



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 Food4Health Alliance (“Food4Health” or the “Alliance”) appreciates the opportunity to submit comments on the final scientific report by the Dietary Guideline Advisory Committee (DGAC or the “Committee”). Food4Health represents leaders from all backgrounds – patients, providers, public health, research, and other advocacy groups with the aim of ensuring the Dietary Guidelines for Americans (DGA) are scientifically sound, methodologically reliable, and include a diversity of dietary options applicable for all Americans.

DGA Needs to be Inclusive of Ethnic Minorities, People Diagnosed with Diet-related Diseases Such as Obesity, Diabetes, and Hypertension, and Other Overlooked Populations.

1. *Exclusion of African-American/black, Hispanic/Latinx, and populations of low socio-economic status*

Food4Health conducted an in-depth analysis of the DGAC report and concluded that more than 90% of the systematic reviews did not account for race, ethnicity, and/or socio-economic status. Moreover, the reviews relied predominantly upon studies of white populations that are questionably generalized to the broader US population. These findings reflect an analysis of the DGAC report’s 56 systematic review questions where the evidence was graded “Strong,” “Medium,” or “Limited.” (The findings do not include some 125 questions where there was insufficient evidence, and the grade was “Not Assignable.”) The report is attached to this submission.



Congress intended for the Dietary Guidelines for Americans (DGA) to be for the “general public,”¹ which, today, is more than one quarter (26%) non-white, including nearly 13% black/African American and 17.6% Hispanic/Latinx.

In its public meetings, 2020 Advisory Committee members spoke frequently of the need to account for race and ethnicity in policy recommendations. Committee Chair Barbara Schneeman stated, “flexibility is needed for different age groups, different ethnic groups, and the choices people make.”ⁱ At another point, she added, “Focus on patterns and food intake are especially useful as we think about dietary guidance that can apply across the life span, and that can be tailored for various racial/ethnic preferences and socioeconomic levels.”ⁱⁱ However, Committee members also recognized that in many cases, they were working from an evidence base that was limited in achieving these goals. This impression is confirmed by the F4H analysis.

According to our analysis, these historically underserved and understudied populations are seldom included in or accounted for in the studies reviewed in the Advisory Committee’s report. This does not insinuate that studies of underserved communities were intentionally excluded. However, the resulting Dietary Guidelines for Americans should note this limitation of available studies.

2. Exclusion of 60% of Americans with one or more diet-related chronic disease

Food4Health also continues to object to the fact that the Dietary Guidelines exclusively addresses only the needs of healthy Americans. As the most recent iteration of the DGA makes clear, the policy’s “recommendations are ultimately intended to help individuals improve and maintain overall health and reduce the risk of chronic disease—its focus is disease prevention.”²

The picture of America’s ill-health is cause for grave concern. Two out of three American adults and one out of three children are overweight or have obesity.³ More than half of adults have diabetes or prediabetes,⁴ and roughly half of adults have high blood pressure,⁵

¹ National Nutrition Monitoring and Related Research Act of 1990 (Section 301 of Public Law 101-445 codified at 7 U.S.C. 5341).

² U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015 – 2020 Dietary Guidelines for Americans*. 8th Edition, Introduction at p.6. December 2015. Available at <https://health.gov/dietaryguidelines/2015/guidelines/>. Accessed July 6, 2019.

³ 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. Accessed July 10, 2019.

⁴ <https://jamanetwork.com/journals/jama/fullarticle/2434682>

⁵ 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



a major risk factor for heart disease and stroke. Furthermore, 13 cancers, including breast, colorectal, esophageal, and uterine, are linked to overweight or obesity.⁶ In total, 60 percent of Americans in 2014 “had at least one chronic condition, and 42 percent had multiple chronic conditions.”⁷ Given the extremely high prevalence of co-morbidities and overweight/obesity, the DGAs need to go beyond mere prevention and equally focus on the amelioration of these conditions by providing advice specifically for these populations.

We note that traditionally underserved populations are experiencing even higher rates of these diseases. Currently nearly 50% of non-Hispanic blacks and 45% of Hispanics have obesity.⁸

The ongoing COVID-19 pandemic also emphasizes the urgent need for nutritional guidance that benefits people with chronic diseases, since populations suffering from these diet-related conditions are at least three times more likely to suffer poor outcomes from Covid-19, including hospitalization, intubation, and death.⁹ These conditions will continue to increase vulnerability to future waves of COVID-19 or other pandemics. Thus, we think it essential that our nation’s nutrition guidance reflect the best science that can combat these diseases, which take such an enormous toll on our nation.

