Potential Impact of House Appropriations Riders on 2015 Dietary Guidelines: Why is Congress Playing Politics with Evidence-Based Tools to Improve Public Health?

The U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) complete a revised Dietary Guidelines for Americans (DGA) every five years. The DGA provide a crucial scientific basis for federal nutrition policy, programs, and nutrition promotion and education. The Guidelines also provide critical science-based advice to the public to help promote health and prevent chronic disease. As two-thirds of Americans are currently overweight or obese and half of the country suffers from chronic diet-related disease, the DGA is a critical tool to ascertain the scientific basis for improvements to public health.

The process to develop the DGA is expansive, transparent, and thoughtful, with multiple opportunities for public input. The Dietary Guidelines Advisory Committee (DGAC) is a 14-member committee of independent scientists convened by the Departments of Agriculture and Health and Human Services ("the Departments"). The 2015 DGAC spent 20 months reviewing the latest scientific evidence on nutrition and physical activity. Like previous iterations of the DGA, their core recommendations focus on a healthy dietary pattern that includes more fruit, vegetables, whole grains and fiber. They also conclude that Americans should consume fewer added sugars, salt, and saturated fat and that Americans should be physically active for health promotion.

The 2015 DGAC Report focuses on the recently developed body of evidence linking food and lifestyle choices to chronic disease. The expert report was developed through a public consultation process, and stakeholders submitted comments during the preparation of the report as well as a recently closed notice and comment period on the full report that was extended for an additional 30 days. Now, the Departments are reviewing the public comments and preparing the final Dietary Guidelines document.

Riders in the proposed Agriculture and Labor/HHS appropriations bills now under consideration in the U.S. House of Representatives would severely curtail the scope and development of the 2015 DGA. At this late stage in the process, the riders would undercut the process of the DGA by freezing the Guidelines' development in time: the riders would limit the level of scientific support the DGA could consider in making any changes to the recommendations in the 2015 DGA to those that received a "Strong" rating and bar any revisions to recommendations not directly related to "diet or nutrient intake."

These arbitrary limitations would produce absurd consequences, allowing Congress to over-ride a carefully executed scientific process. In effect, the riders would gag the 2015 panel by limiting key recommendations regarding new rationales for dietary changes – even those supported by ample science in the panel's expert, informed judgment. The riders would also randomly excise from the DGA critical information about our evolving scientific understanding linking chronic disease and diet.

For example, though the 2015 DGA could continue to advise consumption of a diet rich in fruits, vegetables and whole grains, it could not *upgrade* its rationales to reflect the full body of evidence linking such a healthy diet to reductions in the risk of type-2 diabetes or obesity –

critical public health concerns impacting millions of Americans. And due to the 'diet and nutrient intake' limitation in the riders, the 2015 DGA would be barred from updating advice on physical activity, regardless of advances in science, even from evidence rated as "Strong."

The rider also would block any new policy-based recommendations to advise communities, schools, workplaces or local governments on helpful changes to the food environment to support people's ability to follow the Dietary Guidelines. A diet rich in nutrient-dense foods has been recommended for several past installments of the Guidelines, yet obesity and disease in America continue to proliferate. Policy tools, such as the 2015 DGAC Report recommendation that workplaces implement health and wellness programs, are critically important because they furnish mechanisms to align the food environment with the DGA recommendations.

The restrictions also create scientific inconsistency – although many recommendations in the 2010 guidelines were based on 'Grade 2: Moderate' ratings, these recommendations would be "grandfathered" into the 2015 Guidelines. Had the 2010 Guidelines operated under similar unreasonable restrictions, that DGA would have been barred from recommending many common-sense measures, including that children spend less time watching television, or that families consume fewer fast food meals.

