



The Honorable Sonny Perdue
Secretary
U.S. Department of Agriculture
Washington DC, 20250

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
Washington DC, 20201

June 2, 2020

Dear Secretaries Purdue and Azar:

This letter is intended to alert you to the fact that one or more individuals that comprise the Dietary Guidelines Advisory Committee (DGAC/Committee) recently contacted us with several concerns regarding the Committee process and the review of scientific studies. Due to these concerns, we request that you immediately extend the due date for the submission of the DGAC expert report to the U.S. Departments of Agriculture and Health and Human Services (USDA-HHS), in order to take time to investigate the allegations made by this/these DGAC member(s).

Introduction

The Dietary Guidelines for Americans (DGA/Guidelines) has since 1980 been the government's principal policy providing nutrition recommendations for Americans. The Guidelines are statutorily mandated, requiring that both USDA and HHS jointly update the DGA once every five years. These Guidelines are critical, as they are wide-reaching, influencing government feeding assistance programs and other federal policies. They also influence healthcare practitioners, nutrition educators, and stakeholders in public health, nutrition, and agriculture, as well as the food and pharmaceutical industries.

Importantly, to assess the science that underpins the Guidelines, USDA and HHS are directed, for each iteration of the DGA, to establish a committee of university experts with experience in nutrition science and research. This DGAC, whose work is intended to be advisory, is specifically tasked with reviewing the scientific data relevant to nutritional guidance and making recommendations to the Secretaries of USDA and HHS. It is our understanding that these recommendations are due to you by mid-June 2020.

Many substantive concerns were raised regarding the 2015 DGAC report and the process used to develop the 2015-2020 Guidelines.¹ In response, Congress mandated the National Academies of Sciences, Engineering, and Medicine (NASEM) to review the DGA process, resulting in two reports in

¹ Public Hearing by the Full Committee on Agriculture: "2015 Dietary Guidelines for Americans," October 07, 2015. <https://republicans-agriculture.house.gov/calendar/eventsingle.aspx?EventID=2731>

2017,² at a cost to taxpayers of approximately one million dollars.³ In those reports, which comprised the first-ever outside peer-review of the DGA process, the NASEM identified a series of clear recommendations intended to strengthen the scientific integrity of the DGA process, including measures to enhance transparency, manage biases and conflicts of interest, and most importantly, to ensure that the DGA is based upon rigorous, up-to-date scientific data.

Unfortunately, it appears that regarding many of the issues needing reform, the USDA and HHS rejected the NASEM recommendations and therefore appear on track to produce yet another DGA that lacks scientific rigor and will fall far short of being the trustworthy, reliable guidance that Americans need. The issue is especially important given the continued increases in rates of all diet-related diseases in the U.S. and additionally, the increased risk these individuals experience for more serious coronavirus-related outcomes, including death.

The Concerns

A. Lack of Time to Finish the Scientific Reviews

The member(s) of the DGAC who contacted us expressed concern that the committee could not finish its work properly in the time allotted. For example, at the final public meeting of the DGAC, in March, the following was stated (with emphases added):

“...we have draft conclusion statements, but **we have not yet finished grading those**, so those will not be presented today,”

--Sharon Donovan, for the Subcommittee on Pregnancy and Lactation, 3/12, AM at min 2:14:03.

“For diets based on macronutrient distribution and this outcome, **the full body of evidence is still under review**. And again, though, these are drafts,”

--Carol Boushey, for the Subcommittee on Dietary Patterns, 3/12PM at min 45:24.

“Due to the short timeframe relative to the workload volume, **the subcommittee updated the following exclusion criteria to narrow and strengthen the review**...[including] We excluded studies that assessed serum/lipid ratios solely as outcomes. We also excluded studies that only assessed blood pressure as an intermediate outcome in adults.”

--Linda Snetselaar for the Seafood and Dietary Fats Subcommittee, 3/13AM at 1:36:59

In these cases, there is a fundamental problem that the unfinished work will not be presented at a public meeting and therefore that this omission, at a minimum, will result in a lack of transparency.

B. Reviews Deleted or Added by the DGAC Without Public Notice

- Without public notice, the DGAC appears to have dropped its reviews of the vegan/vegetarian diet, which is [included on the original list of topics to be reviewed](#).

