomena (*i.e.,* memories) from which M–BM data are derived cannot be independently observed, quantified, or falsified; as such, these data are pseudoscientific and inadmissible in scientific research. Fourth, the failure to objectively measure physical activity in analyses renders inferences regarding diet-health relationships equivocal. Given the overwhelming evidence in support of our position, we conclude that M–BM data cannot be used to inform national *Dietary Guidelines* and that the continued funding of M–BMs constitutes an unscientific and major misuse of research resources.

 ■ *Mayo Clin Proc.* 2015;nn(n):1–16.

When the facts change, I change my mind.
What do you do, sir?

JOHN MAYNARD KEYNES [1, p. 19]

Success, Failure, and Confusion in Nutrition Research

During the past century, our nation's food supply and the nutritional status of Americans have improved to a level unparalleled in human history.[2–3] Although this reality may be contrary to the popular belief that our modern diet is inherently inadequate, the data are clear. In the early 20th century, nutritional diseases such as pellagra, beriberi, rickets, and goiter were substantial public health challenges. In the United States alone, pellagra (a disease of niacin deficiency) claimed more than 100,000 lives and severely affected more than three million people.[4] Yet in 2013, the Centers for Disease Control and Prevention's Second National Report on Biochemical Indicators of Diet and Nutrition reported that nearly "80% of Americans (aged ≥6 y) were not at risk of deficiencies in any of the 7 vitamins" [4, p. 938] examined via biomarkers (*i.e.,* vitamins A, B_6, B_{12}, C, D, E, and folate; emphasis added).[2] In addition, approximately 90% of women of childbearing age (12–49 years) were not at risk for iron deficiency, and folate levels have increased by approximately 50% since the previous national report.[2, 5] As such, most of the U.S. population is not at risk for nutritional deficiencies, and neither do they have nutritional deficienciesand associated diseases.

Given these important improvements in diet-related health and recent work demonstrating that nongenetic evolution is the predominant driver of the diseases of excess (*e.g.,* obesity and type 2 diabetes mellitus),[6–8] it can be posited that diet is no longer a major risk factor for disease for most Americans. If accurate, this hypothesis suggests that the billions of research dollars targeted for diet and nutrition-related health research are misdirected.[9–10] Nevertheless, despite the important dietary milestones of the past century and the substantial increases in Federal funding during the past 2 decades,[9–10] research into human nutrition has been increasingly criticized.[11–13] The genesis of these criticisms is the appalling track record of highly publicized nutrition claims derived from epidemiologic studies (*e.g.,* see the studies by Stampfer, *et al.*[14] and Rimm, *et al.*[15]) that consistently failed to be supported when tested using objective study designs. [11, 16] Young and Karr examined [17] more than 50 nutritional claims from observational studies for a variety of dietary patterns and nutrient supplementation and found that "100% of the observational claims failed to replicate" [p. 117] and that five claims were statistically significant "in

Ochsner Heart and Vascular Institute, Ochsner Clinical School the University of Queensland School of Medicine, New Orleans, LA (C.J.L.).

the opposite direction."[p. 117] These outcomes and others[18–21] suggest that as often as not, when epidemiologic nutrition claims are tested against objective research methods, the results are either inconclusive or indicative of a contrary outcome.

A Failed Research Paradigm

Epidemiologic studies suggest that almost any nutrient can be associated with a myriad of outcomes,[11, 22] as observed in Schoenfeld and Ioannidis' article, "Is Everything We Eat Associated With Cancer?"[22, p. 117] With persistent cycles of specious nutrition claims in the media, it is not surprising that the public is confused and incredulous.[23] Insofar as the provision of clear and consistent *Dietary Guidelines* for the consuming public is a goal of nutrition epidemiology, it has failed in decisively answering the simple question, "What should we eat?"[24] Nowhere is this fact more evident than the shifting sands of opinion on the relative risks of fat, salt, cholesterol, and sugar.[25–30] Five decades of controversy surrounding basic *Dietary Guidelines* and nutrition recommendations is a public acknowledgement of a failed research paradigm. The striking incongruence between the improvements in the nutritional status of the U.S. population[2, 5] and the current state of confusion, controversy, and clinical failure of epidemiologic nutrition research could not be clearer and necessitates an examination of the validity and value of epidemiologic nutrition research.

Purpose of this Review

Memory-based dietary assessment methods (M–BMs) (*e.g.,* interviews, questionnaires, and surveys[31–32]) are the dominant data collection protocols in national nutrition surveillance[33] and government-funded epidemiologic nutrition[34] and obesity[33] research. Importantly, M–BM data are used to inform national nutritional policy and *Dietary Guidelines*.[30] The recent Scientific Report of the 2015 Dietary Guidelines Advisory Committee (DGAC) stated explicitly that most of the DGAC data analyses used the M–BMs of the National Health and Nutrition Examination Survey (NHANES) dietary component, What We Eat in America (WWEIA).[30] Although decades of unequivocal evidence demonstrate that the indirect, proxy estimates derived from M–BMs bear little relation to actual energy or nutrient consumption,[13, 33, 35–45] the underlying assumptions regarding the validity of human memory and recall in dietary assessment have not been questioned. To the contrary, M–BM data are vigorously defended as valid and inherently valuable despite no empirical support for those assertions.[46] Although the relationship between two different constructs may be expected to be weak, the trivial relationships between the proxy estimates (*i.e.,* self-reported energy intake [EI] and nutrient intake) and their referents (*i.e.,* actual EI and nutrient intake) are unacceptable. We assert that the explanatory and predictive failure of epidemiologic nutrition research is explained by its reliance on M–BMs, and, as such, the uncritical faith in the validity and value of M–BMs has wasted significant resources and constitutes the single greatest impediment to actual scientific progress in the fields of obesity and nutrition research.

The purpose of this review is to survey the explanatory and predictive failure of nutrition epidemiology in general,[11, 17] with a focus on the WWEIA–NHANES data,[33] and argue that these failures are due to the reliance on M–BMs. First, we present evidence that the anecdotally derived proxy data produced by M–BMs bear little relation to actual EI or nutrient consumption.[13, 33, 35–45] Second, we provide interdisciplinary evidence that human memory is an amalgam of constructive and reconstructive processes[47–52] (*e.g.,* imagination[53]) that render the archival model of human memory[54] and the naïve assumption that recall provides literal, accurate, or precise reproductions of past events indisputably false.[50, 52, 55–58] Third, M–BMs require respondents to undergo protocols[59] and perform behaviors[31] that mimic procedures known to induce false recall.[50, 52, 53, 60, 61] Fourth, the subjective (*i.e.,* private, not publicly accessible) mental phenomena (*i.e.,* memories) from which M–BM data are derived are not subject to independent observation, quantification, falsification, or verification; as such, M–BM data are pseudoscientific and inadmissible in scientific research.[62–66] Fifth, the failure to accurately and objectively measure and control for physical activity (PA), cardiorespiratory fitness (CRF), and other obvious confounders annuls inferences regarding diet-health relationships.

The M–BMs of Nutrition Epidemiology

Self-Reported Dietary Intake

The primary methods of data collection for nutrition epidemiologic research (*e.g.,* the WWEIA–NHANES) are M–BMs (*e.g.,* 24 hour dietary recalls [24HRs] and food frequency questionnaires [FFQs][31–33]). For clarity, these methods do not directly or objectively measure EI or nutrient intake, and neither do they directly or objectively measure food and beverage consumption. The actual data derived from M–BMs are

the a priori numeric values from nutrient databases that are assigned by researchers to the participants' reports of their memories of past eating and drinking behaviors. In other words, nutrition researchers designate numeric values to whatever the respondents are willing or able to recall about what they think (or would like the researcher to think[67]) he or she consumed during the study period. Given the indirect, pseudoquantitative (*i.e.,* number-generating[68]) nature of M–BMs and the fact that the respondents' reports of their memories are subject to intentional and unintentional distorting factors (*e.g.,* perceptual, encoding, and retrieval errors;[69] social desirability;[42] false memories;[55] and omissions[48, 49, 70]), it is not surprising that most conclusions drawn from these number-generating protocols have not been supported when subjected to rigorous objective examination.[11, 17]

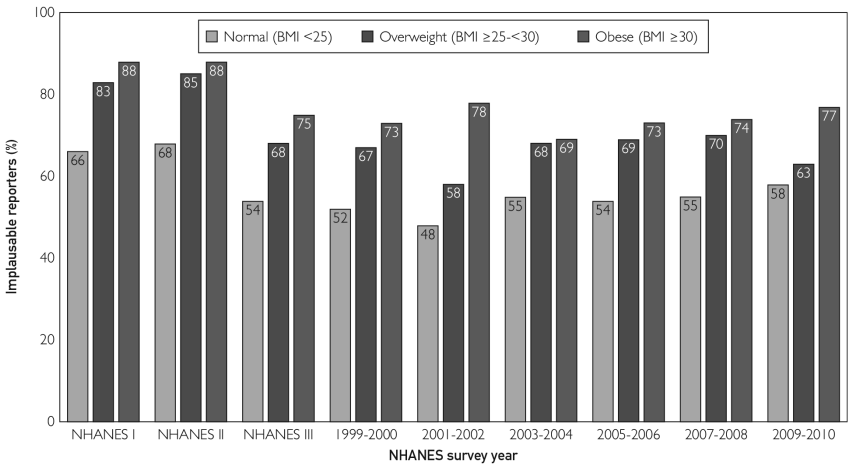
The Implausibility of M–BMs in Dietary Assessment

> *It is the natural tendency of the ignorant to believe what is not true. In order to overcome that tendency it is not sufficient to exhibit the true; it is also necessary to expose and denounce the false.*
>
> H.L. MENCKEN[71, p. 124]

Research into M–BMs reports a wide range of EIs that are not physiologically plausible (*i.e.,* incompatible with survival) and that do not accurately quantify the foods and nutrients consumed.[11, 33, 35, 38–40, 42] Recently, we used multiple methods to ascertain the validity and plausibility of the NHANES and WWEIA–NHANES EI data from 1971 to 2010[33] and found that they had such severe systematic biases as to render them fatally flawed. Given that "[a] cross the 39 year history of the NHANES, [self-reported energy intake] data on the majority of respondents (67.3% of women and 58.7% of men) were not physiologically plausible"[33] (*Figure*), we concluded that these data are not valid for any inferences regarding EI and the etiology of the obesity epidemic. A recent editorial in the *British Medical Journal* concurred and stated that the NHANES dietary data are "incompatible with life."[11, p. 7]

In a previous report,[33] we used two objective, physiologically based methods to determine misreporting: (1) Goldberg cutoff values[44, 45, 72] (*i.e.,* reported EI [rEI] divided by basal metabolic rate [BMR]) and (2) the disparity between the Institute of Medicine total energy expenditure (TEE) equations[73] and rEI via NHANES MBMs. The two methods were in close agreement, demonstrating significant misreporting. The cutoff values we used (*i.e.,* rEI/BMR <1.35 and >2.40) were more generous than the rEI/BMR cutoff value of 1.50 suggested by Goldberg *et al.*[45] when using a single 24HR, and the BMR is "predicted from the Schofield equations" with a sample size of 300 or greater.[45, p. 577] Given the reduced sensitivity of the cutoff values, we captured far fewer under-reporters. As reported, when using the proposed cutoff value of 1.50, under-reporting increased to more than 70% for the entire NHANES sample and to approximately 77% and 85% for obese men and women, respectively. We also reported the large and significant disparity between rEI and the Institute of Medicine TEE: −467 and −554 kcal/d (>17% and 30%) for obese men and women, respectively. In addition to under-reporting, there was significant overreporting in all of the subpopulations (*e.g.,* normal, overweight, and obese men and women). One important caveat with the use of cutoff values is that the term *plausible reporter* is not synonymous with *accurate reporter.* Participants with high levels of PA may substantially underreport yet still be considered plausible reporters.

Figure



Percentage of implausible reporters by body mass index (BMI) for U.S. women aged 20 to 74 years in the National Health and Nutrition Examination Survey (NHANES) (1971–2010). Physiologically implausible values were determined via the following equation: (reported energy intake/basal metabolic rate) ≤1.35. Implausible values may be considered "incompatible with life."[11, p. 7]

Given these results, we ask four questions, (1) What is the value of WWEIA–NHANES M–BM data if 70% to 80% of obese women's self-reported EI is physiologically implausible and, therefore, incompatible with life (*Figure*)? (2) Given the extant objective data on the nutrition-related health status of Americans,[2] why does the DGAC rely on the subjective M–BM data?[30] (3) What is the "unrealized potential"[46, p. 447] and "utility"[74, p. 5] of these data when implausible overreporting and implausible underreporting are demonstrated in all of the subgroups? (4) Can statistical alchemy transform these implausible data into valid estimates of dietary consumption, or will it continue to spawn searches for machinations that generate numbers with improved correlations (*i.e., post hoc* data manipulation) while ignoring the lack of validity?

The Pervasiveness of Implausible Results

The conclusions drawn by our study[33] and the recent *British Medical Journal* editorial[11] are, in fact, supported by many decades of evidence demonstrating that M–BMs have severe, intractable systematic biases that render the data implausible and, therefore, invalid.[11, 13, 37, 44, 75, 76] Research with ". . . motivated . . . well-educated, non-smoking-Caucasians"[35, p. 957] (*i.e.,* respondents less likely to misreport) demonstrated that compared with doubly labeled water, a biomarker for TEE, self-reported dietary intake was significantly misestimated.[35, 38] Men underreported EI 12% to 14% using the average of two 24HRs and 31% to 36% using FFQs. Women underreported by 16% to 20% using the average of two 24HRs and by 34%to 38% using FFQs. Contrary to the oft-repeated statement that additional self-reports improve precision and accuracy, the second administration of the 24HR "showed greater underreporting."[38, p. 12] These results are in agreement with our analyses of the NHANES in which the mean estimates for the second 24HR in every NHANES wave from 2001 to 2010 exhibited significantly greater levels of underreporting than the first. We agree with the authors of the Observing Protein and Energy Nutrition study when they wrote, "[w]e measure energy so poorly . . ."[38, p. 12] and "[t]he 24HR . . . may be particularly problematic in the obese." 35,p956 These words echo statements on underreporting from 60 years ago.[77]

Recently, some of the strongest proponents of M–BMs have provided additional data that clearly demonstrate the futility of the continued use of these methods.[36] In the paper by Freedman, *et al.,*[36] the pooled, squared average correlation between true EI and self-reported EI were similar to our results using NHANES data, ranging from 0.04 to 0.10. This suggests that the measurement noise (*i.e.,* error) is more than nine times greater than the signal (*i.e.,* valid information) derived from M–BMs. Nevertheless, an important finding from the *Observing Protein and Energy*

Nutrition study that Freedman, *et al.*[36] overlook in their analyses is that despite the fact that the second administration of the 24HR "showed greater underreporting,"[38, p. 12] the correlations between true and reported EI increased. This demonstrates an increase in precision with a concomitant reduction in the accuracy of the estimate. These results clearly support our position that M–BM data "offer an inadequate basis for scientific conclusions"[13, p. 1413] and, more importantly, that statistical machinations, however sophisticated, cannot overcome the systematic recall bias that renders all inferences suspect.[41, 78]

The phenomenon of misreporting is not limited to U.S. epidemiologic studies or specific populations.[45] The *European Prospective Investigation Into Cancer and Nutrition* study is one of the largest epidemiologic studies in the world and found strong evidence of systemic underreporting across all study sites, with approximately 10% to 14% of survey respondents being "extreme underreporters,"[79, p. 1329] and ". . . most centres were below the expected reference value."[79, p. 1330] These results are consistent with research from the early 1990s that found that more than 65% of the mean rEI values were physiologically implausible in 37 studies across ten countries.[45] The misreporting value of more than 65% is strikingly similar to our NHANES results using similar methods.[33] In 2015, a multinational report demonstrated that misreporting "in five populations of the African Diaspora"[80, p. 464] was substantial, with the South African cohort exhibiting an astounding 52.1% underreporting of dietary EI.[80] With respect to age, Forrestal[81] found in children and adolescents that misreporting ". . . appeared to be more common than it is among adults."[p. 112] The ubiquitous nature of misreporting and the consistency of research results over many decades and across multiple populations, cohorts, and countries provide strong support that M–BM measures of EI are fatally flawed, and, therefore, diet-health inferences from studies that use M–BMs are essentially meaningless.

Examinations of Dietary Patterns via M–BMs

It is well-established that specific macronutrients, foods, beverages, and food groups (*e.g.,* protein, fat, carbohydrate, alcohol, sugar, and vegetables) are subject to differential misreporting that significantly affects subsequent estimates of EI.[38, 78, 82–88] Because EI is the foundation of dietary consumption and all nutrients must be consumed within the quantity of food and beverages needed to meet minimum energy requirements,[89] it is a logical and analytic truth that dietary patterns (*i.e.,* macronutrient and micronutrient consumption; *e.g.,* protein, carbohydrate, fat, vitamins, and minerals) are differentially and unpredictably misreported when total rEI is physiologically implausible. For example, both macronutrient and micronutrient composition are significantly altered in underreporters, with reported fat and carbohydrate consumption often lower and reported protein, fruit, and vegetable intakes higher.[42, 82, 86] In other words, participants qualitatively and quantitatively misreport owing to both unintentional (*e.g.,* forgetting and false memories) and intentional (*e.g.,* health-related perceptions) factors. This nonuniformity of misreporting leads to macronutrient- and micronutrient-specific errors,[86–87] which alter nutrient to EI ratios in an unpredictable and nonquantifiable manner. This simple fact renders energy adjustments fallacious[41, 78] and demonstrates that the assumption that M–BM data can be used to examine patterns of diet or dietary composition is not logically valid.

The Validity of Human Memory and Recall as Instruments for the Generation of Scientific Data

Overview

The use of M–BMs requires faith in the belief that human perception, memory, and recall are accurate and reliable instruments for the generation of scientific data. Nevertheless, more than 80 years of research demonstrates that this belief is patently false.[50, 58, 70, 90] The discrepancy between objective reality and human memory is well established,[48, 91] and the limitations of recall are widely acknowledged in disciplines outside of nutrition and obesity.[47–49, 69, 70, 92] In fact, the scientific study and analysis of memory would be impossible if it were not for the inherent fallibility of memory.[49] Bartlett[93] presented the first empirical evidence that the human memory is not a literal, accurate, or precise reproduction of past events. During the ensuing 80 years, research has clearly demonstrated that the encoding of memories[69, 91] and subsequent recall depend on constructive and reconstructive processes (*e.g.,* imagination)[48, 69, 53] that are susceptible to errors, distortions, omissions, complete fabrications, false reports, and illusions.[50, 58, 69, 70, 90]

Given the breadth of this research, reported memories, such as those presented in 24HRs and FFQs, can be most accurately defined as mere attributions based on mental experiences that are strongly influenced by the respondents' idiosyncratic

qualities (*i.e.,* education), previous memories and information, knowledge and beliefs, motives, goals, habitual behavior, and the social context in which the memories are encoded or reported.[47, 49, 58] Perhaps the most salient example of the fallibility of memory and recall (and misplaced confidence) is that false reporting (*i.e.,* inaccurate eyewitness testimony) was a key factor in approximately 75% of the first 100 cases of individuals exonerated by DNA evidence after conviction for crimes that they did not commit.[57] The following subsections provide a survey of the evidence to support the contention that data can be only as valid as the accuracy of the instrument used in its collection and that human memory and recall are not valid instruments for the generation of data to be used in the scientific formulation of nutrition guidelines.

The Social Sciences

Numerous studies, dating back more than 50 years, have reported that there is little or no correlation between self-reported behavior and actual behavior.[94–95] Bernard, *et al.*[58] reviewed the validity of self-reported data in "The Problem of Informant Accuracy." Surveying multiple research domains, including health care, child care, communications, nutrition, criminal justice, economics, anthropology, and psychology, Bernard, *et al.*[58] concluded that "[t]he results of all of these studies leads to one overwhelming conclusion: on average, about ½ of what informants report is probably incorrect in some way."[p. 503] Bernard, *et al.*[58] also provide a prescient commentary: "In sum, despite the evidence, the basic fact of informant inaccuracy seems not to have penetrated either graduate training or professional social science research. Informant inaccuracy remains both a fugitive problem and a well-kept open secret."[p. 504] Given the substantial funding of M–BMs each year,[9–10] it seems that this 30 year old commentary also applies to nutrition and obesity research.

Furthermore, when events or behaviors are commonplace (*e.g.,* food and beverage consumption), previous experiences (*e.g.,* previous memories and mental schema[69, 96] of past meals) will determine what is encoded in memory and not the actual perception of behavior. For example, Freeman, *et al.*[97] demonstrated a 52% error rate in recalling social interactions, with reports of social interactions shaped by typical past experiences. They explain their results by suggesting that when events are repeatedly experienced, each specific event will be minimally processed and the "actual memory of such elements will be poor," and "attempts at recall result in a constructive process that taps into the general structure rather than the specific memory."[97, p. 315]

Importantly, Bernard, *et al.*[58] lamented two common problems with social scientific data: (1) the lack of an explicit formal theory of human behavior and (2) objective evidence from which to test the plausibility of self-reported data. Nevertheless, nutrition epidemiologists have both a formal theory (*i.e.,* human metabolism and the basic energy requirements of human life) and voluminous objective data[44–45] by which to test the validity of M–BMs.[33] Despite the availability of formal theory and overwhelming evidence that self-reported EI data are not accurate, "plausible,"[33] or even "compatible with life,"[11, p.7] self-reported EI continues to be assumed a valid-measure of actual energy and nutrient consumption that can be used to inform public nutrition and dietary policy.[30]

A detailed review of the social research literature is beyond the scope of this paper, and we direct our readers to Bernard, *et al.*'s review.[58] Nevertheless, one more notable example is warranted. Immediately on leaving a restaurant, Kronenfeld, *et al.*[98] had participants report on the attire of the waitstaff and the restaurants' choice of music.[58] Participants demonstrated much greater agreement on what the waiters were wearing compared with the waitresses' attire. The interesting finding was that these restaurants had an all-female waitstaff (*i.e.,* there were no waiters in the restaurants). Participants also provided much greater detail on the music from restaurants that were not playing music than from restaurants that were.[58, 98] These results raise the question: What is the possibility that self-reported food and beverage consumption in a restaurant setting will be a literal, accurate, or reliable representation of actual ingestive behavior?

Cognitive Neuroscience

The domain of cognitive neuroscience supports the hypothesis that human memory is an amalgam of dynamic constructive and reconstructive processes.[47–53, 55–57, 69, 70] For example, encoding is not a process that begins *de novo* with each perception. Encoding is the result of the limited amount of information available to perception at any given moment being "patched together to form memories with varying degrees of accuracy"[49, p. 149] (*e.g.,* the process of associative grouping via semantic relatedness[50, 92, 99]) and subject to "the distorting influences of present knowledge, beliefs, and . . . previous experience."[49, p. 149] As such, the general knowledge and

availability of mental schemas from previous eating occasions intrude on the encoding of current consumption to produce false and fuzzy (*i.e.,* gist) memories.[51, 100] Memory and recall are subject to a myriad of unintentional "sins,"[70] including but not limited to distortions, misattribution, suggestibility, simple forgetting, falsehoods, and omissions.[49, 90–91] Because selective and elaborative processes operate on the perceptions that are encoded and recalled, "memory does not [and cannot] operate like a video recording."[57, p. 119]

Recently, the process of reconsolidation (*i.e.,* the reconstruction and re-encoding of memories after recall) has been demonstrated in rodents, and the evidence in humans is supportive.[101–102] Reconsolidation involves the same neural processes as the encoding of the original memory.[91] Therefore, each time a memory is recalled, it is irretrievably changed such that the original memory no longer exists and a new memory of unquantifiable error replaces it.[101–102] This fact has implications for the current state-of-the-art 24HR instrument the U.S. Department of Agriculture (USDA) Automated Multiple-Pass Method.[31] With each pass of the multipass procedure, the process of reconsolidation alters the original memory so that by the end of the data collection period, the result will be an amalgam of multiple new memories and reports with unquantifiable error. As such, neither the researchers nor the participants know the validity or reliability of the reported food and beverage consumption.

False Reporting: An Inherent Design Feature of M–BMs

False Reporting and FFQs

False reports are the recollection of an event, or details of an event, that did not actually occur.[69] False memories and recalls may be produced in multiple contexts (*e.g.,* during research,[55, 103] psychotherapy, and criminal investigatory interviews[60]). Although research has demonstrated that false memories of ingestive behavior and subsequent false reporting of foods occur in laboratory settings,[55, 61, 103] there is a larger literature base outside of nutrition. The Deese-Roediger and McDermott (DRM) paradigm is commonly used in research settings to elicit false reports.[104–105] In this protocol, a list of semantically related words (*e.g.,* breakfast, bacon, sausage, orange juice, and cereal) are presented or read to participants. After a delay (minutes to days), participants are asked to report the words they remember. The mere presentation of lists of semantically related words induces extremely high levels (*i.e.,* >75%) of the false reporting of related but nonpresented words (*i.e.,* critical lures;[49, 99, 105] *e.g.,* the word egg in the previous example). The DRM paradigm is so effective at inducing false reports that memory distortions occur even in the small percentage of individuals with highly superior memories.[50] With the DRM paradigm, respondents are often more confident in their false reports than in the presented words.[92]

Researchers familiar with FFQs will recognize that, by design, FFQs mimic the DRM protocol in that lists of semantically related words (*i.e.,* foods and beverages) are presented and respondents are expected to provide a response. Given that FFQs mimic the procedures designed to produce false recall, it is not surprising that FFQs with longer lists of semantically related words elicit more responses.[106] Given the vast literature demonstrating misreporting with FFQs[35, 38, 42, 107] and the parallel literature on the extremely high level of false reports using the DRM paradigm,[92, 100, 104–105] it is not a question of whether FFQs induce false reporting but to what extent. As stated previously, neither the researchers nor the participants know the validity or reliability of the reported food and beverage consumption, and neither can they quantify the error induced via false reporting. As we discuss in a later section, the inability of current nutrition epidemiologic research designs to independently falsify or confirm M–BM data renders the error due to false reports unquantifiable and, therefore, inadmissible as scientific data.

False Reporting and the WWEIA–NHANES 24HR

Recent research has examined the effects of creating "false memories for food preferences and choices."[55, 61, p. 134] We refer our readers to a review by Bernstein and Loftus.[55] Their work has established that it is relatively simple to "implant false beliefs and memories regarding a variety of early childhood food-related experiences."[55, p. 138] We assert that false memories and reports are induced via the NHANES interview protocol itself, as has been demonstrated in other interviewing contexts.[60] The factors that potentially induce false memories and reporting are well established. For example, the development of a rapport between an authority figure and respondents followed by the use of guided imagery, silence in responding, repetition, props, suggestive or repeated questioning, and encouragement to reminisce, imagine, or elaborate on past behaviors have all been shown to increase false recall.[55, 69, 91, 92, 100, 105] All of these factors are explicitly described in the training

manual for the research personnel who conduct the NHANES 24HR.[59] The use of rapport, silence, imagery, props, repeated questioning, eye contact, and "expectant looks,"[p. 4–12] to "motivate the respondent to answer more fully",[p. 4–4] are explicit and noteworthy in the training manual.[59] For example, the following directive is an exemplar of the potentially false memorye inducing protocol: "If you sit quietly—but expectantly—your respondent will usually think of something. Silence and waiting are frequently your best probes for a 'don't know' reply. Always try at least once to obtain a reply to a 'don't know' response, before accepting it as the final answer."[59, p. 4–13] The use of rapport combined with repeated questioning, silence, eye contact, and expectant looks is especially coercive when applied by an authority figure in a research context. In addition, NHANES personnel are directed to ask respondents to "imagine," and "think" about their food intake and to "encourage" and ensure that the respondents are "convinced of the importance of the survey."[59, p. 4–3] Throughout the manual there are examples of guided imagery and suggestive questioning, such as directing participants to begin "thinking about where you were, who you were with, or what you were doing, like working, eating out, or watching television,"[59, p. 6–2] and directives such as, "Your own state of mind your conviction that the interview is important will strongly influence the respondent's cooperation. Your belief that the information you obtain will be significant and useful will help motivate the respondent to answer fully . . ."[p. 4–4] Although the NHANES training manual states that "[t]his methodology is designed to maximize respondents' opportunities for remembering and reporting foods they have eaten,"[p. 6–2] the scientific literature on false memories and recall strongly supports the contention that the NHANESM–BM generates significant false reporting. Given that imagination and coercive techniques (*e.g.,* the use of silence[59]) are known to increase the probability of illusory (*i.e.,* false) recollections,[53, 60] it may be that most 24HR data are false reports. If true, the NHANES 24HR is a mere exercise in number generation, and, therefore, by design, it does not provide proxy estimates of energy or nutrient consumption. This premise provides an empirically supported explanation why most M–BM data are implausible and have trivial relationships with reality (*i.e.,* actual EI and nutrient intake.) Nevertheless, without objective corroboration it is impossible to quantify what percentage of the recalled foods and beverages are completely false, grossly inaccurate, or somewhat congruent with actual consumption. Regardless, it is clear that people consistently "remember [and report] events that never happened."[105, p. 803]

The Inadmissibility of M–BM Data

Criteria for Scientific Research: Observable, Measurable, and Falsifiable

Although the terms *science* and *research* are used interchangeably, they are not synonymous. Science is more than mere data collection; it is an attempt to discover order, a potentially self-correcting, explanatory, and predictive process that demonstrates lawful relations (*e.g.,* diets high in vitamin C prevent scurvy). In contrast, research is simply the process of collecting information, and many forms of research do not meet the rigor necessary for the results to be scientific. There is a long history of efforts to formally demarcate scientific from nonscientific and pseudoscientific data, the most famous of which may be Popper's falsifiability criterion.[64–66] For example, in U.S. jurisprudence, the Daubert standard[108–109] provides the rules of evidence for the admissibility of expert testimony. The criterion of falsifiability is central to expert scientific testimony and was used by Judge William Overton in ruling in *McLean* v. *Arkansas Board of Education.* This case determined that creation science was not a science because it was not falsifiable and, therefore, could not be taught as science in Arkansas public schools.[110] As we detail in later sections, we assert that M–BM data are akin to creation science in that they fail to meet the basic requirements of scientific research.

Although philosophers continue to debate demarcation criteria, practicing scientists must set forth principles from which to judge the admissibility of data in scientific research. We extend Popper's criterion and proffer the following widely accepted principles of scientific inquiry. First, for results to be scientific, the study's protocols must produce outcomes that are subject to replication. To accomplish this goal, the data must be (1) independently observable (*i.e.,* accessible by others), (2) measureable, (3) falsifiable, (4) valid, and (5) reliable. These nonmetaphysical criteria were first suggested by Roger Bacon in the 13th century and later were elaborated on by the "father of empiricism," Sir Francis Bacon, in the late 16th century.[111] They were again reiterated by Sir Isaac Newton in the 17th century[112] and have been subsequently clarified and defined.[62–66, 68] The skepticism and empirical rigor inherent in these criteria are of such importance to science that The Royal Society of London, the oldest scientific society in the modern world, succinctly summarized them in its motto, *Nullius in Verba.* This phrase, derived from Horace's *Epis-*

tles,[113] is translated as "on the word of no one" or "take no one's word for it" and suggests that scientific knowledge should be based not on authority, rhetoric, or mere words but on objective evidence.

The first three criteria (*i.e.,* independently observable, measureable, and falsifiable) define the phenomena that are in the domain of science (*i.e.,* able to be examined via the scientific method), and the final two criteria (*i.e.,* validity and reliability) refer to the concordance between a measurement and its referent as well as the error associated with the measurement protocols used to collect the data. Together, the five basic tenets distinguish scientific research from mere data collection and pseudoscience. For example, if someone is eating an apple, his or her behavior can be independently observed, measured, and verified or refuted. Yet, if he or she reports eating an apple at some point in the past (*e.g.,* as with an FFQ or 24HR), neither the past behavior nor the neural correlates of the memory of that behavior are independently observable or quantifiable, and without additional information, his or her statement cannot be falsified or confirmed. It is a rather obvious fact that the respondent is the only person who has access to the raw data of M–BMs (*i.e.,* his or her memories of consumption). As such, researchers cannot examine the validity of the memory and base M–BM research results on their faith in the verbal report (*i.e.,* the belief that the participant is telling the truth). Nevertheless, faith and belief are basic tenets of religion, not science. The unwavering credulity of nutrition epidemiologists with respect to verbal reports is literally in direct opposition to *Nullius in Verba* (*i.e.,* take no one's word for it) and skeptical, rigorous science. The confluence of these simple facts and the well-documented failure of self-reported EI to accurately correspond to reality,[33, 35] demonstrate that the memory and subsequent recall of ingestive behavior are not within the realm of the scientific investigation of nutrition and obesity. As the philosopher Karl Popper stated, "all the statements of empirical science must be capable of being finally decided, with respect to their truth and falsity,"[65, p. 17] and it is wholly impossible to verify or refute something that cannot be directly or indirectly independently observed and measured (*e.g.,* memories).

The Pseudoscience of Nutrition Epidemiology

The term *pseudoscience* describes data or results that are presented as scientific but lack plausibility because they cannot be reliably, accurately, and independently observed, quantified, and confirmed or refuted.[62–66] When M–BMs are examined from the perspective of the basic tenets of science, the reason for the explanatory and predictive failure of epidemiologic nutrition research becomes obvious. First and foremost, scientific conclusions cannot result from nonempirical (*i.e.,* unobserved) or subjective (*i.e.,* private, not publically accessible) data that are not subject to independent observation, quantification, and falsification. When a person provides a dietary report, the data collected are not actual food or beverage consumption but rather an error-prone and highly edited anecdote regarding memories of food and beverage consumption. As such, M–BMs do not meet the basic requirements of the scientific method and, by definition, are pseudoscientific when presented as actual estimates of energy or nutrient consumption. Two famous physicists of the 20th century, Wolfgang Pauli and Arthur Schuster, summed up the problem with pseudoscientific data eloquently when they stated, respectively, that a pseudoscientific conclusion "is not only not right, it is not even wrong . . ."[114,p. 186] and "[w]e all prefer being right to being wrong, but it is better to be wrong than to be neither right nor wrong ."[115, p. 117]

It is difficult to determine the empirical consequences of M–BMs because the primary data (*i.e.,* memories: private information to which the respondents have privileged access) do not meet the basic tenets of scientific methods (*e.g.,* independent observation of data, falsifiability, and accuracy). If neither the researchers nor the participants are able to quantify what percentage of the recalled foods and beverages are completely false reports, grossly inaccurate, or reports that are somewhat congruent with actual consumption, it is impossible to know the validity and the error associated with each report. As Dhurandhar, *et al.*[75] recently suggested, the use of M–BM-based data is a context in which ". . . something is not better than nothing."[p. 1] Given the forgoing, M–BM-derived data are inadmissible and constitute a substantial ongoing threat to nutrition and obesity research and national *Dietary Guidelines* because the greatest obstacle to scientific progress is not ignorance but the illusion of knowledge created by pseudoscientific data that are neither right nor wrong.

Nevertheless, performing rigorous science is a skill that can be learned, but only if mentors understand and practice rigorous science. Given the ubiquitous use of M–BMs over many decades, it seems that nutritional epidemiologists have eschewed the inherent rigor and skepticism of *Nullius in Verba* (*i.e.,* take no one's word for

it) and literally replaced it with *Totius in Verba* (*i.e.,* take everyone's word for it). As a result, skeptical rigorous science is not practiced or taught in nutrition and obesity epidemiologic research.[24]

National Nutrition Surveillance: M–BM Data and USDA Food Availability Economic Data

If the two major components of U.S. national nutritional surveillance are valid (*i.e.,* NHANES M–BM data and USDA Food Availability economic data), estimates from these surveillance tools should track together and independently provide population-level approximations of trends in food consumption or use. Nevertheless, history demonstrates that this is not the case. Trends in estimates of macronutrient consumption from population-level epidemiologic surveys (*i.e.,* M–BMs) exhibited statistically significant trends that were in opposition to those of USDA economic data for fat, carbohydrates, protein, and energy (*i.e.,* kilocalories per day) from the 1960s to the late 1980s.[116] It should be apparent that U.S. residents could not be simultaneously consuming more and less fat, protein, carbohydrates, and energy over time. The contradictory patterns and striking lack of correspondence between the two primary U.S. nutrition surveillance tools suggest that one or more likely both protocols are invalid. As with the severe misreporting demonstrated across the globe,[45, 80] these contradictory patterns are not limited to the United States; many countries exhibit considerable disparity between national surveillance via M–BMs and economic/food supply data.[117–120] This fact is further evidence that M–BMs are fatally flawed and diet-health inferences from M–BM-derived data are meaningless.

