



August 13, 2020

The Honorable Sonny Perdue  
Secretary of the U.S. Department of Agriculture  
Jamie L. Whitten Building  
1400 Independence Ave., SW  
Washington, DC 20250

The Honorable Alex Azar  
Secretary of the U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue S.W.  
Washington, D.C. 20201

Dear Secretaries Perdue and Azar:

The Nutrition Coalition (TNC) appreciates the opportunity to submit comments on the final scientific report by the 2020 Dietary Guideline Advisory Committee (DGAC). TNC is a non-profit, non-partisan educational organization, with the primary goal of ensuring that U.S. nutrition policy be based in rigorous scientific evidence. We promote the importance of adopting a state-of-the-art scientific process for ensuring that our nation's nutrition policy is based in rigorous science.

### **Introduction**

Our concerns about the 2020 process for the Dietary Guidelines for Americans (DGA) remain essentially the same as we have stated in our previous comment<sup>1</sup>. Our principal concern is about the lack of adherence, by the USDA, to a rigorous, verified methodology for its scientific reviews, as recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM). The NASEM also made recommendations to increase transparency and manage bias in the DGA process, which the USDA has not adopted. All of these recommendations are standard features of any high-quality scientific paper, and we consider it a matter of great urgency that a report upon which the health of the nation depends should also uphold these basic standards of good science, in order to ensure a policy that is trustworthy and reliable.

TNC notes that the 2020 DGAC Report does not, in many instances, meet legal standards set forth by Congress, namely, that the DGA should be comprised of the "preponderance of scientific and medical knowledge which is current at the time the report is prepared."<sup>2</sup> In quite a few of the DGAC scientific reviews, important studies have been excluded, and some 15 DGAC reviews only

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<sup>1</sup> <https://www.regulations.gov/document?D=FNS-2019-0001-61666>

<sup>2</sup> National Nutrition Monitoring and Related Research Act of 1990 (Section 301 of Public Law 101-445 codified at 7 U.S.C. 5341).

look at evidence from pre-2016 or earlier. These reviews will be five-to-seven years out of date by the time the 2020-2025 DGA is published.

## **History**

Many substantive concerns were raised with regard to the process used to develop the 2015-2020 Guidelines.<sup>3</sup> In response, Congress mandated the NASEM to review the DGA process, resulting in two reports in 2017,<sup>4</sup> at a cost to taxpayers of approximately one million dollars.<sup>5</sup> In those reports, which comprised the first-ever outside peer-review of the DGA process since the policy's inception in 1980, 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 would be based upon rigorous, up-to-date scientific data.

Unfortunately, USDA rejected many of the NASEM recommendations and therefore appears to be on track to produce a DGA that lacks scientific rigor and will fall far short of being the trustworthy, reliable guidance that Americans need. This 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 Covid-19-related outcomes, including death. Reversing rates of these diseases is an imperative for the U.S. to be less vulnerable to this and future pandemics, and to returning our nation to a state of resilience and better health.

## **The Concerns**

### ***1) USDA has Ignored Most of NASEM's Recommendations***

As stated above, the NASEM report was commissioned by Congress as the first-ever outside peer review of the Dietary Guidelines, at a cost of \$1 million to U.S. taxpayers. However, USDA chose not to adopt a majority of the NASEM recommendations.

#### **a. USDA rejects recommendation to upgrade methodology to “develop credible, trustworthy guidelines.”**

We are concerned that the USDA has not fully adopted “state-of-the-art systematic review methods”<sup>6</sup> to “maximize scientific rigor,”<sup>7</sup> which was one of NASEM’s “five values to improve the integrity of a process to develop credible and trustworthy guidelines.”<sup>8</sup>

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<sup>3</sup> 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>

<sup>4</sup> 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>.

<https://www.nap.edu/catalog/24883/redesigning-the-process-for-establishing-the-dietary-guidelines-for-americans>

<sup>5</sup> Consolidated Appropriations Act of 2016, Sec. 735 ( c ) <https://www.congress.gov/bill/114th-congress/house-bill/2029/text>

<sup>6</sup> NASEM, part 2, p. 14.

<sup>7</sup> Ibid., p. 49.

<sup>8</sup> Ibid., p. 6.