- *Decision by the DGAC to Exclude Obesity as a Health Concern*
In our earlier comments, we noted that the DGAC’s decision to exclude analyzing any of the possible treatments for obesity, diabetes or other chronic diseases made little sense, given the pervasiveness of these diseases as well as the fact that no other federal agencies address them.

Previous DGAs have reckoned with the need to stem the ever-rising tide of the obesity epidemic in America. The 2010-2015 Dietary Guidelines made clear, “Primary prevention of obesity and related risk factors is the single most powerful public health approach to reversing America’s obesity epidemic over the long term.”¹⁰ However, as noted above, the 2020-2025 DGAC made the decision to exclude studies on weight loss despite weight loss being the single most effective strategy to prevent obesity. Indeed, one of the 2020 DGAC members noted that many of the public comments had been focused on the need to address obesity,

Practice Guidelines. [J Am Coll Cardiol](#). 2017 Nov 7. pii: S0735-1097(17)41519-1. doi: 10.1016/j.jacc.2017.11.006.

⁶ Centers for Disease Control and Prevention. Cancers Associated with Overweight and Obesity Make up 40 percent of Cancers Diagnosed in the United States. 2017 October. Available at <https://www.cdc.gov/media/releases/2017/p1003-vs-cancer-obesity.html>. Accessed July 10, 2019.

⁷ Buttorff C. Multiple Chronic Conditions in the United States. 2017. Available at http://www.fightchronicdisease.org/sites/default/files/TL221_final.pdf. Accessed July 6, 2019.

⁸ <https://www.cdc.gov/nchs/products/databriefs/db360.htm>

⁹ <https://ebm.bmj.com/content/early/2020/07/09/bmjebm-2020-111451>

¹⁰ [2010 DGAs](#) at 58.

given its prevalence in the American population, and he urged the committee to explain “with a little bit of detail and the reasons” why obesity and diets that might be shown to prevent it were “not taken into consideration in this iteration of the Dietary Guidelines.”¹¹ A Dietary Guidelines that does not address the two-thirds of Americans who are overweight or have obesity is, in our view, a nutrition policy that lacks relevance to much of the general public and reflects an insufficient review of the science.

- *Beyond Obesity: Exclusion of People with Other Diet-Related, Chronic Diseases*
We recognize that the Dietary Guidelines are not intended to be clinical guidelines, but we have concerns with their exclusive focus on the prevention of disease, when it may result in Guidelines that are potentially irrelevant or even possibly harmful to the majority of Americans with a chronic disease.

3. Exclusion of People of Different Age Groups

It is important that the DGA will for the first time provide separate nutritional advice for pregnant and lactating women as well as for those in the first 24 months of life. However, there is still no specialized advice for growing children, teens, or older adults, all populations that are known to have different nutritional needs. For instance, the DGAC should address nutritional strategies to combat sarcopenia (muscle loss) in older adults, since it is very strongly associated with risk of mortality. Comments from the committee suggest that there is an awareness of this need for diverse advice, including “more specifically, [to] add aging as an important opportunity that should be taken up in the next committee’s work.”¹²

The Government Accountability Office issued a 2019 report stating that the “HHS plans to focus on older adults in a future update to the Guidelines but has not documented a plan for doing so.”¹³ It recommends that, “Documenting such a plan could help ensure guidelines better address the needs of the population.”¹⁴

The report assessed the nutrition assistance programs administered by HHS and USDA and intended to meet the nutritional needs of older adults. The report concluded that:

Federal nutrition guidelines are the basis for nutrition assistance programs that serve older adults. However, the guidelines focus on a healthy population and not on

¹¹ Public Meeting of the DGAC, comment by Joan Sabaté, March 13th, afternoon, at minute 25-27.

¹² Public Meeting of the DGAC, comment by B. Schneeman, quoting L. Bazzano, March 12th, afternoon, at minute 58.

¹³ U.S. Government Accountability Office. *NUTRITION ASSISTANCE PROGRAMS: Agencies Could Do More to Help Address the Nutritional Needs of Older Adults*. GAO-20-18: Published: Nov 21, 2019. Publicly Released: Dec 23, 2019 (“GAO Report”), ii.

¹⁴ Ibid.



the needs of many older adults, such as those with common health conditions and those over age 70. Most older adults have more than one chronic condition, such as diabetes or heart disease.

In the meantime, we suggest that the 2020-2025 Dietary Guidelines for Americans make abundantly clear that its recommendations may not be applicable different age groups, especially older adults .