PA and CRF: Essential Elements in Nutrition, Obesity, and Health Research

The lack of explanatory and predictive power of epidemiologic nutrition research may also be explained by the limited acknowledgement of nonnutritional determinants of health and disease, such as nongenetic evolution,[6–8] PA,[121–122] CRF,[123] and other components of nutrient partitioning and energy balance.[124–130] For example, more than 50 years ago the Food and Agriculture Organization of the United Nations and the World Health Organization determined that human food energy requirements should be estimated using TEE and that PA and basal energy expenditure were the primary determinants.[131–132] Yet, most nutrition research does not measure any form of energy expenditure or objectively quantify PA. Currently, there is only one manuscript of which we are aware that uses the NHANES objectively measured PA data to directly assess nutrition-related outcomes [133] and no nutrition-related publications that include the NHANES treadmill CRF data in analyses. The lack of publications may be due to the fact that only two waves in the more than 40 year history of the NHANES include objective measures of PA, and despite the widespread acknowledgment of the necessity of daily PA for health and well-being, it is routinely discounted by governmental public health funding agencies. For example, PA, CRF, and exercise are not even listed on the National Institutes of Health's spreadsheet of categorical spending of nearly 250 classifications through 2016.[9] This is unfortunate given that 80% of Americans are not at risk for most nutritional deficiencies,[2] but 95% of Americans are at risk for PA deficiency (*i.e.,* inactivity or high sedentary behavior) and do not meet the Federal recommendations of 30 minutes per day of moderate to vigorous PA.[134]

Given that PA and CRF are major determinants of health [122–123, 133, 135–137] and that PA is the only major modifiable determinant of TEE and nutrient-energy partitioning (*i.e.,* the metabolic fate of the foods we consume),[6, 124–130, 133] it is clear that PA and CRF must be objectively measured and controlled for in analyses if the health effects of any dietary intervention are to be examined accurately. Yet, because PA questionnaires are susceptible to many of the same systematic biases [75, 138–139] and inadmissibility issues as M–BMs, the failure to objectively-measure PA and control for it in analyses renders health inferences from previous nutrition epidemiologic studies moot. Fortunately, for the science of health and disease, there are objective tools for the measurement of PA (*e.g.,* pedometers and accelerometry-based PA monitors),[140] and despite limitations,[141] these should be used in place of surveys and questionnaires to quantify PA in future examinations of health and disease.

Summary and Future Directions

A wise man proportions his belief to the evidence.

DAVID HUME [142, p. 87]

This critical review provides empirical and analytic evidence to support the position that (1) M–BM estimates of EI and nutrient intake have trivial relationships with actual EI and nutrient intake; (2) the assumption that human memory and recall provide literal, accurate, or precise reproductions of past ingestive behavior is

indisputably false; (3) M–BMs require participants to submit to protocols that mimic procedures known to induce false recall; (4) the subjective (*i.e.,* private, not publically accessible) mental phenomena (*i.e.,* memories) from which M–BM data are derived are not subject to independent observation, quantification, or falsification; therefore, these data are pseudoscientific and inadmissible in scientific research; and (5) the failure to objectively measure and control for PA and CRF in analyses renders inferences regarding most diet-health relationships moot.

Given the overwhelming evidence in support of our hypotheses, we conclude that M–BM data cannot be used to informational *Dietary Guidelines* and that continued funding of M–BMs constitutes an unscientific and major misuse of research resources. In addition, given that there are objective data on the nutrition-related health status of Americans,[2] we find the DGAC's reliance on M–BMs to be without scientific support or merit. We think that skepticism and rigor are essential requirements in scientific investigations, and we fault the overly credulous nature of nutrition epidemiology for the obvious and well-demonstrated failures of the scientific community to properly inform previous Federal *Dietary Guidelines* (*e.g.,* cholesterol consumption).[30, 143] We think that our nation's *Dietary Guidelines* should not be based on the pseudoscientific and highly edited anecdotes of M–BMs, and although others may disagree, we ask that they do as we have done and provide empirical evidence rather than rhetoric to support their positions. Without valid evidence, the dogmatic defense of illusory knowledge and the *status quo* in nutrition and obesity research (*e.g.,* see previous commentaries and guidelines [30, 46, 74]) is an impediment to scientific progress and empirically supported public nutrition and obesity policy.

We began this critical review with evidence that our nation's food supply and the nutritional status of Americans have improved to a level unparalleled in human history.[2–3, 5] Given this reality and recent work on the intergenerational transmission of obesity and type 2 diabetes mellitus,[6–8] we posit that the American diet is no longer a significant risk factor for disease for most individuals. This hypothesis is supported by multiple lines of evidence, such as a 40% decline in the age-adjusted mortality rate from 1969 to 2010,[144] a progressive decades long reduction in age-adjusted cardiovascular disease incidence and mortality,[145–146] and a 1.5% *per annum* reduction in age-adjusted mortality rates from all major cancers as well as significant reductions in lung cancer incidence in men and women between 2001 and 2010.[147] Given the forgoing and the evidence presented herein demonstrating the pseudoscientific nature of M–BMs, we assert that research efforts and funding of M–BMs and diet-health research are misdirected and argue that those resources would be better targeted to the most prevalent disease of deficiency of the 21st century: inactivity (*i.e.,* a lack of PA and exercise and high levels of sedentary behavior).[121, 134]

Conclusion

In this critical review, we argued that the essence of science is the ability to discern fact from fiction, and we presented evidence from multiple fields to support the position that the data generated by nutrition epidemiologic surveys and questionnaires are not falsifiable. As such, these data are pseudoscientific and inadmissible in scientific research. Therefore, these protocols and the resultant data should not be used to inform national *Dietary Guidelines* or public health policy, and the continued funding of these methods constitutes an unscientific and major misuse of research resources.

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Abbreviations and Acronyms: **BMR** = basal metabolic rate; **CRF** = cardiorespiratory fitness; **DRM** = Deese-Roediger and McDermott; **DGAC** = Dietary Guidelines Advisory Committee; **EI** = energy intake; **FFQ** = food frequency questionnaire; **M–BM** = memory-based dietary assessment method; **NHANES** = National Health and Nutrition Examination Survey; **PA** = physical activity; **rEI** = reported energy intake; **TEE** = total energy expenditure; **USDA** = U.S. Department of Agriculture; **WWEIA** = What We Eat in America; **24HR** = 24 hour dietary recall

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EXHIBIT C

Validity of U.S. Nutritional Surveillance: National Health and Nutrition Examination Survey Caloric Energy Intake Data, 1971–2010

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Abstract

Importance: Methodological limitations compromise the validity of U.S. nutritional surveillance data and the empirical foundation for formulating dietary guidelines and public health policies.

Objectives: Evaluate the validity of the National Health and Nutrition Examination Survey (NHANES) caloric intake data throughout its history, and examine trends in the validity of caloric intake estimates as the NHANES dietary measurement protocols evolved.

Design: Validity of data from 28,993 men and 34,369 women, aged 20 to 74 years from NHANES I (1971–1974) through NHANES 2009–2010 was assessed by: calculating physiologically credible energy intake values as the ratio of reported energy intake (rEI) to estimated basal metabolic rate (BMR), and subtracting estimated total energy expenditure (TEE) from NHANES rEI to create 'disparity values'.

Main Outcome Measures: (1) Physiologically credible values expressed as the ratio rEI/BMR and (2) disparity values (rEI–TEE).

Results: The historical rEI/BMR values for men and women were 1.31 and 1.19, (95% CI: 1.30–1.32 and 1.18–1.20), respectively. The historical disparity values for men and women were −281 and −365 kilocalorie-per-day, (95% CI: −299, −264 and −378, −351), respectively. These results are indicative of significant under-reporting. The greatest mean disparity values were −716 kcal/day and −856 kcal/day for obese (*i.e.,* ≥30 kg/m2) men and women, respectively.

Conclusions: Across the 39 year history of the NHANES, EI data on the majority of respondents (67.3% of women and 58.7% of men) were not physiologically plausible. Improvements in measurement protocols after NHANES II led to small decreases in underreporting, artifactual increases in rEI, but only trivial increases in validity in subsequent surveys. The confluence of these results and other methodological limitations suggest that the ability to estimate population trends in caloric intake and generate empirically supported public policy relevant to diet-health relationships from U.S. nutritional surveillance is extremely limited.

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Introduction

The rise in the population prevalence of obesity has focused attention on U.S. nutritional surveillance research and the analysis of trends in caloric energy intake (EI). Because these efforts provide the scientific foundation for many public health policies and food-based guidelines, poor validity in dietary measurement protocols can have significant long-term implications for our nation's health.

In the U.S., population-level estimates of EI are derived from data collected as part of the National Health and Nutrition Examination Survey (NHANES), a complex, cross-sectional sample of the U.S. population. The primary method used in NHANES to approximate EI is the 24 hour dietary recall interview (24HR) [1]. The data collected are based on the subject's self-reported, retrospective perceptions of food and beverage consumption in the recent past. To calculate EI estimates, these subjective data are translated into nutrient food codes and then assigned numeric energy (*i.e.,* caloric) values from food and nutrient databases. Prior to 2001–2002, the NHANES relied upon databases of varying quality and composition for the *post-*

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hoc conversion of food and beverage consumption (24HR) data into energy values [2–5]. After 2001–2002, the NHANES and the U.S. Department of Agriculture's (USDA) Continuing Survey of Food Intakes by Individuals were integrated into the "What We Eat in America" program [6], and the translation process was standardized via use of successive versions of the USDA's National Nutrient Database for Standard Reference (NNBS) [7].

Misreporting

Given the indirect, pseudo-quantitative nature of the method (*i.e.,* assigning numeric values to subjective data without objective corroboration), nutrition surveys frequently report a range of energy intakes that are not representative of the respondents' habitual intakes [8], and estimates of EI that are physiologically implausible (*i.e.,* incompatible with survival) have been demonstrated to be widespread [9–11]. For example, in a group of "highly educated" participants, Subar, *et al.* (2003) demonstrated that when total energy expenditure (TEE) via doubly labeled water (DLW) was compared to reported energy intake (rEI), the raw correlations between TEE and rEI were 0.39 for men and 0.24 for women. Men and women underreported energy intake by 12–14% and 16–20%, respectively. The level of underreporting increased significantly after correcting for the weight gain of the sample over the study period [9], and underreporting was greater for fat than for protein, thereby providing additional support for the well-documented occurrence of the selective misreporting of specific macronutrients (*e.g.,* fat and sugars) [12–15]. These results are consistent with earlier work, in which the correlations between DLW-derived TEE and seven 24HR and the average of two 7 day dietary recalls were 0.33 and 0.30, respectively [16].

Because the NHANES collected dietary data over the period in which the population prevalence of obesity was increasing, these data have been used (despite the widely acknowledged issues [17]) to examine the association of trends in EI with increments in mean population body mass index (BMI) and rates of obesity (*e.g.,* [18–20]). Given that implausible rEI values and the misreporting of total dietary intake render the relationships between dietary factors, BMI and other indices of health ambiguous [21], and diminish the usefulness of nutrition data as a tool to inform public health policy, this report examines the validity of U.S. nutrition surveillance EI data from NHANES I (1971–1974) through NHANES 2010 (nine survey periods) using two protocols: the ratio of reported energy intake (rEI) to basal metabolic rate (rEI/BMR) [22,23] and the disparity between rEI and estimated total energy expenditure (TEE) from the Institute of Medicine's (IOM) predictive equations [24].

Table 1. rEI/BMR values for all men and women from NHANES I through NHANES 2009–2010.

Reported Energy Intake (rEI)/Basal Metabolic Rate (BMR) rEI/BMR >1.35 = plausible U.S. Men & Women (20–74 years); NHANES I–NHANES 2009–2010

NHANES Survey Year	Sex	Estimate rEI/RMR (mean)*	Standard Error	95% Confidence Interval		rEI Value Plausible Y = Yes N = No
				Lower	Upper	
NHANES I	Men (n = 4,652)	1.30	0.012	1.28	1.32	N
	Women (n = 7,709)	1.10	0.010	1.08	1.12	N
NHANES II	Men (n = 5,236)	1.28	0.010	1.26	1.30	N
	Women (n = 6,006)	1.08	0.008	1.06	1.09	N
NHANES III	Men (n = 6,122)	[b] 1.36	0.011	1.34	1.39	Y
	Women (n = 7,127)	[a] 1.22	0.009	1.20	1.24	N
NHANES I999–00	Men (n = 1,600)	1.31	0.018	1.27	1.34	N
	Women (n = 1,886)	[a] 1.23	0.016	1.19	1.26	N
NHANES 2001–2002	Men (n = 1,782)	1.31	0.015	1.28	1.34	N
	Women (n = 2,029)	[a] 1.24	0.011	1.22	1.26	N
NHANES 2003–2004	Men (n = 1,671)	1.32	0.013	1.30	1.35	Y
	Women (n = 1,838)	[a] 1.23	0.018	1.20	1.27	N
NHANES 2005–2006	Men (n = 1,749)	[c] 1.34	0.013	1.31	1.36	Y
	Women (n = 1,998)	[a] 1.21	0.014	1.18	1.24	N
NHANES 2007–08	Men (n = 2,154)	1.27	0.017	1.24	1.30	N
	Women (n = 2,306)	[a] 1.19	0.020	1.15	1.23	N
NHANES 2009–2010	Men (n = 2,319)	1.29	0.013	1.26	1.31	N
	Women (n = 2,532)	[a] 1.20	0.007	1.18	1.21	N
All Surveys	**Men (n = 27,285)**	**1.31**	**0.005**	**1.30**	**1.32**	**N**
	Women (n = 33,431)	**1.19**	**0.005**	**1.18**	**1.20**	**N**

*All estimates are weighted means.

[a] Significantly different from NHANES I at p≤0.001 (Women).
[b] Significantly different from NHANES I at p≤0.001 (Men).
[c] Significantly different from NHANES I at p≤0.05 (Men).
Note: rEI was from NHANES 24HR data and BMR was calculated using the Schofield predictive equations. [26] Values <1.35 are considered implausible and indicative of underreporting. TEE = estimated total energy expenditure; IOM = Institute of Medicine; rEI = reported energy intake; BMR = Basal Metabolic Rate calculated via Schofield predictive equation.
Values <1.35 are not physiologically credible.
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Methods

Population

Data were obtained from the National Health and Nutrition Examination Surveys for the years 1971–2010 [1]. The NHANES is a complex multi-stage, cluster sample of the civilian, non-institutionalized U.S. population conducted by the Centers for Disease Control and Prevention (CDC). The National Center for Health Statistics ethics review board approved protocols and written informed consent was obtained from all NHANES participants.

Inclusion Criteria

The study sample was limited to adults aged ≥20 and ≤74 years at the time of the NHANES in which they participated, and had a body mass index (BMI) ≥18 kg/m^2, and with complete data on age, sex, height, weight, and dietary energy intake.

Dietary Data

Estimates of EI were obtained from a single 24HR from each of the nine NHANES study periods [1]. Energy content of the self-reported food consumption was determined by NHANES using nutrient databases based on previous versions of the USDA National Nutrient Database for Standard Reference (NNDS) [7].

Table 2. rEI/BMR index for all women by BMI categories from NHANES I through NHANES 2009–2010.

Reported Energy Intake (rEI)/Basal Metabolic Rate (BMR) rEI/BMR >1.35 = plausible U.S. Women (20–74 years); NHANES I–NHANES 2009–2010

NHANES Survey Year	BMI Category	Estimate rEI/BMR (mean)*	Standard Error	95% Confidence Interval		rEI Value Plausible Y = Yes N = No
				Lower	Upper	
NHANES I	Normal (n = 4,222)	1.20	0.013	1.18	1.23	N
	Overweight (n = 2,028)	1.00	0.012	0.98	1.02	N
	Obese (n = 1,459)	0.88	0.014	0.86	0.91	N
NHANES II	Normal (n = 3,171)	1.18	0.010	1.16	1.20	N
	Overweight (n = 1,671)	0.98	0.012	0.96	1.01	N
	Obese (n = 1,164)	0.89	0.012	0.87	0.91	N
NHANES III	Normal (n = 2,661)	1.32	0.014	1.30	1.35	Y
	Overweight (n = 2,150)	1.18	0.019	1.14	1.22	N
	Obese (n = 2,316)	1.07	0.015	1.04	1.10	N
NHANES 1999–2000	Normal (n = 555)	1.36	0.020	1.32	1.40	Y
	Overweight (n = 572)	1.19	0.033	1.12	1.25	N
	Obese (n = 759)	1.12	0.030	1.06	1.18	N
NHANES 2001–2002	Normal (n = 630)	1.38	0.018	1.35	1.42	Y
	Overweight (n = 639)	1.26	0.028	1.21	1.32	N
	Obese (n = 760)	1.08	0.012	1.05	1.10	N
NHANES 2003–2004	Normal (n = 550)	1.35	0.031	1.29	1.41	Y
	Overweight (n = 546)	1.19	0.027	1.14	1.25	N
	Obese (n = 742)	1.15	0.026	1.10	1.20	N
NHANES 2005–2006	Normal (n = 615)	1.34	0.026	1.29	1.39	Y
	Overweight (n = 558)	1.19	0.028	1.13	1.24	N
	Obese (n = 825)	1.10	0.024	1.05	1.15	N
NHANES 2007–2008	Normal (n = 634)	1.30	0.038	1.23	1.38	Y
	Overweight (n = 694)	1.17	0.026	1.12	1.22	N
	Obese (n = 978)	1.10	0.020	1.06	1.14	N
NHANES 2009–2010	Normal (n = 690)	1.31	0.022	1.26	1.35	Y
	Overweight (n = 745)	1.23	0.024	1.18	1.28	N
	Obese (n = 1,097)	1.08	0.006	1.06	1.09	N

*All estimates are weighted means.
Note: rEI was from NHANES 24HR data and BMR was calculated using the Schofield predictive equations. [26] Values <1.35 are considered implausible and indicative of underreporting. TEE = estimated total energy expenditure; IOM = Institute of Medicine; rEI = reported energy intake; BMR = Basal Metabolic Rate calculated via Schofield predictive equation.

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Table 3. rEI/BMR index for all men by BMI categories from NHANES I through NHANES 2009–2010.

Reported Energy Intake (rEI)/Basal Metabolic Rate (BMR) rEI/BMR >1.35 = plausible U.S. Men (20–74 years); NHANES I–NHANES 2009–2010

NHANES Survey Year	BMI Category	Estimate rEI/BMR (mean)*	Standard Error	95% Confidence Interval		rEI Value Plausible Y = Yes N = No
				Lower	Upper	
NHANES I	Normal (n = 2,115)	1.41	0.016	1.38	1.44	Y
	Overweight (n = 1,945)	1.24	0.017	1.21	1.28	N
	Obese (n = 592)	1.08	0.025	1.04	1.13	N
NHANES II	Normal (n = 2,431)	1.37	0.009	1.35	1.39	Y
	Overweight (n = 2,111)	1.25	0.015	1.22	1.28	N
	Obese (n = 694)	1.08	0.018	1.05	1.12	N
NHANES III	Normal (n = 2,275)	1.47	0.018	1.43	1.50	Y
	Overweight (n = 2,482)	1.35	0.015	1.32	1.38	Y
	Obese (n = 1,365)	1.20	0.018	1.17	1.24	N
NHANES 1999–2000	Normal (n = 476)	1.42	0.020	1.38	1.46	Y
	Overweight (n = 655)	1.33	0.022	1.28	1.37	Y
	Obese (n = 469)	1.16	0.036	1.09	1.23	N
NHANES 2001–2002	Normal (n = 493)	1.43	0.038	1.35	1.50	Y
	Overweight (n = 774)	1.32	0.017	1.29	1.36	Y
	Obese (n = 515)	1.18	0.027	1.13	1.24	N
NHANES 2003–2004	Normal (n = 465)	1.46	0.029	1.41	1.52	Y
	Overweight (n = 659)	1.35	0.025	1.30	1.40	Y
	Obese (n = 547)	1.18	0.035	1.11	1.24	N
NHANES 2005–2006	Normal (n = 413)	1.51	0.030	1.45	1.57	Y
	Overweight (n = 735)	1.33	0.023	1.29	1.38	Y
	Obese (n = 601)	1.22	0.014	1.19	1.25	N
NHANES 2007–2008	Normal (n = 539)	1.40	0.038	1.32	1.47	Y
	Overweight (n = 835)	1.29	0.017	1.26	1.32	N
	Obese (n = 790)	1.15	0.019	1.12	1.19	N
NHANES 2009–2010	Normal (n = 563)	1.38	0.027	1.33	1.44	Y
	Overweight (n = 872)	1.35	0.021	1.31	1.39	Y
	Obese (n = 884)	1.16	0.016	1.13	1.19	N

*All estimates are weighted means.

Note: rEI was from NHANES 24HR data and BMR was calculated using the Schofield predictive equations. [26] Values <1.35 are considered implausible and indicative ofunderreporting. TEE = estimated total energy expenditure; IOM = Institute of Medicine; rEI = reported energy intake; BMR = Basal Metabolic Rate calculated via Schofieldpredictive equation.

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Determination of Physiologically Credible rEI Values

The ratio of rEI to BMR (rEI/BMR) <1.35 [22,23,25] was used to determine EI values that were implausible. BMR was estimated via the Schofield predictive equations [26]. The <1.35 cut-off for implausible EI values was used because "*it is highly unlikely that any normal, healthy free-living person could habitually exist at a PAL [i.e.,* TEE/BMR] of less than 1.35" [22].

It is important to note that the <1.35 cut-off does not assess all forms of misreporting (*e.g.,* over-reporting). To avoid the confounding effects of potential over-reporting, all rEI/BMR values >2.40 [27] were excluded from analyses of under-reporting. One form of misreporting that neither cut-off addresses is the under-reporting of EI from a high caloric intake associated with elevated levels of physical activity.

Disparity of the rEI and Estimated Total Energy Expenditure (TEE)

In 2002, the IOM used datasets derived from studies using DLW to create factorial equations to estimate energy requirements for the U.S. population. IOM TEE values were subtracted from the NHANES rEI to calculate disparity values. Negative values indicate underreporting.

IOM Equations for Predicting TEE Normal Weight (NW) Adults only (≥19 Years)

Equation 1 Men: TEE= $864-(9.72\times\text{age [y]})+PA^{*}\times(14.2\times\text{weight [kg]}+503\times\text{height[m]})$ (± 202).

Equation 2 Women: TEE = $387-(7.31\times\text{age [y]}+PA^{*}\times(10.8\times\text{weight [kg]}+660.7\times\text{height[m]})$ (± 156).

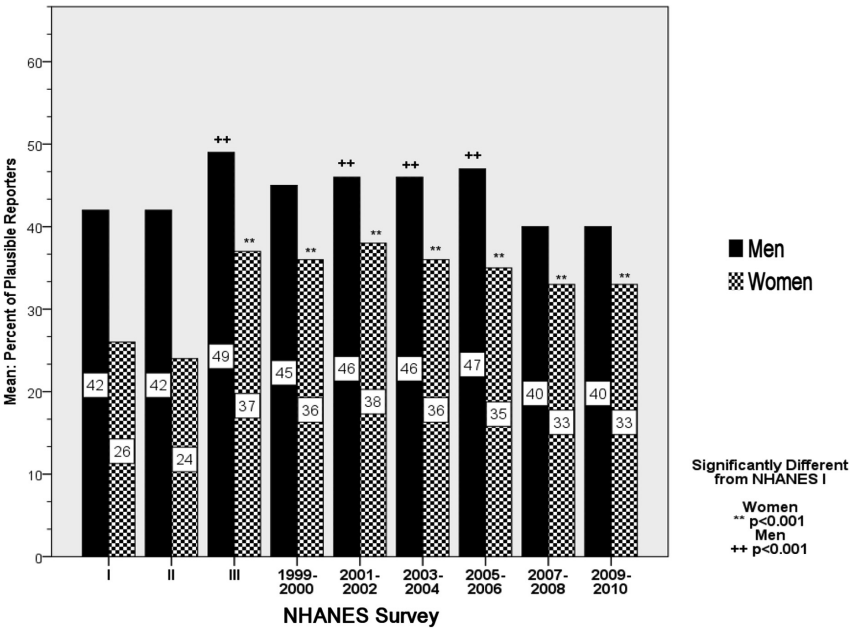
* Physical activity (PA) values were 1.12 and 1.14 for NW men and women, respectively. The use of these values assumes physical activity level (PAL) of ≥1.4 and <1.6, which is indicative of a "low active" population [24].

Figure 1

Percent of Plausible Reporters

(rEI/BMR >1.35)

U.S. Men & Women (20–74 yrs)



Percent of plausible reporters (*i.e.,* rEI/BMR >1.35) by sex from NHANES I to NHANES 2009–2010; U.S. Men and women (20–74 years).

IOM Equations for Predicting TEE Overweight (OW)/Obese (OB) Adults Only (≥19 Years)

Equation 3 Men: TEE= 1,086 − (10.1×age [y])+PA*×(13.76weight [kg]+416×height [m]).

Equation 4 Women: TEE= 448 − (7.95×age [y])+PA*×(11.46weight [kg]+619×height [m]).

* PA values were 1.12 and 1.16 for OW/OB men and women, respectively. The use of these values assumes a physical activity level (PAL) of ≥1.4 and <1.6, which is indicative of a "low active" population [24].

Note: age (years); weight (kg); height (m; meters); BMI= body mass index, (kg/m^2), IOM= Institute of Medicine; TEE = total energy expenditure.

Anthropometry [1]

Body mass was measured to ±0.1 kg. Height was measured to ±0.1 cm. BMI was calculated as weight (kg)/height (m)^2. The sample was divided into three standard BMI categories: BMI ≥18 kg/m^2 and <25 kg/m^2 were normal weight (NW), BMI between 25 kg/m^2 and 29.9 kg/m^2 were overweight (OW), and ≥30 kg/m^2 were obese (OB).

Statistical Analyses

Data processing and statistical analyses were performed using SAS®, V 9.2 and SPSS® V.19 in 2012–2013. Analyses accounted for the NHANES' complex survey design via the incorporation of stratification, clustering and post-stratification weighting to maintain a nationally representative sample for each survey period. All analyses included adjusted means, and α <0.05 (2-tailed) was used to identify statistical significance.

Results

Examination of Underreporting via rEI/BMR

Table 1 depicts the rEI/BMR values for men and women from NHANES I through NHANES 2009–2010. rEI was from NHANES 24HR data and BMR was calculated using the Schofield predictive equations [26]. Values <1.35 are considered implausible and indicative of underreporting.

Table 4. Disparity of rEI and TEE for men and women (20–74 years).

Disparity between rEI and IOM TEE U.S. Men & Women (20–74 years) NHANES I–NHANES 2009–2010

NHANES Survey Year	Sex	Estimate rEI minus TEE (mean)*	Standard Error	95% Confidence Interval (CI)		Validity: 95% CI includes zero (Y = Yes, N= No)
				Lower	Upper	
NHANES I	Men (n = 4,652)	−290.8	20.3	−330.7	−250.9	N
	Women (n = 7,709)	−479.7	14.5	−508.1	−451.3	N
NHANES II	Men (n = 5,236)	−323.2	17.8	−358.1	−288.3	N
	Women (n = 6,006)	−505.8	11.6	−528.4	−483.1	N
NHANES III	Men (n = 6,122)	[b] −183.3	19.1	−220.8	−145.7	N
	Women (n = 7,127)	[a] −325.3	13.5	−351.7	−298.8	N
NHANES 1999–2000	Men (n = 1,600)	−285.3	37.7	−359.3	−211.4	N
	Women (n = 1,886)	[a] −328.7	27.3	−382.3	−275.1	N
NHANES 2001–2002	Men (n = 1,782)	−270.3	26.8	−322.9	−217.7	N
	Women (n = 2,029)	[a] −306.0	15.5	−336.3	−275.6	N
NHANES 2003–2004	Men (n = 1,671)	−255.6	24.7	−304.0	−207.3	N
	Women (n = 1,838)	[a] −308.2	27.2	−361.5	−254.8	N
NHANES 2005–2006	Men (n = 1,749)	−232.2	25.3	−281.8	−182.6	N
	Women (n = 1,998)	[a] −347.5	20.8	−388.4	−306.6	N
NHANES 2007–08	Men (n = 2,154)	−355.0	32.1	−417.9	−292.0	N
	Women (n = 2,306)	[d] −379.4	28.5	−435.3	−323.5	N
NHANES 2009–2010	Men (n = 2,319)	−330.9	22.7	−375.4	−286.4	N
	Women (n = 2,532)	[a] −366.9	9.8	−386.1	−347.7	N
All Surveys	**Men (n = 27,285)**	**−281.4**	**9.1**	**−299.3**	**−263.5**	**N**
	Women (n = 33,431)	**−364.6**	**7.0**	**−378.3**	**−351.0**	**N**

*All estimates are weighted means.
[a] Significantly different from NHANES I at p≤0.001 (Women).
[b] Significantly different from NHANES I at p≤0.001 (Men).
[c] Significantly different from NHANES I at p≤0.05 (Men).
[d] Significantly different from NHANES I at p≤0.05 (Women).
Note: TEE = estimated total energy expenditure; IOM = Institute of Medicine; rEI = reported energy intake; BMR = Basal Metabolic Rate calculated via Schofield predictiveequation.
These values were calculated by subtracting the IOM TEE from the NHANES rEI. Negative values indicate the kilocalorie-per-day (kcal/day) value of underreporting.
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As *Table 1* depicts, the 95% confidence intervals (CI) suggest that all mean rEI values for women and six of nine mean rEI values for men were apparently implausible.

Table 2 depicts the rEI/BMR index for all women by BMI categories from NHANES I through NHANES 2009–2010.

As *Table 2* depicts, the 95% CI suggest that in 20 of the 27 measurement categories (*i.e.,* three BMI categories and nine surveys) the rEI values were not in the physiologically plausible range. The overall mean for rEI/BMR values for the total sample of women (n= 33,431) across all NHANES was 1.19 (95% CI: 1.18, 1.20) and therefore not physiologically plausible.

Table 3 depicts the rEI/BMR index for all men by BMI categories from NHANES I through NHANES 2009–2010.

As shown in *Table 3,* the 95% CI suggest that in 12 of 27 measurement categories (*i.e.,* three BMI categories and nine surveys), the rEI values were not in the physiologically plausible range. The overall mean value for rEI/BMR for the total sample of men (n = 27,285) across all NHANES was 1.31 (95% CI: 1.30, 1.32), and therefore not in the physiologically plausiblerange.

Percent of Plausible Reporters

Figure 1 depicts the percent of plausible reporters (*i.e.,* rEI/BMR >1.35) by sex from NHANES I to NHANES 2009–2010.

As *Figure 1* depicts, across the entire study period (*i.e.,* 1971–2010) the majority of respondents did not report plausible rEI values in any survey. When stratified

by sex and BMI categories, plausible reporting in OB women ranged from a low of ~12% in NHANES I and II to a high of 31% in NHANES 2003–2004. At no point in the history of the NHANES did more than 43% of OW and OB women report plausible values. Plausible reporting in NW women ranged from a low of 32% in NHANES II to 52% in NHANES 2001–2002. Plausible rEI values in OB men ranged from a low of 23% in NHANES II to a high of 35% in NHANES 2005–2006. At no point in the history of NHANES did more than 49% of OW and OB men report plausible rEI values.

Disparity between NHANES rEI and IOM TEE

Table 4 depicts the disparity of rEI and TEE for men and women (20–74 years). These values were calculated by subtracting the IOM TEE from the NHANES rEI. Negative values indicate the kilocalorie-per-day (kcal/day) value of underreporting.

Table 5. Disparity between rEI and the TEE for women (20–74 years) by BMI categories.

Disparity between rEI and IOM TEE; U.S. Women by BMI categories (20–74 years) NHANES I–NHANES 2009–2010

NHANES Survey Year	BMI Category	Estimate rEI minus TEE (mean)*	Standard Error	95% Confidence Interval (CI)		Validity: 95% CI includes zero (Y = Yes, N= No)
				Lower	Upper	
NHANES I	Normal (n = 4,222)	−316.0	17.7	−350.8	−281.2	N
	Overweight (n = 2,028)	−595.3	17.7	−629.9	−560.6	N
	Obese (n = 1,459)	−856.0	23.5	−902.0	−809.9	N
NHANES II	Normal (n = 3,171)	−351.6	13.7	−378.5	−324.8	N
	Overweight (n = 1,671)	−617.6	17.1	−651.1	−584.1	N
	Obese (n = 1,164)	−850.6	19.5	−888.9	−812.3	N
NHANES III	Normal (n = 2,661)	−158.6	17.7	−193.3	−123.9	N
	Overweight (n = 2,150)	−357.1	26.5	−409.1	−305.2	N
	Obese (n = 2,316)	−594.2	22.6	−638.5	−549.9	N
NHANES 1999–2000	Normal (n = 555)	−106.0	27.2	−159.3	−52.6	N
	Overweight (n = 572)	−359.6	48.8	−455.3	−264.0	N
	Obese (n = 759)	−530.1	50.2	−628.5	−431.6	N
NHANES 2001–2002	Normal (n = 630)	−74.0	21.7	−116.6	−31.4	N
	Overweight (n = 639)	−239.6	38.7	−315.5	−163.7	N
	Obese (n = 760)	−591.1	20.5	−631.4	−550.9	N
NHANES 2003–2004	Normal (n = 550)	−116.3	39.2	−193.2	−39.4	N
	Overweight (n = 546)	−339.0	37.7	−413.0	−265.0	N
	Obese (n = 742)	−477.1	42.2	−560.0	−394.2	N
NHANES 2005–2006	Normal (n = 615)	−131.1	34.1	−198.0	−64.3	N
	Overweight (n = 558)	−342.8	38.0	−417.4	−268.3	N
	Obese (n = 825)	−567.3	38.7	−643.2	−491.3	N
NHANES 2007–2008	Normal (n = 634)	−173.2	52.1	−275.4	−71.0	N
	Overweight (n = 694)	−374.1	35.8	−444.4	−303.7	N
	Obese (n = 978)	−567.3	33.2	−632.5	−502.1	N
NHANES 2009–2010	Normal (n = 690)	−173.0	27.8	−227.5	−118.4	N
	Overweight (n = 745)	−288.9	34.0	−355.7	−222.2	N
	Obese (n = 1,097)	−590.5	14.0	−617.8	−563.1	N

Note: BMI = body mass index; TEE = estimated total energy expenditure; IOM = Institute of Medicine; rEI = reported energy intake; BMR = Basal Metabolic Rate calculated via Schofield predictive equation.

These values were calculated by subtracting the IOM TEE from the NHANES rEI for each respondent. Negative values indicate the kcal/day value of underreporting.

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As *Table 4* depicts, in no survey group (*i.e.,* men & women in nine surveys) does the 95% CI for the disparity between rEI and TEE include zero. This suggests that that underreporting of EI occurred in both men and women, and across all surveys. The overall mean value for the disparity of rEI and IOM TEE for the total sample of women (n= 33,431) across all NHANES was −365 kcal/day (95% CI: −378, −351), or ~18% of TEE, and for the total sample of men (n= 27,285) was −281 kcal/day (95% CI: −299, −264), or ~10% of TEE.