Specifically, the NASEM stated that “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.”<sup>9</sup>

The NASEM explained its process: “This National Academies committee assessed the [USDA] NEL systematic review process, identifying several opportunities to advance and align...with existing best practices for systematic reviews.”<sup>10</sup>

Based on this review, the NASEM report made three formal recommendations (Recommendations #5, 6, 7) “for strengthening and adopting appropriate and strategic methodologies so as always to align with current best practices.”<sup>11</sup> Thus, according to the NASEM, these reforms were needed because the DGA’s current systematic reviews of the science *did not meet* standards for best practices and needed to be brought up to speed to assure greater reliability. Concern by the NASEM about the lack of rigor in the DGA reviews is evident, as expressed multiple times throughout the report:

“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. [Emphasis added]

“...scientific rigor needs to be maximized. The process by which the science is evaluated can be strengthened by (1) using validated, standardized processes and methods; and (2) using the most up-to-date data.

““Current methods need to be strengthened to better support the development of credible and trustworthy *DGA* [Dietary Guidelines]”<sup>12</sup>

The NASEM sums up: “To develop a trustworthy DGA, the process needs to be redesigned.”<sup>13</sup>

The NASEM specifically recommends that the USDA adopt one of the leading international scientific methodological standards for the DGA process. These suggested methodologies include “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 the USDA’s “...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

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<sup>9</sup> Ibid., p. 5.

<sup>10</sup> Ibid., p. 185.

<sup>11</sup> Ibid., xi

<sup>12</sup> Ibid., pp. 5, 7, and 96, respectively.

<sup>13</sup> Ibid., p. 51.

nutrition studies, known as NutriGRADE and the AHRQ Evidence-based Practice Centers Program approach.”<sup>14</sup>

Initially, the USDA stated an intention to employ a “modified GRADE” approach, yet the Department subsequently retreated from this idea and said it would continue to use “its own” methodology.<sup>15</sup> The USDA replied to Congress formally, 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.<sup>16</sup> USDA made no commitment in this report to Congress that it would upgrade its methodology to one of those recommended by the NASEM. Indeed, in the USDA report to the House Appropriations Committee, the agency mentions neither GRADE nor any other international standard for reviewing and assessing scientific studies.

**Without rigorous methodology, 2020 DGAC reviews cannot be “trustworthy, credible”**

It is a serious problem that the USDA has no methodology to distinguish between high- and low-quality evidence. “This distinction between high- and low-quality evidence lies at the core of any rigorous evaluation of science,” wrote Gordon Guyatt, in a public comment to USDA. Guyatt is a co-founder of the GRADE methodology, and Distinguished Professor in the Department of Health Research Methods at McMaster University.<sup>17</sup>

Another methodology expert, Bradley Johnston, wrote in a public comment to USDA, that the agency’s “proposed methodology...deviate[s] significantly from basic scientific precepts in a number of important ways. Taken together, these deviations...from international standards for systematic review methodology will result in a non-systematic approach that would **seriously undermine the reliability of these reviews.**”<sup>18</sup> [Emphasis added]

**2020 DGAC also relies on older DGA reviews that NASEM judged lacking in reliability**

For a number of its reviews, the 2020 DGAC relied on previous DGA reviews—even though NASEM concluded that these earlier reviews, from 2015 and 2010, did not meet current standards of practice. The 2020 reviews that depend entirely upon this earlier work include, at a minimum, those on the Dietary Patterns and their relationship to obesity, heart disease, and diabetes.<sup>19</sup> The 2020 DGAC stated that it did not to its own, updated systematic review but instead conducted an “systematic evidence scan” of the more current

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<sup>14</sup> Ibid., p. 81.

<sup>15</sup> Comments by Julie Obbagy, Meeting of the Dietary Guidelines Advisory Committee, Oct. 24, 2019, AM, at min. 57:01 Transcript available [here](#).

<sup>16</sup> “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.