4. *Exclusion of Native American Populations*

Native Americans have high rates of diet-related diseases. According to a 2016 review of the USDA Food Distribution Program on Indian Reservations (FDPIR)¹⁵, an estimated 77 percent of FDPIR households had one or more household members with a health condition. The most frequently reported health conditions were high blood pressure (57 percent), diabetes (39 percent), overweight/obesity (35 percent), and gastrointestinal problems (23 percent). The report also found that 21 percent of participants in FDPIR are older adults, and 29 percent of households only have senior members, many of whom have substantial dietary needs related to health:

These rates of disease imply that federal feeding programs would need to address disease treatment. However, the study notes that foods offered to participants “must be consistent with the Dietary Guidelines for Americans,”¹⁶ which focuses exclusively on prevention and excludes advice on treatment. Due to the universal application of the Dietary Guidelines regardless of health status, therefore, these vulnerable groups are receiving foods that are not appropriate for their nutritional needs.

Vast Impact of the DGA Makes These Changes an Imperative

The fact that the Dietary Guidelines may not be applicable to many Americans is particularly problematic when the Dietary Guidelines have such “a significant impact on nutrition in the United States,” as recognized by the USDA and HHS.^{17 18} These federal

¹⁵ U.S. Department of Agriculture, Food and Nutrition Service. *Study of the Food Distribution Program on Indian Reservations (FDPIR) Final Report*. June 2016

¹⁶ <https://www.fns.usda.gov/fdpir/fdpir-food-package-review-work-group>

¹⁷ According to USDA-HHS, the DGA “(1) form the basis of federal nutrition policy and programs (2) helps guide local, state, and national health promotion and disease prevention initiatives, and (3) informs various organizations and industries (e.g., products developed and marketed by the food and beverage industry).” <https://health.gov/our-work/food-nutrition/about-dietary-guidelines>

¹⁸ See, U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015 – 2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at <https://health.gov/our-work/food-and-nutrition/2015-2020-dietary-guidelines/> at xi (“Additional audiences who may use Dietary Guidelines information to develop programs, policies, and communication for the general public include businesses, schools, community groups, media, the food industry, and State and local governments.”) and 5-6 (“It also is used to inform USDA and HHS food programs, such as USDA’s National School Lunch Program and School Breakfast Program, which feed more than 30 million children each school day, and the Special Supplemental Nutrition Program for Women, Infants and Children, which uses the Dietary Guidelines as the scientific



agencies state, “The Dietary Guidelines for Americans...design and implement food and nutrition programs that feed the American people, such as USDA’s National School Lunch Program and School Breakfast Program, which feed more than 30 million children each school day.”¹⁹ School lunches and other USDA nutrition assistance programs are delivered to our nation’s most unhealthy and vulnerable populations. These feeding assistance programs, are driven by the Guidelines, yet currently, they cannot be flexible in responding to the diverse populations they serve.

If the 2020 DGAC final report is translated into policy without consideration for the profound diversity of Americans and their differing nutritional needs, it will be a policy that does not serve the vast majority of our country.

DGA Needs a Scientifically Reliable Process

Food4Health is disappointed to see that the concerns it expressed regarding scientific rigor and a reliable methodology do not appear to have been addressed in the DGAC final scientific report. The Food4Health Alliance supports the Congressional mandate that the Guidelines be “based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.”²⁰

Our observations are guided by the federal law establishing basic requirements for the quinquennial Dietary Guidelines;²¹ the charter for the 2020 DGAC reiterating that [the DGAs] shall contain nutritional and dietary information and guidelines for the *general public*;²² as well as the Congressionally-mandated 2017 reports by the National Academies of Sciences, Engineering, and Medicine (NASEM), which made a number of recommendations about how to strengthen the DGA process so that these Guidelines could be made reliable, trustworthy, and relevant to all Americans.²³

underpinning for its food packages and nutrition education program with about 8 million beneficiaries. In HHS, the Administration on Aging implements the Dietary Guidelines through the Older Americans Act Nutrition Services programs (i.e., nutrition programs for older adults), with about 5,000 community-based nutrition service providers who together serve more than 900,000 meals a day across the United States.”).

¹⁹ [2015 DGA](#) at vii

²⁰ National Nutrition Monitoring and Related Research Act of 1990 (Public Law 101-445 - Oct. 22, 1990).

²¹ *Ibid.*

²² Secretary of Health and Human Services. Charter: 2015 Dietary Guidelines Advisory Committee. Washington, DC: 2013, section 3, p.1. Available at <https://www.federalregister.gov/d/2013-02502>. Accessed June 4, 2020. (Emphasis added.)