The riders are inconsistent with sound scientific practice. They would undermine the clear purpose, public health goals and process of the DGA. Our analysis of the riders' arbitrary decision rule revealed that only a handful of new conclusions by the 2015 DGAC (described in appendix A of this document) would be allowed as the basis for new recommendations. Given the health challenges currently facing Americans, it is essential that an official government report reflect up-to-date, science-based diet and fitness guidance. These unnecessary and anti-science riders should be removed from both Agriculture and Labor/HHS appropriations.

The Harmful Proposed Appropriations Riders

Appropriations riders in the Agriculture and Labor/HHS bills being considered in the House of Representatives state that "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 eight 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; and
- (B) Shall be limited in scope to only matters of diet and nutrient intake.

Recommended changes to the 2010 Dietary Guidelines for Americans by the 2015 Dietary Guidelines Advisory Committee (DGAC) would be considered only if those recommendations

¹ Millen, B. E. (2015, January 28). Letter to the Secretaries, Department of Health and Human Services. *Cover letter included with the 2015 Dietary Guidelines Advisory Report*. Retrievable at http://health.gov/dietaryguidelines/2015-scientific-report/00-cover-letter.asp. (Hereinafter "2015 DGAC Report Cover Letter").

are based on conclusions rated "Grade I: Strong" using a rubric developed by the Nutritional Evidence Library (NEL) guidelines and are specific to diet and nutrient intake.

Development of the DGA Includes Ample Process to Support Sound Science

The National Evidence Library works with the Dietary Guidelines Advisory Committee to design the methodology for creating the DGAC Scientific Report. Before making recommendations, DGAC creates a set of "systematic review questions" they desire to answer in their report, and create a search plan for the relevant scientific databases.²

After designing the questions for study and a search plan, studies are selected and analyzed, and conclusion statements are constructed to answer questions laid out in the first stages. The NEL grading system applies to these conclusion statements. All of the evidence used to come to a conclusion is reviewed and the conclusion is graded based on how strongly it is supported by that evidence. The appropriations bill states that the Dietary Guidelines cannot be amended or added to via DGAC recommendations that are not based on conclusions with a Grade I: Strong rating.

The "Strong" rating imposes very stringent requirements, included at the end of this document. A "Grade I: Strong" rating requires that *all* studies on the topic have *consistent* findings and that there are several good quality studies. This rating would exclude perfectly solid conclusions based on new studies that have not yet been repeated, as well as studies sponsored by competing interest groups in which disparate results are almost inevitable. The mere presence of conflict, however explained it might be by study design, can be sufficient to downgrade a finding.

Damage to the DGA 2015 from the Riders

It would be back to the future for the DGA if the House rider is enacted. The 2015 DGA would have to look nearly identical to the 2010 DGA, with only a handful of 'strong' and 'diet and nutrient intake'-related recommendations able to be added to the report (see Appendix A). The exclusion of updates recommended by the 2015 DGAC Report is nonsensical and amounts to a political gag on the government's ability to provide science-based advice, which have already been the subject of an extensive public consideration process.

The exclusions would include:

• The 2015 DGA would not be able to use a decreased risk of obesity or type-2 diabetes as a reason to promote a diet high in fruits, vegetables, whole grains, nuts, legumes, unsaturated oils, low-fat dairy, poultry and fish and low in red and processed meat, high-fat dairy, and sugar-sweetened foods and drinks.

• The new Guidelines would not be able to advise parents to use meal times to role model a healthy eating pattern for their children.

² The NEL methodology also requires a search plan that may only include studies on human subjects with "subject populations from countries with high human development," among other limitations, thus excluding animal studies or other studies that might provide useful information. DGAC does not use the NEL search limitations for all of the studies it considers. However, the DGAC does use the NEL grading rubric to assess all of its conclusions. See *Part C: Methodology of the Dietary Guidelines Advisory Committee Scientific Report 2015*, available at http://health.gov/dietaryguidelines/2015-scientific-report/05-methodology.asp