<sup>17</sup> <https://www.regulations.gov/document?D=FNS-2019-0001-6984>

<sup>18</sup> <https://www.regulations.gov/document?D=FNS-2019-0001-7056>

<sup>19</sup> On obesity: <https://nesr.usda.gov/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>, p. 14; On cardiovascular diseases: <https://nesr.usda.gov/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>, p. 14; On diabetes: <https://nesr.usda.gov/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>, p. 14.

science. However, this type of “scan” is not a recognized method, as it has no apparent precedent in the scientific literature.<sup>20</sup>

The Dietary Patterns lie at the very heart of the DGA’s nutrition recommendations. That the evidence-base for these Patterns relies on non-systematic reviews calls into question their basic reliability. Depending on these previous reviews from 2015 and 2010 would mean “incorporating evidence that does not include the totality of evidence and is of questionable reliability,” as one methodology expert wrote in a public comment to USDA.<sup>21</sup>

**b. NASEM recommendations for greater transparency, disclosure of conflicts of interest and management of bias**

The NASEM made several recommendations specific to management of bias and conflicts of interest on the DGAC. These include:

“The Secretaries of USDA and HHS should disclose how provisional nominees’ biases and conflicts of interest are identified and managed by:

- a) Creating and publicly posting a policy and form to explicitly disclose financial and nonfinancial biases and conflicts;
- b) Developing a management plan for addressing biases and conflicts for the panel as a whole and individuals, as needed;
- c) Certifying that a federal ethics officer independently reviewed and judged the advisory committee’s biases and conflicts of interest; and by
- d) Documenting how conflicts of interest were managed in the Dietary Guidelines Advisory Committee report.”<sup>22</sup>

Unfortunately, the USDA has not adopted any of these recommendations, resulting in a lack of transparency and management of bias on the 2020 DGAC.

**Management of Bias**

One important example regarding the failure to manage bias on the 2020 DGAC regards the Subcommittee on Dietary Fats and Seafood, which had the responsibility of reviewing the relationship between saturated fats and heart disease. This four-person Subcommittee, as TNC documented, was unbalanced, allowing strong biases against saturated fats to prevail.<sup>23</sup> This resulted in a review that ignored the last ten years of science on these fats, as described below. At least two members on this Subcommittee had well-known records of publishing papers highly critical of saturated fats, and the other members on the

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<sup>20</sup> A search of “systematic evidence scan” on pubmed.com yields zero results (Searched August 10, 2020)

<sup>21</sup> <https://www.regulations.gov/document?D=FNS-2019-0001-7056>

<sup>22</sup> NASEM, part 2.

<sup>23</sup> <https://www.nutritioncoalition.us/news/unbalanced-subcommittee-on-saturated-fat>, Accessed June 10, 2020.

Subcommittee had little documented experience in the field. USDA took no apparent measures to guard against this bias, despite clear recommendations by the NASEM.

### **Conflicts of Interest on the 2020 DGAC**

Regarding conflicts of interest, the NASEM recommended disclosure of the DGAC's conflicts of interests. This panel is enormously powerful, determining nutrition guidance for an entire nation, and its potential conflicts of interest should be known. Disclosing conflicts of interest is a standard practice among medical and scientific journals.<sup>24</sup>

The Nutrition Coalition's own, cursory examination of these conflicts revealed many, serious potential problems, including one DGAC member who is a consulting Medical Director for Nestlé, Inc., another who is a longtime former employee of the pharmaceutical giant Merck & Co., and one who is a devout member of the Seventh Day Adventist Church, which espouses the vegetarian diet as a principal matter of its faith.<sup>25</sup> A second investigation by TNC of the Birth-to-24 Month Subcommittee found that four out of the six panel members have significant financial ties to infant formula or food companies with an interest in the B-to-24 market.<sup>26</sup>

Another group investigating the 2020 DGAC found that more than half have ties to the International Life Sciences Institute (ILSI), a group founded by Coca-Cola whose members include a long list of multinational food and pharmaceutical companies.<sup>27</sup> One of the 2020 DGAC members is a lobbyist for ILSI.

Finally, an investigation by the venerable investigative reporting group, ProPublica, found multiple serious conflicts of interest among members of the 2020 DGAC, including the fact that one member has consulted for or received research support from at least nine companies and trade groups, including Japanese food and biotechnology company [Ajinomoto](#), the [California Walnut Commission](#), the [Almond Board of California](#), and [Welch Foods](#). He also sat on the scientific boards of [ConAgra and the Grain Foods Foundation](#) and has consulted for [ConAgra and life-science clinical-research company Biofortis](#). Further, he has received support from [Procter & Gamble](#) and [PepsiCo Global R&D](#) to the [Alliance for Potato Research and Education](#).<sup>28,29</sup> ProPublica reported that another 2020 DGAC member has conducted work supported by the [Sugar Association](#), [Nestle](#), and [Barilla pasta](#); Since 2014, her research has received funding from the dietary supplement company [Pharmavite](#), and in a [study](#) on maternal health, she disclosed that she was a consultant for [Nestle](#). The ProPublica article also reports that the Nestle Medical Director on the DGAC

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<sup>24</sup> <http://icmje.org/conflicts-of-interest/>

<sup>25</sup> <https://www.nutritioncoalition.us/2020-dietary-guidelines-info/dietary-guidelines-committee-conflicts>, Accessed June 10, 2020.