² National Academies of Sciences, Engineering, and Medicine. 2017. *Optimizing the process for establishing the Dietary Guidelines for Americans: The selection process*. Washington, DC: The National Academies Press.

doi: <https://doi.org/10.17226/24637>; National Academies of Sciences, Engineering, and Medicine. 2017. *Redesigning the process for establishing the Dietary Guidelines for Americans*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/24883>.

³ Consolidated Appropriations Act of 2016, Sec, 735 (c) <https://www.congress.gov/bill/114th-congress/house-bill/2029/text>

There has been no mention of any review focused specifically on these diets at any of the public meetings.

- Without public notice, the DGAC has added a review on dietary cholesterol, which was not on the original list of topics to be reviewed. In the case of this review, there will be no opportunity for public comment at any point in the process since it was not announced until the March 2020 meeting that this review was taking place.⁴

C. *Lack of Consistent Standards Across DGAC Subcommittees*

The member(s) of the DGAC who contacted us expressed concern that the various subcommittees have been siloed in their work and have not had time to harmonize standards of review or consider their data in the context of the larger picture, which are essential for the production of rational guidelines.

- At a public meeting, one DGAC member expressed her concern this way:
“...we’ve been fairly siloed in our individual committees, and now we’re just beginning to see the data on intakes, and also, the food pattern modeling, which is going to be very critically important, I think, to pulling it all together,”
Sharon Donovan, in the discussion period, 3/12, PM, at min 2:44:09
- At one public meeting, there was a disagreement among committees about what kinds of ratings to give observational studies where there are inconsistent or often null findings. The Dietary Fat and Seafood committee stated that it was giving a “moderate” rating to such evidence, regarding the relationship of seafood to various health outcomes. There is debate about this grading, which was inconsistent with other Subcommittees, but the issue was not resolved at this meeting and was not further discussed publicly.⁵

A lack of consistency across Subcommittees has also led to different standards for the inclusion or exclusion of evidence. For example:

- The Dietary Fats and Seafood Subcommittee, as well as, the Sugar and Sweetened Beverages Subcommittee is including all studies four weeks or longer, whereas the Dietary Patterns Subcommittee is including only studies 12 weeks or longer.
- Some subcommittees are relying on previous DGA reviews as the foundation of their current work. In effect, they “inherit” a review, along with its potential biases, from a previous DGA. This leads to problems, since a previous DGA review may not harmonize with the current inclusion/criteria of the current process. Moreover, previous DGA reviews were deemed “non-systematic” by the NASEM, which makes them scientifically unreliable as foundations for the current reviews (see below)

⁴ <https://www.dietaryguidelines.gov/sites/default/files/2020-03/DGACMtg5Day2-DietaryFatsAndSeafoodSubcommittee.pdf>

⁵ Dietary Guidelines Advisory Committee Meeting 4, Day 1, January 23, 2020, p. 155-156, pg 165 line 2

<https://www.dietaryguidelines.gov/sites/default/files/2020-03/2020DGACMtg4TranscriptDay1FINAL.pdf>.

D. Lack of Time for USDA to Adopt Reforms Urged by the NASEM

In response to the NASEM reports referenced above, the USDA stated, in a 2019 report mandated to the House Appropriations Committee, that due to “time and resource constraints” it would not adopt quite a few of the NASEM recommendations.⁶ However, the ignored recommendations are among the most critical to ensuring that the DGA uses a rigorous and reliable scientific review process. This includes the need to properly prioritize the most rigorous scientific evidence available. A strengthened scientific process, as NASEM recommended, is essential.

The NASEM Report urges the USDA to adopt one of the leading scientific methodological standards for the DGA reviews of the science. These suggested methodologies included Grading of Recommendations, Assessment, Development and Evaluations (GRADE), Cochrane, and the standards set by the Agency for Healthcare Research & Quality (AHRQ), which HHS itself developed. The Report goes on to say that “...original systematic reviews will need to be transparent and follow state-of-the art methods, such as the GRADE approach, the GRADE approach specifically adapted for nutrition studies, known as NutriGRADE and the AHRQ Evidence-based Practice Centers Program approach.”⁷

Despite USDA’s initial stated commitment to employ a verified scientific approach in early 2019, the Department has since retreated from this idea. Indeed, in the USDA report to the House Appropriations Committee, the agency neither mentions GRADE nor any other international standard for reviewing and assessing scientific studies. At the October 2019 public meeting of the DGAC, the USDA stated that it would use “its own” methodology.