When stratified by sex and BMI categories (see *Tables 5* & *6*), the disparities between rEI and TEE in OB women ranged from 2,856 kcal/day (95% CI: −902, −810), an underreporting of ~41% of TEE, to 2477 kcal/day (95% CI: −560, −394), an underreporting of 20% of TEE. The disparities between rEI and TEE in OB men ranged from −717 kcal/day (95% CI: −790, −643) in NHANES II to −464 kcal/day (95% CI: −527, −401) underreporting of 25% and 15%, respectively.

Trends in Underreporting

After the removal of over-reporters, both protocols, that is rEI/BMR (*Figure 1*) and the disparity between rEI and IOM TEE (*Table 4*) exhibited significant decreases in underreporting from NHANES II and NHANES III ($p<0.001$). There were significant negative linear trends for both men and women in changes in underreporting total caloric intake from NHANES I to NHANES 2009–2010 (rEI/BMR: $p<0.001$, and disparity: $p=0.028$).

Trends in Over-Reporting

Across the study period, approximately 4.9% of men and 2.9% of women reported rEI/BMR values suggestive of over-reporting (*i.e.,* rEI/BMR >2.4) with no significant trends. The greatest increase in the percentage of over-reporters between survey periods occurred from NHANES II to NHANES III, with men increasing from 4.1% to 6.4%, and women from 1.7% to 3.4% (both $p<0.001$). The greatest absolute percentage of over-reporters was in NHANES III, with 6.4% of men over-reporting and NHANES 2003–2004, with 3.9% of women over-reporting.

Table 6. Disparity between rEI and the TEE for all men (20–74 years) by BMI categories.

Disparity between rEI and IOM TEE; U.S. Men by BMI categories (20–74 years) NHANES I–NHANES 2009–2010

NHANES Survey Year	BMI Category	Estimate rEI minus TEE (mean)*	Standard Error	95% Confidence Interval (CI)		Validity: 95% CI includes zero (Y = Yes, N= No)
				Lower	Upper	
NHANES I	Normal (n = 2,115)	−96.3	26.8	−149.0	−43.6	N
	Overweight (n = 1,945)	−374.7	30.8	−435.1	−314.2	N
	Obese (n = 592)	−702.1	49.7	−799.7	−604.5	N
NHANES II	Normal (n = 2,431)	−178.7	15.9	−209.9	−147.6	N
	Overweight (n = 2,111)	−367.6	27.0	−420.5	−314.6	N
	Obese (n = 694)	−716.5	37.3	−789.8	−643.3	N
NHANES III	Normal (n = 2,275)	−8.8	31.1	−69.8	52.2	Y
	Overweight (n = 2,482)	−191.5	27.9	−246.3	−136.7	N
	Obese (n = 1365)	−494.4	38.0	−569.0	−419.9	N
NHANES 1999–2000	Normal (n = 476)	−87.2	34.8	−155.6	−18.8	N
	Overweight (n = 655)	−221.8	41.5	−303.3	−140.2	N
	Obese (n 469)	−590.9	76.8	−741.6	−440.2	N
NHANES 2001–2002	Normal (n = 493)	−64.1	63.1	−188.0	59.9	Y
	Overweight (n = 774)	−229.2	29.5	−287.1	−171.3	N
	Obese (n = 515)	−527.5	55.3	−636.1	−418.9	N
NHANES 2003–2004	Normal (n = 465)	−6.8	47.3	−99.6	86.0	Y
	Overweight (n = 659)	−175.4	46.9	−267.4	−83.4	N
	Obese (n = 547)	−549.8	72.0	−691.1	−408.5	N
NHANES 2005–2006	Normal (n = 413)	70.4	53.0	−33.7	174.5	Y
	Overweight (n = 735)	−222.4	39.7	−300.3	−144.4	N
	Obese (n = 601)	−464.2	32.1	−527.2	−401.2	N
NHANES 2007–2008	Normal (n = 539)	−117.9	64.8	−245.2	9.3	Y
	Overweight (n = 835)	−286.7	31.3	−348.1	−225.2	N
	Obese (n = 790)	−608.0	42.2	−690.8	−525.2	N
NHANES 2009–2010	Normal (n = 563)	−154.4	43.5	−239.8	−69.1	N
	Overweight (n = 872)	−178.9	42.1	−261.5	−96.4	N
	Obese (n = 884)	−590.9	32.9	−655.4	−526.4	N

Note: BMI = body mass index; TEE = estimated total energy expenditure; IOM = Institute of Medicine; rEI = reported energy intake; BMR = Basal Metabolic Rate calculated via Schofield predictive equation.

These values were calculated by subtracting the estimated IOM TEE from the NHANES rEI for each respondent. Negative numbers indicate the kcal/day value of underreporting.

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Discussion

Validity of NHANES EI Data

Our results suggest that across the 39 year history of U.S. nutrition surveillance research, rEI data on the majority of respondents (67.3% of women and 58.7% of men) were not physiologically plausible. The historical average rEI/BMR values for all men and women were 1.31 and 1.19 respectively (*Table 1*). These values are indicative of substantial underreporting. The expected average values for healthy, free living men and women are ~1.55, with a range of >1.35 to <2.40 [23, 27]. In no survey did at least 50% of the respondents report plausible EI values (*Figure 1*). These

data are consistent with previous research demonstrating that the misreporting of EI in nutrition surveys is widespread [9, 11, 28–34]. Goldberg, *et al.* (1991) demonstrated that in 37 studies across ten countries, >65% of the mean rEI/BMR values were below the study-specific plausibility cut-off [23]. In addition to the extensive underreporting in our sample, 4.9% of men and 2.9% of women reported rEI/BMR values suggestive of over-reporting (*i.e.,* rEI/BMR >2.40).

Disparity between NHANES rEI and IOM Derived TEE

Throughout the study period (*i.e.,* 1971–2010) the disparity between rEI and TEE values were large and variable across BMI and sex categories suggesting substantial systematic biases in underreporting (*Tables 4, 5, 6*). The overall mean disparity values for men and women were −281 kcal/day and 2365 kcal/day, respectively. The greatest mean disparity values were −717 kcal/day (25% of TDEE) and −856 kcal/day (41% of TEE) in OB men and women, respectively.

Trends in the Validity and Inferences from NHANES rEI Data

As depicted in *Tables 1* and *2,* and *Figure 1,* there were large decreases in underreporting between NHANES II and NHANES III. This is clearly evidenced by the increase in rEI/BMR index (*Table 1*), the large and significant increase in the percent of plausible reporters (*Figure 1*), and the reduction in the disparity between NHANES rEI and NAS/IOM EER (*Table 4*). This decrement in underreporting between NHANES II and subsequent surveys across all sex and BMI categories is likely the result of improvements in survey protocols for NHANES III, such as the inclusion of more days of dietary recall (*i.e.,* weekends), automated multi-pass methodology, and increased staff training and quality control (see [35]), The extent of these improvements is notable; for example, the percentage of OB women reporting implausible values decreased from ~88% in NHANES II to 74% in NHANES III.

These changes in measurement protocols led to an apparent increase in mean rEI values that has been reported as an actual increase in population-level EI despite caveats that the "*Interpretation of trends in energy and nutrient intakes is difficult when methodologic changes occur between surveys*" [36]. Nevertheless, Briefel and Johnson state (without caveat) in their abstract, "*During the 30 year period, mean energy intake increased among adults . . .*" [37]. The data presented in the present report refute this inference. When the NHANES dietary measurement protocols were altered after NHANES II, the improved method captured a higher percentage of actual intakes. The apparent increase in mean rEI was merely an artifact of improved measurement protocols and not indicative of a true increase in caloric consumption. Despite this fact, the apparent increase has been regularly published and uncritically accepted as a true upward trend in caloric consumption (*e.g.,* [37, 38]) and the cause of the obesity epidemic (*e.g.,* [39, 40]).

Changes in Underreporting and Public PolicyRecommendations

In addition to the ubiquity of misreporting, there is strong evidence that the reporting of 'socially undesirable' (*e.g.,* high fat and/or high sugar) foods has changed as the prevalence of obesity has increased [12–15]. Additionally, research has demonstrated that interventions emphasizing the importance of 'healthy' behaviors may lead to increased misreporting as participants alter their reports to reflect the adoption of the 'healthier' behaviors independent of actual behavior change [17, 41]. It appears that lifestyle interventions "teach" participants the socially desirable or acceptable responses [17, 42]. As such, the ubiquity of public health messages to 'eat less and exercise more' may induce greater levels of misreporting and may explain the recent downward bias in both self-reported EI [20] and body weight [17, 43], especially given that social desirability bias is often expressed in the underreporting of calorically dense foods [44].

Selective misreporting of specific macronutrients has important ramifications for epidemiological research and nutrition surveillance. Heitmann and Lissner (2005) demonstrated that the selective misreporting of dietary fat by groups at an increased risk of chronic non-communicable diseases may result in an overestimated association between fat consumption and disease [45]. If the potentially negative effects of high-fat diets are overestimated due to selective misreporting, current recommendations for fat intake may be overly conservative [45].

Additional Systematic Biases of Nutrition Surveillance Data

In addition to known sources of systematic reporting error, there are numerous sources of systematic bias in nutrition surveillance research protocols that are not addressed via our data. Another potentially large source of error is the translation of food and beverage consumption data (*e.g.,* 24HR) into nutrient energy values via nutrient composition databases. The accuracy of this translation relies on a number of assumptions that are rarely justified. As cited earlier, research on misreporting

shows that reports do not accurately reflect the quantity or number of foods consumed, and are not representative of usual intakes [12–15, 46–50]. Given that the basic methodological assumptions are violated, it is not surprising that research has demonstrated that food data to nutrient energy conversions are "*riddled with potential pitfalls at all stages*" that "*hamper the interpretability of the results*" [51–53], and represent a major source of systematic error in national nutrition surveillance efforts [2].

Throughout its history, the NHANES has relied upon databases of varying quality and composition for the *post-hoc* conversion of food and beverage consumption (*i.e.,* 24HR) data into energy values [2–5, 53]. This makes the analysis of trends extremely complex because the nutrient energy (*i.e.,* caloric) values in the databases varied considerably over time [54, 55]. Additionally, research has demonstrated that the energy content of restaurant food (and especially fast-food outlets) vary significantly when compared to the industry values used in the NNDS [56], and an internal quality review of NHANES 2003–2004 data led to ~400 substantive changes in nutrient and energy values. [57]. The result of these limitations are discussed in detail elsewhere, see [4, 5, 58].

As with the improvements in the NHANES survey protocols, the progressive alterations to the nutrient database combined with changes in the types of foods that are available for consumption led to artifactual differences in nutrient and energy consumption estimates that frustrate efforts to examine trends in caloric consumption [58]. To account for these changes, researchers must maintain the real differences in the composition of foods while correcting for artifactual differences attributable to improvements in the quality of nutrient data [58]. Given the lack of comprehensive crossover studies and metrics for adjustment as the food and nutrient databases evolved, papers examining trends in caloric consumption must be treated with skepticism [51,58].

Commercially Prepared Foods and Meals Away From Home

One of the most prominent systematic errors from 24HR data-to-nutrient energy conversions is due to the increased reliance on the food service industry and the substantial rise in meals eaten 'away from home' [59–61]. As stated previously, the vast majority of foods and beverages in the NNDS have not been evaluated empirically and research has demonstrated that the energy and macro/micro nutrient content of commercially prepared foods varies significantly compared to the industry values used in the NNDS [56]. When foods or commodities are not in the database, substitutions are necessitated. For these interpolations to be accurate, the analogues must be similar in composition to the consumed food or beverage. This is extremely difficult to perform in practice because no two foods or commodities are identical, and local *vs.* imported foods/commodities differ significantly. For example, in survey data collection, knowledge of the specific preparation and cut of beef are essential since the energy content of generic beef substitutions may differ dramatically (*e.g.,* 166 kcals per 100 grams in round steak to 257 kcals in top sirloin [62]) [63,64]. Given these realities, USDA estimates of caloric consumption may be increasingly inaccurate as the number of food and beverages supplied by the commercial sector expands rapidly.

Recent research has attempted to quantify the changes in consumer packaged foods and beverages, and their impact on the American diet [65]. Nevertheless, these efforts suffer from the same limitations as all food data-to-nutrient energy value conversions via nutrient composition databases. Additionally, the translation of "as-purchased" foods and beverages (using information from the commercial sector) to "as-consumed" energy and macro/micronutrient content for national surveillance relies on the accurate quantification of food preparation and waste [65]. Unfortunately, these data are limited and highly variable [52, 66]. In a report from the USDA's Economic Research Service, Muth, *et al.* (2011) state that the current data are incomplete and overstate actual consumption because the level of "*documentation of food losses . . . ranged from little to none for estimates at the retail and customer levels.*" [67]. These results clearly demonstrate the conceptual and methodological complexity of translating food and beverage purchases into nutrient energy and macro/micronutrient intake in the context of a rapidly evolving food supply.

Methods of Adjustment for Systematic Biases

There are various methods that attempt to improve estimates of caloric consumption derived from self-reported dietary intake [32, 68–72]. While these methods may improve the shape of the distribution of the estimates, none can address the significant systematic biases described in this report. For example, the National Research Council and the Iowa State University methods provide significantly improved estimates of the shape of the distribution, but do not substantially improve estimates

of mean energy intake (10–15% underestimation) or protein consumption (6–7% underestimation) [70]. 291.

Strengths and Limitations

A strength of the present study was the use of the established rEI/BMR method for the determination of physiologically implausible EI values. We used a liberal cut-off (*i.e.,* <1.35) that is below the study-specific theoretical cutoff for our smallest sub-group (*i.e., n* >400). The use of the more conservative cutoff of rEI/BMR <1.50 recommended by Goldberg, *et al.,* (1991) [22] increased underreporting by 10% in women and 7% in men across all surveys. A second strength was the use of a rEI/BMR >2.4 for the elimination of potential over-reporters to correct the limitations of previous research [29].

Finally, the use of the IOM factorial equations for estimating TEE for specific sub-groups (*i.e.,* OW & OB respondents) in the calculation of disparity values is a significant strength. The results of this additional protocol demonstrated significant underreporting in all surveys, and that the disparity values closely paralleled the implausible values in 15 of the 18 sub-groups (*i.e.,* men & women in nine surveys). The close agreement between these two dissimilar protocols increases confidence in our results and conclusions.

A potential limitation to our analysis was the use of the Schofield predictive equation for estimating BMR. The Schofield predictive equations may overestimate BMR in some populations [73, 74]. If the Schofield equation overestimated BMR, a greater percentage of survey respondents would be classified as underreporters. To address this potential limitation, we performed the analyses using the Mifflin equation [75], which has been validated in OW and OB populations such as the U.S. [74]. The results of those analyses were similar to those obtained using the Schofield equation, with substantial underreporting (>50%) in all surveys, significant trends in changes in underreporting, and a small increase in over-reporting. To remain consistent with past research on implausible rEI and underreporting [29, 33], we chose to present the results from the Schofield predictive equations.

Conclusions

Throughout its history, NHANES dietary measurement protocols have failed to provide accurate estimates of the habitual caloric consumption of the U.S. population. Furthermore, successive changes to the nutrient databases used for the 24HR data-to-energy conversations and improvements in measurement protocols make it exceedingly difficult to discern temporal patterns in caloric intake that can be related to changes in population rates of obesity. As such, there are no valid population-level data to support speculations regarding trends in caloric consumption and the etiology of the obesity epidemic. Because under-reporting and physiologically implausible rEI values are a predominant feature of U.S. nutritional surveillance, the ability to generate empirically supported public policy and *Dietary Guidelines* relevant to the obesity epidemic based on these data is extremely limited.

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The data used in this study are available at: *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm*.

Author Contributions

Conceived and designed the experiments: E.A., S.N.B. Performed the experiments: E.A. Analyzed the data: E.A., G.A.H., S.N.B. Wrote the paper: E.A.

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SUBMITTED LETTER BY SHANNON CAMPAGNA, DIRECTOR, FEDERAL GOVERNMENT AFFAIRS, MARS, INCORPORATED

October 6, 2015

Hon. K. MICHAEL CONAWAY,
Chairman,
House Agriculture Committee,
Washington, D.C.;

Hon. COLLIN C. PETERSON,
Ranking Minority Member,
House Agriculture Committee,
Washington, D.C.

Dear Chairman Conaway and Ranking Member Peterson:

Mars, Incorporated (Mars) is pleased to submit these comments to the House Agriculture Committee in advance of its hearing titled, "Public Hearing: *2015 Dietary Guidelines for Americans*" scheduled for Wednesday, October 7. Mars shares its recommendations to improve the scientific review process of the *Dietary Guidelines for Americans* (DGAs or policy document).

Mars, Incorporated is a private, family-owned business with more than a century of history and some of the best-loved brands in the world including M&M'S®, PEDIGREE®, DOUBLEMINT® and UNCLE BEN'S®. Headquartered in McLean, VA, Mars has more than $33 billion in sales from six diverse business segments: Petcare, Chocolate, Wrigley, Food, Drinks, and Symbioscience. More than 75,000 Associates across 73 countries are united by the company's Five Principles: Quality, Efficiency, Responsibility, Mutuality, and Freedom and strive every day to create relationships with stakeholders that deliver growth we are proud of as a company.

Recommendations to Improve the Scientific Review Process

Mars believes that the scientific review process of the DGAs can be improved to ensure its integrity. For example, Mars understands that the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) can only address issues in the DGAs if scientific studies have been properly submitted to the National Evidence Library (NEL) and have been reviewed and rated by the Dietary Guidelines Advisory Committee (DGAC). Mars' concern, however, is that if the DGAC elects not to conduct a systematic review of the scientific studies for a variety of reasons that do not pertain to the quality of the studies, HHS and USDA cannot use their discretion to address the issue in the policy document.

For example, during the most recent DGAC scientific review process, over 50 scientific studies and literature on the oral health benefits of chewing sugar-free gum

were submitted properly and in a timely manner to the NEL. The scientific studies covered over 40 years of research showing that chewing sugar-free gum stimulates salivary flow, which neutralizes plaque acids and enhances remineralization of the tooth enamel, as well as reduces dental caries.

The 2015 DGAC, however, decided for reasons unclear to us not to conduct a scientific review of this evidence, which means that these studies were never rated as strong, moderate, or weak. Because these studies were never rated, HHS confirmed that neither Department has the discretion to include guidelines on the oral health benefits of chewing sugar-free gum, even if the preponderance of evidence exists. As such, stakeholders must wait until the 2020 DGAs to address the issue. Therefore, **we recommend that if the DGAC decides not to conduct a scientific review of studies on a specific topic, then it must provide a justification for its decision. This would be especially helpful when past DGACs have provided recommendations on that topic and there are properly submitted studies and literature looking to update those recommendations.** By taking this approach, USDA and HHS would then have greater discretion to decide whether the agencies should address the topic in the policy document along with stakeholder input and other considerations.

For example, in the 2005 scientific report, the DGAC concluded that there is a relationship between the intake of sugars and starches and the formation of dental caries. The report also focused on how to best optimize oral hygiene practices and recommended drinking fluoridated water and/or using other fluoride containing dental hygiene products to help reduce the risk of dental caries.[1] The 2010 DGAC affirmed these recommendations in its scientific report, but the 2015 DGAC did not reaffirm these conclusions or make additional recommendations on oral health measures despite receiving over 50 studies on the oral health benefits of chewing sugar-free gum.[2]

Mars also recommends that if a DGAC fails to conduct a scientific review, HHS and USDA should have the discretion to address the issue in the policy document if either Department has previously made a decision on that issue in a formal rulemaking or through another significant proceeding. As it relates to the oral health benefits of chewing sugar-free gum, USDA previously recognized that chewing sugar-free gum after meals reduces dental caries through the Smart Snacks rulemaking, which was based on the exact same studies submitted to the NEL for the 2015 DGAC scientific review process. In the final rule allowing sugar-free gum products to be sold in schools, USDA stated that "[c]linical studies have shown that chewing sugarless gum for 20 minutes following meals can help prevent tooth decay."[3] Therefore, **if an issue has already been reviewed through a formal rulemaking or another significant proceeding within HHS or USDA, this could be considered to be evidence, similar to a DGAC's scientific recommendation.** Otherwise, it would appear that the DGAC has absolute authority to foreclose opportunities for USDA and HHS to address topics in the DGAs, even when there is a preponderance of scientific evidence that the agency has already examined. This raises concerns as USDA and HHS are authoritative bodies, as opposed to the DGAC.

Last, Mars notes that during the 2015 scientific review process the DGAC considered studies that were not submitted properly to the NEL. By doing so, **the DGAC has set a disruptive precedent** that must be addressed. Currently, studies properly submitted to the NEL do not have to be reviewed, which means that they can be automatically disqualified from consideration by HHS and USDA. Studies not submitted to the NEL, however, can be used to support the DGAC's recommendations and thus give authority for HHS and USDA to address the issue in the policy document. We are not necessarily arguing that studies cannot supplement the DGAC's findings, but we do have concerns that such studies may take priority over those properly submitted to the NEL.

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[1] 2005 Dietary Guidelines Advisory Committee, "The Report of the Dietary Guidelines Advisory Committee on Dietary Guidelines for Americans, 2005," at Part A: Executive Summary, page 6, (2005), available at *http://www.health.gov/dietaryguidelines/dga2005/report/* (last accessed September 29, 2015).

[2] 2010 Dietary Guidelines Advisory Committee, "Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010," at Part D: Carbohydrates, page 286, (2010), available at *http://www.cnpp.usda.gov/sites/default/files/dietary_guidelines_for_americans/2010DGACReport-camera-ready-Jan11-11.pdf* (last accessed September 29, 2015).

[3] *National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010,* 78 FED. REG. 125 (June 28, 2013) (to be codified at 21 CFR pts. 210 and 220).

Conclusion

Once again, Mars recognizes the significant effort undertaken by the DGAC, as well as USDA and HHS, to update the DGAs to reflect the latest nutritional science. Specifically, Mars supports the DGAC's recommendations on limiting intake of added sugars and sodium.

We also thank the Committee for considering our concerns with the current scientific review process. For the Committee's review, we have attached a letter signed by 13 Members of Congress expressing similar concerns about the DGAC's failure to conduct a scientific review of the studies on the oral health benefits of chewing sugar-free gum.

If you would like to discuss our positions, please do not hesitate to contact Shannon Campagna at [**Redacted**] or [**Redacted**].

Sincerely,

SHANNON CAMPAGNA,
Mars, Incorporated.

ATTACHMENT

May 13, 2015

Hon. THOMAS "TOM" J. VILSACK,
Secretary,
U.S. Department of Agriculture,
Washington, D.C.;

Hon. SYLVIA MATHEWS BURWELL
Secretary,
U.S. Department of Health and Human Services,
Washington, D.C.

Dear Secretaries Vilsack and Burwell:

We are concerned that the *2015 Scientific Report of the Dietary Guidelines Advisory Committee* (DGAC) did not meaningfully address oral health despite the fact that both the 2005 and 2010 editions of the *Dietary Guidelines for Americans* (DGAs) recognized oral health as a public health priority.

The absence of oral health as a public health priority in the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* is a step backward in the Federal Government's long-standing effort to address the chronic, yet preventable disease of tooth decay. Fifteen years ago, in the first Surgeon General's report on oral health, the Surgeon General called for a "national effort to improve oral health among all Americans." The report found that "oral health is integral to general health," and stated that "you cannot be healthy without oral health."

In recognizing oral health as a public health priority, both the 2005 and 2010 DGAs concluded that there is a relationship between the intake of sugars and starches and the formation of dental cavities. Both DGAs also focused on how to best optimize oral hygiene practices and recommended drinking fluoridated water and/or using other fluoride-containing dental hygiene products to help reduce the risk of dental cavities. The *2015 Scientific Report,* however, did not make such recommendations. Therefore, we request that the 2015 Policy Document reaffirm the oral health conclusions from the 2005 and 2010 DGAs.

We also strongly encourage the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) to identify additional scientifically-proven ways to optimize hygiene practices, including the chewing of sugar-free gum after eating meals. Over 40 years of research has shown that chewing sugar-free gum stimulates salivary flow, which neutralizes plaque acids and enhances remineralization of the tooth enamel, as well as reduces dental cavities.

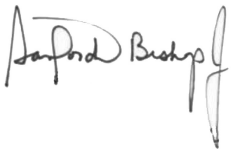
This research, which includes over 50 scientific studies and literature, was submitted properly and in a timely manner to USDA's National Evidence Library; however, the 2015 DGAC decided for reasons unclear to us not to conduct a systematic review of this evidence. Therefore, we request HHS and USDA conduct a systematic review of the submitted evidence or affirm USDA's science-based regulatory finding in the Smart Snacks rule that chewing sugar-free gum after meals reduces dental cavities. In that rule, and based on USDA's review of the same studies submitted to the 2015 DGAC, USDA recognized that "[c]linical studies have shown that chewing sugarless gum for 20 minutes following meals can help prevent tooth decay" in allowing sugar-free gum products to be sold in schools.

As a global leader, the United States should continue to make great strides in addressing tooth decay, which remains the most prevalent chronic disease in both children and adults, yet it is largely preventable. We ask that HHS and USDA continue

to make oral health a public priority in the *2015 Dietary Guidelines for Americans* because oral health is essential to improving general health.

Sincerely,

Hon. DOUG COLLINS,
Member of Congress;



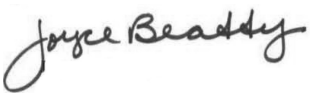
Hon. SANFORD D. BISHOP, JR.,
Member of Congress;

Hon. BRENDA L. LAWRENCE,
Member of Congress;

Hon. STEVE CHABOT,
Member of Congress;

Hon. JOSEPH J. HECK,
Member of Congress;

Hon. DONALD M. PAYNE, JR.,
Member of Congress;



Hon. JOYCE BEATTY,
Member of Congress;

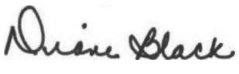
Hon. BRIAN BABIN,
Member of Congress;

Hon. RYAN A. COSTELLO,
Member of Congress;

Hon. DINA TITUS,
Member of Congress;

Hon. LYNN JENKINS,
Member of Congress;

Hon. PAUL COOK,
Member of Congress;



Hon. DIANE BLACK,
Member of Congress.

SUBMITTED LETTER BY PAMELA SCHOENFELD, M.S., R.D., EXECUTIVE DIRECTOR; ADELE HITE, M.P.H., R.D., PUBLIC POLICY ADVISOR, HEALTHY NATION COALITION

House Committee on Agriculture
Washington, D.C.;

U.S. Senate Committee on Agriculture, Nutrition, and Forestry,
Washington, D.C.

Why the USDA/HHS *Dietary Guidelines for Americans* (DGA) development process must be overhauled:

The DGA:

1. *Exceed the language of their authorizing statute.*
2. *Do not achieve the stated goals of prevention of chronic disease and promotion of healthyweight.*
3. *Are inappropriate for large sectors of the American population—especially children.*
4. *Do not ensure that Americans meet essential nutrition needs.*
5. *Are out-of-step with our multicultural nation and diverse dietary practices.*
6. *Do not reflect the most up-to-date and comprehensive research findings.*
7. *Act to limit or restrict the availability of certain categories of foods.*
8. *Are not held to rigorous scientific standards.*
9. *May be contributing in part to our nation's health problems.*
10. *Should be replaced by guidance, for use by the general public, focused on essential nutrition.*

1. The DGA exceed the language of their authorizing statute.

According to Secretary Vilsack: "I struggle with the *Dietary Guidelines* because I think it is important to understand precisely what they are and are not. These guidelines are a set of recommendations based on a series of well-informed opinions that create a framework that is designed to encourage and educate Americans about what they can do to increase their chance of prevention of chronic disease. This is not about treating disease, this is about trying to prevent chronic disease."[1]

Vilsack continues "We're looking at what the law requires us to do, and that is focus on dietary and nutritional guidelines relative to prevention."[2]

As posted on the Department of Health and Human Services website (*http://health.gov/dietaryguidelines/purpose.as*):

> These recommendations aim to:
>
> - Promote health.
> - Prevent chronic disease.
> - Help people reach and maintain a healthy weight.

Yet, there exists no language in the legislation that specifies that the DGA should be designed for the prevention of chronic disease. The key part of the legislative mandate is below:

> 7 U.S. Code § 5341—Establishment of dietary guidelines
>
> (1) IN GENERAL
>
> At least every 5 years the Secretaries shall publish a report entitled "*Dietary Guidelines for Americans*." Each such report shall contain nutritional and dietary information and guidelines for the general public, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.
>
> (2) BASIS OF GUIDELINES
>
> The information and guidelines contained in each report required under paragraph (1) shall be based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.

Note that the report is to contain guidelines for the "general public."

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[1] Quote found at 00:12:18 of October, 7, 2015 Full Committee on Agriculture hearing (*http://www.c-span.org/video/?328598-1/secretaries-tom-vilsack-sylvia-burwell-testimony-nutritional-guidelines*); this is the source for all quotation time marks used herein.

[2] 01:25:00.

The "general public" is a demographically diverse population with an equally diverse set of nutritional needs. Attempting to design guidelines for the prevention of chronic disease has led to a narrow and limited focus and has shifted our priority away from ensuring the intake of adequate levels of essential nutrients demonstrated to be required for human health, reproduction, and growth. In the past, USDA dietary guidance emphasized the inclusion of a wide variety of animal and plant foods with the goal of meeting essential nutritional requirements.[3]

2. The DGA do not achieve the above stated goals of prevention of chronic disease and promotion of healthy weight.

While there are no goals specifically mandated in the legislation, the increases in the prevalence of obesity, diabetes, and related diseases such as non-alcoholic fatty liver, demonstrate that the DGA have not had the desired impact on the health of Americans.

These increases should not come as a surprise: the food patterns in the DGA have "not been specifically tested for health benefits."[4] Although we might surmise that the "goal" of the DGA from their inception was to reduce incidence of chronic disease, this has never been shown to be the case.

3. The DGA are inappropriate for large sectors of the American population—especially children.

The following exchange from the hearing illustrates this critical point:

Rep. Rodney Davis raised his "most serious concern today is what I see as a lack of evidence to show that the recommended dietary patterns proposed by the DGA have been based on any evidence on children. According to citations in some previous advisory reports for recommendations, the recommended diet has been tested almost exclusively on middle age men and women whose nutritional needs obviously are very different from young people and growing children. In particular, I am concerned because young children need certain vitamins and minerals obviously in order to grow and develop." Of note is the fact that the recommended diet has not been tested at all; the studies used to support the guidelines have been conducted in adults, generally males.[5]

Secretary Burwell addressed [her] concern: "My team brought up the issue of children yesterday as we look to making sure we have appropriate evidence for a number of the things that you are talking about for the next set [of guidelines in 2010]. Because I think what you are appropriately reflecting is *the research doesn't exist* because it is on older [adults]. So we need to get started on that now. So with regard to the issue of do we need to understand this better. We don't have the facts yet. We don't have a science base. If we start now we will for the next" [emphasis added].[6]

It is clear that applying guidelines to children where "research doesn't exist" is irresponsible at best. We should be very careful not to draw conclusions or make recommendations when we cannot even meet the required preponderance of evidence standard. The DGA as they stand now must not be applied to children (inclusive of birth to 18 years of age). In the interim, guidelines to ensure essential nutritional needs for children are met, including vitamins and minerals, should be developed in their place. We already have a strong evidence base to use in their development, which are the *Dietary Reference Intakes published by the Institute of Medicine* (*http://iom.nationalacademies.org/Activities/Nutrition/SummaryDRIs/DRI-Tables.aspx*).

4. The DGA do not ensure that Americans meet essential nutrition needs.

This is an extension of the previous concern.

In the 2015 DGAC report, the Committee characterized the following as shortfall nutrients: "vitamin A, vitamin D, vitamin E, vitamin C, folate, calcium, magnesium, fiber, and potassium. For adolescent and premenopausal females iron also is a shortfall nutrient. Of the shortfall nutrients, calcium, vitamin D, fiber, and potassium also are classified as nutrients of public health concern because their underconsumption has been linked in the scientific literature to adverse health outcomes. Iron is included as a shortfall nutrient of public health concern for adolescent fe-

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[3] For examples of historical USDA dietary guidance please see: *http://www.nal.usda.gov/fnic/history/8549v.gif* (WWII era); *http://www.nal.usda.gov/fnic/history/0007v.gif* (post-war era); and others at: *https://nutritionhistory.nal.usda.gov/*.

[4] *2010 Dietary Guidelines for Americans,* p. 50

[5] 01:44:30.

[6] 01:47:10.

males and adult females who are premenopausal due to the increased risk of iron-deficiency in these groups."[7]

Zinc, while not cited by the Committee as a shortfall nutrient, is an important mineral that may be underconsumed when animal proteins, especially red meat, are limited. This is of particular concern for young children, who have high physiologic requirements for iron and zinc to support rapid growth and brain development. The recommended "healthy vegetarian pattern" is devoid of red meat and is thus inappropriate to indiscriminately recommend for children.

The recommendations of previous and the current DGA have actually served to increase the risk for below-adequate intake of several of the above-listed nutrients. We provide scientific support on the reasons for this in the attached commentary previously submitted to the USDA/HHS through their website during the allotted period.[8]

Of significance, as recent as 2000, the DGA continued to include beef, turkey dark meat, and liver and other organ meats and dark meat as good sources of iron.[9] Previous DGA editions also included pork and lamb. No mention of organ or dark meat is made in either the current 2010 DGA or the 2015 DGAC Report. In addition, USDA-sponsored family and consumer literature published by the University of Arkansas Division of Agriculture in 2010 do recommend liver a source of iron for infants and toddlers: and for young children.[10] We highly recommend that liver and other organ meats be re-evaluated as a nutrient dense food for inclusion in the DGA recommendations.

5. The DGA are out-of-step with our multicultural nation and diverse dietary practices.

Unfortunately, the DGAC Report does not consider this diversity when deciding on the three recommended dietary patterns: the Healthy U.S.-style Pattern, the Healthy Mediterranean-style Pattern, and the Healthy Vegetarian Pattern (Report: Part D. Ch 1. Line 2827). We ask that the USDA and HHS be required to consider the foodways of our immigrant and native populations when making population-wide recommendations. This is especially necessary given the DGAC's recognition of a need for future research to "[e]xpand WWEIA (*What We Eat in America*) participation to include more respondents from race/ethnic minorities and non-U.S. born residents; while acknowledging that '[v]ery little is known about the dietary habits of many of the cultural subgroups in the United States. This knowledge is essential to moving forward any nutrition programs for first and second generation immigrants.'"[11]

Secretary Burwell discussed keeping the DGA information "simple enough" that it can be used "in your own cultural context";[12] Secretary Vilsack highlighted the USDA programs that are "working with Native Americans to reflect [their] traditions and culture."[13] We commend these ideas and efforts and urge they be emphasized in the upcoming edition.

6. The DGA do not reflect the most up-to-date and comprehensive research findings.

To illustrate the lack of sound scientific methodology that has permeated the DGA processes from its inception please consider the following:

The 2015 DGAC reversed the long-standing opinions of previous DGACs and recommendation of previous DGA that dietary cholesterol should be limited to less than 300 mg per day, stating: "The 2015 DGAC will not bring forward this recommendation because available evidence shows no appreciable relationship between consumption of dietary cholesterol and serum cholesterol, consistent with the conclusions of the AHA/ACC report (2, 35). Cholesterol is not a nutrient of concern for over-consumption."[14] The *same evidence* was available to the 2010 DGAC which

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[7] *Scientific Report of the 2015 DGAC: Executive Summary.* Part A. p 2., herein cited as "Report."

[8] See point number 3 on page 9 of the attached commentary,* where we address nutrient shortfalls. Your attention to the entire attached letter (written by the undersigned on behalf of the Weston A. Price Foundation) would be very much appreciated as we have outlined several others scientifically supported concerns we have with the 2015 DGAC Report as well as the process utilized for the development of the DGA.

* **Editor's note:** The document referred to is retained in Committee file.