<sup>26</sup> <https://www.nutritioncoalition.us/2020-dietary-guidelines-info/birth-to-24-months-guidelines>

<sup>27</sup> <https://www.corporateaccountability.org/resources/dietary-guidelines-corporate-america/>

<sup>28</sup> <https://www-chronicle-com.laneproxy.stanford.edu/article/many-public-universities-refuse-to-reveal-professors-conflicts-of-interest/>

<sup>29</sup> <https://projects.propublica.org/dollars-for-profs/>

also consulted for [Amgen, Boehringer Ingelheim, Novo Nordisk, and Eisai](#) and received research support from both Nestle and pharmaceutical company [VIVUS](#).

2) *DGA Focus Exclusively on “Healthy” Americans; Lack of Compliance with Law Requiring Guidelines to Serve the “General Public”*

**The 2020 DGAC report is focused exclusively on “Healthy Americans,” thereby excluding the 60% of Americans diagnosed with one or more diet-related chronic condition.**

Congress has mandated that the DGA be for the “general public,”<sup>30</sup> yet the DGA remains focused exclusively on disease prevention, for those Americans not yet diagnosed with a diet-related, chronic disease. This is not the general public.

People with obesity, diabetes and other diet-related conditions are desperately in need of guidance. Two out of three American adults and one out of three children are overweight or have obesity,<sup>31</sup> and more than half of adults have diabetes or prediabetes.<sup>32</sup> Roughly half of adults also have high blood pressure,<sup>33</sup> a major risk factor for heart disease and stroke. The estimate of the proportion of Americans who are healthy range from a high of 40%, who are those without a diagnosed metabolic disease,<sup>34</sup> down to 12%, who are those without the symptoms of metabolic syndrome, an indicator of diet-related ill-health and chronic disease.<sup>35</sup>

Yet the DGA ignores these populations.

For the USDA to develop a policy so narrowly focused on the small portion of Americans who are in good health makes little sense, especially since these Guidelines are applied broadly, via the USDA feeding assistance and educational programs, for the sick and well alike.

We agree with previous iterations of the Dietary Guidelines that making “[p]rimary prevention of obesity and related risk factors...the single most powerful public health approach to reversing America’s obesity epidemic over the long term.”<sup>36</sup>

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<sup>30</sup> National Nutrition Monitoring and Related Research Act of 1990 (Section 301 of Public Law 101-445 codified at 7 U.S.C. 5341).

<sup>31</sup> Fryar CD, Carroll MD, Ogden CL. Prevalence of overweight, obesity, and extreme obesity among adults aged 20 and over. *National Center for Health Statistics*. 2016 July. Available at [https://www.cdc.gov/nchs/data/hestat/obesity\\_adult\\_13\\_14/obesity\\_adult\\_13\\_14.htm](https://www.cdc.gov/nchs/data/hestat/obesity_adult_13_14/obesity_adult_13_14.htm). Accessed July 10, 2019.

<sup>32</sup> <https://jamanetwork.com/journals/jama/fullarticle/2434682>

<sup>33</sup> Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2017 Nov 7. pii: S0735-1097(17)41519-1. doi: 10.1016/j.jacc.2017.11.006.

<sup>34</sup> <https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm>

<sup>35</sup> <https://pubmed.ncbi.nlm.nih.gov/30484738/>

<sup>36</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010 at 58. (See also “We are releasing the seventh edition of the Dietary Guidelines at a time of rising concern about the health of the American population. Americans are experiencing an epidemic of overweight and obesity. Poor diet and physical inactivity also are linked to major causes of illness and death.” [2010 DGAs](#) at i)

### 2020 DGAC Ignored Obesity: Excluded All Studies on Weight Loss<sup>37</sup>

The exclusion of all trials on weight loss is described and documented in our last public comment. It is worth emphasizing that one DGAC member noted the many public comments about the need to address obesity, and this member urged the committee to explain “with a little bit of detail and the reasons” why obesity was “not taken into consideration in this iteration of the Dietary Guidelines.”<sup>38</sup> However the DGAC Report does not appear to offer any explanation for why it excluded any consideration of trials on weight loss.