- The new Guidelines would not be able to advise that families in federal food assistance programs be counseled to choose healthy foods within their limited budgets.
- The 2015 DGA would not be able to advise that workplaces implement health and wellness programs.
- The DGA would not be able to explicitly recommend an added sugars section on the Nutrition Facts Panel or front-of-package labeling regarding added sugars in foods.
- The 2015 Guidelines would not be able to recommend economic or other incentives to decrease consumption of added sugars.
- The 2015 DGA would not be able to encourage physical activity based on the decreased risk it promises for cardiovascular disease, bone disease, anxiety and depression, cardiorespiratory illness, hypertension, diabetes, colon cancer, and breast cancer.
- The new Guidelines would not be able to advise disabled people to exercise in order to improve cardiovascular, muscular, skeletal and mental strength.
- The new Guidelines would not be able to inform older adults of the benefits of low-intensity physical activity, such as reduction in falls and improved quality of life.
- The 2015 DGA would not be allowed to propose many practical changes to the food system to further their dietary advice, such as advising food manufacturers to reformulate their dishes to include less sodium and saturated fat.
- The 2015 Guidelines would also be restricted from proposing policy changes in the healthcare system, including a paradigm shift from treatment to prevention of diet-related disease.

Specific Public Health Messages Excluded by the Riders

1. Dietary patterns and health

As already put forth in the 2010 Guidelines, the 2015 DGAC Report recommends a diet high in fruits, vegetables, whole grains, nuts, legumes, unsaturated oils, low-fat dairy, poultry and fish and low in red and processed meat, high-fat dairy, and sugar-sweetened foods and drinks. However, while in the 2010 Guidelines this diet was recommended as generally healthy, the 2015 DGAC Report points to the benefits of this diet in reducing the risk of obesity and type-2 diabetes.³ As one-half of Americans currently suffer from a preventable, diet-related chronic

There is moderate evidence that, in adults, increased adherence to dietary patterns scoring high in fruits, vegetables, whole grains, legumes, unsaturated oils, and fish; low in total meat, saturated fat, cholesterol, sugar-sweetened foods and drinks and sodium; and moderate in dairy products and alcohol is associated with more favorable outcomes related to body weight or risk of obesity, with some reports of variation based on gender, race or body weight status. (Moderate)

³ The following conclusions were rated 'Moderate' or 'Limited':

[•] There is moderate evidence that adherence to a dietary pattern that emphasizes vegetables, fruits, and whole grains is associated with modest benefits in preventing weight gain or promoting weight loss in adults. (Moderate)

[•] Dietary patterns in childhood or adolescence that are higher in energy-dense and low-fiber foods, such as sweets, refined grains, and processed meats, as well as sugar-sweetened beverages, whole milk, fried potatoes, certain fats and oils, and fast foods increase the risk of obesity later on in life.(Limited).

[•] There is limited evidence that adherence to a dietary pattern rich in fruits, vegetables, legumes, cereals/whole grains, nuts, fish, and unsaturated oils, and low in meat, and high fat dairy, assessed using an index or score, is associated with decreased risk of type 2 diabetes. (Limited)

disease, 4 it is important to allow the DGA to publish specific recommendations linking diet to reductions in those diseases.

2. Individual food and fitness choices

Many of DGAC's recommendations about food and fitness choices can be used, because they were already included in the 2010 report *despite being based on conclusions that received less than a 'strong' rating.* For example, a recommendation that Americans eat fewer meals from fast food restaurants is based on a body of evidence rated "Moderate" or "Limited." Similarly, the 2010 Guidelines stressed calorie-counting and monitoring portion sizes, while the 2015 DGAC Report found only "Moderate" evidence to support this practice. 6

Should the appropriations riders be enacted, the following would have to be cut from the DGA:

- The DGA would not be able to advise that families use meal times to role model a healthy eating pattern.⁷
- The DGA would not be able to advise that families in federal food assistance programs be counseled to choose healthy foods within their limited budgets.⁸

3. Food environment and settings

The 2015 DGAC uses moderate evidence⁹ to recommend that workplaces implement health and wellness programs to encourage diet and behavioral changes in employees. Under the appropriations rider these recommendations would be excluded by the 2015 DGA.