[9] *https://nutritionhistory.nal.usda.gov/download/CAT40000623/PDF*

[10] *https://nutritionhistory.nal.usda.gov/download/1759104/PDF; https://nutritionhistory.nal.usda.gov/download/1759103/PDF.*

[11] Report: Part D. Ch. 1, Line 2838.

[12] 01:37:40.

[13] 01:38:10.

[14] Report: Part D. Ch. 1, Line 642.

continued to recommend cholesterol limits; these limits were carried forward into the 2010 DGA.

Graded evidence is not provided by the 2015 DGAC to support this revision. This is unfortunate considering the language of H.R. 3049: "Each revision to any nutritional or dietary information or guideline contained in the 2010 edition of the *Dietary Guidelines for Americans* and any new nutritional or dietary information or guideline to be included in the eighth edition of the D*ietary Guidelines for Americans*—(A) shall be based on scientific evidence that has been rated "Grade I: Strong" by the grading rubric developed by the Nutrition Evidence Library of the Department of Agriculture."

We strongly encourage your committees to reconsider the language of the proposed bill. We respectfully offer that *any standing guideline be carried forward only if it can be supported by Grade I: Strong evidence per the NEL process,* subject to an independent scientific review.[15]

7. The DGA act to limit or restrict the availability of certain categories of foods.

A key example here is the removal of whole (3.5% fat) milk from the National School Lunch Program (NSLP). Preventive public health measures must provide an expected benefit to the individual upon whom the intervention is imposed, with minimal risk of harm, as ascertained by strict standards of evidence. For example, whole milk has been removed from the NSLP. However, there is limited evidence of benefit from restricting whole milk, and there has been no recognition of potential harm from alternative choices, such as inadequate nutrition (if students refuse to drink milk at all rather than drink reduced-fat milk) or excess intake of sugar (if students choose sweetened milk when full-fat milk is unavailable). Parents may feel it is better for their children to have whole milk rather than no milk or sweetened milk. That choice should not be made by government officials without strong evidence of the singular benefits of reduced-fat milk and the specific harms of whole milk.

A recent *Washington Post* article (*http://www.washingtonpost.com/news/wonkblog/wp/2015/10/06/for-decades-the-government-steered-millions-away-from-whole-milk-was-that-wrong/*) presented more up-to-date scientific findings that whole milk has a place in a nutritionally balanced diet. Not mentioned in the article is additional research showing that whole milk consumption is associated with a lower risk for overweight/obesity in children.[16]

8. The DGA are not held to rigorous scientific standards.

Notwithstanding Secretary Vilsack's current view that a "gold standard process" [17] is being adhered to, the current process lacks rigor. For future DGA, scientific standards should be raised to "beyond a reasonable doubt" that a recommendation will provide benefit and will not cause harm.

For the development of 2020 DGA, we concur with Rep. Trent Kelly who suggested that the preponderance of evidence standard is not the right standard to use: "Maybe it is clear and convincing evidence or maybe it's *beyond a reasonable doubt* that when we have science that we hold them to a standard that makes sure that the end result is something that we have a good belief that it will be viable and it will be the right answer" [emphasis added].[18] The right answer may not be a single answer for all individuals; it should however ensure that we provide the best fundamental information so that the majority of Americans can meet their basic nutritional needs. Secretary Vilsack is in agreement with Rep. Trent and provides an opportune solution: "We have to follow the Congressional mandate. So if you all believe that it should be a higher standard, that is your call and whatever your call is, we will follow it." [19]

9. The DGA may be contributing in part to our nation's health problems.

During the hearing, statistics were cited on the rising prevalence of obesity and diabetes. We cannot afford to wait another 5 years; our survival as a great nation depends on getting this right. According to Rep. David Scott, "Agriculture is indeed our most important industry. It's the food we eat. It's the water we drink. It's our

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[15] Other examples of weak scientific methodology are detailed in the attached commentary * to the USDA/HHS; point number 1, page 2, provides a key example.

* **Editor's note:** The document referred to is retained in Committee file.

[16] Berkey *et al.,* 2005 ARCH. PEDIATR. ADOLESC. MED. 159(6); Scharf *et al.,* 2013 ARCH. DIS. CHILD. doi :10.1136/archdischild-2012–302941.

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[18] 01:41:04.

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survival. And I think that you got the feeling from this Committee how important this is."[20] We wholeheartedly concur with the Rep. Scott and other Members of the Committee and ask that the entire DGA process and resulting guidelines be given an immediate and thorough review by Congress and by an independent scientific panel selected by Congress and under their direction.

10. The DGA should be replaced by guidance, for use by the general public, focused on essential nutrition.

The DGA should, first and foremost, provide general dietary guidance on selecting from a variety of foods that supply adequate essential nutrients. This could look like previous editions produced by the USDA (examples cited above in point 1), perhaps with multicultural versions to meet our diverse population's dietary preferences. To ensure scientific rigor, the DRIs should be utilized. Any and all guidance for the prevention of chronic disease must be limited to that designated as Grade 1: Strong evidence by the USDA Nutrition Evidence Library and directed only at relevant demographic group(s).

In conclusion, any measurement of the success of the DGA must not be in regard to how well the American public applies and adheres to them as Secretary Vilsack states.[21] Success must be measured by nutrition and health outcomes including the following:

- Are Americans, especially children, meeting all of their nutrient needs?
- Are we seeing meaningful declines in the prevalence of obesity, diabetes, fatty liver, and other diseases that are afflicting our children?

From the questions asked of Secretaries Burwell and Vilsack, we know that a number of policymakers share our concerns. We commend the language in the House's Departments of Agriculture, Rural Development, Food and Drug Administration and Related Agencies (section 734) and Departments of Labor, Health and Human Services and Education and Related Agencies, (section 230) Fiscal Year 2016 Appropriations Bills that indicates a call for the *highest standards of evidence, and we suggest that these standards be applied to all national nutrition guidance.*

Respectfully submitted by,

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SUBMITTED STATEMENT BY NINA TEICHOLZ, AUTHOR, *THE BIG FAT SURPRISE: WHY BUTTER, MEAT AND CHEESE BELONG IN A HEALTHY DIET*

I want to thank Chairman Michael Conaway (R–TX) and Ranking Member Collin Peterson (D–MN) for holding this important hearing on the U.S. *Dietary Guidelines for Americans.* My name is Nina Teicholz and I am an investigative journalist who spent 10 years researching the science, politics and history of U.S. nutrition policy and particularly how we came to believe that dietary fat is bad for health. This work culminated in my best-selling book, *The Big Fat Surprise: Why Butter, Meat and Cheese Belong in an Healthy Diet,* which was named a "Best Book" of 2014 by the *Economist, Wall Street Journal, Forbes, Mother Jones, Library Journal,* and *Kirkus Reviews,* and received strong review in both the *BMJ* and *American Journal of Clinical Nutrition.* In the spring of 2015, I received a grant from the Laura and John Arnold Foundation to undertake a comprehensive scientific analysis of the *Dietary Guidelines*, resulting in a report ("Critical Review") that is available to the public at *www.forbetterdietaryguidelines.com*. Based on that work, I wrote a comprehensive peer-reviewed, fact-checked investigation of the guidelines that was published by the *British Medical Journal* (*BMJ*), available to read here: *http://www.bmj.com/content/351/bmj.h4962*. My testimony today is based on this body of work.

In general, I found that expert report underpinning the next set of U.S. *Dietary Guidelines for Americans* fails to reflect much relevant scientific literature in its reviews of crucial topics and therefore risks giving a misleading picture. The omissions seem to suggest a reluctance by the committee behind the report to consider any evidence that contradicts the last 35 years of nutritional advice.

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My analysis for the *BMJ* found that the committee's report used weak scientific standards, reversing recent efforts by the government to strengthen the scientific review process. This backsliding seems to have made the report vulnerable to internal bias as well as outside agendas.

The 2015 report states that the committee abandoned established methods for most of its analyses. Since its inception, the guideline process has suffered from a lack of rigorous methods for reviewing the science on nutrition and disease, but a major effort was undertaken in 2010 to implement systematic reviews of studies to bring scientific rigor and transparency to the review process. The U.S. Department of Agriculture set up the Nutrition Evidence Library (NEL) to help conduct systematic reviews using a standardized process for identifying, selecting, and evaluating relevant studies.[3]

However, my *BMJ* analysis found that on questions requiring reviews of the scientific literature, the committee did not use the NEL for 63% of them. The questions include some of the most controversial issues in nutrition today.[4] Instead, the committee relied on systematic reviews by external professional associations, almost exclusively the American Heart Association (AHA) and the American College of Cardiology (ACC), or conducted ad hoc examinations of the scientific literature without well defined systematic criteria for how studies or outside review papers were identified, selected, or evaluated.

Use of external reviews by professional associations is problematic because these groups conduct literature reviews according to different standards and are supported by food and drug companies. The ACC reports receiving 38 percent of its revenue from industry in 2012, and the AHA reported 20 percent of revenue from industry in 2014. Potential conflicts of interest include, for instance, decades of support from vegetable oil manufacturers, whose products the AHA has long promoted for cardiovascular health. This reliance on industry backed groups clearly undermines the credibility of the government report.

Saturated Fats

On saturated fats, for example, the committee did not ask the NEL to conduct a formal review of the literature from the past 5 years, even though this topic clearly merited re-examination. When the committee started its work in 2012, there had been several prominent papers, including a meta-analysis[5] that failed to confirm an association between saturated fats and heart disease, and two major reviews (one systematic)[6–7] that did not consistently show an causal effect of saturated-fat reduction on cardiovascular mortality.

Restrictions on saturated fats have been a foundation of nutrition policy since the first guidelines in 1980 and have had a dominant role in determining which foods, such as low fat dairy and lean meats, are considered "healthy." Instead of requesting a new NEL review for the recent literature on this crucial topic, however, the 2015 committee recommended extending the current cap on saturated fats, at 10% of calories, based on a review by the AHA and ACC,[8] a 2010 NEL review, and the 2015 committee's *ad hoc* selection of seven review papers (see table A on *thebmj.com*).[9]

The NEL systematic review on saturated fats from 2010[10] covers only the literature published from 2004 to 2009, the period which the 2010 committee had been asked to review. Fewer than 12 small trials are cited, and none supports the hypothesis that saturated fats cause heart disease (see table B on *thebmj.com*).

More significantly, the 2010 review omits a large controlled clinical trial, the Women's Health Initiative, which included nearly 49,000 people and achieved a significantly lower intake of saturated fat in the intervention group yet, compared with controls, observed no benefits for this group in incidence of fatal and non-fatal coronary heart disease events and total cardiovascular disease, including stroke.[11]

Papers on saturated fats published since 2010 were covered by the committee's *ad hoc* review, which did not use a systematic method to select or evaluate studies. One of the meta-analyses it cited was arguably inappropriately included because it considered polyunsaturated vegetable oils rather than saturated fats.[12] Another analysis cited in great detail had already been covered by the 2010 NEL review, so including it again amounted to double counting.[13] Three meta-analyses concluded that saturated fats did not increase cardiovascular mortality,[14–16] but the committee downplays these findings. And two other included meta-analyses had mixed results: saturated fats generally looked more atherogenic than polyunsaturated fats but less atherogenic than carbohydrates or monounsaturated fat.[17–18] Despite this conflicting evidence, however, the committee's report concludes that the evidence linking consumption of saturated fats to cardiovascular disease is "strong."

Perhaps more important are the studies that have never been systematically reviewed by any of the Dietary Guideline committees.[19] These include the large, gov-

ernment funded randomized controlled trials on saturated fats and heart disease from the 1960s and 1970s. Taken together, these trials followed more than 25,000 people, some for up to 12 years. They are some of the most ambitious, well controlled nutrition studies ever undertaken.[20–25] These studies showed mixed health outcomes for saturated fats, but early critical reviews, including one by the National Academy of Sciences, which cautioned against the inconclusive state of the evidence on saturated fats and heart disease, were dismissed by the USDA when it launched the first *Dietary Guidelines* in 1980.[26] Subsequent guideline committees have never gone back to systematically review these early trials but instead relied on other government reports.

Low Carbohydrate Diets

Another important topic that was insufficiently reviewed is the efficacy of low carbohydrate diets. Again, the 2015 committee did not request a NEL systematic review of the literature from the past 5 years. The report says that this was because, after conducting "exploratory searches" of the literature since 2000, the committee could find "only limited evidence [on] low-carbohydrate diets and health, particularly evidence derived from U.S. based populations."[27]

The report provides no documentation of these "exploratory searches," yet many studies of carbohydrate restriction have been published in peer review journals since 2000, nearly all of which were in U.S. populations. These include nine pilot studies, 11 case studies, 19 observational studies, and at least 74 randomised controlled trials, 32 of which lasted 6 months or longer (see table C on *thebmj.com*). A meta-analysis and a critical review have concluded that low carbohydrate diets are better than other nutritional approaches for controlling type 2 diabetes,[28–29] and two meta-analyses have concluded that a moderate to strict low carbohydrate diet is highly effective for achieving weight loss and improving most heart disease risk factors in the short term (6 months).[30–31] Weight loss benefits on different diets tended to converge over the long term (12 months), according to various reviews, but a recent meta-analysis found that if carbohydrates are kept "very low," weight loss is greater than with a low fat diet maintained for a year.[32] Given the growing toll taken by these conditions and the failure of existing strategies to make meaningful progress in fighting obesity and diabetes to date, one might expect the guideline committee to welcome any new, promising dietary strategies. It is thus surprising that the studies listed above were considered insufficient to warrant a review.

New Strategies

The committee's approach to the evidence on saturated fats and low carbohydrate diets reflects an apparent failure to address any evidence that contradicts what has been official nutritional advice for the past 35 years. The foundation of that advice has been to recommend eating less fat and fewer animal products (meat, dairy, eggs) while shifting calorie intake towards more plant foods (fruits, vegetables, grains, and vegetable oils) for good health. And in the past decades, this advice has remained virtually unchanged.[33]

Because the guidelines have obviously not led to better health, however, there has been a need to find new strategies to tackle nutrition related diseases. The committee's most significant shift, which began in 2010, however, has been to redouble its efforts towards emphasizing a plant based diet. This can be seen in a number of ways in the 2015 report, none of which is supported by strong evidence.

New proposals by the 2015 report include not only deleting meat from the list of foods recommended as part of its healthy diets, but also actively counseling reductions in "red and processed meats."[34] This advice has been the subject of much debate, which guideline supporters have successfully characterized as a conflict between the self interested meat industry *versus* virtuous efforts to safeguard health (and the environment).[35–36] Yet framed this way, the debate fails to address the question fundamental to nutrition: would reducing meat lead to better health? Consulting the NEL for a review on this topic turns up a surprising fact: a systematic review on health and red meat has not been done. Although several analyses look at "animal protein products," these reviews include eggs, fish, and dairy and therefore do not isolate the health effects of red meat, or meat of any kind.[37]

Importantly, some of the report's findings also contradict the dietary committee's advice on red meat. For example, to support the idea that red meat harms health, the committee repeatedly cites one large randomized trial conducted in Spain. However, this trial did not intend to lower consumption of red and processed meats in the experimental group, compared with the control group, so cannot be said to support the committee's advice.[38] Also, the sole diagram on red meat in the committee's report, which plots the data from observational studies, shows a roughly equal num-

ber of health benefits associated with the diets higher in red meat as with diets lower in red meat.[39]

Recommended Diets

Another clear move towards a plant based approach in the report is the introduction of the "healthy vegetarian diet" as one of three recommended diets (the others are: "healthy Mediterranean-style" and "healthy U.S.-style").[2] A NEL review of a healthy vegetarian diet does exist, but it concludes that the evidence for this diet's disease fighting powers is only "limited," which is the lowest rank for available data.[40] Moreover, although the NEL conducted eight reviews on fruits and vegetables, none found strong (grade 1) evidence to support the assertion that these foods can provide health benefits.[41]

In general, the quality of the evidence supporting the report's three recommended diets is limited (table D on the *bmj.com*). The committee could find only "limited" to "not assignable" evidence to show that its diets protect against osteoporosis, congenital abnormalities, or neurological or psychological illnesses.[27] The NEL review found only "limited" or "insufficient" evidence that the diets could combat diabetes.[42] In a highly unorthodox move, the guideline committee overruled the NEL's systematic reviews on this topic and decided to upgrade the rank to "moderate," based on its opinion that one review paper on observational data, which showed positive results, was particularly strong.

And are the recommended diets better than other diets in helping people lose weight? On this question, the report ranked the evidence as moderate, yet to support this claim, it presents only a single clinical trial in 180 people with metabolic syndrome, which found the Mediterranean diet produced more weight loss than a low fat diet.[43] One randomized controlled trial listed by the review did not actually test weight loss, only the ability to adhere to the diet,[44] which, although important, is relevant only if the diet works. Three trials[45–47] and an AHA/ACC review[48] concluded that compared with other diets, those recommended by the *Dietary Guidelines* offered at best a marginal advantage in fighting obesity (less than a pound over trial periods lasting up to 7 years).

The report also gave a strong rating to the evidence that its recommended diets can fight heart disease.[27] Again, several studies are presented, but none unambiguously supports this claim. Eight trials reviewed by the NEL to support its strong grade include one trial that should not have been included because it lacked a comparable control group;[49] three that showed no beneficial effects on cardiovascular health other than improved blood pressure (and studied hypertensive populations)[50–52]; another, also in hypertensive people, showing that the recommended diet had poorer cardiovascular outcomes than other options that were higher in monounsaturated fat or protein;[53] one showing mixed results on cardiovascular risk factors (although low density lipoprotein cholesterol fell, so did "good" high density lipoprotein cholesterol);[54] and the largest one, which concluded that the diet was ineffective for reducing cardiovascular risk.[11] The committee also cites an AHA/ACC review, but this paper examines trials already covered by the NEL review, so including them again amounts to double counting.[8] The committee reviewed other, more recent studies but not using any systematic or predefined methods.

In conclusion, the recommended diets are supported by a minuscule quantity of rigorous evidence that only marginally supports claims that these diets can promote better health than alternatives. Furthermore, the NEL reviews of the recommended diets discount or omit important data. There have been at a minimum, three National Institutes of Health funded trials on some 50,000 people showing that a diet low in fat and saturated fat is ineffective for fighting heart disease, obesity, diabetes, or cancer.[46, 11, 55–59] Two of these trials are omitted from the NEL review. The third trial is included, but its results are ignored. This oversight is particularly striking because this trial, the Women's Health Initiative (WHI), was the largest nutrition trial in history.[55–56] Nearly 49,000 women followed a diet low in fat and high in fruits, vegetables, and grains for an average of 7 years, at the end of which investigators found no significant advantage of this diet for weight loss, diabetes, heart disease, or cancer of any kind.[11, 56–59] Critics dismiss this trial for various reasons, including the fact that fat consumption did not differ enough significantly between the intervention and control groups, but the percentage of calories from both fat and saturated fat were more than 25% lower in the intervention group than in the control group (26.7% *v.* 36.2% for total fat and 8.8% *v.* 12.1% for saturated fats).[57] The WHI findings have been confirmed by other sizeable studies and are therefore hard to dismiss. When the omitted findings from these three clinical trials are factored into the review, the overwhelming preponderance of rigorous evidence does not support any of the dietary committee's health claims for its recommended diets.

My Critical Review makes additional points about the recommended diets. One is that although the committee states that these diets offer "multiple ways" for people to eat a healthy diet, they are, in fact, all still virtually the same. In other words, the committee is still recommending a "one-size-fits-all" diet. This is problematic, given that there is clearly great variation in the nutrition needs of various populations, depending on age, gender, genetic background and state of metabolic disease state. (see Critical Review, pages 31–32). Moreover, the recommended diets are nearly identical to previous DGA dietary advice (pages 29–30), so in effect, "Dietary Patterns" are simply a new name on the same diet that has been recommended for more than a decade.

Moreover, this diet is modeled, in the tables of the report, to be low in fat (32–34% of calories as fat), even though the report concludes that a diet low in fat worsens important heart disease risk factors. In effect, this low-fat advice may potentially worsen heart-attack risk.

Another serious problem with the recommended diets is that, according to the committee, they are not nutritionally sufficient. The committee states that the nutrients "for which *adequacy goals are not met*" in most of the recommended diets are "potassium, vitamin D, vitamin E, and choline."[1] Vitamin A sufficiency is reported as borderline,[2] and without consumption of fortified grains, primarily refined-grain breakfast cereals, the diets are also deficient in iron and folate.[3] Thus, although the committee recommends consuming primarily whole grains, the reality is that the recommended diets remain just as high in refined grains as in the past, due to the need for nutrients from fortification. Indeed, the recommended diets contain an equal amount of refined grains as whole grains.

The committee does not address the issue of how its recommended diets might become nutritionally sufficient. However, it does note that for a number of nutrients for which the American population is currently "under-consumed," including calcium, iron, and Vitamin D, the best and most bioavailable sources of these nutrients are animal foods. For example, red meat is "an excellent source" of heme iron, and the greatest amount of calcium, in its most bioavailable form, is in hard cheeses, yet these foods are limited in the recommended diets due to the overall cap on saturated fat. The evidence suggests that easing or eliminating the limit on saturated fat would eliminate these nutritional deficiencies. A more complete discussion of these issues can be found in my Critical Review.

A final area examined by *The BMJ* where the report offers advice that contradicts its data is on sodium. The committee says that it "concurs" with a recent report by the Institute of Medicine, which states that the evidence is "inconsistent and insufficient to conclude that lowering sodium intakes below 2,300 mg/day will have any effect on cardiovascular risk or overall mortality."[9] Yet the report recommends that sodium intake "should be less than 2,300 mg/day" and encourages the choice of low salt options without reservation.

Questions About Bias

The overall lack of sound science and proper methods in the 2015 report could be seen as a reluctance to depart from existing dietary recommendations. Many experts, institutions, and industries have an interest in keeping the status quo advice, and these interests create a bias in its favor. Abandoning the NEL review methods, as the 2015 committee has done, opens the door not only for bias but also for influence from outside agendas and commercial interests, and all of these can be observed in the report.

For example, a bias towards the longstanding view that saturated fats are harmful can be seen in the report's designation of them, together with sugar, as a new category it calls "empty calories."[2] The report repeatedly mentions the need to reduce "sugar and solid fats," because, "both provide calories, but few or no nutrients."[2] Yet this pairing is unsupported by nutrition science. Unlike sugar, saturated fats are mostly consumed as an inherent part of foods such as eggs, meat, and dairy, which together contain nearly all of the vitamins and minerals needed for good health.

Not following the NEL methods has also allowed outside agendas to enter into the report, most clearly in the form of the new consideration for environmental sustainability. Although, as the report states, the environmental effects of food and

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[1] DGAC report, (Part D, Ch. 1, p. 22, lines 827–828 (*http://www.health.gov/dietaryguidelines/2015-scientific-report/06-chapter-1/d1-2.asp*)) (Appendix E–3.1, Text and Figure 4 (*http://www.health.gov/dietaryguidelines/2015-scientific-report/15-appendix-E3/e3-1.asp*)).

[2] 2015 DGAC report, Part D, Ch. 1, Figure D1.1, p. 131.

[3] Appendix E–3.2, Table 3, (*http://health.gov/dietaryguidelines/2015-scientific-report/15-appendix-e3/e3-2.asp*) see "grains" for the contributions of these foods to nutritional sufficiency.

drink production are considerable, they are outside the committee's formal mandate to provide the Federal Government with the "current scientific evidence on topics related to diet, nutrition, and health."[2] In a new development for 2015, the USDA hired a food policy analyst focused on environmental issues to oversee the guideline committee's work, reflecting a new agenda in the process.[60]

Much has been written about how industries try to influence nutrition policy, so it is surprising that unlike authors in most major medical journals, guideline committee members are not required to list their potential conflicts of interest. A cursory investigation shows several such possible conflicts: one member has received research funding from the California Walnut Commission[61] and the Tree Nut Council,[62] as well as vegetable oil giants Bunge and Unilever.[63–64] Another has received more than $10,000 from Lluminari, which produces health related multimedia content for General Mills, PepsiCo, Stonyfield Farm, Newman's Own, and "other companies."[65] And for the first time, the committee chair comes not from a university but from industry: Barbara Millen is President of Millennium Prevention, a company based in Westwood, MA, that sells web-based platforms and mobile applications for self health monitoring. While there is no evidence that these potential conflicts of interest influenced the committee members, the report recommends a high consumption of vegetable oils and nuts as well as use of self monitoring technologies in programs for weight management.

Still, it's important to note that in a field where public research dollars are scarce, nearly all nutrition scientists accept funding from industry. Of far greater influence is likely to be bias in favor of an institutionalized hypothesis as well as a "white hat" bias to distort information for what is perceived as righteous ends.[66]

The report is highly confident that its findings are supported by good science, stating that "The evidence base has never been stronger to guide solutions."[2] Millen told *The BMJ,* "You don't simply answer these questions on the basis of the NEL. Where we didn't feel we needed to, we didn't do them. On topics where there were existing comprehensive guidelines, we didn't do them. We used those resources and that time to cover other questions. The notion that every question that we posed should have a NEL is flawed." She said she would "go to the mat" to defend the committee's approach. "That's why you have an expert committee . . . to bring expertise," including "our own original analyses."

"These folks know how to do this work. People who criticize this are coming from the point of view that they don't like the answer. They don't like the fact that randomised controlled trials testing these dietary patterns are successful. I think you have to read the report. NEL helped us to do the searches to update the literature. That is stated. If it doesn't satisfy you, that is all I can say. It's well stated and been reviewed by dozens of people."

On saturated fats, especially, she said, "We thought we nailed it." Millen said that her committee's work had not been entirely without methodology but had "worked with the NEL and USDA assistance to identify the research literature." She said that "it was clear that polyunsaturated fats reduced heart disease risk and mortality," yet that the "evidence is not as clear on whether replacement of saturated fat with monounsaturated fats or carbohydrates reduces cardiovascular disease risk, and likely depends on the type and source."

On diets low in carbohydrates, she said that there was "not substantial evidence" to consider. "Many popular diets don't have evidence. But can you achieve healthiness, the answer is yes."

Regarding the committee's conflicts of interest, she said that members were vetted by counsel to the Federal Government. She would not reveal details of her company's activities. Critics of the report, she said, "are coming from the point of view that they don't like the answer."

The argument by the USDA has been that the Guidelines have not been successful because people do not adequately follow them. However, government data contradicts this explanation: from 1970 to 2005, Americans increased consumption of vegetables by 23% (with one of the biggest percentile increases being in leafy greens), fruit by 13%, grains by 41% and vegetable oils by 91%. At that same time, Americans have decreased consumption of animal fats by 16%, red meat by 17%, (beef by 22%), whole milk by 73%, butter by 14%, and eggs by 17%. (67) These numbers suggest that Americans have successfully followed the Guidelines, yet clearly better health has not been the result.

After 35 years of pursuing the same flawed nutrition policy, the time has come for an objective scientific review of the proposed *Dietary Guidelines.* Congress initiated the guidelines 35 years ago and Congress should require an objective scientific review of the guidelines by the National Academy of Sciences, and the Administration should embrace this transparent, objective analysis of one of the fundamental tenets of national nutrition policy.

Notes

- Competing interests: I have received modest honorariums for presenting my research findings presented in the book to a variety of groups related to the medical, restaurant, financial, meat, and dairy industries. I am also a board member of a nonprofit organization, the Nutrition Coalition, dedicated to ensuring that nutrition policy is based on rigorous science.
- This article was fully funded with a grant from the Laura and John Arnold Foundation. The analysis was conducted independently, and the report reflects the views of the author and not necessarily those of the foundation. The article was submitted in June and provisionally accepted for publication in July of 2015.
- Provenance and peer review: Commissioned; externally peer reviewed and fact checked.

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SUBMITTED LETTER BY KRISTIN PEARSON WILCOX, VICE PRESIDENT OF GOVERNMENT RELATIONS, INTERNATIONAL BOTTLED WATER ASSOCIATION

October 7, 2015

Hon. K. MICHAEL CONAWAY,
Chairman,
House Committee on Agriculture,
Washington D.C.;

Hon. COLLIN C. PETERSON,
Ranking Minority Member,
House Committee on Agriculture,
Washington D.C.

Dear Chairman Conaway and Ranking Member Peterson:

On behalf of the members of the International Bottled Water Association (IBWA), thank you for holding the hearing today on the importance of basing the *2015 Dietary Guidelines for Americans* (DGA) on sound science.

IBWA is the primary, authoritative source of information on bottled water. This includes all types of water, such as spring, mineral, sparkling, artesian and purified bottled water. Our membership includes over 700 United States and international bottlers, suppliers and distributors that are small, medium and large-sized companies. IBWA and the bottled water industry are committed to making safe and healthy products. In addition to U.S. Food and Drug Administration (FDA) and state regulations, IBWA member bottlers must adhere to the IBWA Bottled Water Code of Practice. In some cases, the FDA and IBWA standards for bottled water are more stringent than the U.S. Environmental Protection Agency (EPA) regulations for tap water.

We appreciate your attention today to the nutritional health of our citizens. Every American is affected by the nutritional recommendations made in the *Dietary Guidelines.* It is essential for them to be based on consistent, and sound nutritional science. We want to provide you with our insights on the nutritional importance of water, and its role in health, as you examine the Administration's efforts to finalize the *2015 Dietary Guidelines.* We believe the science supports having the final guidelines stress the importance of water consumption, including bottled water consumption.

Making healthy hydration an equally important part of the wellness equation, along with a well-balanced diet and daily physical activity for all Americans, should be a clear focus of the 2015 DGAs. Bottled water presents a healthy option for consumers when making a beverage choice. Having no calories and no sugar, it is often the best choice as a beverage on the go. This simplicity gives bottled water an advantage over other packaged beverages when consumers are trying to make a healthy beverage selection.

Scientific studies clearly demonstrate the importance of water consumption, and science and health professionals are speaking up on behalf of water. For example, on September 10, 2014, fourteen researchers, scientists, nutritionists, clinicians, and public health professionals wrote a letter to the Dietary Guidelines Advisory Committee (DGAC) asking them to strengthen the language for drinking water in the *2015 Dietary Guidelines* and adding a water graphic to the MyPlate nutrition guide. We think the science is clear, and researchers and clinicians are saying Americans should drink more water. And, consumers are listening.

Americans' consumption of bottled water increased by 7.3 percent to 11 billion gallons in 2014 and bottled water sales were up 6.4 percent to $13 billion (wholesale) over the previous year. Americans upped their annual bottled water consumption by almost 11 gallons per person during the period 2004 to 2015. It went from 23.2 gallons per person in 2004 to 34 gallons in 2014, according to Beverage Marketing Corporation (BMC). BMC reported that over the past 5 years alone, bottled water has increased its "share of stomach" of the overall beverage market from 14.4 percent in 2009, to 17.8 percent in 2014.

We hope that the revised DGA's will take this growth, and the advice of nutrition experts, into account in the final 2015 DGA document. Numerous peer-reviewed scientific studies indicate that water consumption can aid in weight management and that there is a need to promote the consumption of water. IBWA submitted a full list of the scientific research supporting the importance of water consumption to the DGAC.

This impressive list of academic endorsements of the importance of water consumption is supported by the government's own data. The U.S. Department of Agriculture's (USDA) National Health and Nutrition Examination Survey (NHANES) IV data show that older adults are not consuming enough water. Neither are children. Water accounted for only 29% of children's total fluid intake; the majority coming from soda, sports drinks and teas. Of children 4–8 years, 75% failed to satisfy the Daily Recommended Intake (DRI) for water. Dr. Adam Drewnoski, of the Center for Public Health Nutrition at the University of Washington, who conducted this study of NHANES data, concluded, "Increasing total water consumption can be achieved through various means, though promotion and encouragement of non-caloric beverages is likely to be the most successful avenue for increasing water consumption."

IBWA and its members believe the *Dietary Guidelines* should encourage the consumption of water of all kinds: bottled, filtered, and tap. It is our hope that the *2015 Dietary Guidelines* will reinforce those healthy behaviors that are already changing for the better. As noted, people are forming new habits like drinking more water—both bottled and tap. Besides growing in consumption nationally, bottled water is already outselling carbonated soft drinks in supermarkets here in Washington, D.C. and in 17 other major markets, including New York, Los Angeles, Miami, and Philadelphia. And according to BMC, bottled water will become the number one beverage product in the United States by 2020.

The message to drink more water is resonating around the world. For example, the Mediterranean Diet Pyramid includes drinking water as an essential component of a healthy diet. The DGAC has discussed the merits of the Mediterranean Diet during its deliberation of the 2015 Guidelines. The Japanese Food Guide also includes water at the top of its pyramid. Again, they all recognize water as an important element of a well-balanced lifestyle. Other countries, such as France, Spain, Germany, and Austria, include water in their dietary guideline visual depictions. We believe the U.S. should join these countries and include water in its *Dietary Guidelines* and on the MyPlate visual.

The DGAs do not need to pit healthy foods and beverages against each other. No one supports healthy beverage choices, such as milk, more than our industry and

we recognize the nutrient value of milk and 100% fruit juice. We are, however, suggesting that science supports having water, along with milk and dairy, on the MyPlate nutrition guide. According to a recent W.K. Kellogg Foundation poll, 90 percent of the people polled say they support making water a preferred beverage in the new *2015 Dietary Guidelines for Americans*. IBWA commissioned a study by the Artemis Strategy Group on the different MyPlate visuals. One of the visuals included the original USDA/HHS MyPlate, which has a dairy cup next to a plate. Another visual had a cup of dairy and cup of water next to one another alongside the plate. Among the 76% of those surveyed who reported that they are very or somewhat likely to consume dairy when viewing the original MyPlate, 49% of them said they that they would drink both water and dairy when they saw a MyPlate visual including water and dairy.

The *2015 Dietary Guidelines* and MyPlate will serve as a platform for Americans to begin or continue living a healthy lifestyle. We hope that both will include messaging and visuals to encourage the adoption of healthy hydration habits. Americans should be healthier and drink more water. If we want Americans to drink more water, there should be a consistent "think water" encouragement in the *Dietary Guidelines*' final recommendations. Delivery of this message to American families is critical.

We are concerned about two messages in the DGAC recommendations. In particular, its steps into providing economic rather than nutritional advice when the DGAC stresses that consumers should drink "free" water. We think the final Guidelines should encourage consumers to drink "accessible" water.

We are also concerned about the DGAC's straying into a discussion of environmental sustainability. We want to make sure that you are aware of bottled water's small impact on the environment, and on our small water use, as you deliberate on what beverages to promote. Bottled water has the smallest environmental footprint among all packaged beverages.

Statistics show that the bottled water industry is a sustainability leader. From an environmental standpoint, when people choose bottled water instead of any other canned or bottled beverage, they are choosing less packaging, less energy consumption, and less use of natural resources. According to a 2014 Antea Group Study, bottled water facilities have the lowest water use ratio and energy use ratio when compared to other beverage products, including sugar-sweetened beverages. These ratios represent the average amount of water and energy used within the facility to produce 1 liter of bottled water. The Antea study found that it only takes 1.32 liters of water to produce 1 liter of bottled water and that includes the liter that is consumed.

PET plastic bottled water containers are the single most recycled item in nationwide curbside collection programs. And large 3 and 5 gallon bottled water containers are washed, sanitized and reused between 30–50 times before being recycled. Data derived from EPA figures demonstrate that plastic water bottles make up less than ⅓ of 1 percent of the entire U.S. waste stream.

Bottled water producers, like the American farmers this Committee works to uplift and protect, care about the quality of the water and land that produce the food and beverage products that Americans and people around the world consume.

We pledge to remain good stewards of water resources. And we stand ready to partner with you and the Administration to help ensure good nutritional health for all Americans.

Thank you for this opportunity to comment on this important issue.

Sincerely,

KRISTIN PEARSON WILCOX
Vice President of Government Relations.