This exclusion of evidence extends to at least 65 clinical trials, **on low-carbohydrate diets**, as identified by an advocacy group called the Low-carb Action Network.<sup>39</sup> The 2020 DGAC could not find these studies, even though they have been reviewed by the American Diabetes Association, Diabetes Canada, and the European Society of Diabetes, all of which have found sufficient scientific studies to justify endorsing low-carb and keto diets as safe and highly effective for blood glucose control as well as the management of many cardiovascular risk factors.<sup>40 414243</sup> It is worth noting that the previous DGAC, in 2015, conducted a formal systematic review of the low-carb literature and decided to put it in the methodology section of the Scientific Report, where it did not belong. One DGAC member objected to “burying” the evidence on low-carbohydrate diets, which he referred to as “an enormous amount of research.”<sup>44</sup> Five years later, the body of research on low-carb diets has only grown.

The 2020 DGAC has clearly continued the USDA’s effort to ignore this fast-growing body of scientific literature on low-carbohydrate diets. This must be considered an omission--or even suppression--of the science.

### 3) 2020 DGAC relying on outdated science. Does not comply with law requiring DGA to use the science “that is current at the time the report is prepared ”

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<sup>37</sup> 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

<sup>38</sup> Transcript of March 13, 2020 Afternoon Meeting of Dietary Guidelines Advisory Committee at minute 25-27; Sabaté. Available at [https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289852&tp\\_key=6cf027ef9d](https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289852&tp_key=6cf027ef9d).

<sup>39</sup> <https://lowcarbaction.org/more-low-carb-studies-ignored-by-advisory-committee/>, Accessed August 12, 2020.

<sup>40</sup> <https://care.diabetesjournals.org/content/early/2018/09/27/dci18-0033>

<sup>41</sup> <https://care.diabetesjournals.org/content/42/5/731>

<sup>42</sup> <https://care.diabetesjournals.org/content/early/2018/09/27/dci18-0033>

<sup>43</sup> [https://www.canadianjournalofdiabetes.com/article/S1499-2671\(20\)30097-6/pdf?fbclid=IwAR3ewelg3qbmFdLVt\\_EYLszBvNmdSX2QnuzrXRC28eQERU\\_9VK1iGqWK5FY](https://www.canadianjournalofdiabetes.com/article/S1499-2671(20)30097-6/pdf?fbclid=IwAR3ewelg3qbmFdLVt_EYLszBvNmdSX2QnuzrXRC28eQERU_9VK1iGqWK5FY)

<sup>44</sup> <https://www.nutritioncoalition.us/news/low-carb-strategy-for-fighting-the-pandemics-toll>, Accessed Aug. 12, 2020.

By law, the DGA must reflect the “scientific and medical knowledge which is current at the time the report is prepared,”<sup>45</sup> yet the 2020 process did not meet this standard in a significant number of reviews. The DGA is published every five years and is expected to cover at least the previous five years of scientific studies. In the 2020 DGAC report, many reviews cover the science through 2019 or even early 2020, which is appropriate.

However, our analysis found that:

- Half of the reviews (11 out of 22) by the Subcommittees on **Pregnancy and Lactation** and **Birth to 24 Months** looked at the science only through mid-July 2016.<sup>46</sup> The apparent reason for this omission is that these 11 reviews were conducted before the 2020 DGAC had been convened. This means that when the 2020-2025 DGA is published towards the end of 2020, the science in these 11 reviews will almost be *five years out of date*. Given that the DGA is published every five years in order to be as current as possible with the science, these outdated reviews will not comply with the mandate for the science to be “current at the time the report is prepared.”
- The science underpinning the **Dietary Patterns**, which comprise the core of the DGA recommendations about what to eat, is based on systematic reviews only through 2015, and indeed these 2015 reviews depend in part on science going back to 2010. This is true for the reviews of the Dietary Patterns and their relationship to heart disease, obesity, and diabetes.<sup>47</sup> As described above, the 2020 DGAC stated that it did an “systematic evidence scan” of the more current evidence, but this type of “scan” is not a recognized method, as it has no apparent precedent in the scientific literature.<sup>48</sup> Thus, the *USDA’s recommended Dietary Patterns will be somewhere between 5 to 10 years out of date* at the time of publication of the 2020 DGA.