²³ 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>.



A. Scientific Reliability

The Food4Health Alliance is dedicated to ensuring that the Dietary Guidelines are based on a reliable scientific foundation established through a state-of-the-art process leading to “credible and trustworthy guidelines” consistent with the National Academies’ recommendations.²⁴ We respectfully note several areas of concern with the process to date and seek clarification from the Committee regarding the process and the National Academies’ recommendations as it reconciles and finalizes its work into its Scientific Report.

1) *Excluded Science*

The Food4Health Alliance is concerned that the DGAC appears to have excluded all (or almost all) studies “designed to induce weight loss or treat overweight and obesity through energy restriction”, according to a discussion at the March meeting by the Subcommittee on Dietary Patterns.²⁵ We are very concerned about the possibility that the Guidelines will lack advice for the majority of Americans seeking to lose or maintain their weight by using calorie restrictions. We further believe that the exclusion of important science violates the 1990 Congressional mandate for the DGA to be based on the “preponderance of scientific and medical knowledge that is current at the time.”²⁶

Further, we reiterate one of the three primary goals established by the Departments of Agriculture (USDA) and Health and Human Services (HHS) for the Dietary Guidelines is to help Americans “reach and maintain a healthy weight.”²⁷ The Committee understands that there are 66 percent of Americans with overweight or obesity²⁸ for whom inducing weight loss is the single most effective strategy enabling them to reach and maintain a healthy weight. It simply makes no sense for the protocols to exclude *from the outset* virtually all studies examining the dietary patterns enabling the vast majority of Americans to achieve one of the DGA’s primary goals. We agree with previous iterations of the Dietary Guidelines making “[p]rimary prevention of obesity and related risk factors [] the single most

²⁴ NASEM 2 at 6. Available at <https://www.nap.edu/download/24883#>. Accessed May 27, 2020.

²⁵ USDA, Public Meeting #5 of the Dietary Guidelines Advisory Committee, March 23, Afternoon, Minute 29:16. A non-official yet professional transcript of this public meeting can be found [here](https://static1.squarespace.com/static/5a4d5666bff20053c65b7ff2/t/5e73d18616772f0fd8940644/1584648584430/March+12%2C+2020+-+Afternoon+Session+-+2020+Dietary+Guidelines+Advisory+Committee+Public+Meeting.pdf): <https://static1.squarespace.com/static/5a4d5666bff20053c65b7ff2/t/5e73d18616772f0fd8940644/1584648584430/March+12%2C+2020+-+Afternoon+Session+-+2020+Dietary+Guidelines+Advisory+Committee+Public+Meeting.pdf> (3/12PM at 11; Boushey)

²⁶ H.R. 1608, op. cit.

²⁷ About the Dietary Guidelines. U.S. Department of Health and Human Services website. Last updated October 21, 2019. Available at <https://health.gov/our-work/food-nutrition/about-dietary-guidelines>. Accessed May 28, 2020.

²⁸ 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. Accessed July 10, 2019.



powerful public health approach to reversing America’s obesity epidemic over the long term.”²⁹

The DGAC further excluded from review the majority of the scientific literature on low-carbohydrate diets. The DGAC created exclusion criteria that were the very definition of a low-carbohydrate diet (*i.e.*, a study protocol that does not include a full description of foods and beverages consumed but is instead based on a target for a single type of macronutrient),³⁰ and these criteria appears to be the reason that at least 52 low-carb clinical trials were either not found or actively excluded from review.³¹

Also excluded was any of the contested science on saturated fats despite the topic of “Types of Dietary Fats” included as a specific new topic added as a result of public comment. These fats have undergone a major reconsideration in the scientific community worldwide over the past 10 years, with a consensus that saturated fats have no effect on cardiovascular or total mortality.³² Well more than a dozen review papers have been published during this time, based on clinical trials that were conducted in the 1960s and 70s and were never directly reviewed by any previous DGAC.³³ However, this reconsideration of the science is not reflected in the current DGAC reviews of saturated fats, despite many public comments, including some by prominent scientists in the field, on this important topic.³⁴

2) Outdated Science

The 13 systematic reviews on the “Birth-to-24-Months” population cover the scientific literature only through mid-2016. The DGAC stated that an “informal search” of the post-2016 science was conducted but not in a systematic way³⁵. Relying on science only through 2016 would seem to violate the statutory requirement that the DGA be based on science that is “current at the time.”³⁶ For the most part, the DGAC’s other reviews include science through the fall of 2019 or even early 2020. We note that as a result, Committee members

²⁹ 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)

³⁰ <https://www.dietaryguidelines.gov/sites/default/files/2020-04/DP-CVD-Protocol-DPSC-04-22-2020.pdf>, Accessed June 1, 2020. See: Exclusion Criteria for Intervention/Exposure 1a. and 2b.