SUBMITTED LETTER BY GRAIN CHAIN*

October 19, 2015

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*American Bakers Association; American Institute of Baking International Grain Foods Foundation; Independent Bakers Association; National Association of Wheat Growers; National Pasta Association; North American Millers' Association; Retail Bakers of America; USA Rice Federation; Wheat Foods Council.

Hon. K. MICHAEL CONAWAY,
Chairman,
House Agriculture Committee
Washington, D.C.

RE: Grain Chain Comments for Hearing Record: House Agriculture Committee Hearing on *2015 Dietary Guidelines for Americans* (October 7, 2015)

Dear Chairman Conaway:

As the organizations comprising the Grain Chain, a grains industry coalition from farm to table, we are pleased to provide written comments for the public hearing record on the House Agriculture Committee's recent hearing to review the *2015 Dietary Guidelines for Americans*.

We commend the Chairman and the Committee on analysis of the dietary guideline review process and for emphasizing that as the 2015 recommendations are finalized by HHS and USDA, there needs to be a base of strong scientific evidence and within scope.

The Grain Chain comments provide detailed justification for the following specific recommendations:

1. Retain the DGAC 2010 recommendation for six servings of grains with balance between whole and enriched (refined);
2. Use the term "enriched grains" when referring to refined grains, since more than 95% of the refined grains in the U.S. are enriched and fortified;
3. Reject the DGAC 2015 recommendation to limit added sugar to no more than 10% of total calories;
4. Reject the DGAC 2015 recommendation to restrict dietary sodium to less than 2300 mg per day;
5. Acknowledge the emerging evidence of the beneficial effects of whole grains on maintaining a healthy microbiome;
6. Note the negative health implications of fad diets.

In the following sections we provide the scientific rationale for each of our recommendations.

1. Retain the DGAC 2010 Recommendation for Six Servings of Grains with Balance Between Whole and Enriched (Refined)

The Crucial Role of Enriched Grains in the Diet

The Grain Chain fully endorses the 2015 Dietary Guidelines Advisory Committee's decision to "bring forward" the recommendation of the *2010 Dietary Guidelines for Americans* which called for ½ of all grain intake to come from whole grains. This would allow Americans to reap the multiple, established health benefits of whole grains, leaving the other ½ of daily grain intake for enriched grain products, which have their own unique benefits. Furthermore, because at least 95% of the refined grains in the U.S. are enriched and fortified and labeled as such, it is more appropriate to use the term "enriched grains" as opposed to "refined grains," especially when speaking to staple grain products [see below, section on "Clarification of Terminology"]. Since Americans have yet to achieve the current *Dietary Guidelines* recommendation for whole grain intake, the recommendation's goal is still valid and vital in the setting of a calorically appropriate diet. As well, the science does not show that there are benefits to higher daily intake of whole grains beyond "making ½ your grains whole grains," reinforcing that all grains have a place in a balanced eating pattern.

As a category, grain foods contribute vital, and often underconsumed, nutrients to the American diet, including 43.7% of all fiber.[1] Approximately ⅔ of the grain contribution to total fiber intake comes from enriched grains.[2] The contributions of both whole and enriched grains to total fiber intake are important because *more than 90% of adults and children fall short of dietary fiber recommendations.*[2] Enriched grains also are the largest contributor of folate in the American diet.[3] Although the current dietary fiber shortfall could theoretically be made up by consuming more fruits and vegetables, which together contribute 43.8% of total dietary fiber intake,[1] a reduction in enriched grain intake could have unintended health consequences (*e.g.,* nutrient shortfalls from reduced intake of enriched grain products—see section 2, below). Furthermore, a number of scientific reports have demonstrated the distinctive benefits of cereal fiber compared to fiber from fruits and vegetables. For example:

- A 2007 meta-analysis including nine cohort studies demonstrated a 33% reduction in type 2 diabetes incidence associated with cereal fiber intake, but no association with either fruit or vegetable fiber intake.[4]
- A 2014 analysis of data from 17 prospective studies found an inverse linear relationship between cereal fiber intake and reduction in type 2 diabetes risk but no such associations with fruit or vegetable fiber intake.[5]
- A 2014 publication using data on survivors of myocardial infarction among participants in the Nurses' Health Study and Health Professionals Follow-up Study showed a 27% reduced risk in all-cause and CVD mortality associated with cereal fiber intake, but no association with fiber from either fruit or legumes.[6]

These articles are not presented to diminish the established benefits of fruits and vegetables, but rather to highlight the findings that when compared head-to-head, a considerable body of evidence (*i.e.,* 28 separate cohorts examined in these three studies) indicates that cereal fiber may be more important for reducing all-cause and some cause-specific mortality. Fiber from enriched grains makes up approximately ⅔ of total cereal fiber in the American diet.

While whole grains have a well-established link to reduced obesity risk, the 2015 DGAC has overstated the evidence against refined (enriched) grains. For example:

- A systematic review of the literature showed little relationship between refined (enriched) grain intake and body mass index.[7]
- A 2012 special review for *Nutrition Reviews* concluded that the published data on the relationship between refined (enriched) grain intake and body weight are mixed, with no clear and consistent trends.[8]
- Refined (enriched) grain intake was not associated with any measure of body fat distribution in older adults.[9]
- Among adolescent girls and boys in the NHANES III study, both refined (enriched) grain intake and whole grain intake were inversely associated with central adiposity, measured by waist circumference.[10]

With respect to facilitating weight loss, both refined (enriched) grains and whole grains may be equally effective:

- A 2014 report showed that when consuming a hypocaloric diet, enriched-grain foods and whole-grain foods were equally effective in facilitating weight loss and reducing abdominal adipose tissue in men and women with increased waist circumference.[11]
- A 2008 publication demonstrated that whole- and enriched-grain diets produced equal weight loss and improvements in several CVD risk markers in men and women with the Metabolic Syndrome.[12]

Refined (Enriched) Grain Intake and Chronic Disease: Weak Scientific Evidence

The 2015 DGAC concluded that higher consumption of refined (enriched) grains is linked to higher risk of several chronic diseases. This conclusion is not consistent with a large body of scientific evidence and again, reflects the disconnect in how staple grain products are classified. We have shared some examples of these inconsistencies but ultimately request a continued recommendation for balanced intake between enriched and whole grains.

Some examples:

- The 2015 DGAC report cited a 2014 meta-analysis in the *Journal of Human Nutrition and Dietetics* that indicated a positive relationship between refined (enriched) grain intake and risk of type 2 diabetes.[13] However, refined grains were not analyzed separately, but only as part of a dietary pattern. Surprisingly, the 2015 DGAC report did not cite a 2013 meta-analysis published in the *European Journal of Epidemiology* that showed no relationship between refined (enriched) grain intake and diabetes risk.[14] The impact factor for the *Journal of Human Nutrition and Dietetics* is 2.07, while the impact factor for the *European Journal of Epidemiology* is 5.15. It is important to note that the article not cited by the committee found no association between diabetes risk and refined grain intake, even up to seven servings per day. This information is extremely relevant because *Figure D1.28* in the DGAC report (p. 144) shows that refined (enriched) grain intake ranged between three and 6.5 servings per day, depending on sex and age group, between 2001 and 2010 (based on NHANES data). Furthermore, the reduced diabetes risk associated with whole grain intake was maximized at three servings per day, which is completely consistent with the current recommendations of ~3 servings per day of whole grains. If

total grain intake is to stay at six servings per day, there is no reason to advocate that all servings should come from whole grains.

- A report from the Framingham Heart Study showed that the lowest level of visceral abdominal fat was observed in persons who consumed approximately two servings per day of refined (enriched) grains and approximately three servings per day of whole grains. There was no benefit of reducing refined (enriched) grain intake to less than one serving per day.[15]
- A 2012 review concluded, "The totality of evidence shows that consumption of up to 50% of all grain foods as refined-grain foods (without high levels of added fat, sugar, or sodium) is not associated with any increased disease risk."[16]
- Among 28,926 participants in the Women's Health Study, refined (enriched) grain intake was not associated with hypertension, but whole grain intake was inversely associated with hypertension risk. The lack of an association with refined (enriched) grain intake was observed even at intakes of six or more servings per day.[17]

All Grain-Based Foods Can Be Part of a Healthy Diet

Recent data analyses presented at the 2015 Experimental Biology meeting in Boston that was supported by the Grain Foods Foundation revealed how many grain-based foods can cost-effectively fit into a healthy diet.[18–20] The results of these three separate analyses are described below:

- The 2015 DGAC relied on food pattern modeling analyses performed by the 2005 and 2010 DGACs to answer questions related to the impact of reducing refined/enriched grain consumption, and overall grain consumption, on nutrient intake. We would like to bring to your attention recent modeling research, supported by the Grain Foods Foundation, and presented at the 2015 Experimental Biology meeting.[18] The modeling analysis was conducted within a 2,000 kcal/d USDA ideal food pattern where the ideal USDA grain food composite was replaced with ten different grain food patterns based on data from What We Eat In America 2005–2010. All patterns were compared to the USDA ideal and USDA typical food patterns. All ten models examined provided less energy in comparison to the USDA typical food pattern. Several grain patterns, including refined grains, contributed nutrient and energy intakes similar to USDA recommendations. In fact, a pattern that included three servings of refined grains, two high-fiber grain servings and one serving of whole grains resulted in less sodium intake and greater intake of folate and fiber than a dietary pattern that included six servings of whole grains.
- A cluster analysis using data from What We Eat in America 2005–2010 found that there were no significant differences observed comparing those in the "no grains" cluster to those in several different grain patterns, including many non-whole grain-based foods, for body mass index or fasting blood concentrations of glucose, insulin, total cholesterol, LDL-cholesterol and triglycerides.[19] Thus, inclusion of several grain foods patterns in the diet is associated with several health- and nutrition-related outcomes in adults.
- A cost-of-nutrients analysis used NHANES 2003–2004 data and the USDA Center for Nutrition Policy and Promotion prices database to show that certain grain-based foods are a "nutrition bargain" for American consumers.20 The rolls/buns category and the rice category were particularly cost effective, each ranking in the top five most cost effective food categories for 13–14 of the nutrients/substances evaluated, including dietary fiber, protein, folate, iron, magnesium, calcium, niacin and thiamin.

2. Clarification of Terminology: Use the Term "Enriched Grains" When Referring to Refined Grains

We would like to clarify some important points on grains terminology.

Although the 2015 DGAC acknowledged the enrichment and fortification of grains, its repeated recommendations to reduce consumption of "refined" grains to improve health undermines the established benefits of enriched grain products.

Furthermore, rather than "refined," "enriched" is a more appropriate term to describe the grain products that the average American sees in the grocery aisle. These staple foods contain some fiber and are enriched with important nutrients, like thiamin, niacin, riboflavin and iron. They are fortified with folic acid, which is essential for women of childbearing age to help prevent neural tube birth defects. The rate of neural tube defects in the United States has decreased by 35 percent since the fortification of enriched grains began in 1998.[21]

Enriched grains, as mandated by the U.S. Government since 1941, have the three major B vitamins and iron replaced in equal or larger amounts to those in whole

grain products as defined by the standards of identity. These essential B vitamins help maintain a healthy nervous system, increase energy production, and may play a role in lowering cholesterol. Due to this enrichment policy, serious diseases, including pellagra and beriberi, have been eradicated from the U.S. population. The reduction in neural tube defects has reduced health care costs associated with spina bifida and anencephaly, resulting in annual savings in total direct costs of approximately $508 million for the NTD-affected births that were prevented with folic acid fortification.[21]

Enriched, fortified grain foods are the primary source of folic acid in Americans' diets. This is particularly important for women of child-bearing age, the majority of which do not take folic acid supplements. Furthermore, folic acid is better absorbed by the body than natural folate, almost twice as efficiently.[22] The U.S. also has a growing Hispanic population, and adequate consumption of folate-rich foods is critical for this group since statistically, Hispanic women are 1.5 to 3 times more likely to have a baby with an NTD.[23]

A Centers for Disease Control and Prevention (CDC) proclamation in 2011 named the fortification of folic acid to enriched grains as one of the top ten health achievements in the first decade of this century.[24] This fortification policy has also almost totally eradicated folate-deficiency anemia in older adults in the U.S.[25]

3. Reject the DGAC 2015 Recommendation To Limit Added Sugar To No More Than 10% of Total Calories

The 2015 DGAC recommends limiting added sugars to a maximum of 10% of total daily caloric intake. This recommendation was based on the food pattern modeling analysis conducted by the 2015 DGAC and on the scientific evidence review on added sugars and chronic disease risk conducted by the Committee. The DGAC rated the evidence as "strong." But the two major meta-analyses that the 2015 DGAC relied heavily upon reported rather small associations between sugar intake and body weight.[26–27] Moreover, the committee did not include several published reports that showed no significant relationships between sugar intake and a number of health outcomes.[28–34]

The association with obesity, for example, has been shown to be primarily due to caloric excess rather than sugar itself.[31–32] Furthermore, data on adults from the 1999–2006 National Health and Nutrition Examination Surveys (NHANES) demonstrated that sugar consumption was not positively associated with body weight or indicators of the metabolic syndrome.[33] Similarly, among children ages 6–18 participating in the 2003–2006 National Health and Nutrition Examination Survey, intake of added sugars was not associated with body weight, BMI z-score or any measure of adiposity.[30] In fact, added sugar consumption explained less than 0.25% of the variance in BMI z-scores of the children in this study, indicating that more than 99.75% of the variation in BMI z-scores of these children was due to factors *other than sugar*. It is difficult to justify specific recommendations for sugar consumption when this macronutrient's contribution to body weight and blood biomarkers for cardiovascular health is so small. Sugars have no specific role as a determinant of body weight other than being one of many sources of energy.[34]

We would also like to point out that the benefits of whole-grain consumption are independent of sugar consumption, and can be documented even with relatively high sugar intakes:

- In children ages 2–5, 6–12, and 13–18, whole-grain intake was found to be associated with higher diet quality (assessed by the Healthy Eating Index that reflects recommendations of the *Dietary Guidelines for Americans*), despite the fact that total sugar intake did not differ across quartiles of whole-grain intake. Highest diet quality was observed in children consuming more than three servings of whole grains per day. Sugar intake in these groups accounted for 19–23% of total calories.[28]
- In adults ages 51 and older participating in the National Health and Nutrition Examination Survey, 1999–2004, whole-grain intake was associated with a significantly higher Healthy Eating Index score, despite no differences in total sugar intake across quartiles of whole-grain intake.[29]

4. Reject the DGAC 2015 Recommendation To Restrict Dietary Sodium to Less Than 2,300 mg Per Day

The recommendation of the 2015 DGAC for dietary sodium intake to below 2,300 mg may not be compatible with minimizing risk for mortality or cardiovascular disease as stated in the 2013 Institute of Medicine (IOM) report on "Sodium Intake in Populations: Assessment of Evidence" and in other peer reviewed journals.[35–41] Evidence linking sodium intake to mortality outcomes is scant and inconsistent.[36–41] Several publications in 2014 and 2015 have demonstrated an increased mortality

risk associated with low sodium intake.[38–41] Because sodium reduction has physiological effects that may adversely affect health outcome, it is premature to recommend sodium levels lower than 2300 mg until more definitive data can justify such broad population-wide advice.

5. Acknowledge the Emerging Evidence of the Beneficial Effects of Whole Grains on Maintaining a Healthy Microbiome

In recent years there has been heightened interest in the role of the gastrointestinal system in overall health, but after conducting an exploratory search the 2015 DGAC concluded that there was insufficient evidence to address the role of diet in the microbiome.

While we agree that this is an emerging area of study, we would also like to emphasize that published research indicates that grains, especially those with high amounts of resistant starches, are important for maintaining a healthy composition of gut bacteria. Whole grain cereals, among other plant foods, are associated with the up-regulation of various bacteria that are beneficial to gut health.[42] Resistant starches found in whole grains have a prebiotic action that helps create a healthy composition of gut bacteria which may reduce risk of some cancers, inflammatory conditions and cardiovascular disease.[43–50] Despite the relatively small number of studies, the data that have been published call attention to a very prominent role for grain-based foods in creating a healthy microbiome. We think that this should be at least acknowledged in the *2015 Dietary Guidelines,* especially as an area for future study.

6. Note the Negative Health Implications of Fad Diets

Fad diets are temporary interventions that may carry long-term health consequences for the American public.

Contrary to the nature of fad diets, the *Dietary Guidelines for Americans* are focused on setting the stage for a long-term, healthful eating pattern for all Americans, one that is based on a common sense approach built on balance, variety and moderation. As a Grain Chain, we believe that healthy weight maintenance/loss relies on the simple equation of balancing calories in (consumed) with calories out (expended), not eliminating specific foods or relying primarily on one food group.

While there are countless fad diet plans available to the average American, we would like to briefly address the evidence countering three plans which often receive attention in the popular press: low-carbohydrate/Atkins, grain- and wheat-free (such as the plans detailed in the books *Wheat Belly* and *Grain Brain*) and gluten-free.

Low-carbohydrate/Atkins: Two meta-analyses published in 2014 showed no difference between low-fat and low-carbohydrate diets for weight loss or cardiovascular risk factors; researchers concluded that weight loss is determined by calorie deficit regardless of calorie type and asserted most cardiovascular improvements can be attributed to the weight loss.[51–52] More importantly, in a sample of nearly 44,000 Swedish women followed for an average of 15.7 years, study organizers found "low carbohydrate, high-protein diets used on a regular basis and without consideration of the nature of carbohydrates or the source of proteins are associated with increased risk of cardiovascular disease."[53] Carbohydrate consumption is also associated with better body weights. According to a study published in the *Journal of the Academy of Nutrition and Dietetics,* those who consume a medium-to-high percentage of carbohydrates in their diets have a reduced risk of obesity. The study also showed that people following a low-carbohydrate diet actually had a higher risk of being overweight or obese.[54]

Grain- and wheat-free: Carbohydrates are the preferred fuel source for the human brain; beyond this necessary role, grain consumption has been shown to have positive effects on brain function, specifically:

- As part of an overall healthful eating pattern, specifically one that follows the principles of the Mediterranean diet, consuming whole grain foods has been shown to positively impact cognitive function.[55–60]
- Consumption of dietary fiber and B vitamins found in grain foods is associated with better cognitive health.[61–63]
- Folic acid fortification of enriched grain foods has been shown to be a cost effective method of improving cognitive health and brain development *in utero.*[64–68]

Gluten-free: Gluten-free dieting has gained popularity in the general population out of proportion to the prevalence of gluten-related disorders such celiac disease (CD), non-celiac gluten sensitivity (NCGS), and wheat allergy; supporting this are findings from a 2013 survey by Mintel indicating that 65% of American adults say they eat gluten-free products because they think they are more healthful, and 27% eat gluten-free products to lose weight.

Despite these claims for gluten-free eating, no published experimental evidence supports a weight loss claim for a gluten-free diet or suggests that the general population would be better off by avoiding gluten.[69] Furthermore, no published studies have found that a gluten-free diet produces weight loss in patients without CD or NCGS. This may be because gluten-free foods are not necessarily low-calorie and often times contain more calories than their gluten-containing counterparts. Moreover, a gluten-free diet may also result in lower intake of whole grains and dietary fiber and some evidence suggests that following a gluten-free diet reduces concentrations of beneficial gut bacteria; on the other hand, a gluten-rich diet may boost the numbers of beneficial gut bacteria.

We appreciate the opportunity to provide comments to the public hearing record. Should the Committee have questions or seek additional information, please contact Lee Sanders, American Bakers Association Senior Vice President for Government Relations and Public Affairs at [**Redacted**] or at [**Redacted**].

Sincerely,

American Bakers Association (ABA);
American Institute of Baking International;
Grain Foods Foundation (GFF);
Independent Bakers Association;
National Association of Wheat Growers (NAWG);
National Pasta Association (NPA);
North American Millers' Association;
Retail Bakers of America;
USA Rice Federation;
Wheat Foods Council (WFC).

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Descriptions of Grain Industry Organizations

American Bakers Association (ABA) is the Washington, D.C.-based voice of the wholesale baking industry. Since 1897, ABA has represented the interests of bakers before the U.S. Congress, Federal agencies, and international regulatory authorities. ABA advocates on behalf of more than 700 baking facilities and baking company suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious baked products for America's families. The baking industry generates more than $103 billion in economic activity annually and employs 633,000 highly skilled people. [**Redacted**]

American Institute of Baking International (AIB) is a corporation founded by the North American wholesale and retail baking industries in 1919 as a technology transfer center for bakers and food processors. The original mission of the organization was to "put science to work for the baker," which is still central to all of the programs, products, and services provided by AIB to baking and general food production industries worldwide. [**Redacted**]

Grain Foods Foundation (GFF), a joint venture of members of the milling, baking and allied industries formed in 2004, is dedicated to advancing the public's understanding of the beneficial role grain-based foods play in the human diet. Directed by a board of trustees, funding for the Foundation is provided through voluntary donations from private grain-based food companies and is supplemented by industry associations. [**Redacted**]

Independent Bakers Association (IBA) The Independent Bakers Association is a Washington, D.C. based national trade association of over 400 mostly family owned wholesale bakeries and allied industry trades. The Association was founded in 1968 to protect the interests of independent wholesale bakers. [**Redacted**]

National Association of Wheat Growers (NAWG) is a federation of 21 state wheat grower associations that works to represent the needs and interests of wheat producers before Congress and Federal agencies. Based in Washington, D.C., NAWG is grower-governed and grower-funded, and works in areas as diverse as Federal farm policy, trade, environmental regulation, research and climate change. [**Redacted**]

National Pasta Association (NPA) Founded in 1904, NPA is an organization of pasta and pasta-related product manufacturers, millers and suppliers to the U.S. pasta industry serving as a cohesive industry advocate, a promoter of pasta and a center of knowledge for its members, the government and the public. [**Redacted**] and [**Redacted**]

North American Millers' Association (NAMA) is the trade association of the wheat, corn, oat, and rye milling industries. Member companies operate mills in 38 states and Canada, representing more than 90 percent of total industry production capacity. [**Redacted**]

Retail Bakers of America (RBA) was founded in 1918. Its purpose is to assist retail bakers in furthering the health of the nation by making available delicious bakery foods; to foster a better relationship between the public and the baking industry; to promote and encourage the production of high quality, wholesome, healthful bakery foods; and to represent the baking industry, especially its retail branch, to the government. [**Redacted**]

USA Rice Federation is the global advocate for all segments of the U.S. rice industry with a mission to promote and protect the interests of producers, millers, merchants and allied businesses. Over 20 billion pounds of long, medium, and short grain, and organic and specialty rice is grown and harvested each year by farmers in Arkansas, California, Louisiana, Texas, Mississippi and Missouri. [**Redacted**]

Wheat Foods Council (WFC) is a nonprofit organization formed in 1972 to help increase public awareness of grains, complex carbohydrates, and fiber as essential components of a healthful diet. The Council is supported voluntarily by wheat producers, millers, bakers and related industries. [**Redacted**]

SUBMITTED QUESTIONS

Joint Response from Hon. Sylvia M. Burwell, Secretary, U.S. Department of Health and Human Services; Hon. Thomas "Tom" J. Vilsack, Secretary, U.S. Department of Agriculture

Question Submitted by Hon. Randy Neugebauer, a Representative in Congress from Texas

Question. Secretary Burwell, what instructions were given to the Advisory Committee members regarding the FACA and the Advisory Committee's disbandment?

Answer. HHS and USDA are strongly committed to an open and transparent process around their Federal Advisory Committees. The two Departments conducted an administrative webinar with the 2015 Dietary Guidelines Advisory Committee (DGAC) in January 2015 a few weeks before its *Advisory Report* was submitted to HHS and USDA. At this webinar, the Committee was reminded that it would formally disband upon submittal of its *Advisory Report* to the Secretaries as specified in its charter; the transition from being a Special Government Employee (SGE) as a Federal advisory committee member to being a former SGE/member after disbandment was described. Included in this discussion was a specific instruction that after disbandment each former member cannot speak on behalf of the U.S. Government or the DGAC (while in no way limiting their ability to speak as individual citizens on their own behalf). This instruction is an important point that each individual should convey in any situation that he/she chooses to engage in regarding the Committee's works, such as media interviews or professional presentations. After disbandment, each former DGAC member only represents themselves. When former Committee members held a public event regarding the Advisory Report, they were no longer SGEs and were not speaking on behalf of the Committee or the Federal government. They were private citizens voicing their opinions. As such, the Federal government has not assisted or provided support for former members for public speaking events.

Questions Submitted by Hon. Eric A. "Rick" Crawford, a Representative in Congress from Arkansas

Question 1. In light of the controversial nature of many of the comments and recommendations of the 2015 Dietary Guidelines Advisory Committee (DGAC), and in light of the fact that the final Guidelines are prepared with very limited transparency, will the Departments of Health and Human Services, and Agriculture consider publishing the draft Guidelines in the *Federal Register,* and allowing for a 60–90 day public comment period before producing your final Guidelines?

Answer. We understand that an open and transparent *Dietary Guidelines* process is a priority and share your interest. We place a high value upon public input and have prioritized it throughout the development of the *Dietary Guidelines.* The Dietary Guidelines Advisory Committee (DGAC) deliberated on the scientific evidence through seven public meetings, spanning June 2013 to December 2014. The public attended the meetings, provided oral comments during one of the meetings, and was invited to submit written comments to the DGAC throughout the 19 months of its

deliberations. All of the scientific studies they reviewed were posted on *DietaryGuidelines.gov* after each public meeting, during which the studies' topics were discussed and deliberated, providing transparency of the evidence being examined and allowing the public to provide sufficient comment on that and anything else the DGAC covered. A new public comment period opened when the *2015 Advisory Report* was published in February 2015. During this period, HHS and USDA also held a public meeting for oral testimony from the public. The public comment period also was extended from the scheduled 45 days to 75 days. For context, the public comment period for the *2010 Advisory Report* was 30 days. In addition, HHS and USDA provided several briefings on the *Dietary Guidelines* to House Agriculture Committee and Appropriations Subcommittee staff in 2015. We have and will continue to conduct our business with the utmost integrity and transparency, in accordance with all legal requirements.

Question 2. I recognize this would be a slightly extraordinary step in the process, but don't you agree that the American public's acceptance of the scientific validity of the data supporting the final Guidelines outweighs an arbitrary deadline for their publication?

Answer. The National Nutrition Monitoring and Related Research Act of 1990 (NNMRRA) requires HHS and USDA to publish the *Dietary Guidelines for Americans* at least every 5 years. The public was invited to participate in the process through meeting participation and public comment throughout the 19 months of the DGAC's scientific review, and during the 75 day period for public comment on the published *Advisory Report.* Throughout this time and up to the present, all science informing the *Advisory Report* has been listed for the public on *DietaryGuidelines.gov.* Every comment received from Federal agencies and the public is reviewed by HHS and USDA. Although all public comments are valued, to ensure the scientific foundation of the *2015 Dietary Guidelines for Americans,* emphasis is placed on those comments with scientific justification. As required by the NNMRRA, the *2015 Dietary Guidelines* will be based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.

Question 3. On several occasions during the House Agriculture Committee hearing you noted that the final *Dietary Guidelines* will be based on 'the *preponderance* of scientific evidence'. In light of the fact that the Dietary Guidelines Advisory Committee acknowledged it employed the USDA's Nutrition Evidence Library (NEL) for less than 25% of its final recommendations—and based many of its findings on limited-grade evidence (nearly the lowest of the NEL's grading scale)—how are the Agencies interpreting the term "*preponderance*"?

Answer. The 2010 and 2015 Dietary Guidelines Advisory Committees (DGAC) both utilized four science-based sources of evidence to answer their research questions: (1) Original systematic reviews conducted by USDA's Nutrition Evidence Library (NEL); (2) High-quality existing reports, comprised primarily of systematic reviews; (3) Data analyses of the typical American diet; and (4) Food pattern modeling to ensure Americans meet their food and nutrient needs. For each research question, the DGAC determined which method was appropriate, given the nature of the question. For example, questions regarding current intakes of different foods and nutrients in the United States were answered using data analyses, as this information is not available through a systematic review of scientific studies. Food pattern modeling was used to answer questions about how Americans can meet the Daily Reference Intakes (DRIs).

The NEL is a systematic review methodology designed specifically to analyze food, nutrition and public health science. For context, the medical field has used systematic reviews as the gold standard and standard practice for more than 25 years to inform the development of national guidelines for health professionals. Use of systematic reviews in nutrition, became common practice more recently. At the time that the NEL was created by USDA for use in informing the *2010 Dietary Guidelines for Americans,* it was among the first to apply the systematic review methodology in the field of nutrition—thus, there were very few existing nutrition-focused systematic reviews that the 2010 DGAC could draw from. Since that time, systematic reviews in the nutrition field have become common practice. Therefore, as stated in their *Advisory Report* on *DietaryGuidelines.gov,* "unlike the 2010 DGAC, the 2015 Committee was able to use existing sources of evidence to answer an additional 45 percent of the questions . . ." and that "[t]his was done to prevent duplication of effort and promote time and resource management." The 2015 DGAC answered 70 percent of its research questions using NEL systematic reviews or existing reviews and reports. The Committee used existing systematic reviews when available and complemented them with original reviews of evidence newly published since the existing review was conducted. Existing systematic reviews underwent

quality assessment to ensure they were just as rigorous and were held to the same high standards as the NEL systematic reviews. The remaining questions were answered using data analyses and food pattern modeling, consistent with the 2010 DGAC's scientific review.

The Committee considers all evidence at the time of the systematic review that (1) addresses the question they seek to answer and (2) meets the pre-determined inclusion criteria. The quality of each included study is evaluated using the NEL Bias Assessment Tool. The DGAC then looks at the entire body of evidence as a whole to draw a conclusion statement and uses predefined criteria to evaluate and grade the strength of the evidence. The grade communicates to decision makers and stakeholders the strength of the evidence supporting a specific conclusion statement. The grade for the body of evidence and conclusion statement is based on five elements outlined in the NEL grading rubric: quality, quantity, consistency, impact and generalizability.

Questions Submitted by Hon. Jackie Walorski, a Representative in Congress from Indiana

Question 1. In testimony before the House Agriculture Appropriations Subcommittee last month, Angie Tagtow of USDA's Center for Nutrition Policy and Promotion described the Nutrition Evidence Library as "the gold standard for informing recommendations" and stated in her written testimony:

> The NEL provides a rigorous and transparent system to review the scientific literature and uses the preponderance of science to inform nutrition policy and programs. The NEL also ensures compliance with the Consolidated Appropriations Act of 2001, or Data Quality Act, which mandates that Federal agencies ensure the quality, objectivity, utility, and integrity of the information used to form Federal guidance.

I applaud the NEL's development, which was first developed by 2005 Advisory Committee out of need to ensure a transparent process for reviewing and ranking the overwhelming amount of science that needs to be considered. Then the 2010 Advisory Committee was able to use it and relied heavily on it for the majority of their recommendations.

Now the 2015 Dietary Guidelines Advisory Committee's report states that it did not use the Nutrition Evidence Library for more than 70 percent of its analyses. Instead, the report states that it used the following approaches:

- Outside systematic reviews used for 45 percent of research questions; and
- Original data analyses and food pattern modeling analyses used for 30 percent of research questions.

One example of the concern with systemic reviews is caffeine. Secretary Vilsack, you mentioned in your written testimony the "Cochrane Collaboration" approach as being a well-respected and it is. But in the example of caffeine, as stated on page 381 of the report, it was a "modification" of that method that was used. So while DGAC correctly acknowledge that new scientific evidence existed since the last report, making it the first Advisory Committee on caffeine's positive health benefits, it did not use the gold-standard NEL. Instead they used a systematic review of the data that allowed them to make claims that straight black coffee was the only acceptable approach to consuming caffeine, as opposed to energy drinks or other alternatives.

For comparison, the 2010 Advisory Committee used the NEL for nearly three out of every four of their recommendations. Why did the 2015 DGAC circumvent the NEL process for more than 70% of their recommendations? Do the existing reports that were used follow the same scientific rigor and approach as the NEL?

Under FACA, this is your Advisory Committee so I ask, how was the decision made that the NEL should not be used for a particular research question? Was it *ad hoc,* or were there established criteria?

Answer. Thank you for raising this issue. The 2010 and 2015 Dietary Guidelines Advisory Committees (DGAC) both utilized four science-based sources of evidence to answer their research questions: (1) Original systematic reviews conducted by USDA's Nutrition Evidence Library (NEL); (2) High-quality existing reports, comprised primarily of systematic reviews; (3) Data analyses of the typical American diet; and (4) Food pattern modeling to ensure Americans meet their food and nutrient needs. For each research question, the DGAC determined which method was appropriate, given the nature of the question. For example, questions regarding current intakes of different foods and nutrients in the United States were answered using data analyses, as this information is not available through a systematic re-

view of scientific studies. Food pattern modeling was used to answer questions about how Americans can meet the Dietary Reference Intakes (DRIs).

The NEL is a systematic review methodology designed specifically to analyze food, nutrition and public health science. For context, the medical field has used systematic reviews as the gold standard and standard practice for more than 25 years to inform the development of national guidelines for health professionals. Use of systematic reviews in nutrition became common practice more recently. At the time that the NEL was created by USDA for use in informing the *2010 Dietary Guidelines for Americans,* it was among the first to apply the systematic review methodology in the field of nutrition—thus, there were very few existing nutrition-focused systematic reviews that the 2010 DGAC could draw from. Since that time, systematic reviews in the nutrition field have become common practice. Therefore, as stated in the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (*Advisory Report*) on *DietaryGuidelines.gov,* "unlike the 2010 DGAC, the 2015 Committee was able to use existing sources of evidence to answer an additional 45 percent of the questions . . ." and that "[t]his was done to prevent duplication of effort and promote time and resource management." The 2015 DGAC answered 70 percent of its research questions using NEL systematic reviews or existing reviews and reports. The Committee used existing systematic reviews when available and complemented them with original reviews of evidence newly published since the existing review was conducted. Existing systematic reviews underwent quality assessment to ensure they were just as rigorous and were held to the same high standards as the NEL systematic reviews. The remaining 30 percent of the questions that could not be answered using the systematic review methodology were answered using data analyses and food pattern modeling, consistent with the 2010 Advisory Committee's scientific review.

Question 2. In a letter dated October 2, 2015 from Secretaries Vilsack and Burwell to U.S. Senator Johnny Isakson you stated that "in regard to caffeine and energy drinks, the (Advisory) Committee noted that these drinks are highly variable in caffeine content" and that "until safety has been demonstrated, limited or no consumption of high-caffeine drinks or other caffeine-containing products is advised for children and adolescents." This statement also holds true for coffee (*i.e.,* home brewed *vs.* coffee house, where the range could be 50–400mg of caffeine).

According to the American Beverage Association, mainstream energy drinks—which represent more than 95% of the entire American energy drink market—contain the same, or less, caffeine than coffee. Further, there is no chemical difference between the caffeine in coffee and the caffeine in energy drinks, tea, or soda and all leading and credible health authorities from around the world have acknowledged that caffeine metabolism is a function of body weight and composition (body fat, *etc.*) rather than age.

Last, it is worth noting the conclusion reached by the European Food Safety Authority, which was published in its extensive report, *Scientific Opinion on the Safety of Caffeine:* "The single doses of caffeine considered to be of no concern for adults (3mg/kg bw per day) may also be applied to children, because the rate at which children and adolescents process caffeine is at least that of adults, and the studies available on the acute effects of caffeine on anxiety and behavior in children and adolescents support this level."

Given this body of evidence, how do you rationalize the recommendations made by the Advisory Committee to focus on only one class of products when it comes to limiting caffeine intake? If there is to be any recommendations consistent with the evidence, shouldn't it be about caffeine intake generally, regardless of the class of products?

Answer. The 2015 Dietary Guidelines Advisory Committee (DGAC) developed its report to provide advice and recommendations to the government on the current state of scientific evidence on nutrition and health for the general public. The DGAC identified the area of caffeine consumption as a public health concern. It included the safety of caffeinated drinks for children and adolescents in its review of the evidence because of case reports of adverse events associated with consumption of high-caffeine drinks and in light of recommendations of caution from the American Academy of Pediatrics and the American Medical Association. The Committee also noted that the limited evidence in regard to high-caffeine energy drinks and health outcomes shows mixed results. Much of the available evidence on caffeine focuses on coffee intake. The Committee stated that moderate coffee consumption (three to five 8 oz. cups/day, or providing up to 400 mg/day of caffeine) can be incorporated into healthy eating patterns.