#### 4) *Lack of Consistent Standards Across 2020 DGAC Subcommittees*

Member(s) of the 2020 DGAC who contacted TNC in March and wished to remain anonymous expressed concern that the various subcommittees were siloed in their work and did not have time to harmonize standards of review or consider data in the context of the larger picture, which is essential for the production of rational guidelines. A lack of consistency across Subcommittees has led to different standards for the inclusion or exclusion of evidence. For example:

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<sup>45</sup> National Nutrition Monitoring and Related Research Act of 1990 (Public Law 101-445 - Oct. 22, 1990).

<sup>46</sup> The “Pregnancy and Lactation” Subcommittee answered four questions using existing systematic reviews that searched studies through July 2016 <https://nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee>; The “Birth-to-24” Subcommittee answered 7 questions using this same method: <https://nesr.usda.gov/project-specific-overview-pb-24-0>;

<sup>47</sup> On obesity: <https://nesr.usda.gov/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>, p. 14; On cardiovascular diseases: <https://nesr.usda.gov/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>, p. 14; On diabetes: <https://nesr.usda.gov/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>, p. 14.

<sup>48</sup> A search of “systematic evidence scan” on pubmed.com yields zero results (Searched August 10, 2020)

- The Dietary Fats and Seafood Subcommittee as well as the Sugar and Sweetened Beverages Subcommittee including studies four weeks or longer, whereas the Dietary Patterns Subcommittee used a more stringent standard, including only studies 12 weeks or longer.

*5) DGAC review on saturated fats excludes the last 10 years of science.*

The Subcommittee on Dietary Fats and Seafood stated that the evidence showing that saturated fats cause heart disease was “strong” and suggested a continued cap on these fats, at 10% of calories. The Subcommittee stated that saturated fats should be replaced by polyunsaturated vegetable oils.

These conclusions are entirely contrary to the last ten years of science. Separate groups of scientists across the globe have, over the past decade, reassessed the data on saturated fats. The relationship between these fats and heart disease was tested in numerous clinical trials, on some 75,000 people, and the results consistently showed that saturated fats have no effect on cardiovascular or total mortality.<sup>49</sup> These trials were long overlooked, because they were mainly conducted in the 1960s and 70s; In fact, no DGAC has ever reviewed these trials directly and only looked at them for first time in 2015, via a few selected review papers.<sup>49</sup> Now, there are now almost 20 review papers on this subject, nearly all of which have concluded that caps on saturated fats are no longer warranted.<sup>50</sup> These papers also conclude, on the whole, that there is little evidence to support the recommendation to replace saturated fats with polyunsaturated vegetable oils.

A particularly prominent group of scientists sent a letter in February to the Secretaries of USDA and HHS, stating, “we respectfully request....that [you] give serious and immediate consideration to lifting the limits placed on saturated fat intake for the upcoming 2020 Dietary Guidelines for Americans. This request is based on a review of the most rigorous scientific data available.”<sup>51</sup>

They added, “The most rigorous science available is likely to have unintended or even potentially harmful consequences to health.”

This group of scientists included three former members of previous U.S. DGACs, including a member of the Subcommittee that reviewed saturated fats in 2015 and the Chair of the 2005 DGAC. This group also submitted multiple public comments to USDA,<sup>52</sup> with significant scientific documentation, and recently, they published their findings in a “State of the Art

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<sup>49</sup> Teicholz, N. *The BMU* 2015.

<sup>50</sup> <https://www.nutritioncoalition.us/saturated-fats-do-they-cause-heart-disease>

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<https://static1.squarespace.com/static/5a4d5666bff20053c65b7ff2/t/5e4eba3e5ceeae299ebb07ae/1582217791211/FINAL+letter+to+secretaries+of+USDA+17th+Feb+2020.pdf>

<sup>52</sup> <https://www.regulations.gov/document?D=FNS-2019-0001-42017>, <https://www.regulations.gov/document?D=FNS-2019-0001-52079>, <https://www.regulations.gov/document?D=FNS-2020-0015-1573>

Review” in the prestigious *Journal of the American College of Cardiology*,<sup>53</sup> which they submitted with their final public comment.