- Moderate evidence indicates that multi-component worksite approaches⁹ can increase vegetable and fruit consumption of employees. (Moderate).
- Moderate and consistent evidence indicates that worksite nutrition policies, alone and in combination with environmental changes and/or individual-level nutrition and health improvement strategies, can improve the dietary intake of employees. Multi-component interventions appear to be more effective than singlecomponent interventions. (Moderate)
- Moderate and consistent evidence indicates that multi-component worksite approaches targeting physical activity and dietary behaviors favorably affect weight-related outcomes. (Moderate).

⁴ 2015 DGAC Report Cover Letter.

⁵ Based on the following 'Limited' and 'Moderate' conclusions:

[•] Among children and adults, limited to moderate evidence from prospective cohort studies in populations ages 40 years or younger at baseline indicates higher frequency of fast food consumption is associated with higher body weight, body mass index (BMI), and risk for obesity. (children – Limited, adults -Moderate)

⁶ Based on the following 'Moderate' conclusion:

[•] Moderate evidence, primarily in overweight adult women living in the United States, indicates that self-monitoring of diet, weight, or both, in the context of a behavioral weight management intervention, incorporating goal setting and performance feedback, improves weight-loss outcomes. (Moderate)

⁷ Based on the following 'Limited' conclusion:

^{• &#}x27;Limited evidence from prospective studies shows inconsistent relationships between the number of family shared meals and body weight of children and adolescents. (Limited)'

⁸ Based on the following 'Limited' conclusion:

^{• &#}x27;Limited and inconsistent evidence from studies conducted in adults and children ages 3 to 6 years suggests that a positive association may exist between persistent and/or progressing household food insecurity and higher body weight in older adults, pregnant women, and young children. No studies reported a relationship with lower body weight. (Limited).'

⁹ Based on the following 'Moderate' conclusions:

4. Food sustainability and safety

Sustainability

The 2010 Guidelines do advise a diet rich in fruits and vegetables, but not for reasons of sustainability. As sustainability is not related to 'matters of diet or nutrient intake,' the 2015 DGA would not be able tout sustainability as a supporting rationale for a diet rich in plant-based foods.¹⁰

Coffee

Despite a 'moderate'-rated conclusion that moderate coffee consumption is associated with a reduced risk of type 2 diabetes and liver and endometrial cancer, the 2015 DGA would not be able to recommend moderate coffee consumption to reduce risk of these diseases.

5. Cross-cutting topics of public health importance

Added sugars

The recommendation that Americans should restrict added sugars to less than 10% of their daily energy intake is supported by strong evidence and related to diet and nutrient intake. However, some of the recommendations based on this strong evidence are not related to diet and nutrient intake and would be excluded:

¹⁰ Based on the following 'Strong' and 'Moderate' conclusions:

- The DGAC concurs with the FAO report that consistent evidence demonstrates that capture fisheries increasingly managed in a sustainable way have remained stable over several decades. However, on average, capture fisheries are fully exploited and their continuing productivity relies on careful management to avoid over-exploitation and long-term collapse. (Strong, but not related to 'diet and nutrient intake.')
- Consistent evidence indicates that, in general, a dietary pattern that is higher in plant-based foods, such as vegetables, fruits, whole grains, legumes, nuts, and seeds, and lower in animal-based foods is more health promoting and is associated with lesser environmental impact (GHG emissions and energy, land, and water use) than is the current average U.S. diet. A diet that is more environmentally sustainable than the average U.S. diet can be achieved without excluding any food groups. The evidence consists primarily of Life Cycle Assessment (LCA) modeling studies or land-use studies from highly developed countries, including the United States.(Moderate)
- ¹¹ Based on the following 'Strong' and 'Moderate' conclusions:
 - Strong and consistent evidence shows that intake of added sugars from food and/or sugar-sweetened beverages are associated with excess body weight in children and adults. The reduction of added sugars and sugar-sweetened beverages in the diet reduces body mass index (BMI) in both children and adults. Comparison groups with the highest versus the lowest intakes of added sugars in cohort studies were compatible with a recommendation to keep added sugars intake below 10 percent of total energy intake.(Strong and related to diet and nutrient intake)
 - Strong evidence shows that higher consumption of added sugars, especially sugar-sweetened beverages, increases the risk of type 2 diabetes among adults and this relationship is not fully explained by body weight. (Strong and related to diet and nutrient intake).
 - The DGAC concurs with the World Health Organization's commissioned systematic review that moderate consistent evidence supports a relationship between the amount of free sugars intake and the development of dental caries among children and adults. Moderate evidence also indicates that caries are lower when free-sugars intake is less than 10 percent of energy intake. (Moderate, but established in the 2010 Dietary Guidelines)