HHS and USDA are considering the information in the Committee's report as well as public and Federal agency comments in the development of the *2015 Dietary*

Guidelines for Americans. We look forward to working on this issue with you moving forward.

Question Submitted by Hon. David Rouzer, a Representative in Congress from North Carolina

Question. Can the House Committee on Agriculture be assured that you will both work to ensure that the final *Dietary Guidelines* state that protein is critical to a balanced diet and that the inclusion of lean meats are essential to a "balanced diet?"

Answer. We understand this is a priority for you and share your interest. The *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (*Advisory Report*) states that "lean meats can be a part of a healthy dietary pattern." While we cannot comment on the content of the *2015 Dietary Guidelines for Americans,* which is still under development, we can highlight that the amount of "meat, poultry, and eggs" recommended in the *Advisory Report* is the same as the amount recommended in the *2010 Dietary Guidelines for Americans*—26 oz. per week for a 2,000 calorie diet. The *Advisory Report* recommends reducing the amount of red and processed meat consumed *compared to current consumption,* ***not*** compared to the *2010 Guidelines.*

Questions Submitted by Hon. John R. Moolenaar, a Representative in Congress from Michigan

Question 1. I have personally met with a wide variety of constituents on the topic of school nutrition in my District in Michigan, including a local school food service director. On multiple occasions, my constituents expressed concerns regarding sodium limits in the National School Lunch and School Breakfast Programs, and the dramatic effect the implementation of the target levels has had on consumption and food waste.

As you are aware, the sodium limits were placed on a time line, with key targets to reach by designated years. A primary concern I have is the implementation of any further reductions to sodium to reach the target two and final target levels. In your findings, is there sound scientific evidence that the target two levels of sodium limits were necessary?

If target two levels are implemented, what effect do you believe this will have on other foods, such as cheeses and others that are served in school meal programs?

Answer. USDA remains committed to applying the most up-to-date, evidence-based guidelines to all nutritional parameters set forth in Child Nutrition Programs regulations. As required by both the FY 2012 Agriculture Appropriations Act and the *Consolidated and Further Continuing Appropriations Act, 2015,* USDA continues to evaluate the science as it relates to sodium intake and human health. The 2015 Dietary Guidelines Advisory Committee (DGAC) reviewed and analyzed the most recent scientific literature evaluating the relationship between sodium intake and blood pressure among children and their findings can be found in their *Advisory Report,* which was submitted to HHS and USDA in February 2015. The DGAC used an extensive systematic review process to critique relevant literature on this topic, and the *Advisory Report* affirmed that sodium reduction to the levels reflected in the targets is beneficial to children.

USDA is providing significant technical assistance to help school food operators lower the sodium content of school meals. Consistent with the Congressional directive, prior to requiring school compliance with the second (school year 2017–18) and final (school year 2022–23) sodium targets, USDA's Food and Nutrition Service (FNS) will review the *2015 Dietary Guidelines for Americans,* once released. Because the sodium goals apply to the average meal offered over the course of the school week, menu planners have and will retain under target 2 the flexibility to incorporate some higher sodium items, such as cheese, into some of the meals. To help menu planners offer a variety of nutritious and flavorful foods, while lowering the sodium content of meals, USDA recently unveiled *What's Shaking? Creative Ways to Boost Flavor with Less Sodium.* This is a national collaborative sodium reduction initiative to foster creative ways to boost flavor and maximize taste in an effort to lower the sodium content of school meals. The website, *http://healthymeals.nal.usda.gov/menu-planning/sodium-reduction* is dedicated to helping schools find the resources they need to increase awareness of the need for dietary sodium reduction, and move in the right direction.

Question 2. I am concerned about the selective nature taken by the Dietary Guidelines Advisory Committee (DGAC) with respect to existing data. For example, when it comes to energy drinks, the Committee noted that the evidence was of a limited grade. At the same time, the DGAC chose to completely disregard an extensive and authoritative body of evidence developed by the European Food Safety Authority (EFSA), and in particular its most recent Scientific Opinion on the Safety of Caffeine. Is there any reason why the DGAC appeared to disregard the EFSA's work?

What are your thoughts on the information from EFSA that was disregarded by the DGAC?

Also, as you develop the final guidelines, what threshold of evidence will be used to determine whether to issue a recommendation, and will limited grade evidence be permitted in the classification of preponderance of scientific evidence"?

Answer. The European Food Safety Authority (EFSA) published its *Scientific Opinion on the Safety of Caffeine* in May of 2015. The 2015 Dietary Guidelines Advisory Committee (DGAC) released its *Scientific Report* in February of 2015. As such, the DGAC had disbanded prior to the release of the EFSA report. It should be noted that the 2015 DGAC did use the *EFSA Scientific Opinion on the Re-evaluation of Aspartame as a Food Additive* for their question on aspartame and health. This report was published within the timeframe of the DGAC's work. As mandated in the National Nutrition Monitoring and Related Research Act of 1990, the *2015 Dietary Guidelines for Americans* will be based on the preponderance of the scientific and medical knowledge which is current at the time it is prepared. While we cannot comment on the content of the *2015 Dietary Guidelines for Americans,* which are still under development, the recommendations will be made based on the strongest available evidence. The *2010 Dietary Guidelines* included statements supported by different grades of evidence. As described in the *2010 Dietary Guidelines,* "[w]hen appropriate, specific statements in *Dietary Guidelines for Americans, 2010* indicate the strength of the evidence (*e.g.,* strong, moderate, or limited) related to the topic as summarized by the 2010 DGAC. The strength of evidence is provided so that users are informed about how much evidence is available and how consistent the evidence is for a particular statement or recommendation. This information is useful for educators when developing programs and tools. Statements supported by strong or moderate evidence can and should be emphasized in educational materials over those with limited evidence." When only limited evidence is available on a topic, it may still be appropriate for discussion in the *Dietary Guidelines,* such as when the evidence for that topic reinforces recommendations on related topics that have a stronger evidence base, to clarify that it is not possible to make a recommendation, or to identify an area of emerging research.

Question 3. According to the *Charter for the 2015 Dietary Guidelines Advisory Committee* (DGAC), Committee members were selected based upon their knowledge in the fields of human nutrition and chronic disease. However, it appears the DGAC made many recommendations far outside of the scope of its Charter and far beyond issues of human nutrition and chronic disease.

For example, matters involving ingredient safety (*i.e.,* caffeine and aspartame) and risk assessment rest squarely within the scope of the Food and Drug Administration (FDA), not the *Dietary Guidelines.* Despite this, the DGAC chose to offer recommendations on what is and is not safe.

During your testimony you noted that the FDA, along with the National Institutes of Health and the Centers for Disease Control and Prevention, are providing technical expertise as you finalize the Guidelines.

Is it the intention of both Departments to make new assertions about ingredient safety in the *Dietary Guidelines* that have not been previously made by the FDA? If yes, will matters of such importance be subject to the appropriate rulemaking by the relevant agency in charge?

Answer. No, the Departments will not make new assertions about ingredient safety in the *Dietary Guidelines.* The purpose of the *Dietary Guidelines* does not include rulemaking. The charge of the 2015 DGAC included identifying areas it felt were of public health concern. The DGAC chose to address the relationship of caffeine consumption and of aspartame consumption to health because they are of high public health concern, are commonly consumed in food and beverages, and evidence had been recently updated in the scientific literature. Dealing with these issues was within the scope of the DGAC's charge to provide the Government with advice and recommendations on the current state of scientific evidence on nutrition and health. We appreciate your feedback on this topic.

Questions Submitted by Hon. Dan Newhouse, a Representative in Congress from Washington

Question 1. I understand the HHS and USDA are planning to note that moderate alcohol consumption is an important part in a healthy diet pattern, which I appreciate. *What are your Departments doing to provide recommendations on how best to inform consumers about what that looks like?*

Answer. Thank you for raising this important issue. HHS and USDA are working together to finalize the *2015 Dietary Guidelines,* which are expected to be completed in December of this year. We are unable to comment on the final content of the forthcoming edition of the *Dietary Guidelines* at this time, as they are still under

development. However, to clarify, the Dietary Guidelines Advisory Committee (DGAC) found that moderate alcohol consumption can be a component of a healthy eating pattern but did not include alcohol in its three examples of healthy, nutrient dense food patterns (Healthy U.S.-style, Healthy Vegetarian, and Healthy Mediterranean-style). The DGAC stated, "it is not recommended that anyone begin drinking or drink more frequently on the basis of potential health benefits."

Question 2. The *2010 Dietary Guideline*'s section on sodium seems to suggest that all alcoholic beverages are the same, and there is such a thing as a standard drink. It does nothing to differentiate different benefits or risks derived from wine, beer, distilled spirits, hard ciders, and so on, or that alcohol levels can vary significantly even internally in each of these categories. Many scientific studies claim different health effects depending on the type of alcohol consumed, and the Tax and Trade Bureau guidance from May 2013 refutes the idea of a "standard drink" as a tool to inform consumers. *Can you tell me if there are any plans in the **2015 Dietary Guidelines** to clarify or establish different nutritional benefits or drawbacks related to different alcohol types?*

Answer. As noted above, HHS and USDA are working together to finalize the *2015 Dietary Guidelines for Americans,* which is expected to be completed in December of this year. We are unable to comment on the final content of the forthcoming edition of the *Dietary Guidelines* at this time, as they are still under development. HHS and USDA are cognizant of the variability of alcohol content in different alcoholic beverages and the value in better articulating this variability in dietary guidance. Several industry associations and individuals have provided both oral and written comments on this issue, which we will take into consideration as we develop the *Dietary Guidelines.*

Question 3. The Dietary Guidelines Advisory Committee claimed that Americans are eating more meat than recommended; however, the DGAC also holds up the so-called Mediterranean Diet as a healthy dietary pattern. When compared to the Mediterranean Diet, Americans are consuming less than recommended. *How do you account for this discrepancy?*

Answer. There are numerous studies based on different variations of a Mediterranean Diet, and, as such, there is not "one" Mediterranean Diet. Therefore, there is not a single, consistent recommendation on meat for comparison. The DGAC used current research to inform the development of its Healthy Mediterranean-Style Eating Pattern. As shown in the *Advisory Report,* the quantitative amount of meat, poultry, and eggs the DGAC recommended in the Healthy U.S.-Style Eating Pattern and the Healthy Mediterranean-Style Eating Pattern are identical—26 oz. per week for a 2,000 calorie diet.

Question 4. The Dietary Guidelines Advisory Committee recommends that Americans continue to eat the same quantity of lean meat as the *2010 Dietary Guidelines* recommend, but the current DGAC report also recommends that Americans consume less processed meat. *What is the recommendation for lean, processed meat?*

Answer. The *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (*Advisory Report*) states that "lean meats can be a part of a healthy dietary pattern." While we cannot comment on the content of the *2015 Dietary Guidelines for Americans,* which are still under development, we can highlight that the amount of "meat, poultry, and eggs" recommended in the *Advisory Report* is the same as the amount recommended in the *2010 Dietary Guidelines*—26 oz. per week for a 2,000 calorie diet. The *2010 Dietary Guidelines for Americans* and the *2015 Advisory Report* do not make a quantitative recommendation specifically for lean processed meat.

Question 5. In testimony before the House Appropriations Agriculture Subcommittee, Angie Tagtow of USDA's Center for Nutrition Policy and Promotion stated, "the Nutrition Evidence Library (NEL) provides a rigorous and transparent system to review the scientific literature and uses the preponderance of science to inform nutrition policy and programs." That being said, the 2015 Dietary Guidelines Advisory Committee only used the NEL in 27 percent of their nutritional recommendations, while the 2010 one used NEL for more than 70 percent. *What justification can you provide for the departure from such an important resource? Did USDA or HHS provide any guidance to the Dietary Guidelines Advisory Committee on what resources were available or which should be used?*

Answer. The 2010 and 2015 DGACs both utilized four science-based sources of evidence to answer their research questions: (1) Original systematic reviews conducted by USDA's Nutrition Evidence Library (NEL); (2) High-quality existing reports, comprised primarily of systematic reviews; (3) Data analyses of the typical American diet; and (4) Food pattern modeling to ensure Americans meet their food and nutrient needs. For each research question, the DGAC determined which method

was appropriate, given the nature of the question. For example, questions regarding current intakes of different foods and nutrients in the United States were answered using data analyses, as this information is not available through a systematic review of scientific studies. Food pattern modeling was used to answer questions about how Americans can meet the Dietary Reference Intakes (DRIs).

The NEL is a systematic review methodology designed specifically to analyze food, nutrition and public health science. For context, the medical field has used systematic reviews as the gold standard and standard practice for more than 25 years to inform the development of national guidelines for health professionals. Use of systematic reviews in nutrition became common practice more recently. At the time that the NEL was created by USDA for use in informing the *2010 Dietary Guidelines for Americans,* it was among the first to apply the systematic review methodology in the field of nutrition—thus, there were very few existing nutrition-focused systematic reviews that the 2010 DGAC could draw from. Since that time, systematic reviews in the nutrition field have become common practice. Therefore, as stated in their *Advisory Report* on *DietaryGuidelines.gov,* "unlike the 2010 DGAC, the 2015 Committee was able to use existing sources of evidence to answer an additional 45 percent of the questions . . ." and that "[t]his was done to prevent duplication of effort and promote time and resource management." The 2015 DGAC answered 70 percent of its research questions using NEL systematic reviews or existing reviews and reports. The Committee used existing systematic reviews when available and complemented them with original reviews of evidence newly published since the existing review was conducted. Existing systematic reviews underwent quality assessment to ensure they were just as rigorous and were held to the same high standards as the NEL systematic reviews. The remaining 30 percent of the questions that could not be answered using the systematic review methodology were answered using data analyses and food pattern modeling, consistent with the 2010 DGAC's scientific review.

Question 6. FDA recently announced that it is proposing additional revisions to the Nutrition Facts Panel. The supplemental proposal would require the declaration of daily reference value and percent daily value for added sugars. The additional declarations for added sugars are based on new information and findings from the 2015 Dietary Guidelines Advisory Committee's (DGAC) technical report. This is a great departure from the past because FDA has a long history of relying on the Institute of Medicine (IOM) to develop Dietary Reference Intakes. The 2015 DGAC recommendation of less than 10% of total calories from added sugar as noted in the supplemental proposal is based on, "modeling of dietary patterns, current added sugars consumption data, and a published meta-analysis on sugars intake and body weight." I am concerned that a balanced, scientifically rigorous process such as that used by the IOM was not used to develop the recommendation. *Why is FDA applying the DGAC recommendations to develop nutrition labeling regulations instead of the most recent IOM recommendations? Do you believe this is appropriate, given your testimony on the scope and nature of the DGAC recommendations, and how they differ from the actual guidelines?*

Answer. The Food and Drug Administration (FDA or the Agency) considered the scientific evidence underpinning the recommendations provided in the 2015 Dietary Guidelines Advisory Committee (DGAC) technical report in setting a proposed Dietary Reference Value (DRV) for added sugars. The 2015 DGAC report evaluated more recent scientific evidence than the evidence that had been evaluated by the Institute of Medicine (IOM) when it issued its 2002 report. FDA will consider all of the public comments received by the Agency as it proceeds with this rulemaking process and will keep your office updated as we progress.

Question 7. I am interested in the recommendations related to coffee. According to the Dietary Guidelines Advisory Committee, three to five cups of coffee per day are not associated with long-term health risks. It was also noted that this amount of coffee correlated with reduced risk for heart disease and type 2 diabetes. *Can you share what scientific evidence or process the DGAC used to suggest this change?*

Answer. The 2015 DGAC examined the relationship between usual caffeine consumption and health. Specifically, they asked the question, *What is the relationship between usual coffee/caffeine consumption and health?* Furthermore, they examined the relationship between coffee/caffeine consumption and its impact on total mortality, cardiovascular disease, type 2 diabetes, cancers, Parkinson's disease, cognitive function, and pregnancy. Below is the list of scientific evidence examined by the Advisory Committee to answer the questions related to coffee/caffeine consumption.

It is important to note that while the DGAC was interested in usual caffeine intake, most of the available research was conducted with coffee as the source of caf-

feine. After reviewing the evidence, the Committee stated that moderate coffee consumption can be incorporated into a healthy lifestyle. However, the DGAC noted that caloric additions from cream, milk, and added sugars should be minimized. Furthermore, the Advisory Committee stated that individuals who do not consume caffeinated coffee should not start to consume it for potential health benefits alone. The Advisory Committee recommendations are not binding on the Departments, but are intended to inform the Departments' work.

For additional details on this body of evidence, visit: *Appendix E–2.39a Evidence Portfolio* ***available at*** *http://health.gov/dietaryguidelines/2015-scientific-report/14-appendix-E2/e2-39a.asp*. (*Attachment 1*)

Question 8. I think it would be helpful for you to provide the Committee evidence in writing to confirm that your agencies did, in fact, make attempts to oversee the Advisory Committee once it became clear they were delving to areas of public policy. In response I would like to see evidence that your agencies provided instructions to the committee during their assembly to ensure they were staying focused on the right guidance, and not straying into policy matters outside their scope or mandate. And, likewise, I would like to receive documented evidence of the instructions agencies provided to the committee on the public law to help them understand their report must be based on the preponderance of scientific and medical knowledge that is current at the time of publication.

Answer. Thank you for raising this issue. Shortly after the 2015 DGAC was appointed by the Secretaries of HHS and USDA in May 2013 and before its first meeting held on June 13–14, 2013, HHS and USDA conducted two administrative webinars with the Committee members to provide orientation and training. (Note that meetings of the full Committee that are solely administrative in nature are not required by the Federal Advisory Committee Act (FACA) to be open to the public.) Topics included the charge to the Advisory Committee, the National Nutrition Monitoring and Related Research Act, the charter and bylaws of the Advisory Committee, and FACA, which included a presentation by an HHS attorney in the Office of the General Counsel.

Below are some of the materials you requested.

1. FACA Pamphlet—*http://www.gsa.gov/portal/content/101010* (*Attachment 2*)
2. Ethics Rules for SGEs—*https://ethics.od.nih.gov/topics/SGE-Training-Oct-04.pdf* (*Attachment 3*)
3. Charge—*http://health.gov/dietaryguidelines/2015-BINDER/meeting1/chargeCommittee.aspx* (*Attachment 4*)
4. Charter—*http://health.gov/dietaryguidelines/2015/committee-resources.asp* (*http://health.gov/dietaryguidelines/dgac2015-charter-final.pdf*) (*Attachment 5*)

At the first public meeting (June 13–14, 2013), the charge was reviewed by USDA Under Secretary Concannon and subsequently the objectives and purpose of the Advisory Committee were presented by the Designated Federal Officer (DFO). The agenda, meeting summary, and videocast of this first meeting are available at *http://health.gov/dietaryguidelines/2015-BINDER/meeting1/index.aspx*. In addition, at that public meeting, the DGAC members were divided into three work groups, which met separately in the afternoon of the first day of this meeting; at those work group meetings, the first item on the agenda was a discussion led by federal staff on the charge and guiding principles for their work.

Throughout the DGAC's work, the DFO or his representative was present on all work-group/subcommittee calls or meetings, and at all public Committee meetings to ensure FACA was being followed; this includes following the charge as approved by the charter. The DGAC's charge was read at each public Committee meeting and during Subcommittee meetings.

Question 9. And, finally, I would like to welcome your comments on any advice you could give future secretaries as to future Advisory Committees, and how they could stay focused on their charter, and produce a recommendation that really stays coloring with in the lines. So I would appreciate a response. Thank you.

Answer. We would advise future secretaries to continue the process of distinguishing what the *Dietary Guidelines for Americans* are and what they are not. There is a misunderstanding that the DGAC's report is the *Dietary Guidelines for Americans* or a draft of the Guidelines—it is not. The Guidelines are recommendations for the general public, intended to *prevent* diet-related conditions, not to treat disease.

Diabetes and other chronic, diet-related diseases cost Americans billions of dollars annually and contribute to rising health care costs across the health system. How-

ever, we know that diet plays a critical role in disease prevention and in both individual and public health—a good diet can help prevent diabetes, high blood pressure, and cardiovascular disease. The *Dietary Guidelines* are a critical tool to help Americans make healthy choices in their daily lives to prevent these diseases and enjoy a healthy diet. They are used to inform the development of federal food, nutrition, and health policies and programs.

Questions Submitted by Hon. Suzan K. DelBene, a Representative in Congress from Washington

Question 1. Ensuring that the Federal Government is providing women with latest, science-based nutrition advice based on the latest science to benefit both their body and their children is of utmost importance. One area where there is substantial confusion today is regarding seafood consumption during pregnancy. It was encouraging when FDA issued updated draft seafood advice in June 2014 that attempted to clarify that confusion. According to the *Federal Register* notice (*http://www.gpo.gov/fdsys/pkg/FR-2014-06-11/pdf/2014-13584.pdf*), this draft advice was based on data from the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO) and the FDA's net effects report entitled: "A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment from Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children)." Will FDA be issuing final seafood advice that follows the draft advice with changes to make it consistent with the FAO, WHO and FDA's latest science?

Answer. Thank you for raising this issue. The final seafood consumption advice is undergoing review. In developing it, HHS has taken and will continue to take steps to ensure that it is reflective of the latest nutrition science.

By way of background, in June 2014, FDA and the Environmental Protection Agency (EPA) jointly issued a draft update to the seafood advice they last issued in 2004. The joint advice in the draft update is consistent with the current recommendation in the *Dietary Guidelines for Americans 2010,* in that it advises pregnant women, women who may become pregnant, and nursing women to eat at least 8, and up to 12, ounces per week of a variety of fish lower in mercury in order to optimize the developmental benefits that fish could provide.

The FDA Risk Communication Advisory Committee held a public meeting on the advice provided in the draft update in November 2014, and the comment period for the draft updated advice closed in March 2015.

FDA and EPA have studied the public comments, are making the appropriate modifications to the advice, and then will publish the final advice. As with the 2014 draft version of the advice, the purpose is to provide useful and science-based information to pregnant and breastfeeding women and to caregivers of young children. We will keep your office updated as we progress on this issue.

Question 2. I was interested to learn about the information related to coffee consumption. The report indicated that consumption of coffee within the moderate range (three to five cups per day) is not associated with increased long-term health risks and is associated with reduced risk of type 2 diabetes and cardiovascular disease in adults. Can you share some of the other diseases prevention or risks also associated with moderate coffee intake?

Answer. The 2015 Dietary Guidelines Advisory Committtee (DGAC) addressed this issue in the question, "What is the relationship between usual coffee/caffeine consumption and health?" In reviewing chronic disease health outcomes, evidence was available primarily on coffee consumption and total mortality, cardiovascular disease (CVD), type 2 diabetes, and cancer. The Committee identified research on coffee consumption and CVD, stroke, heart failure, hypertension, and several intermediate outcomes including blood pressure, blood lipids, and blood glucose; the specific findings are detailed in its Advisory Report. The DGAC examined several types of cancer in regard to coffee consumption, including lung, liver, breast, prostate, ovarian, endometrium, bladder, pancreas, upper digestive and respiratory tract, esophagus, stomach, colon, and rectum. Regular coffee consumption is associated with reduced risk of cancer of the liver and endometrium.

Questions Submitted by Hon. James P. McGovern, a Representative in Congress from Massachusetts

Question 1. According to the National Consumers League, a typical serving of coffee, soda or an energy drink all contain about the same amount of caffeine. The Dietary Guidelines Advisory Committee report recommends the establishment of a guideline for caffeine but also recommends that coffee be classified as a 'normal' caffeine drink and energy drinks as 'high' caffeine drinks. If each of these products are

essentially the same, how can you support such a distinction? Can you elaborate on the scientific rational for this distinction?

Answer. The Dietary Guidelines Advisory Committee (DGAC) did not recommend that HHS and USDA classify coffee as a "normal" caffeine drink or energy drinks as "high" caffeine drinks. Instead, the references the Committee made to "coffee" and "high-caffeine energy drinks" were to the evidence it reviewed related to intake of these products and health outcomes. For example, the literature that the Committee reviewed demonstrated the highly variable amount of caffeine in energy drinks and shots; a table in the article by Reissig, *et al.* (reference 122 in Part D, *Chapter 5: Food Sustainability and Safety*) shows that many energy drinks are in the same caffeine concentration range as coffee although many have serving sizes twice that of an 8 oz. coffee serving. The table also lists "higher caffeine energy drinks" as well as "high concentration energy drinks" also known as energy shots. Much of the available evidence on caffeine focuses on coffee intake. The Committee stated that moderate coffee consumption (three to five 8 oz. cups/day, or providing up to 400 mg/day of caffeine) can be incorporated into healthy eating patterns. The Committee also noted there is not currently enough available evidence to support a recommendation for the general population regarding energy drinks.

Question 2. As you may know, cranberries are the state fruit of Massachusetts, one of three fruits native to North America, and a perennial crop grown commercially in five states. They are power packed with unique compounds that have documented health benefits, but not blessed by Mother Nature with natural sweetness like other juices and dried fruit products.

Cranberry growers are concerned that if required to include a % Daily Value (%DV) in a modified Nutrition Facts Panel for added sugar in addition to total sugars as currently proposed, consumers will be misled to believe that cranberry products, for which sugar is added for palatability, are less nutritious than other fruit products containing the same or higher levels of intrinsic or natural sugar. They are also concerned that these consumers will be misled about how much total sugar is contained in cranberry products.

While the *Dietary Guidelines for Americans* are updated every 5 years, modifications to the Nutrition Facts Panel happen less frequently. Therefore, it is critical that we get the labels right. How can FDA ensure that consumers will not be misled about the healthfulness of cranberry products under the proposed FDA Nutrition Facts Panel labeling regulation? Specifically, has FDA considered how consumers will react when comparing products with natural sugars that contain equal or more total sugars and calories than cranberry products with a declared %DV? If not, is additional information needed?

Answer. FDA is reviewing its own consumer research and other research that has been submitted to the Agency, along with the science regarding an added sugars declaration and Percent Daily Value (%DV). FDA will also consider all of the comments submitted regarding the healthfulness of foods containing added sugars, including cranberry products, as it proceeds with this rulemaking process.

Question 2a. Has FDA considered the potential economic impact to agriculture producers of perennial crops like cranberries in which producers cannot rotate into other fruit, vegetable or row crops to offset potential losses and broader agribusinesses? If not, why was this not considered?

Answer. FDA's estimate of the total cost of the proposed Nutrition Facts Label and Serving Size rules is an aggregate measure of costs, and captures relabeling costs associated with adding the added sugars declaration and percent daily value to the Nutrition Facts Panel, and reformulation costs associated with product reformulation aimed at reducing added sugars content in products (*e.g.,* substituting a high-intensity, low-calorie sweetener for sugar). FDA did not explicitly consider the potential economic impact to agriculture producers of perennial crops like cranberries because the industry may reformulate products to include less added sugars (by using other sweeteners, for example, or using other juice blends).

Question 2b. It is my understanding that FDA has based the proposed added sugar labeling requirements on the findings of the *2015 Dietary Guidelines Committee Report* which is currently still under review by HHS and USDA. Is it correct that the Committee's findings do not agree with the Institute of Medicine's (IOM) current recommendations for upper limits on added sugar and that added sugar consumption is declining to levels nearly 50% below the upper limit as recommend by the IOM?

Answer. FDA considered the scientific evidence underpinning the recommendations provided in the 2015 DGAC technical report in setting a proposed Dietary Reference Value (DRV) for added sugars. The 2015 DGAC report evaluated more recent scientific evidence than the evidence that had been evaluated by the Institute of

Medicine (IOM) when it issued its 2002 report. In 2002, the IOM provided a suggested maximum intake level of 25 percent or less of calories for added sugars based on data that demonstrated decreased intakes of some micronutrients among American subpopulations whose intake of added sugars exceeded this level. This suggested maximum intake level, however, is not considered an upper level of intake, which are set by the IOM for many other nutrients. The 2015 DGAC recommended that ten percent or less of calories should come from added sugars. The current average U.S. intake of added sugars is approximately 13.4 percent of total calories, with some subpopulations such as adolescents and young adults consuming greater amounts. Added sugars intake has decreased for both males and females across all age groups between 2001–2004 and 2007–2010, but intakes still exceed the amount that can be consumed while meeting food group and nutrient needs within the calorie levels. FDA will consider the scientific evidence and all of the public comments received by the Agency as it proceeds with this rulemaking process.

Questions Submitted by Hon. Ann Kirkpatrick, a Representative in Congress from Arizona

Question 1. The *Dietary Guidelines* are aimed at general populations based on age and gender. But, obesity on tribal land is especially severe. How do the *Dietary Guidelines* help my tribal constituents eat healthier? And will these guidelines be achievable for people of all cultures and socioeconomic levels?

Answer. HHS and USDA are working together to finalize the *2015 Dietary Guidelines for Americans,* which are expected to be completed in December of this year. We are unable to comment on the final content of the forthcoming edition of the *Dietary Guidelines* at this time, as they are still under development. However, the review of the evidence conducted by the Dietary Guidelines Advisory Committee (DGAC) included obesity as an outcome on several research questions when applicable, and thus there is evidence on obesity available in the *Advisory Report* that the Departments are taking under consideration when updating the *Dietary Guidelines.*

HHS and USDA recognize that many factors influence the diet and physical activity choices individuals make. The United States is a diverse nation, with people from many backgrounds, cultures, and traditions with varied personal preferences. In addition, significant health and food access disparities exist, with many U.S. households having insufficient resources to acquire adequate food to meet their needs. All of these factors can have a profound impact on choices. The *Dietary Guidelines* are meant to provide a sound, healthy diet for the general population, including those at increased risk for obesity and obesity-related chronic diseases. It is not a rigid prescription, but rather, an adaptable framework in which individuals can meet their personal, cultural, and traditional food preferences and stay within their budget, including those within tribes in the State of Washington.

Question 2. A typical serving of coffee, soda or an energy drink all contain about the same amount of caffeine. The Dietary Guidelines Advisory Committee recommends that you establish a guideline for caffeine, for the first time, but then recommends that you classify coffee as a 'normal' caffeine drink and energy drinks—and only energy drinks—as a 'high' caffeine drink. What is the scientific justification for this distinction?

Answer. The DGAC did not recommend that HHS and USDA classify coffee as a "normal" caffeine drink or energy drinks as "high" caffeine drinks. Instead, the references the Committee made to "coffee" and "high-caffeine energy drinks" were to the evidence it reviewed related to intake of these products and health outcomes. For example, the literature that the Committee reviewed demonstrated the highly variable amount of caffeine in energy drinks and shots; a table in the article by Reissig, *et al.* (reference 122 in Part D, *Chapter 5: Food Sustainability and Safety*) shows that many energy drinks are in the same caffeine concentration range as coffee, although many have serving sizes twice that of an 8 oz. coffee serving. The table also lists "higher caffeine energy drinks" as well as "high concentration energy drinks," also known as energy shots. Much of the available evidence on caffeine focuses on coffee intake. The Committee stated that moderate coffee consumption (three to five 8 oz. cups/day, or providing up to 400 mg/day of caffeine) can be incorporated into healthy eating patterns. The Committee also noted that the limited evidence in regard to high-caffeine energy drinks and health outcomes shows mixed results.

Response from Hon. Sylvia M. Burwell, Secretary, U.S. Department of Health and Human Services

Question Submitted by Hon. John R. Moolenaar, a Representative in Congress from Michigan

Question. In an 18 month process, spanning June 2013–December 2014, the DGAC waited until September 2014 to form its Added Sugars Working Group. This gave the Committee a mere 90 days to collect, review, synthesize and formulate conclusions on the extensive body of literature on sugars.

Considering the complexity and recent controversy around sugars intake, why wasn't the review of the scientific evidence on sugars initiated at the very beginning of the process?

Do you believe 90 days was a sufficient amount of time allocated for stakeholders to review and provide comment on the scientific evidence used, and conclusions made, by this DGAC regarding sugars intake?

Answer. The work of the 2015 Dietary Guidelines Advisory Committee (DGAC) on the topic of added sugars spanned its entire 19 months of work, during which time the public was invited to submit comments to the Advisory Committee. The process chosen by the Advisory Committee to address the topic was comprehensive and consistent with the methodology it applied across its *Advisory Report.* The Committee began its discussion on added sugars at its first public meeting in June 2013 when it began developing the questions it wanted to examine. The Science Review Subcommittee, which served as an executive subcommittee to provide guidance to the full Committee to support its reviews of the evidence, decided to form the Added Sugars Working Group in June 2014 based on extensive discussion that had already occurred within various topic-specific subcommittees and at public meetings. These discussions made it clear that an Added Sugars Working Group would be the most efficient and consistent way to comprehensively address the topic. The Added Sugars Working Group had its first meeting on July 16, 2014, not in September 2014. After the Advisory Report was released in February 2015, a public comment period ending May 8, 2015 provided additional time for the public to review this issue and submit comments to HHS and USDA.

Response from Hon. Thomas "Tom" J. Vilsack, Secretary, U.S. Department of Agriculture

Questions Submitted by Hon. Collin C. Peterson, a Representative in Congress from Minnesota

Question 1. In an 18 month process, spanning June 2013–December 2014, the DGAC waited until September 2014 to form its Added Sugars Working Group. This gave the Committee a mere 90 days to collect, review, synthesize and formulate conclusions on the extensive body of literature on sugars.

Considering all of the complexity and recent controversy around sugars intake, why wasn't this review of the scientific evidence on sugars initiated at the very beginning of this process?

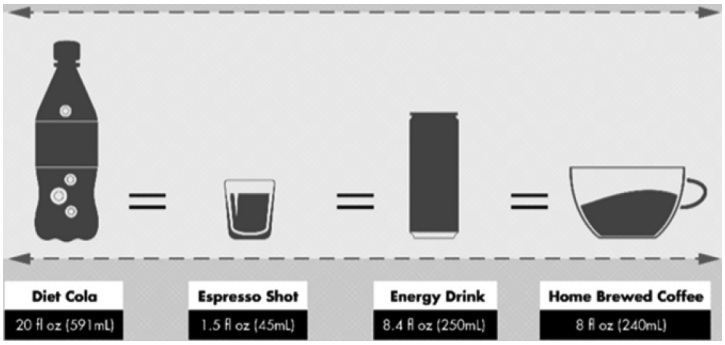
Were fewer than 90 days a sufficient amount of time for stakeholders to review and provide comment on the scientific evidence used, and conclusions made, by this DGAC regarding sugars intake?

Answer. The work of the 2015 Dietary Guidelines Advisory Committee (DGAC) on the topic of added sugars spanned its entire 19 months of work, during which time the public was invited to submit comments to the Advisory Committee. The process chosen by the Advisory Committee to address the topic was comprehensive and consistent with the methodology it applied across its *Advisory Report.* The Committee began its discussion on added sugars at its first public meeting in June 2013 when it began developing the questions it wanted to examine. The Science Review Subcommittee, which served as an executive subcommittee to provide guidance to the full Committee to support its reviews of the evidence, decided to form the Added Sugars Working Group in June 2014 based on extensive discussion that had already occurred within various topic-specific subcommittees and at public meetings. These discussions made it clear that an Added Sugars Working Group would be the most efficient and consistent way to comprehensively address the topic. The Added Sugars Working Group had its first meeting on July 16, 2014 not in September 2014. After the Advisory Report was released in February 2015, a public comment period ending May 8, 2015 provided additional time for the public to review this issue and submit comments to HHS and USDA.

Question 2. The following chart was published on the National Consumers League website during March 2015, National Nutrition Month, along with an article entitled "What's the Buzz on Caffeine?".

Caffiene Equivalence

70–90 mg of Caffeine



http://www.nclnet.org/whats_the_buzz_on_caffeine.