It is concerning that the DGAC appears not to have considered this last decade of science on saturated fats nor any of the public comments on this topic submitted to the Committee. These comments include not only those of scientists mentioned above but also a comment by at least one other top expert in the field<sup>54</sup> and comprehensive comments on the subject by The Nutrition Coalition.<sup>55</sup> It is also notable that as of April 2018, the 2020 DGAC had already received some 1,145 unique public comments on the issue of the caps on saturated fats.<sup>56</sup>

The Nutrition Coalition also submitted a complaint to the USDA Office of Inspector General on April 10, 2020 (attached), that the 2020 Subcommittee on Dietary Fats was one-sided and unbalanced in its views. TNC believes that because the Subcommittees on the 2020 DGAC acted in isolation from each other, each Subcommittee was, in effect, acting as its own, independent committee. The lack of balance on the saturated-fats Subcommittee, we believe, may have been a violation of the Federal Advisory Committee Act (FACA) which requires that federal advisory committees be balanced in their views.

Congress intended for the DGA to reflect the science “that is current at the time.” This should logically include this past decade of important contributions to the scientific literature on saturated fats.

6) *The Dietary Patterns recommended by the 2020 DGAC do not meet nutritional adequacy goals.*

The Dietary Patterns presented in the 2020 DGAC Report for [adults fail to meet nutrient goals for choline, iron, Vit. D, Vit. E](#).<sup>57</sup> Infant/toddler diets are also short on zinc and potassium. The DGA diets are therefore designed in a way that *cannot* ensure proper growth for children or good health for adults. Some of these shortfalls can be remedied with supplements, but many people do not absorb nutritional supplements as well as they do nutrients consumed from foods.<sup>58</sup>

We strongly believe that essential nutrients should come from *real, whole, natural foods*. The Dietary Guidelines should be a whole-foods diet.

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<sup>53</sup> <https://www.onlinejacc.org/content/76/7/844>

<sup>54</sup> <https://www.regulations.gov/document?D=FNS-2018-0005-0956>

<sup>55</sup> <https://www.regulations.gov/document?D=FNS-2018-0005-6069>; The Nutrition Coalition published a comprehensive critique of the scientific review on saturated fats by the 2020 DGAC, which is available here: <https://www.nutritioncoalition.us/news/experts-again-condemn-saturated-fats>; It was also submitted as public comment, number 1k4-9h6l-t8lp.

<sup>56</sup> <https://www.nutritioncoalition.us/news/2018/4/4/thousands-tell-usda-update-guidelines-to-reflect-the-latest-science-onsaturated-fat-and-low-carb-diets?rq=thousands>

<sup>57</sup> <https://www.dietaryguidelines.gov/food-pattern-modeling-2-years-and-older>

<sup>58</sup> See, for example these articles on the absorption of iron and folate: <https://pubmed.ncbi.nlm.nih.gov/12949395/>, <https://pubmed.ncbi.nlm.nih.gov/11925486/>, <https://pubmed.ncbi.nlm.nih.gov/22254106/>

### *7) DGA needs to be inclusive of ethnic minorities and people of low socio-economic status (SES)*

The Nutrition Coalition is part of a group called the Food4Health (F4H) Alliance, and we echo its concerns as documented in its recent report, that African-Americans/black, Hispanic and low SES populations have been excluded from the evidence base of the DGA.

Food4Health conducted an in-depth analysis of the 2020 DGAC report and concluded that more than 90% of the systematic reviews did not account for race, ethnicity, and/or SES. Moreover, the reviews relied predominantly upon white populations which are questionably generalized to the broader U.S. population. These findings reflect an analysis of the DGAC report's 56 systematic review questions where the evidence was graded "Strong," "Medium," or "Limited."

Congress intended for the Dietary Guidelines for Americans (DGA) to be for the "general public,"<sup>59</sup> which, today, is more than one quarter (26%) non-white, including nearly 13% black/African American and 17.6% Hispanic/Latinx.

According to F4H's analysis, these historically underserved and understudied populations are seldom included in or accounted for in the studies reviewed by the DGAC's report.

### *8) Communication and the 2020 DGAC*

TNC was 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 was highly limited and that therefore, there was procedurally no mechanism for dissent among DGAC members or further conversations to harmonize standards where inconsistencies existed. Conversations in full committee on these inconsistencies were very brief and were often left unresolved. For example:

- 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.<sup>60</sup>

There was also a concern, by the DGAC member(s) who contacted us that fear of retaliation created an environment where some committee members were left to simply "suffer in silence."