³¹ <https://lowcarbaction.org/low-carb-studies/>, Accessed June 1, 2020.

³² <https://www.onlinejacc.org/content/early/2020/06/16/j.jacc.2020.05.077>

³³ <http://www.bmj.com/content/351/bmj.h4962>

³⁴ <https://www.regulations.gov/document?D=FNS-2019-0001-42017>;
<https://www.regulations.gov/document?D=FNS-2019-0001-52079>

³⁵ Dietary Guidelines Advisory Committee Meeting 4, January 23, 2020. Page 43, line 19
. <https://www.dietaryguidelines.gov/sites/default/files/2020-03/2020DGACMtg4TranscriptDay1FINAL.pdf>

³⁶ H.R. 1608, op. cit.



emphasized “the need for more data” and that “particularly as [they were] looking at this B-24 and the pregnancy and lactation[, . . .they] have very few studies to look at.”³⁷

3) *Scientific Methodology*

We are concerned that the USDA has not fully adopted a recognized, “state-of-the-art systematic review methods”³⁸ to “maximize scientific rigor,”³⁹ which was one of NASEM’s “five values to improve the integrity of a process to develop credible and trustworthy guidelines.”⁴⁰ . 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.”⁴¹ The NASEM report made three formal recommendations about how to increase the scientific rigor of the DGA (Recommendations #5, 6, 7). It states, “This National Academies committee assessed the NEL systematic review process, identifying several opportunities to advance and align...with existing best practices for systematic reviews.”⁴² The report concludes, “Current methods need to be strengthened to better support the development of credible and trustworthy *DGA* [Dietary Guidelines]”⁴³

The USDA adopted some of the NASEM recommendations, such as the introduction of a form of peer review of its scientific reviews. However, there is little evidence that the USDA has aligned itself with best practices of scientific reviews; for instance, there is no explanation in the methodology about how different types of evidence will be graded (*i.e.*, randomized, controlled clinical trials vs. prospective cohort studies). Without this kind of methodology, it is not clear if USDA is meeting the NASEM requirements to develop a more “credible and trustworthy DGA.”

B. The Guidelines Must Be Applicable to All Americans

The Food4Health Alliance suggests delaying implementation of the 2020-2025 DGA until the above issues can be remedied.

As an alternative, we suggest issuing the 2020-2025 DGA in a way that makes its limitations clear to the general public.

³⁷ (3/12PM at 56; Donovan)

³⁸ NASEM, part 2, p. 14.

³⁹ NASEM, part 2, p. 49.

⁴⁰ NASEM, part 2, p. 6.

⁴¹ NASEM, part 2, p. 5.

⁴² NASEM, part 2, p. 185

⁴³ NASEM, part 2, p. 96.



In this case, the 2020-2025 DGA should state clearly that it is not intended to help people lose weight or address any diet-related condition such as obesity, diabetes, heart disease, cancer, or hypertension.

The 2020-2025 DGA should also make abundantly clear to the public that its recommendations may not be applicable to African-American/blacks, Hispanic/Latinx, Native Americans, older adults, teens, or growing children, as these populations either were not studied, accounted for, or the DGAC lacked data on them.

Food4Health also urges the USDA to reexamine the usefulness the DGAs in informing USDA nutrition assistance programs, since these programs disproportionately serve the populations listed above, and to whom the DGAs, given its lack of data and narrow scope, does not reliably apply. The recommendations should be applied carefully to populations for which there is insufficient research and should be modified to reflect specific needs routinely identified in these populations.

Respectfully,

Members of the Food4Health Alliance (www.food4health.org)

Defeat Malnutrition Today
Grapevine Health
National Hispanic Medical Association
The Nutrition Coalition

ⁱ Transcript of March 13, 2020 Morning Meeting of Dietary Guidelines Advisory Committee at 24; Schneeman. Available at https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289846&tp_key=af6515fc8a

ⁱⁱ Transcript of March 13, 2020 Afternoon Meeting of Dietary Guidelines Advisory Committee at 27; Schneeman citing Stang. Available at https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289852&tp_key=6cf027ef9d