This decision is alarming for several reasons, since it is imperative that the upcoming DGA use an established, verified methodology. Several of the NASEM recommendations address the deficiencies in the current scientific reviews: “The methodological approaches to evaluating the scientific evidence require increased rigor to better meet current standards of practice....there are many ways in which the analyses need to be strengthened,” stated the NASEM.⁸

For this reason, the reliance by Subcommittees upon previous DGA reviews is highly problematic and will almost certainly result in unreliable information being incorporated into reviews for the 2020 DGA.

As one methodology expert stated in a public comment to the USDA, “previous literature reviews clearly have not met the international standards for systematic reviews that Cochrane and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) have set forth.”^{9 10} Thus, relying on these previous reviews would mean incorporating evidence that does not include the totality of evidence and is of questionable reliability.”¹¹

⁶ “A Response to the National Academies of Engineering, Science and Medicine Report: A Report to Congress” Center for Nutrition Policy and Promotion, U.S. Department of Agriculture Food and Nutrition Services. August 2019.

⁷ The National Academies of Sciences, Engineering and Medicine, “Redesigning the Process for Establishing the Dietary Guidelines for Americans,” September 2017. Pages 81. <https://www.nap.edu/catalog/24883/redesigning-the-process-for-establishing-the-dietary-guidelines-for-americans>

⁸ The National Academies of Sciences, Engineering and Medicine, “Redesigning the Process for Establishing the Dietary Guidelines for Americans,” September 2017. Page 5. <https://www.nap.edu/catalog/24883/redesigning-the-process-for-establishing-the-dietary-guidelines-for-americans>

⁹ Cochrane Handbook, Chapter 6, Searching for Studies. <https://handbook-5-1.cochrane.org/>

¹⁰ Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009 Jul 21;6(7):e1000097

¹¹ <https://www.regulations.gov/document?D=FNS-2019-0001-7056>

E. Inconsistent Evaluation of Scientific Evidence, Exclusion of Evidence

The one or more members of the DGAC who contacted us also expressed concern that time pressures have led to a reduction in the science that is being reviewed, with, in some cases, important science being excluded.

Comments by DGAC members at the March meeting reveal that research protocols are being modified mid-review. This is problematic, because it could—and indeed has—led to the exclusion of evidence and a failure to consider the entirety of the evidence. Set forth below are a few examples of statements made (Emphases added):

“...due to the short timeline relative to the workload volume, this subcommittee discussed and applied additional inclusion and **exclusion criteria that would both narrow and strengthen the body of evidence** for the remaining questions.”

Carol Boushey reports at the Subcommittee on Dietary Patterns, 3/12/ PM, at min 27:00

“The **cancer outcomes were streamlined** to focus on four types of cancer...”

--Carol Boushey reports for the Subcommittee on Dietary Patterns, 3/12, PM, at min 11:00

“**In addition to this streamlined inclusion/exclusion criteria, intermediate outcomes were included only** in intervention studies in adults or all study designs in children,”

--Carol Boushey reports for the Subcommittee on Dietary Patterns, 3/12, PM, at min 45:59

It was reported by one or more members of the DGAC that this language was intended to limit and reduce the number of studies to be examined by the DGAC.

The DGAC’s decision has also led to the exclusion of scientific analyses. For example,

- The Pregnancy/Lactation subcommittee appears to have omitted several analyses,¹² specifically, any analysis of iron, vitamin D, vitamin B12, iodine, and “other nutrients of public health concern.” The subcommittee analyzed only folic acid and omega-3 fatty acids (Slide 3).¹³
- The Dietary Patterns Subcommittee, by excluding all trials shorter than 12 weeks, excluded a large body of clinical trials. This decision, as mentioned above, is also inconsistent with the other Subcommittees which excluded only trials shorter than 4 weeks.
- The Dietary Patterns Subcommittee, by imposing new exclusion criteria, effectively excluded at least 52 clinical trials on low-carbohydrate diets, as documented by an advocacy group.¹⁴
- The Dietary Patterns Subcommittee has decided to exclude “all studies on weight loss.”¹⁵