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<sup>59</sup> National Nutrition Monitoring and Related Research Act of 1990 (Section 301 of Public Law 101-445 codified at 7 U.S.C. 5341).

<sup>60</sup>Dietary 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>,

## 9) 2020 DGAC using weak evidence to make recommendations

In at least one instance, the DGAC has issued a “strong” recommendation based exclusively on a weak type of science, called epidemiology. The question was the following:

*“What is the relationship between dietary patterns consumed and all-cause mortality?”*

The committee considered the evidence to be “**strong**” that the USDA dietary patterns (Mediterranean, “US-Style,” and Vegetarian) could reduce all-cause mortality, despite the fact that not a single experiment (clinical trial) was cited to support this claim. Instead, the committee cited exclusively observational—or epidemiological—studies, which can only show associations. Epidemiological data are useful for generating hypotheses but in the field of nutrition, they have never reliably been able to ‘prove’ causality. The leap to assuming causation can only be made rarely, when certain standards, called the “Bradford Hill Criteria” are satisfied.<sup>61</sup> The number *one* criteria is the *size* of the effect, or “strength of association.” In fact, Dr. Hill stated that this criteria was “First upon my list,” since it was the most important.

When the strength of association is large, such as the 20-30-times greater risk of dying from lung cancer seen among heavy smokers compared to never-smokers, causality can be considered, provided the rest of the Bradford Hill criteria are also satisfied. However, in nutritional epidemiology, this effect size rarely exceeds 2. Such a small number cannot be considered reliable (due to lack of precision from food-frequency questionnaires and residual confounding, among other things).

By contrast, the DGAC committee members found this weak evidence convincing, because it was so “consistent.” However, “consistency” is Bradford Hill’s *second* criteria. Without strong effects, consistency is not enough to assume causation. Indeed, this type of consistency could simply reflect bias in the field—as so many governments worldwide have followed the U.S. in adopting the same type of diet. Researchers relying on government grants have every incentive of finding in favor of the diet promoted by their funders.

Moreover, committee members noted numerous problems regarding inconsistencies among the 152 epidemiological studies they were combining together for analysis, including some fifteen different methods for analyzing the data and “different definitions of food and beverages” among the studies.<sup>62</sup> Unfortunately, researchers have found that such dramatic heterogeneity among definitions of a dietary pattern ultimately mean that such studies cannot be combined with “any degree of reliability.”<sup>63</sup> This calls the analyses of the Dietary Patterns by the 2020 DGAC further into question.

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<sup>61</sup> Hill AB. “The environment and disease: association or causation?” *Proc R Soc Med*. 1965;58:295–30

<sup>62</sup> 2020 DGAC public meeting, March 12, afternoon, mins. [0:22:58 – 0:25:59. Transcript available here.](#)

<sup>63</sup> [https://pubmed.ncbi.nlm.nih.gov/26545641/?from\\_term=%22Dietary+Pattern%22+definition+range&from\\_pos=1](https://pubmed.ncbi.nlm.nih.gov/26545641/?from_term=%22Dietary+Pattern%22+definition+range&from_pos=1)

Findings from nutritional epidemiology have a track record of being mostly incorrect. When properly tested in clinical trials, they are confirmed only 0-20% of the time. These are of course very low odds on which to bet the public health.<sup>64</sup> Thus, clinical trial data should be a necessity for issuing any “strong” recommendation.

The Nutrition Coalition urges USDA-HHS to delay the 2020 DGA in order to correct these serious oversights so that the nation can have the unbiased, trustworthy and reliable Guidelines that it deserves. Given the crushing load of chronic, diet-related disease endured by the American public, now all the more grave given the increased risk suffered by these populations under assault from COVID-19, our population deserves Guidelines based on thorough, balanced reviews of the most rigorous science.

Thank you for your attention to these important considerations.

Most sincerely,



Nina Teicholz  
Executive Director  
The Nutrition Coalition



Dr. Sarah Hallberg  
Chair, Scientific Council  
The Nutrition Coalition

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<sup>64</sup> <https://rss.onlinelibrary.wiley.com/doi/full/10.1111/j.1740-9713.2011.00506.x>  
<https://journals.plos.org/plosmedicine/article?id=10.1371%2Fjournal.pmed.0020124>