- A section for "added sugars" on the Nutrition Facts Panel
- Front-of-package labeling regarding added sugars in foods
- Economic incentives to decrease consumption of added sugars, such as a sugarsweetened beverage tax

6. Physical activity

Exercising to prevent disease

The 'diet and nutrient intake' restrictions would mean the 2015 DGA can make no new recommendations related to physical activity. The Dietary Guidelines have long included physical activity as an important component of weight management, however, the 2015 DGAC Report lays out strong new evidence that physical activity can reduce the risk of cardiovascular disease, increase bone health, reduce anxiety and depression, enhance cardiorespiratory fitness, and protect against hypertension, diabetes, colon cancer, and breast cancer. Because the 2010 DGA did not address exercise in relation to disease, the 2015 DGA would be excluded from highlighting these additional incentives to exercise, which might motivate people to engage in more physical activity.

Exercise in particular groups

Some exercise recommendations in the 2015 DGAC Report are based on studies of the effects of exercise on older and disabled people, but would be excluded under the appropriations rider recommendations because they are not related to diet or nutrient intake:

- Disabled people should exercise to improve cardiovascular, muscular, skeletal and mental strength ¹².
- Older adults should regularly engage in lower-intensity physical activity to reduce chance of falling and improve quality of life. ¹³

7. Unrated policy recommendations

• For people with physical disabilities, strong evidence shows that exercise can increase cardiorespiratory, musculoskeletal, and mental health outcomes; and for people with cognitive disabilities, strong evidence shows that exercise can improve musculoskeletal health and select functional health and mental health outcomes. (Strong but not related to diet or nutrient intake)

- Because the exercise capacity of adults tends to decrease as they age, older adults generally have lower exercise capacities than younger persons. Thus, they may need a physical activity plan that is of lower absolute intensity and amount (Strong but not related to diet or nutrient intake)
- For older adults at risk of falling, strong evidence exists that regular physical activity is safe and reduces falls by about 30 percent (Strong but not related to diet or nutrient intake).
- In older adults with existing functional limitations, fairly consistent evidence indicates that regular physical activity is safe and has a beneficial effect on functional ability. Consistent evidence indicates that physically active adults and older adults have better quality sleep and health-related quality of life (Moderate).

¹² Based on the following 'strong' conclusions:

¹³ Based on the following 'Strong' and 'Moderate' conclusions:

The 2015 DGAC Scientific Report contains many recommendations based on prevalence data and research conducted by the committee that were not rated using the NEL rubric. These recommendations would be summarily ignored by the 2015 DGA. These include:

- Proposed real changes to food policy that would help Americans decrease consumption
 of sodium, saturated fat and added sugars, like advising food manufacturers to
 reformulate their dishes to contain less sodium or saturated fat and recommending free
 water in all public settings.
- Recommendations that connect obesity with disease and suggest a healthcare shift from treatment to prevention of diet-related diseases.
- A long list of topics that the Committee felt needed further research, including research that would investigate the true benefits of fortified processed foods.