If a typical serving of coffee, soda or an energy drink all contain about the same amount of caffeine, do you think final dietary guidance to consumers should be based upon recommendations that classify coffee as 'normal' caffeine, energy drinks—and only energy drinks—as 'high' caffeine and did not take tea or other common caffeine sources into account whatsoever as far as contribution to daily caffeine intake of Americans is concerned?

Answer. The DGAC did not recommend that HHS and USDA classify coffee as a "normal" caffeine drink or energy drinks as "high" caffeine drinks. Instead, the references the Committee made to "coffee" and "high-caffeine energy drinks" were to the evidence it reviewed related to intake of these products and health outcomes. For example, the literature that the Committee reviewed demonstrated the highly variable amount of caffeine in energy drinks and shots; a table in the article by Reissig, *et al.* (reference 122 in Part D, *Chapter 5: Food Sustainability and Safety*) shows that many energy drinks are in the same caffeine concentration range as coffee although many have serving sizes twice that of an 8 oz. coffee serving. The table also lists "higher caffeine energy drinks" as well as "high concentration energy drinks" also known as energy shots. Much of the available evidence on caffeine focuses on coffee intake. The Committee stated that moderate coffee consumption (three to five 8 oz. cups/day, or providing up to 400 mg/day of caffeine) can be incorporated into healthy eating patterns. The Committee also noted that the limited evidence in regard to high-caffeine energy drinks and health outcomes shows mixed results.

Question Submitted by Hon. Vicky Hartzler, a Representative in Congress from Missouri

Question. Has the USDA considered moving the Nutrition Evidence Library from CNPP to ARS to allow for more open access of the nutrition science data for all government agencies?

Answer. The Nutrition Evidence Library (NEL) is unique in its special focus on systematic reviews specifically in nutrition to help inform Federal nutrition policies and programs—it requires the expertise of the professionals at CNPP. Since its inception, the NEL has been fully available and accessible to the public on *NEL.gov,* and all government agencies have had access not only to its contents, but also to its staff at CNPP. For example, USDA's Food and Nutrition Service (FNS) utilized the NEL for a series of systematic reviews in order to answer targeted nutrition education-related questions to inform guidance, policy, and program development related to FNS-administered nutrition education programs.

ATTACHMENT 1

Appendix E–2.39a: Evidence Portfolio

Part D. Chapter 5: Food Sustainability and Safety

Usual Caffeine Consumption and Health

Systematic Review Question: Total Mortality

What is the relationship between usual caffeine consumption and total mortality?

Conclusion Statement: Strong and consistent evidence shows that consumption of coffee within the moderate range (3 to 5 cups/d or up to 400 mg/d caffeine) is not associated with increased risk of major chronic diseases, such as cardiovascular disease (CVD) and cancer and premature death in healthy adults.

DGAC Grade: Strong

Key Findings

- Coffee consumption was associated with reduced risk of total mortality (3–4% lower mortality with 1 cup/day), especially cardiovascular mortality.
- Decaffeinated coffee consumption was associated with a lower risk of death (5 studies only).
- The limited number of studies on decaffeinated coffee indicates that protective association of coffee consumption may not be due to caffeine alone.

Description of the Evidence

Two systematic reviews and/or meta-analyses (SR/MAs) of 20 and 23 prospective cohort studies (Je, 2013 and Malerba, 2013, respectively). Je, *et al.* examined total mortality and Malerba, *et al.,* examined total, CVD, and cancer mortality. Evidence suggests a significant inverse relationship between coffee consumption of 1–4 cups/day with total mortality, especially cardiovascular disease mortality. This evidence is based on three meta-analyses of more than 20 prospective cohort studies (Je, 2013; Malerba, 2013; **Crippa,** 2014). In general, results were similar for men and women. The risk reduction associated with each cup of coffee per day was between 3–4 percent. In addition, Je (2013) found a significant inverse association between coffee consumption and cardiovascular disease mortality. This association was stronger in women (16% lower risk) than in men (8% lower risk). However, no association was found for cancer mortality. Crippa, *et al.,* found that the lowest risk was observed for 4 cups/d for all-cause mortality (16%, 95% CI = 13–18) and 3 cups/d for CVD mortality (21%, 95% CI = 16–26),

Systematic Review Question: Cardiovascular Disease

What is the relationship between usual caffeine consumption and cardiovascular disease?

Conclusion Statement: Consistent observational evidence indicates that moderate coffee consumption is associated with reduced risk of type 2 diabetes and cardiovascular disease in healthy adults. In addition, consistent observational evidence indicates that regular consumption of coffee is associated with reduced risk of cancer of the liver and endometrium, and slightly inverse or null associations are observed for other cancer sites.

DGAC Grade: Moderate

Key Findings

CVD

- Non-linear association between coffee intake and risk of CVD
- Moderate coffee consumption was inversely associated with CVD risk
  - Lowest risk at 3–5 cups/d
- Heavy consumption was not associated with higher CVD risk

Stroke

- Non-linear association between coffee intake and risk of stroke
- Moderate coffee consumption was inversely associated with stroke
  - Lowest risk at 3–4 cups/d
- Higher intakes were not associated with higher stroke risk

CHD

- Moderate coffee consumption was associated with lower CHD risk

- Higher intakes were not associated with higher CHD risk

Heart Failure

- Moderate (1–5 cups/d) coffee consumption was inversely associated with risk of heart failure
- The largest inverse association observed for 4 cups/d

Blood Pressure & Hypertension

- No effect of coffee on long-term BP or risk of HTN
- For habitual coffee consumption, consumption of >3 cups/d was not associated with increased risk of HTN compared with <1 cup/d
  - There was a slightly elevated risk of HTN for light to moderate consumption (1–3 cups/d)
- In hypertensive individuals, caffeine intake produces an acute increase in BP for ≥3 h, but there is no evidence of an association between long-term coffee consumption and increased BP
- Regular caffeine intake (median 410 mg/d) increases BP in short-term RCTs, although when ingested through coffee, BP effect of caffeine was smaller but significant

Atrial Fibrillation

- Caffeine was not associated with increased risk of atrial fibrillation
- Low-dose caffeine exposure (<350 mg) may have a protective effect

Blood Lipids

- Caffeinated, but not decaffeinated coffee, had significant effect on serum lipids. The effects were mostly found in unfiltered coffee.
  - Coffee consumption increased TC, LDL–C, and TG
  - Positive dose-response relation between coffee intake and TC, LDL–C, and TG

Description of the Evidence

Twelve SR/MAs examined CVD (Ding, 2014; Caldiera, 2013; Cai, 2013; Kim, 2012; Mostofsky, 2012; Steffen, 2012; Zhang, 2011; Mesas, 2011; Larrson, 2011; Wu, 2009; Soffi, 2007; Noordjiz, 2005). Some SR/MAs covered only RCTs (Cai, 2013). Others included only prospective cohort studies (Larsson, 2011; Zhang, 2011; Kim, 2012; Mostofsky, 2012; Wu, 2009). Other SR/MAs covered RCTs and cohort studies (Steffen, 2012); controlled trials (randomized and non-randomized) and cohort studies (Mesas, 2011); prospective studies and case-control (Soffi, 2007); prospective cohort studies, case-cohort, and nested case-control studies (Ding, 2014); and RCT, prospective or retrospective cohorts and case-control studies (Caldiera, 2013). The number of studies included in the SR/MAs ranged from 5–36.

A large and current body of evidence directly addressed the relationship between normal coffee consumption and risk of cardiovascular disease (CVD). The evidence included 12 systematic reviews with meta-analyses, all of which had high quality ratings (AMSTAR scores 8/11–11/11). CVD incidence and mortality, as well as coronary heart disease (CHD), stroke, heart failure, and hypertension were assessed by meta-analyses that consisted primarily of prospective cohort studies; intermediate outcomes such as blood pressure, blood lipids, and blood glucose were assessed by meta-analyses of randomized controlled trials.

CVD risk was assessed by a current meta-analysis of 36 prospective cohort studies on long-term coffee consumption (Ding, 2014). This analysis showed a non-linear association, such that the lowest risk of CVD was seen with moderate coffee consumption (3–5 cups/day), but higher intakes (>5 cups/day) were neither protective nor harmful. Overall, moderate consumption of caffeinated, but not decaffeinated, coffee was associated with a 12 percent lower risk of CVD.

Results from the assessment of CHD risk in three meta-analyses (Ding, 2014; Wu, 2009; Sofi, 2007) were inconsistent. Ding (2014) found 10 percent lower CHD risk with moderate coffee consumption (3–5 cups/day) in a meta-analysis of 30 prospective cohort studies, whereas Wu (2009) and Sofi (2007) in meta-analyses of 21 and 10 prospective cohort studies, respectively, found no association between coffee consumption and CHD risk. However, in sub-group analysis, Wu (2009) found that habitual moderate coffee consumption (1–4 cups/day) was associated with an 18 percent lower risk among women. Overall, the meta-analyses of Sofi (2007) and Wu (2009) were conducted with smaller bodies of evidence and Ding (2014) assessed sev-

eral more recent studies. One reason for the inconsistent associations may be that coffee brewing methods have changed over time and the filter method has become more widely used, replacing unfiltered forms of coffee such as boiled coffee that were more widely consumed by participants in earlier studies.

Risk of stroke was assessed in two systematic reviews with meta-analyses of prospective cohort studies (Larsson, 2011; Kim, 2012) with consistent findings. Kim (2012) found that coffee intake of 4 or more cups/day had a protective effect on risk of stroke. Larsson (2011) documented a non-linear association such that coffee consumption ranging from 1 to 6 cups/day was associated with an 8 percent–13 percent lower risk of stroke, and higher intakes were not associated with decreased or increased risk. The inverse associations were limited to ischemic stroke and no association was seen with hemorrhagic stroke.

Regarding blood pressure, three meta-analyses evaluated the effect of coffee and caffeine on systolic and diastolic blood pressure using controlled trials (Steffen, 2012; Mesas, 2011; Noordzij, 2005). The most recent meta-analysis of 10 randomized controlled trials by Steffen, *et al.* (2012) showed no effect of coffee on either systolic or diastolic blood pressure. Similarly, in another meta-analysis of 11 coffee trials and 5 caffeine trials, caffeine doses of <410 mg/day had no effect on systolic and diastolic blood pressure while doses of 410 or more mg/day resulted in a net increase (Noordzij, 2005). A third meta-analysis showed that among individuals with hypertension, 200–300 mg of caffeine (equivalent to ~2–3 cups filtered coffee) resulted in an acute increase of systolic and diastolic blood pressure (Mesas, 2011). Additionally, two meta-analyses quantified the effect of coffee on incidence of hypertension (Steffen, 2012; Zhang, 2011) and found no association between habitual coffee consumption and risk of hypertension. However, Zhang, *et al.* (2011) documented a slightly elevated risk for light to moderate consumption (1–3 cups/day) of coffee compared to less than 1 cup/day. Regarding blood lipids, in a quantitative analysis of short-term randomized controlled trials, Cai, *et al.* (2012) revealed that coffee consumption contributed significantly to an increase in total cholesterol, LDL-cholesterol, and triglycerides, and that unfiltered coffee had a greater effect than filtered coffee. Interestingly, caffeinated, but not decaffeinated (more likely to be filtered), coffee had this effect on serum lipids.

In a meta-analysis of observational study data, including prospective, retrospective, and case-control studies, higher amounts of coffee or caffeine had no association with risk of atrial fibrillation, but low doses of caffeine (<350 mg/day) appeared to have a protective effect (Caldeira, 2013). In contrast, coffee consumption of 1–5 cups/day was found to be inversely associated with risk of heart failure in a meta-analysis of 5 prospective studies (Mostofsky, 2012). A non-linear association was documented and the lowest risk was observed for 4 cups/day (Mostofsky, 2012).

Systematic Review Question: Type 2 Diabetes

What is the relationship between usual caffeine consumption and type 2 diabetes?

Conclusion Statement: Consistent observational evidence indicates that moderate coffee consumption is associated with reduced risk of type 2 diabetes and cardiovascular disease in healthy adults. In addition, consistent observational evidence indicates that regular consumption of coffee is associated with reduced risk of cancer of the liver and endometrium, and slightly inverse or null associations are observed for other cancer sites.

DGAC Grade: Moderate

Key Findings

- Coffee consumption was inversely associated with T2D risk in a dose-response manner.
- Both caffeinated and decaffeinated coffee were associated with lower T2D risk.
- Increased coffee consumption by 1 cup/d was associated with 7% lower T2D risk.
- Similar associations were seen in men and women.
- A smaller number of studies on decaffeinated coffee indicate that protective association of coffee consumption is unlikely to be due to caffeine alone.
- In T2D individuals, ingestion of caffeine (~200–500 mg) significantly increased blood glucose, serum insulin, and lowered insulin sensitivity in those with T2D in short-term RCTs.

Description of the Evidence

Five SR/MAs examined T2D (Ding, 2014; Jiang, 2014; Whitehead, 2013; Huxley, 2009; van Dam, 2005). One SR/MA covered controlled trials (Whitehead, 2013) and two others covered only prospective cohort studies (Jiang, 2014; Huxley, 2009). Other SR/MAs covered both prospective cohort and nested case-control studies (Ding, 2014) or prospective cohort and cross-sectional studies (van Dam, 2005). The number of studies included in the SR/MAs ranged from 9–31.

Coffee consumption has consistently been associated with a reduced risk of type 2 diabetes. In four meta-analyses of prospective cohort studies (Ding, 2014; Jiang, 2014; Huxley, 2009; van Dam, 2005) and cross-sectional studies (van Dam, 2005), coffee consumption was inversely associated with risk of type 2 diabetes in a dose-response manner. Risk for type 2 diabetes was 33 percent lower for those consuming 6 cups/day in the analysis by Ding, *et al.* (2014) while the risk was 37 percent lower for those consuming 10 cups/day in the analysis by Jiang, *et al.* (2014). Using a subset of the prospective cohorts in the Ding, *et al.* (2014) and Jiang, *et al.* (2014) meta-analyses, Huxley (2009) documented that each cup of coffee was associated with a 7 percent lower risk of type 2 diabetes. Similarly, van Dam (2005) noted that consumption of ≥6 or ≥7 cups/day was associated with a 35 percent lower risk of type 2 diabetes. Three meta-analyses (Ding, 2014; Jiang, 2014; Huxley, 2009) found protective associations for decaffeinated coffee. Moderate decaffeinated coffee consumption (3–4 cups/day) was associated with a 36 percent lower risk of type 2 diabetes (Huxley, 2009). Each cup of decaffeinated coffee was associated with a 6 percent lower risk (Ding, 2014) while every 2 cups were associated with a 11 percent lower risk (Jiang, 2014). Both reports also documented a dose-response association between caffeine and type 2 diabetes risk such that every 140 mg/day was associated with an 8 percent lower risk in the Ding, *et al.* (2014) meta-analysis while every 200 mg/day was associated with a 14 percent lower risk in the analysis by Jiang, *et al.* (2014). However, it remains unclear if this inverse association is independent of coffee consumption as Ding et al (2014) indicated that none of the studies included in the caffeine dose-response analysis adjusted for total coffee.

Only one systematic review of 9 randomized controlled trials examined the effects of caffeine on blood glucose and insulin concentrations among those with type 2 diabetes (Whitehead & White 2013). Ingestion of 200–500 mg of caffeine acutely increased blood glucose concentrations by 16–28 percent of the area under the curve and insulin secretions by 19–48 percent of the area under the curve when taken prior to a glucose load. At the same time, these trials also noted a decrease in insulin sensitivity by 14–37 percent. Although it is not clear if the acute effects of caffeine on blood glucose and insulin persist in the long term, evidence from prospective cohorts indicate that caffeine may have no adverse effect on the risk of type 2 diabetes.

Systematic Review Question: Cancer

What is the relationship between usual caffeine consumption and cancer?

Conclusion Statement: Consistent observational evidence indicates that moderate coffee consumption is associated with reduced risk of type 2 diabetes and cardiovascular disease in healthy adults. In addition, consistent observational evidence indicates that regular consumption of coffee is associated with reduced risk of cancer of the liver and endometrium, and slightly inverse or null associations are observed for other cancer sites.

DGAC Grade: Moderate

Key Findings

Total Cancer

- Total Cancer Coffee drinkers had a modestly lower total cancer incidence compared to nondrinkers or those with the lowest intakes.

Lung Cancer

- Coffee consumption was associated with higher risk of lung cancer, but the association was mainly explained by smoking. An association was not founder among nonsmokers.

Liver Cancer

- Significant inverse association between coffee consumption and liver cancer risk seen in both case-control and cohort studies (after adjustment for existing liver disease).

- Risk of hepatocelluar carcinoma was reduced by 40% for any coffee consumption versus no coffee consumption.

Breast Cancer

- No association between caffeine, coffee, or decaffeinated coffee and breast cancer risk.
  - An inverse association was seen in postmenopausal women and a strong inverse association seen in BRCA1 mutation carriers.
- Borderline lower risk for highest versus lowest coffee consumption.
  - For all studies together, an increase of 2 cups of coffee per day was associated with a 2% marginally lower breast cancer risk.

Prostate Cancer

- Regular coffee consumption associated with modestly lower risk of prostate cancer.
- Significant inverse association documented for cohort studies. For case-control studies, a 2 cup increment was associated with a higher risk of prostate cancer.
- Dose-response meta-analysis of coffee consumption showed inverse association with prostate cancer mortality, but not incidence.

Ovarian Cancer

- No association between coffee consumption and ovarian cancer risk in high *versus* low or dose-response meta-analysis.

Endometrial Cancer

- Increased coffee intake was associated with a reduced risk of endometrial cancer in both cohort and case-control studies.
- A reduction of ~20% in endometrial cancer risk among coffee drinkers; >20% and >30% reduction in risk among low to mod and heavy drinkers, respectively.

Bladder Cancer

- Data from case-control studies suggest that consumption of coffee is associated with an increased risk for bladder cancer, but no significant association was seen in prospective cohort studies.

Pancreatic Cancer

- Meta-analysis of prospective cohort studies showed that coffee drinking was inversely associated with pancreatic cancer risk (in sub-group analyses, there was a reduced risk in men but not women).
- A positive association was found between coffee intake and pancreatic cancer in case-control studies that did not adjust for smoking. An inverse association was found in prospective cohort studies.

Upper Digestive & Respiratory Cancer

- Coffee drinking was inversely related to oral/pharyngeal cancer risk while there was no relation with laryngeal cancer, ESCC, and EAC.

Gastro-esophageal Cancer

- Coffee consumption was inversely, but non-significantly, associated with risk of esophageal cancer.
- No association between coffee consumption and gastric cancer risk in cohort or case-control studies.

Colorectal Cancer

- Case-control studies suggest coffee consumption decreases risk of colorectal and colon cancer, especially in women; the association was inverse, but marginally non-significant, for cohort studies for colorectal and colon cancer.
- Prospective cohort studies showed no association between coffee consumption on colorectal cancer risk (a suggestive inverse association was slightly stronger in studies that adjusted for smoking and alcohol).

Description of the Evidence

A large number of SR/MAs addressed cancer, including total cancer (Yu, 2011), lung cancer (Tang, 2010), liver cancer (Sang, 2013; Bravi, 2013), breast cancer (Jiang, 2013; Li, 2013; Tang 2009), prostate cancer (Cao, 2014; Zhong, 2013; Discacciati, 2013; Park, 2010), ovarian cancer (Braem, 2012), endometrial cancer (Je, 2012; Bravi, 2009), bladder cancer (Zhou, 2012), pancreatic cancer (Turati, 2011;

Dong, 2011), upper digestive and respiratory tract cancer (Turati, 2011), esophageal cancer (Zheng, 2013), gastric cancer (Botelho, 2006), and colorectal cancer (Li, 2012; Galeone, 2010; Je, 2009). The majority of the studies included cohort and cross-sectional studies, although some covered only prospective cohort studies or case-control studies. The number of studies included in the SR/MAs ranged from 3–54.

Several systematic reviews and meta-analyses examined the association between coffee consumption and risk of cancer. Types of cancer examined by the Committee included total cancer, cancers of the lung, liver, breast, prostate, ovaries, endometrium, bladder, pancreas, upper digestive and respiratory tract, esophagus, stomach, colon, and rectum.

In a quantitative summary of 40 prospective cohort studies with an average follow-up of 14.3 years, Yu (2011) found a 13 percent lower risk of total cancer among coffee drinkers compared to non-drinkers or those with lowest intakes. Risk estimates were similar for men and women. In sub-group analyses, the authors noted that coffee drinking was associated with a reduced risk of bladder, breast, buccal and pharyngeal, colorectal, endometrial, esophageal, hepatocellular, leukemic, pancreatic, and prostate cancers.

Tang, *et al.* (2010) evaluated 5 prospective cohorts and 8 case-control studies and found that overall those with the highest levels of coffee consumption had a 27 percent higher risk for lung cancer compared to never drinkers or those with least consumption. An increase in coffee consumption of 2 cups/day was associated with a 14 percent higher risk of developing lung cancer. However, because smoking is an important confounder, when analyses were stratified by smoking status, coffee consumption was marginally protective in non-smokers and was not associated with lung cancer among smokers. When estimates from 2 studies that examined decaffeinated coffee were summarized, there was a protective association with lung cancer. No association was seen with lung cancer when only case-control studies were considered.

Results from two meta-analyses indicate the coffee consumption is associated with a 50 percent lower risk of liver cancer (Sang, 2013) and a 40 percent lower risk of hepatocellular carcinoma (Bravi, 2013) when considering both cohort and case-control studies. Associations were significant in men but not in women (Sang, 2013).

Three meta-analyses of observational studies found no association between coffee consumption (Jiang, 2013; Li, 2013; Tang, 2013), caffeine consumption (Jiang, 2013), or decaffeinated coffee consumption (Jiang, 2013) and risk of breast cancer. In all 3 reports, each 2 cup/day of coffee was marginally associated with a 2 percent lower risk of breast cancer. However, in sub-group analyses, coffee consumption was protective against breast cancer risk in postmenopausal women (Jiang, 2013), BRCA1 mutation carriers (Jiang, 2013), and women with estrogen receptor negative status (Li, 2013).

The association between coffee consumption and risk of prostate cancer was mixed. Cao (2014) and Zhong (2013) found that regular or high coffee consumption, compared to non- or lowest levels of consumption, was associated with a 12 percent–17 percent lower risk of prostate cancer in prospective cohort studies. Further, each 2 cups of coffee per day was associated with a 7% lower risk of prostate cancer. However, no associations were seen with case-control data alone or when these studies were examined together with prospective cohort studies. Using a combination of both prospective cohort and case-control data, Discacciati (2013) found that each 3 cups/day of coffee was associated with a 3% lower risk of localized prostate cancer and an 11% lower risk of mortality from prostate cancer. On the other hand, after summarizing data from 12 prospective cohort and case-control studies, Park (2010) found a 16% higher risk of prostate cancer. However, in sub-group analyses by study design, the higher risk was observed in case-control but not in cohort studies.

Consumption of coffee was not associated with risk of ovarian cancer in a meta-analysis of 7 prospective cohort studies with over 640,000 participants (Braem, 2012).

Two meta-analyses confirmed an inverse association between coffee consumption and risk of endometrial cancer (Je, 2012; Bravi, 2009). In the most recent and updated meta-analysis of prospective cohort and case-control studies, compared to those in the lowest category of coffee consumption, those with the highest intakes of coffee had a 29% lower risk of endometrial cancer (Je, 2012). Each cup of coffee per day was associated with an 8% lower risk of endometrial cancer. Similar results were found in the meta-analysis by Bravi (2009) that included a sub-set of the studies in Je (2012) and documented a 20% lower risk of endometrial cancer overall, and a 7% decrease for each cup of coffee per day. However, the association was significant only in case-control studies but not in cohort studies, most likely due to lower statistical power.

A recent meta-analysis of 23 case-control studies by Zhou (2012) found coffee was a risk factor for bladder cancer. There was a smoking-adjusted increased risk of bladder cancer for those in the highest (45%), second highest, (21%), and third highest (8%) groups of coffee consumption, compared to those in the lowest group. No association was, however, seen in cohort studies.

Two meta-analyses of coffee consumption and pancreatic cancer risk provided mixed results (Turati, 2011; Dong, 2011). Using both prospective cohort and case-control studies, Turati (2011) found that coffee consumption was not associated with risk of pancreatic cancer. However, an increased risk was seen in case-control studies that did not adjust for smoking. Using a sub-set of prospective cohorts included in the Turati (2011) meta-analysis, Dong (2011) found that coffee drinking was inversely associated with pancreatic cancer risk but did not separate studies based on their adjustment for smoking status. Sub-group analyses revealed a protective association in men, but not in women.

Turati (2011) quantified the association between coffee consumption and various upper digestive and respiratory tract cancers using data from observational studies. Coffee consumption was associated with a 36% lower risk of oral and pharyngeal cancer but not with risk of laryngeal cancer, esophageal squamous cell carcinoma, or esophageal adenocarcinoma. In a meta-analysis of prospective cohort and case-control studies, Zheng (2013) noted that coffee was inversely, but non-significantly, associated with risk of esophageal cancer. Regarding gastric cancer, no association between coffee consumption and risk was seen in a meta-analysis of observational studies by Botelho (2006).

Three meta-analyses on the association between coffee consumption and colorectal cancer risk (Li, 2012; Galeone, 2012; Je, 2009) have yielded mixed findings. Results from case-control studies suggested coffee consumption was associated with lower risk of colorectal (15% lower) and colon cancer (21% lower), especially in women. However, this inverse association was non-significant for cohort studies. Using all but one of the case-control studies, Galeone (2012) arrived at similar conclusions as the Li (2012) analysis although associations were in general stronger. Galeone (2012) also provided suggestive evidence for a dose-response relationship between coffee and colorectal cancer such that each cup of coffee was associated with a 6% lower risk of colorectal cancer, 5% lower risk of colon cancer, and 3% lower risk of rectal cancer. Using several prospective cohort studies as in the Li (2012) meta-analysis, Je (2009) found no significant association of coffee consumption with risk of colorectal cancer. Interestingly, no differences were seen by sex but the suggestive inverse associations were slightly stronger in studies that adjusted for smoking and alcohol.

Systematic Review Question: Cognitive Function

What is the relationship between usual caffeine consumption and cognitive function?

Conclusion Statement: Limited evidence indicates that caffeine consumption is associated with a modestly lower risk of cognitive decline or impairment and lower risk of Alzheimer's disease.

DGAC Grade: Limited

Key Findings:

- There was a trend toward a protective effect of caffeine from different sourcesand cognitive impairment/dementia.

Description of the Evidence

Two systematic reviews (Arab, 2013; Santos, 2010) and one meta-analysis (Santos, 2010) examined the effects of caffeine from various sources, including coffee, tea, chocolate, on cognitive outcomes. Arab (2013) systematically reviewed six longitudinal cohort studies evaluating the effect of caffeine or caffeine-rich beverages on cognitive decline. Most studies in this review used the Mini Mental State Examination Score as a global measure of cognitive decline. The review concluded that estimates of cognitive decline were lower among consumers, although there was no clear dose-response relationship. Studies also showed stronger effects among women than men. In a metaanalysis of nine cohort and two case-control studies, caffeine intake from various sources was associated with a 16% lower risk of various measures of cognitive impairment/decline. Specifically, data from four studies indicate that caffeine is associated with a 38% lower risk of Alzheimer's disease.

Systematic Review Question: Parkinson's Disease

What is the relationship between usual caffeine consumption and Parkinson's disease?

Conclusion Statement: Consistent evidence indicates an inverse association between caffeine intake and risk of Parkinson's disease.

DGAC Grade: Moderate

Key Findings

- There was a non-linear inverse association between coffee and Parkinson's disease risk with maximum protection at ~3 cups/d (adjusted for smoking).
- For caffeine consumption, a linear inverse association was found (adjusted for smoking); every 300 mg/day was associated with a 24% lower risk of Parkinson's disease.

Description of the Evidence

Evidence from two systematic reviews (Ishihara, 2005; Costa, 2010) and one quantitative meta-analysis (Qi, 2013) confirmed an inverse association between coffee, caffeine, and risk of Parkinson's disease. Qi (2013) evaluated six case-control studies and seven prospective articles and documented a non-linear relationship between coffee and risk of Parkinson's disease, overall. The lowest risk was observed at ~3 cups/day (smoking-adjusted risk reduction was 28%). For caffeine, a linear dose-response was found and every 200 mg/day increment in caffeine intake was associated with a 17% lower risk of Parkinson's disease. Using a combination of cohort, case-control, and cross-sectional data, Costa (2010) summarized that the risk of Parkinson's disease was 25% lower among those consuming the highest *versus* lowest amounts of caffeine. Like Qi (2013), Costa documented a linear dose-response with caffeine intake such that every 300 mg/day was associated with a 24% lower risk of Parkinson's disease. In both reports, associations were weaker among women than in men.

Systematic Review Question: Pregnancy outcomes

What is the relationship between usual caffeine consumption and pregnancy outcomes?

Conclusion Statement: Consistent evidence from observational studies indicates that caffeine intake in pregnant women is not associated with risk of preterm delivery. Higher caffeine intake (especially >=300 mg/day) is associated with a small increased risk of miscarriage, stillbirth, low birth weight, and small for gestational age (SGA) births. However, these data should be interpreted cautiously due to potential recall bias in the case-control studies and confounding by smoking and pregnancy signal symptoms.

DGAC Grade: Moderate

Key Findings

- No important association between caffeine intake during pregnancy and risk of pre-term birth were observed in either cohort or case-control studies.
- Consumption of caffeine from various sources was associated with a significantly increased risk of spontaneous abortion and low birth weight. Control for confounders such as maternal age, smoking, and ethanol use was not possible.

Description of the Evidence

Two SR/MAs assessed observational studies on the association of caffeine intake with adverse pregnancy outcomes (Greenwood, 2014; Maslova, 2010). The pregnancy outcomes included miscarriage, pre-term birth, stillbirth, small for gestational age (SGA), and low birth-weight. The most recent SR/MA by Greenwood, *et al.,* quantified the association between caffeine intake and adverse pregnancy outcomes from 60 publications from 53 separate cohort (26) and case-control (27) studies. The evidence covered a variety of countries with caffeine intake categories that ranged from non-consumers to those consuming >1,000mg/day. They found that an increment of 100 mg caffeine was associated with a 14% increased risk of miscarriage, 19% increased risk of stillbirth, 10% increased risk of SGA, and 7% increased risk of low birth weight. There was no significant increase in risk of preterm delivery. The magnitude of these associations was relatively small within the range of caffeine intakes of the majority women in the study populations, and the associations became more pronounced at higher range (>=300 mg/day). The authors also note the sub-

stantial heterogeneity observed in the meta-analyses shows that interpretation of the results should be cautious. In addition, the results from prospective cohort studies and case-control studies were mixed together. Since coffee consumption is positively correlated with smoking, residual confounding by smoking may have biased the results toward a positive direction.

The other SR/MAs did not cover all of the above pregnancy outcomes, but for those adverse outcomes covered, the results were in agreement with Greenwood, *et al.,* Maslova (2010) reviewed 22 studies (15 cohort and 7 case-control studies) and found no significant association between caffeine intake and risk of pre-term birth in either casecontrol or cohort studies. For all of the observational studies assessed across the three SR/MAs, most studies did not adequately adjust for the pregnancy signal phenomenon, *i.e.,* that nausea, vomiting, and other adverse symptoms are associated with a healthy pregnancy that results in a live birth, whereas pregnancy signal symptoms occur less frequently when the result is miscarriage. Coffee consumption decreases with increasing pregnancy signal symptoms, typically during the early weeks of pregnancy, and this confounds the association (Peck, *et al.* 2010). Greenwood, *et al.,* state that this potential bias is the most prominent argument against a causal role for caffeine in adverse pregnancy outcomes. Only one randomized controlled trial of caffeine/coffee reduction during pregnancy has been conducted to date (Bech, 2007). The study found that a reduction of 200 mg of caffeine intake per day did not significantly influence birth weight or length of gestation. The trial did not examine other outcomes.

Research Recommendations

1. Evaluate the effects of coffee on health outcomes in vulnerable populations, such as women who are pregnant (premature birth, low birth weight, spontaneous abortion).
2. Examine the effects of coffee on sleep patterns, quality of life, and dependency and addiction.
3. Evaluate the prospective association between coffee/caffeine consumption and cancer at different sites.
4. Examine prospectively the effects of coffee/caffeine on cognitive decline, neurodegenerative diseases, and depression.
5. Understand the mechanisms underlying the protective effects of coffee on diabetes and CVD.
6. Understand the association between coffee and health outcomes in individuals with existing CVD, diabetes, cancer, neurodegenerative diseases, or depressive symptoms.

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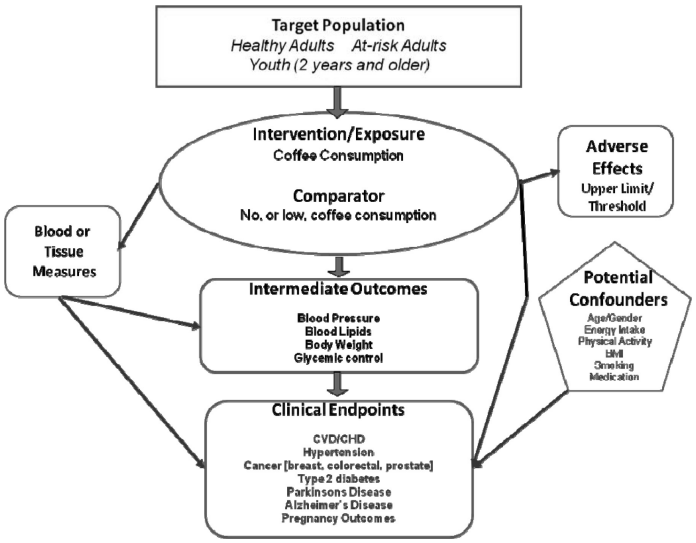
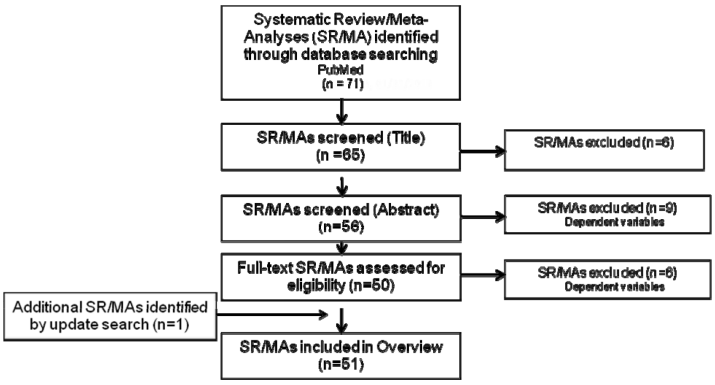
Analytical Framework



Inclusion Criteria

PubMed was searched for original research articles published in English in peer-reviewed journals. Studies published since January 2000 with subjects who were healthy or at elevated chronic disease risk from countries with high or very high human development were considered. Study design was limited to systematic reviews or systematic reviews with meta-analyses. All other study designs were excluded. Studies were required to specify level of caffeine and included caffeine from any source. Both short- and long-term health outcomes were included. Studies that examined low-calorie diets and other treatment diets were excluded. Finally, studies were required to include a description of the dietary pattern along with sustainability or food security outcomes.

Search Results



ATTACHMENT 2

The Federal Advisory Committee Act (FACA) Brochure

An Overview

U.S. General Services Administration,
Office of Governmentwide Policy,
Committee Management Secretariat,

Washington, D.C. 20417

Advisory committees have played an important role in shaping programs and policies of the Federal Government from the earliest days of the Republic. Since President George Washington sought the advice of such a committee during the Whiskey Rebellion of 1794, the contributions made by these groups have been impressive and diverse.

Today, an average of 1,000 advisory committees with more than 60,000 members advise the President and the Executive Branch on such issues as the disposal of high-level nuclear waste, the depletion of atmospheric ozone, the national fight against Acquired Immune Deficiency Syndrome (AIDS), efforts to rid the nation of illegal drugs, to improve schools, highways, and housing, and on other major programs.