¹² Dietary Guidelines Advisory Committee’s “Topics and Scientific Questions” Meeting 1, Day 2, March 29, 2019 <https://www.dietaryguidelines.gov/sites/default/files/2019-05/Day%20%20Topics%20and%20Scientific%20Questions.pdf>

¹³ Dietary Guidelines Advisory Committee “Pregnancy and Lactation Subcommittee” Meeting 5, Day 1, March 12, 2020 <https://www.dietaryguidelines.gov/sites/default/files/2020-03/DGACMtg5Day1-PregnancyAndLactationSubcommittee.pdf>

¹⁴ See public comments: 1k4-9fsj-tvpq and 1k4-9fv7-40vx

¹⁵ Public meeting of the Dietary Guidelines Advisory Committee, March 23, 2020, <https://static1.squarespace.com/static/5a4d5666bff20053c65b7ff2/t/5e73d18616772f0fd8940644/1584648584430/March+12%2C+2020+-+Afternoon+Session+-+2020+Dietary+Guidelines+Advisory+Committee+Public+Meeting.pdf>, Minute 29:16

F. Communication and the DGAC

Additionally, we were advised by one or more members of the DGAC that communication among Committee members about the process and content of the guidelines outside official meetings is highly limited and that therefore, there is procedurally, no mechanism for dissent among DGAC members or further conversations to harmonize standards where inconsistencies exist. Conversations in full committee on these inconsistencies have been very brief and are often left unresolved. For example and as highlighted earlier in this letter:

- At one public meeting, there was a disagreement among committees about what kinds of ratings to give observational studies where there are inconsistent or often null findings. The Dietary Fat and Seafood committee stated that it was giving a “moderate” rating to such evidence, regarding the relationship of seafood to various health outcomes. There is debate about this grading, which was inconsistent with other Subcommittees, but the issue was not resolved at this meeting and was not further discussed publicly.¹⁶

There is also a concern, by the DGAC member(s) who contacted us that fear of retaliation is creating an environment where some committee members are left to simply “suffer in silence.”

H. Conclusions

Mr. Secretaries, the allegations set forth above by one or more members of the DGAC pose a serious threat to the integrity and trustworthiness of the 2020 DGA. Ensuring that *all* the best and most current science is properly reviewed for the purposes of establishing the 2020 DGA is fundamental, and any action to rely upon unreliable reviews or exclude scientific evidence must be considered flawed. The thought that many dozens, if not hundreds of scientific studies are being excluded by the DGAC is unconscionable.

We believe the allegations set forth here must be addressed objectively and thoroughly prior to the issuance of the expert report in June or, as an alternative, that the June deadline be postponed so that the DGAC can implement its reviews fully and systematically, according to the standards recommended by the NASEM, and also so that the final results can be fully shared with the public at a public meeting for full transparency. We would also point out that there are seven medical doctors who are members of the DGAC and whose attention may have been focused on addressing the COVID-19 crisis in recent months.

We stand ready to assist in any way possible and look forward to hearing from you soon.

Sincerely,



Nina Teicholz
Executive Director
The Nutrition Coalition

¹⁶Dietary Guidelines Advisory Committee Meeting 4, Day 1, January 23, 2020, p. 155-156, p. 165 line 2
<https://www.dietaryguidelines.gov/sites/default/files/2020-03/2020DGACMt4TranscriptDay1FINAL.pdf>.

CC:

The Honorable Ron Johnson
Chairman
Senate Committee on Homeland Security and Governmental Affairs

The Honorable Gary Peters
Ranking Member
Senate Committee on Homeland Security and Governmental Affairs

The Honorable Pat Roberts
Chairman
Senate Committee on Agriculture, Nutrition and Forestry

The Honorable Debbie Stabenow
Ranking Member
Senate Committee on Agriculture, Nutrition and Forestry

The Honorable Carolyn Maloney
Chairwoman
House Committee on Oversight and Reform

The Honorable Jim Jordan
Ranking Member
House Committee on Oversight and Reform

The Honorable Collin Peterson
Chairman
House Committee on Agriculture

The Honorable K. Michael Conaway
Ranking Member
House Committee on Agriculture

The Honorable Christi Grimm
Principal Deputy Inspector General
Office of Inspector General at the United States Department of Health and Human Services

The Honorable Phyllis Fong
Inspector General
Office of Inspector General at United States Department of Agriculture