Appendix A: 2015 DGAC Report additions to 2010 DGA allowed by rider

Appendix A: 2015 DGAC Report add	Appendix A: 2015 DGAC Report additions to 2010 DGA allowed by rider				
Conclusions	Recommendations				
There is strong and consistent evidence that in	Like the 2010 Guidelines, the 2015				
healthy adults increased adherence to dietary	Guidelines can recommend that Americans				
patterns scoring high in fruits, vegetables,	eat diets high in plant foods and low in red				
whole grains, nuts, legumes, unsaturated oils,	and processed meats and sugary foods. In				
low-fat dairy, poultry and fish; low in red and	addition, the Guidelines can recommend				
processed meat, high-fat dairy, and sugar-	specifically that people with CVD or looking				
sweetened foods and drinks; and moderate in	to avoid CVD should eat these foods, as they				
alcohol is associated with decreased risk of	are associated with lower risk.				
fatal and non-fatal cardiovascular diseases,					
including coronary heart disease and stroke.					
(Strong, related to diet and nutrient intake)					
Strong evidence demonstrates that	The 2015 Guidelines can recommend				
implementing school policies for nutrition	improvements in school food.				
standards to improve the availability,					
accessibility, and consumption of healthy					
foods and beverages sold outside the school					
meal programs (competitive foods and					
beverages) and (or) reducing or eliminating					
unhealthy foods and beverages are associated					
with improved purchasing behavior and result					
in higher quality dietary intake by children					
while at school. (Strong).					
Strong and consistent evidence shows that	The 2015 Guidelines can recommend that less				
intake of added sugars from food and/or	than 10% of total energy intake be from				
sugar-sweetened beverages are associated	added sugars.				
with excess body weight in children and					
adults. The reduction of added sugars and					
sugar-sweetened beverages in the diet reduces					
body mass index (BMI) in both children and					
adults. Comparison groups with the highest					
versus the lowest intakes of added sugars in					
cohort studies were compatible with a					
recommendation to keep added sugars intake					
below 10 percent of total energy					
intake.(Strong, related to diet, nutrient intake)					
Strong evidence shows that higher	The 2015 Guidelines can recommend that				
consumption of added sugars, especially	Americans consume less added sugar to				
sugar-sweetened beverages, increases the risk	decrease their risk of type-2 diabetes.				
of type 2 diabetes among adults and this					
relationship is not fully explained by body					
weight. (Strong and related to diet and					
nutrient intake).					

APPENDIX B: USDA Nutrition Evidence Library Conclusion Statement Evaluation Criteria Criteria for judging the strength of the body of evidence supporting the Conclusion Statement

Elements	Grade I: Strong	Grade II: Moderate	Grade III: Limited	Grade IV: Grade Not Assignable*
Quality (as determined using the RDI checklist) •Scientific rigor and validity •Consider study design and execution	Studies of strong design Free from design flaws, bias, and execution problems	Studies of strong design with minor methodological concerns OR only studies of weaker study design for question	Studies of weak design for answering the question OR inconclusive findings due to design flaws, bias, or execution problems	Serious design flaws, bias, or execution problems across the body of evidence
Consistency of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with very minor exceptions	Some inconsistency in results across studies in direction and size of effect, degree of association, or statistical significance	Unexplained inconsistency among results from different studies	Independent variables and/or outcomes are too disparate to synthesize OR single small study unconfirmed by other studies
QuantityNumber of studiesNumber of subjects in studies	Several good quality studies, Large number of subjects studied, Studies have sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Available studies do not directly answer the question OR no studies available
Impact •Directness of studied outcomes •Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful	Some study outcomes relate to the question indirectly Some doubt about the clinical significance of the effect	Most studied outcomes relate to the question indirectly Size of effect is small or lacks clinical significance	Studied outcomes relate to the question indirectly Size of effect cannot be determined
Generalizabilityto the U.S. population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Highly unlikely that the studied population, intervention AND/OR outcomes are generalizable to the population of interest