Through enactment of the Federal Advisory Committee Act (FACA) of 1972 (Public Law 92–463), the U.S. Congress formally recognized the merits of seeking the advice and assistance of our nation's citizens. At the same time, the Congress also sought to assure that advisory committees:

- Provide advice that is relevant, objective, and open to the public;
- Act promptly to complete their work; and
- Comply with reasonable cost controls and record keeping requirements.

Role of Federal Advisory Committees

With the expertise from advisory committee members, federal officials and the nation have access to information and advice on a broad range of issues affecting federal policies and programs. The public, in return, is afforded an opportunity to provide input into a process that may form the basis for government decisions.

Federal Agency Responsibility

Each Federal agency that sponsors advisory committees must adhere to the requirements established by the FACA, as well as regulations promulgated by the U.S. General Services Administration's (GSA) Committee Management Secretariat. GSA has had the responsibility for overseeing the FACA since 1977.

GSA's Role Under the FACA

With approximately 1,000 advisory committees in existence at any given time, special attention is required to assure compliance with the FACA, the Freedom of Information Act, and related regulations, as well as to encourage effective and efficient use of committee resources.

While Executive Branch departments and agencies are responsible for continually reviewing committee performance and compliance in these areas, the General Services Administration was designated by the President in 1977 to monitor committee activities government-wide. As part of this responsibility, GSA:

- Conducts annual reviews of advisory committee activities and accomplishments;
- Responds to requests from agencies on establishing new committees or the renewal of existing groups; and
- Maintains a FACA database on the internet from which advisory committee information may be obtained.

Together, GSA and the Federal community work to eliminate the overlap or duplication of advisory bodies, terminate unnecessary or inactive committees, and develop committee management regulations, guidelines, and training in response to requirements of the Executive Branch and Congress.

Complying with FACA

Any advisory group, with limited exceptions, that is established or utilized by a federal agency and that has at least one member who is not a Federal employee, must comply with the FACA. To find out if a group comes under the FACA, contact the sponsoring agency's Committee Management Officer. The GSA Committee Management Secretariat is an additional resource (see the last section "*For More Information . . .*").

Requirements for Establishing and Managing Advisory Committees

Under the Federal Advisory Committee Act, advisory committees can be created only when they are essential to the performance of a duty or responsibility conveyed upon the Executive Branch by law or Presidential Directive. Before committees can be set up, high-level officials within the sponsoring agency must review and approve the request. Once a committee is approved, a charter is prepared outlining the committee's mission and specific duties and forwarded to GSA's Committee Manage-

ment Secretariat for final review. Following a required public notification period, and the filing of the charter with Congress, the committee may begin operation.

Committee Management Officer and Designated Federal Officer

The Federal Advisory Committee Act also provides that each agency sponsoring a federal advisory committee must appoint a Committee Management Officer to oversee the administration of the Act's requirements.

In addition, a Designated Federal Officer must be assigned to each committee to:

- Ensure compliance with FACA, and any other applicable laws and regulations;
- Call, attend, and adjourn committee meetings;
- Approve agendas;
- Maintain required records on costs and membership;
- Ensure efficient operations;
- Maintain records for availability to the public; and
- Provide copies of committee reports to the Committee Management Officer for forwarding to the Library of Congress.

Expiration of a Committee's Charter

Unless the renewal of a committee charter is justified under the FACA, the charter automatically expires after a 2 year period (or as otherwise provided by law).

Advisory Committee Members

Federal advisory committee members are drawn from nearly every occupational and industry group and geographical section of the United States and its territories. The FACA requires that committee memberships be "fairly balanced in terms of the points of view represented and the functions to be performed."

As a result, members of specific committees often have both the expertise and professional skills that parallel the program responsibilities of their sponsoring agencies. In balancing committee memberships, agencies are expected to consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and function of the advisory committee.

Appointing Committee Members

Agency officials, Members of Congress, the general public, or professional societies or current and former committee members may nominate potential candidates for membership on a committee.

Selection of committee members is made based on the FACA's requirements and the potential member's background and qualifications. Final selection is made by the president or heads of departments or agencies.

Prior to accepting an appointment with a Federal advisory committee, each prospective member should clarify his/her role, obligations, duties, allowable expenses, compensation limitations, and any ethics requirements with their committee's Designated Federal Officer and/or Committee Management Officer, as appropriate.

Federal Ethics and Conflict of Interest Laws

Agency officials must provide prospective advisory committee members with information regarding any applicable standards of conduct—including those imposed by federal conflict of interest statutes. In some instances, members may be subject to special limitations during the course of their service on an advisory committee. For some members, these restrictions also may apply (for limited periods) after their committee assignments have ended.

Some agencies may impose additional administrative requirements as well. To avoid potential conflicts, each advisory committee member should assure that he or she receives adequate information from the sponsoring agency and completes any required appointment papers and disclosure forms prior to service on a committee.

Oral briefings and other explanatory material may be obtained through the sponsoring agency's Committee Management Officer, Designated Agency Ethics Official, or from the Office of Government Ethics, which has government-wide jurisdiction on federal ethics issues.

Limits on Membership Terms

Each agency may set limits (unless provided by law or Presidential Directive) on the lengths of terms for serving on advisory committees to allow for new membership.

Open Access to Committee Meetings and Operations

Under the provisions of the Federal Advisory Committee Act, Federal agencies sponsoring advisory committees must:

- Arrange meetings that are reasonably accessible and at convenient locations and times;
- Publish adequate advance notice of meetings in the *Federal Register;*
- Open advisory committee meetings to the public (with some exceptions—see the section on "Government in the Sunshine Act" below);
- Make available for public inspection, subject to the Freedom of Information Act, papers and records, including detailed minutes of each meeting; and
- Maintain records of expenditures.

Government in the Sunshine Act

Advisory committee meetings may be closed or partially closed to the public based upon provisions of the Government in the Sunshine Act of 1976 (Public Law 94–409). Examples of meetings that may be closed under the FACA are:

- Those including discussions of classified information;
- Reviews of proprietary data submitted in support of Federal grant applications; and
- Deliberations involving considerations of personnel privacy.

For More Information . . .

For more information on the requirements of the Federal Advisory Committee Act, contact the General Services Administration's Committee Management Secretariat at *cms@gsa.gov* or via the internet at:

http://www.gsa.gov/faca; or
http://www.gsa.gov/committeemanagement

Examples of materials available on the Committee Management Secretariat website are:

- Federal Advisory Committee Act (*http://www.gsa.gov/portal/content/100916*)
- GSA Final Rule on Federal Advisory Committee Management (*http://www.gsa.gov/portal/content/104034*)
- Guidance documents
- Access to the Federal Advisory Committee Act database (*http://www.facadatabase.gov/*)
- Information on the Federal Advisory Committee Act Training course (*http://www.gsa.gov/portal/content/162635*).

Other materials, such as samples of nominating letters and committee reports, are available from each sponsoring agency.

(Accessed December 10, 2015.)

ATTACHMENT 3

Office of the General Counsel Ethics Division
Revised October 2004 (Previous Editions Obsolete)

Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees (SGEs)

Introduction

This summary has been prepared primarily for individuals appointed to serve as "special Government employees" (SGEs) on Department of Health and Human Services (HHS) advisory committees or Presidential boards, councils, or commissions that are attached to HHS for purposes of administration. The information also will be useful to other SGEs without advisory committee responsibilities, such as "experts or consultants" or "personal services contractors."

New appointees, especially those that provide temporary, intermittent services only a few days a year, often are surprised by, or even resentful of, the complexity of the rules governing Federal employees. The ethics rules do not appear to many people to be logical, intuitive, or even, fair. Ignoring these rules, however, can result in serious consequences or embarrassment, both personally and for the Department. Criminal conflict of interest violations are "strict liability" offenses, and even an inadvertent, "technical" violation will require the initiation of an Inspector General investigation and possible referral to the Department of Justice. Moreover, the entire matter in which a violator participates may be considered so compromised that the Department may have to nullify, cancel, or retract any agency action that is perceived as tainted by the conflict. Therefore, if you have questions on any of the top-

ics covered in this guidance, you should consult with the Designated Federal Official responsible for your committee or the Deputy Ethics Counselor assigned to your operating or staff division.

Definition of a Special Government Employee (SGE)

A "special Government employee" is an officer or employee in the Executive Branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days. 18 U.S.C. § 202(a). This status is important because the ethics rules for SGEs are somewhat *less* restrictive than the rules for other Federal employees and officials. Some members of advisory committees are appointed for a multi-year term. During each year of their term of appointment, committee members generally will not be expected to perform work for HHS in excess of 130 days during any period of 365 consecutive days. Thus, most committee members will be considered "SGEs."

In addition, individuals who provide advice as an "expert or consultant" or render assistance under a "personal services contract" for a period that is not expected to exceed 130 days do so as the functional equivalent of an employee and thus are treated as SGEs for ethics purposes. Only "true" independent contractors are excluded from the definition. Although several factors are evaluated to determine independent contractor status, this category, for the most part, comprises individuals who produce a defined "end product" or "deliverable" without detailed supervision by a Federal employee.

Financial Disclosure Reporting Requirements

HHS advisory committee members appointed as SGEs are required under the Ethics in Government Act, as amended by the Ethics Reform Act of 1989, and 5 CFR Part 2634, to file a financial disclosure report when first appointed and annually thereafter on the anniversary date of their appointment. Committee members also may be required to update the information on the report before each meeting throughout their term of appointment. (Certain committee members are permitted to utilize an alternative reporting system, *e.g.,* FDA Form 3410, that focuses solely on each filer's assets and associational interests that are directly implicated by the subjects on the meeting agenda.) The information reported is used to determine the matters for which a committee member must be disqualified under the criminal financial conflict of interest statute, 18 U.S.C. § 208(a), and the matters for which a committee member may be granted a waiver under 18 U.S.C. § 208(b).

Complete reporting is essential to protect the committee member from inadvertently violating any of the criminal conflict of interest statutes, and to assure the public that the advice provided by an HHS advisory committee is free from any real, or perceived, conflicts of interest. The information reported by committee members is confidential and may not be released except under the limited circumstances described in the Privacy Act notice provided with the report or by order of a Federal court. (SGEs who serve more than 60 days in any period of 365 consecutive days and who are compensated at certain pay levels may be required to file a publicly available financial disclosure report.)

Criminal Conflict of Interest Statutes

The following criminal conflict of interest statutes apply to SGEs:

18 U.S.C* § *201. Section 201, commonly known as the "bribery and illegal gratuities" statute, prohibits Federal employees, including SGEs, from seeking, accepting, or agreeing to receive anything of value in return for being influenced in the performance of an official act.

18 U.S.C.* § *203. Section 203 prohibits an SGE from receiving compensation for *representational services* rendered by the employee or another person before HHS or another Federal agency or other specified entity (such as a court or commission) in any *particular matter involving a specific party* (i) in which the SGE has participated personally and substantially as a government employee, or (ii) which is pending in the government agency in which the SGE is serving if the SGE has served for more than 60 days during the immediately preceding 365 days.

Exempted from this rule are representations required in the proper discharge of official duties. Also exempted are representations determined by the head of the agency to be required in the performance of work under a grant, contract or other agreement with or for the benefit of the government.

A *particular matter involving specific parties* is a matter that is focused upon the interests of identified persons in a specific proceeding or an isolatable transaction or related set of transactions. Examples include, but are not limited to, reviews of grant proposals or contract applications, or similar funding decisions; recommendations or approvals of scientific studies, projects, clinical trials, new drug applica-

tions; and other actions that involve deliberation, decision, or action affecting the legal rights of identified parties.

In contrast, a *particular matter of general applicability* is a matter that is focused on the interests of a discrete and identifiable class of persons or entities, but does not involve specific parties. Examples include recommendations or consideration of legislative proposals, regulatory initiatives, or policy development that affect an industry, group of manufacturers, or health care providers.

Pay close attention to which type of particular matter is involved in your assignment because the ethics rules may differ depending upon whether a "specific party matter" or a "general policy matter" is involved. The terms "matter" or "particular matter," without more description, are deemed to encompass both types.

Representational services include communications (written or oral) and appearances made on behalf of someone else, generally with the intent to influence or persuade the government. An inquiry as to the status of a pending matter is not necessarily a representation, although depending upon the context of the inquiry, it could give rise to the appearance of a prohibited representation.

To avoid appearance problems, during the period in which a committee is in session, committee members are advised not to contact Department staff concerning any matters pending before the agency, or as to which the agency has an interest. Such matters would include, for example, applications for Federal funding, progress reports regarding Cooperative Research and Development Agreements (CRADAS) or clinical trials, and pending drug investigations or applications.

18 U.S.C. § 205. Section 205 prohibits an SGE from *representing* a party, with or without compensation, before HHS or another Federal agency or other specified entity (such as a court or commission) in any *particular matter involving a specific party* in which the United States is a party or has a direct and substantial interest: (i) that the SGE participated in personally and substantially as a government employee; or (ii) which is pending in the agency in which the SGE is serving, if the SGE has served for more than 60 days during the immediately preceding 365 days.

18 U.S.C. § 207. Section 207, the "post-employment" statute, imposes a lifetime ban on a former SGE from *representing* another person or entity to HHS or another Federal agency or other specified entity (such as a court or commission) in any *particular matter involving a specific party* in which the former SGE participated personally and substantially while serving in the government. In addition, for two years after terminating Federal employment, an SGE may not make such representational communications to the government regarding specific party matters that were pending under his or her official responsibility during the last year of government service. Moreover, "senior employees," those paid at an annual rate equivalent to level ES–5 in the Senior Executive Service, are subject to a one-year "cooling-off" period which precludes any contacts with their former agency on any matter for which official action is sought, even if the former employee had no involvement with the matter while in government service. For SGEs, this one-year "cooling-off" period does not apply if the SGE served less than 60 days in the one-year period prior to termination of senior employee status.

18 U.S.C. § 208. Section 208(a), the main *conflict of interest* statute, prohibits an SGE from participating personally and substantially in *any particular matter* that could affect the financial interests of the SGE, the SGE's spouse, minor child, general partner, an organization in which the SGE serves as an officer, director, trustee, general partner, or employee, or an organization with which the SGE is negotiating or with which the SGE has an arrangement for prospective employment.

Under this statute, for example, an SGE would be prohibited from reviewing a grant application submitted by a researcher from the same university in which the SGE is employed, or a contract proposal from an association for which the SGE serves as a member of the board of directors. In these instances, the SGE would be required to recuse from participation in the reviews.

Section 208 might also prohibit the SGE from participating in setting standards for grantees or contractors in general, to the extent that the SGE's university (or any organization with which the SGE is affiliated as an officer or board member) would be affected by those standards. (Under this scenario, however, a waiver could be issued to permit the SGE to participate in such general policy matters. Also, a regulatory waiver might apply to this situation. See discussion below.)

A *waiver* for advisory committee members may be granted under 18 U.S.C. § 208(b)(3). Section 208(b)(3) authorizes issuance of a waiver to an SGE who serves on a committee subject to the Federal Advisory Committee Act if the official responsible for the individual's appointment certifies in writing that the need for the individual's services outweighs the potential for a conflict of interest created by the particular financial interest involved. The waiver granted is considered a "general" waiver, in that it allows participation in matters that affect all institutions, or types

of institutions, similarly. Even with a general waiver, however, SGEs must disqualify themselves from participation in all matters that specifically and uniquely affect their financial interests.

The Designated Federal Official responsible for a committee will explain the procedures for disqualification. SGEs who do not serve on advisory committees are subject to more exacting waiver requirements in 18 U.S.C. § 208(b)(1), and a Deputy Ethics Counselor should be consulted.

In addition, under regulations issued by the Office of Government Ethics, a regulatory (*i.e.,* automatic) waiver of the disqualification requirement of 18 U.S.C. § 208 is available under certain circumstances, including instances involving the following classes of financial interests:

- interests held in broadly diversified investment funds;
- publicly traded securities of $15,000 or less;
- publicly traded securities of $25,000 or less if the matter is a general policy matter and the total value of all investments in the affected industry sector is no more than $50,000;
- employment in one campus of a multi-campus state university if the matter affects only another campus and the employee does not have multi-campus responsibilities.

In addition, there is an automatic exemption which allows SGEs serving on Federal advisory committees to participate in particular matters of general applicability where the otherwise disqualifying financial interest arises solely from the committee member's non-Federal employment or prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class. This exemption is unavailable if the employee (or those persons whose interests are imputed to the employee) owns stock, stock options, or has some other financial interest in the employer other than his or her employment interest.

18 U.S.C* § *219. Section 219 prohibits an SGE from acting as an "agent of a foreign principal" as defined under the Foreign Agents Registration Act (FARA) or a "lobbyist" on behalf of a foreign entity that is required to register under the Lobbying Disclosure Act of 1995 (LDA).

The ban on participating in foreign agent activities covered by FARA prohibits representation of foreign governments or foreign political parties before the United States Government, as well as a number of other activities conducted within the United States on behalf of such entities: (1) political activities; (2) public relations counseling; (3) publicity agent activities; (4) information services; (5) political consulting; and (6) solicitation or disbursement of contributions, loans, money, or other things of value; where such services are rendered with the intent to influence the American public or the government, with reference to formulating the domestic or foreign policies of the United States, or with reference to the political or public interests, policies or relations of a government of a foreign country or a foreign political party.

There are certain FARA exceptions related to trade or commerce, legal representation, humanitarian fundraising, and religious, scholastic, or scientific pursuits. The head of an agency may authorize the employment of an agent for a foreign entity as a special government employee upon a certification that such action is in the national interest. The LDA ban prohibits certain lobbying of covered legislative and executive branch officials on behalf of foreign corporations, associations, or other organizations.

Standards of Ethical Conduct

In addition to criminal statutes, the conduct of SGEs is governed by a series of ethics rules that apply 24 hours per day and even on days during which the SGE provides no Federal services. The following are some of the major Standards of Ethical Conduct regulations (5 CFR Part 2635) that pertain to HHS SGE advisory committee members during the term of their appointment:

*I. Teaching, Speaking and Writing in a Personal Capacity (**i.e.,** Other Than as a Government Employee)*

Generally, during their term of appointment, committee members may continue to receive fees, honoraria, and other compensation for teaching, speaking and writing undertaken in their personal or non-governmental capacities. However, there are some limitations:

(A) An SGE is prohibited from receiving compensation for teaching, speaking, and writing that "relates to the employee's official duties." 5 CFR § 2635.807. The "relatedness" test is met for an SGE if:

(1) the activity is undertaken as an official government duty;

(2) the circumstances indicate that the invitation to engage in the activity was extended to the SGE *primarily* because of the employee's position in the government rather than the employee's expertise in the particular subject matter;

(3) the invitation to engage in the activity or the offer of compensation for the activity was extended to the employee, directly or indirectly, by a person who has interests that may be affected substantially by the performance or nonperformance of the employee's official duties; *or*

(4) the information conveyed through the activity draws substantially on ideas or official data that are confidential or not publicly-available.

(B) Additionally, if a committee member serves for 60 days or less during a one-year period, the SGE may *not* accept compensation for teaching, speaking, and writing if the subject matter of the teaching, speaking or writing concerns a *particular matter involving specific parties* in which the SGE participated or is participating personally and substantially as a government employee.

For example, an AIDS researcher has been appointed to a 4 year term as a member of an advisory committee established for the purpose of surveying and recommending modification of procedures that deter the development of treatments for HIV infection and HIV-related diseases. The committee member is not expected to serve more than 60 days each year during her 4 year term of appointment.

The committee member may accept compensation for an article or speech about the deterrent effect of certain procedures required for clinical investigations and trial designs even though such issues are being discussed by the advisory committee. Clinical procedures in general are *not* a particular matter involving specific parties. The committee member could *not* accept compensation for an article or speech which recounts committee deliberations that took place in a closed meeting, or which relies upon other, non-public information. In addition, the committee member could *not* accept compensation for an article or speech about specific collaborations in the HIV drug development process which were discussed by the committee, since the collaborations are considered a *particular matter involving specific parties.*

(C) If a committee member serves for **more** than 60 days, the SGE is additionally prohibited from receiving compensation for teaching, speaking, and writing if the subject of the activity deals in significant part with any matter to which the SGE is presently assigned or was assigned during the previous one-year period.

Exceptions:

1. This rule does not preclude a committee member from receiving compensation for teaching, speaking, or writing on a subject within the committee member's discipline or inherent area of expertise based on the SGE's educational background or experience. The outside activity must not be about or distinctly related to the work the SGE is providing to the government.
2. These restrictions also do *not* apply to teaching a course requiring multiple presentations that is part of the regularly established curriculum of an institution of higher education, an elementary or secondary school, or a program of education or training sponsored and funded by the Federal, State, or local government.

II. Gifts

Any gift given to a committee member because of the member's service on an HHS advisory committee would raise concerns. The Designated Federal Official responsible for the committee should be consulted should this situation arise. Gifts given to an SGE because of the SGE's position or achievements in the private (non-government) sector generally are not problematic.

III. Charitable Fundraising

A committee member may engage in charitable fundraising in a personal capacity as long as the committee member does not personally solicit funds or other support from any person or entity known to the committee member to be a person or entity whose interests may be substantially affected by the performance or nonperform-

ance of the committee member's Federal duties. 5 CFR § 2635.808. If specific questions concerning particular fundraising events or activities should arise, the Designated Federal Official responsible for the committee should be consulted.

IV. Expert Witness

A committee member cannot serve as an expert witness, in a proceeding before a United States court or agency in which the United States is a party or has a direct and substantial interest, except on behalf of the United States, *if* the committee member participated, while a Federal employee, in the particular proceeding, unless authorized by the HHS Designated Agency Ethics Official (DAEO), who can be reached at (202) 690–7258.

In addition, a committee member who was appointed by the President, serves on a commission established by statute, or has served or is expected to serve for more than 60 days in a period of 365 consecutive days, cannot serve, other than on behalf of the United States, as an expert witness, with or without compensation, in any proceeding before a United States court or agency in which the committee members's employing agency is a party or has a direct and substantial interest unless authorized by the DAEO. 5 CFR § 2635.805.

V. Impartiality

Although committee members are prohibited under 18 U.S.C. § 208(a) from participating in matters in which they have a financial interest, there may be other circumstances in which a committee member's participation in a *particular matter involving specific parties* would raise a question regarding the member's impartiality in the matter. For example, a committee member asked to review a grant application submitted by the SGE's mentor, or someone with whom the SGE has a close personal or professional relationship, would raise a concern about the committee member's impartiality in the review. In such circumstances, the committee member should discuss the relationship with the Designated Federal Official responsible for the committee and a determination will be made as to whether the member should be disqualified from participation in the specific party matter, or should be granted an "authorization" to permit the member to participate in such matter. 5 CFR § 2635.502.

VI. Misuse of Position

Committee members are subject to a number of prohibitions intended to address the use, or appearance of use, of "public office for private gain." 5 CFR Part 2635, Subpart G. These prohibitions include:

(A) Using their HHS titles or referring to their government positions for their own private gain, the private gain of friends, relatives, or anyone with whom they are affiliated in a non-governmental capacity (including nonprofit organizations which they serve as officers, members, employees, or in any other business relationship), or for the endorsement of any product, service, or enterprise.

(B) Using their HHS titles or government positions to coerce or induce another person to provide any benefit to themselves or another person.

(C) Using non-public government information in a financial transaction to further their private interests or those of another, or disclosing confidential or non-public information without authorization.

(D) Using government property for unauthorized purposes.

Employment by, or Gifts from, Foreign Governments

The Constitution prohibits a committee member's employment by a foreign government, including political subdivisions of a foreign government. For SGEs, this provision has particular relevance to positions with foreign universities that are government-operated, as opposed to private institutions. United States Constitution, art. I § 9, cl. 8. There are also statutory provisions restricting acceptance of gifts from foreign governments. 5 U.S.C. § 7342. Committee members should consult with the Designated Federal Official responsible for their committee for details about these restrictions. Employment or consultation with a foreign entity for the purpose of providing foreign agent representation or lobbying is barred by a criminal statute; see the discussion above concerning 18 U.S.C. § 219. All SGEs are required to complete HHS Form 697, Foreign Activities Questionnaire, for the purpose of determining whether a committee member's foreign connections are incompatible with Federal service.

Lobbying Activities

In their official capacities or as a group, committee members are prohibited from engaging in any activity which directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. 18 U.S.C. § 1913. When authorized, committee members may appear before any individual or group for the purpose of informing or educating the public about a particular policy or legislative proposal. Committee members also may communicate to Members of Congress *at the request of any Representative or Senator.* Communications to Members of Congress initiated by committee members, in their official capacity as members of the committee, should be coordinated through the Office of the Assistant Secretary for Legislation.

As private citizens, committee members may express their personal views (but not the views of the committee as a whole or the opinions of HHS) to anyone. In doing so, committee members may state their affiliation with the committee, may factually state the committee's official position on the matter (to the extent that non-public information is not used), but may *not* take new positions and represent those views as the committee's position on the matter. Moreover, in expressing their private views, as with all other personal (non-governmental) activities, committee members are not permitted to use government computers, copiers, telephones, letterhead, staff resources, or other appropriated funds. All personal activities must occur "off duty time."

Committee members are prohibited in their personal capacities from making representations on behalf of others, to the government, on *particular matters involving specific parties* in which they were involved as Federal employees. (See discussion above under 18 U.S.C. §§ 203 and 205.)

Political Activities

The Hatch Act (5 U.S.C. §§ 7321–7326) prescribes the restrictions on certain political activities of Federal employees (see the explanatory chart on the following page). Unlike the criminal conflict of interest statutes and the ethics rules which are fully applicable to an SGE throughout the SGE's entire term of appointment, the Hatch Act restrictions apply only during the period of any day in which the SGE actually is performing government business. For example, if an SGE attends an advisory committee meeting from 8:00 a.m.–1:00 p.m., the SGE could attend a political fund raiser at 3:00 p.m. and even solicit political contributions from the attendees.

A series of criminal political statutes (18 U.S.C. §§ 595, 600–603, 606–607, 610) applies to SGEs even on non-duty hours. These sections, which focus on patronage crimes and election offenses, prohibit coercive "political shakedowns," intimidation regarding political activities, campaign fundraising on Federal property, and the use of public office or authority for the purpose of affecting the outcome of an election.

Hatch Act Political Activity Restrictions

Permissible Activities	Prohibited Activities (while on duty)
• *May be candidates for public office in nonpartisan elections*	• *May not use their official authority to interfere with an election.*
• *May register and vote as they choose.*	• *May not collect political contributions, unless both individuals are members of the same Federal labor organization and the one solicited is not a subordinate employee.*
• *May assist in voter registration drives.*	• *May not knowingly solicit or discourage the political activity of any person who has business before the agency.*
• *May express opinions about candidates and issues.*	• *May not engage in political activity while on duty.*
• *May contribute money to political organizations.*	• *May not engage in political activity in any government office.*
• *May attend and be active at political rallies and meetings.*	• *May not engage in political activity while wearing an official uniform.*
• *May attend political fund raising functions.*	• *May not engage in political activity while using a government vehicle.*
• *May join and be an active member of a political party or club.*	• *May not solicit political contributions from the general public.*
• *May sign nominating petitions.*	• *May not actively participate as a candidate for public office in a partisan election.*
• *May campaign for or against referendum questions, constitutional amendments, municipal ordinances.*	
• *May campaign for or against candidates in partisan elections.*	
• *May distribute campaign literature in partisan elections.*	
• *May hold office in political clubs or parties (except Treasurer).*	

ATTACHMENT 4

Initial Meeting Materials

Charge to the 2015 Dietary Guidelines Advisory Committee

The *Dietary Guidelines for Americans* provide science-based advice on how nutrition and physical activity can help promote health and reduce the risk for major chronic diseases. The Guidelines form the basis of Federal nutrition policy, standards, programs, and education for the general public. The *Dietary Guidelines* are published jointly by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture every 5 years.

The Dietary Guidelines Advisory Committee (DGAC), whose duties are time-limited and solely advisory in nature, will:

- Examine the *Dietary Guidelines for Americans, 2010* and determine topics for which new scientific evidence is likely to be available that may inform revisions to the current guidance or suggest new guidance.
- Place its primary focus on the systematic review and analysis of the evidence published since the last DGAC deliberations.
- Place its primary emphasis on the development of food-based recommendations that are of public health importance for Americans ages 2 years and older.
- Prepare and submit to the Secretary of Health and Human Services and the Secretary of Agriculture a report of technical recommendations, with rationales, to inform the development of the *2015 Dietary Guidelines for Americans.* DGAC responsibilities include providing authorship for this report; however, responsibilities do not include translating the recommendations into policy or into communication and outreach documents or programs.
- Disband upon the submittal of the Committee's recommendations via the *Report of the Dietary Guidelines Advisory Committee on the* ***Dietary Guidelines for Americans, 2015*** to the Secretaries.
- Complete all work within the required 2 year charter time frame.

(Accessed December 10, 2015.)

ATTACHMENT 5

Charter

2015 Dietary Guidelines Advisory Committee Authority

The 2015 Dietary Guidelines Advisory Committee (the Committee or 2015 DGAC) is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C., App.), which sets forth standards for the formation and use of advisory committees.

Objectives and Scope of Activities

Under Section 301 of Public Law 101–445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III) the Secretaries of Health and Human Services (HHS) and Agriculture (USDA) are directed to jointly issue at least every 5 years a report entitled *Dietary Guidelines for Americans.* The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public, shall be based on the preponderance of scientific and medical knowledge current at the time of publication, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program. The *Dietary Guidelines for Americans* was issued voluntarily by HHS and USDA in 1980, 1985, and 1990; the 1995 edition was the first statutorily mandated report, followed by subsequent editions at the appropriate intervals.

The 2015 DGAC is established to provide independent, science-based advice and recommendations for development of the *Dietary Guidelines for Americans, 2015,* which forms the basis of Federal nutrition programs, nutrition standards, and nutrition education for the general public. A variety of services and tools will be made available to the Committee to support development of recommendations that promote health and reduce chronic disease risk for Americans. The USDA Nutrition Evidence Library will assist the Committee in conducting and creating a transparent database of systematic reviews reflecting the most current research available on a wide range of food and nutrition-related topics to inform its recommendations.

Description of Duties

The work of the Committee will be solely advisory in nature and time-limited. The Committee will examine the current *Dietary Guidelines for Americans,* take into consideration new scientific evidence and current resource documents, and then develop a report to be submitted to the Secretaries that outlines its science-based recommendations and rationale which will serve as a basis for developing the eighth edition of *Dietary Guidelines for Americans.*

Agencies or Officials to Whom the Committee Reports

The HHS Assistant Secretary for Health and USDA Under Secretaries of the Food, Nutrition, and Consumer Services (FNCS) and Research, Education and Economics (REE) will provide guidance and oversight for the Committee's function and activities.

Support

Management and support services for the 2015 DGAC primarily will be provided by the Office of Disease Prevention and Health Promotion (ODPHP) within the Department of Health and Human Services. The ODPHP is a program office within Office of the Assistant Secretary for Health (OASH), which is a staff division in HHS Office of the Secretary. Responsibility for administrative services will be shared with staffs of the USDA FNCS and REE. USDA administrative leadership and Nutrition Evidence Library support will come from the Center for Nutrition Policy and Promotion within FNCS. REE agencies will provide administrative and data analysis support.

Estimated Annual Operating Costs and Staff Years

The estimated annual HHS cost for operating the DGAC, including travel and per diem expenses for members, but excluding staff support is $400,000. It is estimated that the annual person-years of HHS staff support required is 4.4 FTEs, at an estimated cost of $430,000.

Designated Federal Officer

The HHS Assistant Secretary for Health will appoint two Co-Executive Secretaries from HHS, one of whom will serve as the Designated Federal Officer (DFO). USDA Under Secretaries of FNCS and REE will appoint two Co-Executive Secretaries from USDA, one from the Center for Nutrition Policy and Promotion, who will serve as the lead for USDA, and the other from the Agricultural Research Service.

Since HHS has responsibility for providing management support for the 2015 DGAC, the HHS Co-Executive Secretaries will, in collaboration with the USDA Co-Executive Secretaries, schedule and approve all meetings of the 2015 DGAC, and make logistical arrangements that are necessary for public meetings of the 2015 DGAC, including meetings of any established subgroups. The DFO, in collaboration with the USDA Co-Executive Secretaries, will prepare and approve all meeting agendas; development of the meeting agenda also can include consultation with the Committee Chair.

The DFO or other official to whom the authority has been delegated will be present at all meetings of the full Committee and any subgroups that have been established to assist the Committee. The DFO has authority to adjourn meetings, when it is determined to be in the public interest, and may also chair the committee meetings when directed to do so by the Assistant Secretary for Health and/or other authorized official.

Estimated Number and Frequency of Meetings

It is estimated that the 2015 DGAC will meet approximately five times during the projected period for its operation. More meetings will be held if it is necessary to accomplish the mission of the Committee and funds are available to support additional meetings. It is required that ⅔ of the appointed members be present for the Committee to meet to conduct business. Meetings will be open to the public, except as determined otherwise by the Secretaries of HHS and USDA or other official to whom this authority has been delegated, in accordance with guidelines under Government in the Sunshine Act at 5 U.S.C. 552b(c) and the FACA. Notice of all meetings will be provided to the public. Meetings will be conducted and records of the proceedings will be kept, as required by applicable laws and Departmental policies.

Duration

The 2015 DGAC is established to accomplish a single, time-limited task. It is expected that the Committee will complete the mission for which it was established within two years from the date this charter is filed.

Termination

Unless renewed by appropriate action prior to its expiration, the 2015 DGAC will terminate after delivery of its final report to the Secretaries of HHS and USDA or 2 years from the date this charter is filed, whichever comes first.

Membership and Designation

The 2015 DGAC will consist of not more than 17 members, with the minimum number being 13; one or more members will be selected to serve as the Chair, Vice Chair, and/or Co-Chairs. Individuals will be selected to serve as members of the Committee who are familiar with current scientific knowledge in the field of human nutrition and chronic disease. Expertise will be sought in specific specialty areas that may include but are not limited to cardiovascular disease; type 2 diabetes; overweight and obesity; osteoporosis; cancer; pediatrics; gerontology; maternal/gestational nutrition; epidemiology; general medicine; energy balance, which includes physical activity; nutrient bioavailability; nutrition biochemistry and physiology; food processing science, safety and technology; public health; nutrition education and behavior change; and/or nutrition-related systematic review methodology.

Members will be invited to serve for the duration of the Committee. Individuals who are appointed to serve as members of the Committee will be jointly agreed upon by the Secretaries of HHS and USDA. All appointed members of the 2015 DGAC will be classified as special government employees (SGEs).

Pursuant to an advance written agreement, the appointed members will receive no compensation for the advisory service they render during their tenure on the 2015 DGAC. However, as authorized by law and in accordance with Federal travel regulations, members of the 2015 DGAC will receive per diem and reimbursement for travel expenses incurred while performing duties and/or conducting business related to the Committee.

Subcommittees/Working Groups

To accomplish its mission, and with approval of the official to whom authority has been given, the 2015 DGAC may establish subcommittees and/or working groups that are composed of members of the parent committee and non-member special consultants and/or individuals with demonstrated expertise in the specialty areas designated for the Committee membership.

The established subgroups will provide advice and/or make recommendations to the parent committee. All reports and recommendations developed by an established subgroup of the 2015 DGAC must be submitted to the parent committee for the appropriate action to be taken. An established subgroup may not report its findings to any Federal official unless there is specific statutory authority for such reporting.

The Department Committee Management Officer will be notified if any subgroup is established for the 2015 DGAC, and will be provided information regarding the name of the subgroup, function, membership, and estimated frequency of meetings.

Recordkeeping

Records of the Committee and any established subgroup will be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be made available to the public for inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date: February 19, 2013

Approved

January 9, 2013
Date

//s//
KATHLEEN SEBELIUS

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