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Perspectives

An analysis of the recent US dietary guidelines process in light of its federal mandate and a National Academies report

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Abstract

The US Dietary Guidelines for Americans is an enormously influential policy that has guided US nutrition programs since 1980. During these last 40 years, some researchers have expressed concern that the guidelines are based on an insufficiently rigorous assessment of the scientific evidence, a view that was largely substantiated by a Congressionally mandated 2017 report by the National Academies of Sciences, Engineering, and Medicine, which identified a need for enhanced transparency, greater scientific rigor, and updates to the scientific methodology for the DGA process. This paper traces the history of these ideas and contextualizes the DGA within the law and regulations that govern its process. The paper also discusses how recent iterations of the Dietary Guidelines have not fully adhered to these guiding documents, which has resulted in diminished independence of the expert committee in charge of evaluating the science for the DGA and a continued lack of a fully rigorous scientific process for producing consistent and trustworthy guidelines for the public.

Keywords: dietary guidelines, nutrition policy, chronic disease, obesity, dietary fat

Introduction

The US Dietary Guidelines for Americans (DGA) is a highly influential policy, deemed by the US government to be "a gold standard" based on the "best available science" (1). By statute, its recommendations form the foundation of all federal nutrition programs in the United States (2, 3). The trustworthiness of the scientific process underpinning the DGA is, therefore, of paramount importance.

The DGA was launched in 1980 jointly by two federal agencies, the US Departments of Agriculture and Health and Human Services (USDA–HHS), with three editions published, in 1980,1985, and 1990, before Congress passed a statute governing the policy: the National Nutrition Monitoring and Related Research Act (NNMRR) of 1990 (2). This act stated that "[a]t least every 5 years the Secretaries [of USDA–HHS] shall publish a report entitled 'Dietary Guidelines for Americans'," which "shall contain nutritional and dietary information and guidelines for the general public, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health programs." The act further stated that the DGA "shall be based on the preponderance of the scientific and medical knowledge, which is current at the time the report is prepared." Unfortunately, today's evidence-based approaches to assessing scientific information do not reach general agreement on a definition for the "preponderance" of knowledge, how to measure it, or whether it is a sufficient standard upon which to base policy. Early iterations of the DGA, based on the scientific standards of their times, reflected a subjective interpretation of this term, while the USDA has, over time, come to define "preponderance" as its agency's own systematic reviews of the science. Nonetheless, as discussed below, these systematic reviews do not consistently meet current systematic review standards of the field.

Following the release of the first DGA, Congress additionally directed USDA–HHS "to seek outside scientific expert advice prior to the Departments developing the next edition of the *Dietary Guidelines*" (4). This mandate led to the introduction of a Dietary Guidelines Advisory Committee (DGAC) in 1983, which is appointed by USDA–HHS anew for each iteration of the DGA. Despite the movement of all scientific endeavors toward increased transparency of both the scientific process and reporting on conflicts of

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interest (COI), the DGAC appointment process remains wholly opaque, without disclosure of the potential nominees nor any explanation as to why or how certain nominees are selected while others rejected. The DGAC is governed by the Federal Advisory Committee Act (FACA), which, among other things, states "that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority. . .but will instead be the result of the advisory committee's independent judgment" (5). Thus, responsibility for the integrity of the DGA scientific review process appears to rest with the DGAC, an impression that was confirmed by the USDA designated federal officer for the 2020 process, who stated, at a public meeting, ". . .the ultimate conclusions and recommendations are of the committee. So, we are here to help facilitate the work, to ensure that we follow processes, but at the end of the day, it's your report and the committee's recommendations to us" (6).

For each iteration of the DGA, the DGAC has historically reviewed the relevant science and produced a "Dietary Guidelines Advisory Committee Report" ("DGAC report" or "expert report"), which is then translated by USDA–HHS officials into the public-facing policy document, known as the DGA. This document is distributed to both healthcare professionals and the public. To date, criticism of the DGA process has focused principally on the translation process, whereby outside interests are assumed to weaken the DGAC expert advice as it is converted into federal policy (7). However, evidence presented in this paper suggests that the scientific review process itself has also been insufficiently rigorous and that the DGAC committee has lacked independence from the USDA–HHS.

History of concern

Concern about the scientific rigor of our nation's dietary advice dates back to 1977, even before issuance of the first DGA, when the US Senate published the *Dietary Goals*, a document written principally by a Senate staffer without expertise in nutrition or public health (8). This document laid out the basic recommendations that would later become the basis of the Guidelines. A number of experts, including the president of the National Academies of Science and the director of the National Heart, Lung and Blood Institute, urged restraint, noting a lack of scientific evidence for these recommendations and the potential for unintended consequences (9). A report by the National Academies of Sciences that examined the foundational studies for the Guidelines concluded that the proposed diet had "generally unimpressive results" (10). A task force set up by the American Society for Nutrition found insufficient clinical trial evidence to restrict saturated fat or fat generally for the prevention of heart disease, but the group did not see evidence showing that such measures would cause harm, either (11). At the same time, the US Surgeon General came out with a report in favor of the *Dietary Goals*, as did leaders at the National Institutes of Health (12). Mark Hegsted, a Harvard nutritionist who had been an expert source for the *Goals* and who went on to become the first administrator at USDA to oversee the DGA, also defended the *Dietary Goals*, writing in the Senate report, "There will undoubtedly be many people who will say we have not proven our point," yet when questioning the risks, Hegsted responded, "There are none that can be identified and important benefits can be expected" (13).

Debate over the *Goals* remained robust throughout the late 1970s, with the Congress, the media, and the nation's top scientists involved. Much of the debate centered on dietary recommendations for the prevention of cardiovascular disease, the nation's leading cause of death. By the mid-1980s, however, this controversy abated, as influential experts successfully argued that a cholesterol-lowering diet should have similar effects to the benefits seen with cholesterol-lowering drugs (14), even though long-term studies had not consistently supported the benefit of dietary interventions for lowering cholesterol in achieving meaningful health outcomes, including heart attacks, cancer, and death (15, 16).

It is important to emphasize that members of the DGAC have invariably taken their responsibility seriously and that commentary about the Guidelines process has been generally positive and supportive (17). Less well-known, however, is that over the past 15 years, scientists including at least seven members of previous DGACs, have raised serious concerns about the DGA methodology and/or the resulting recommendations. In large part, these concerns have arisen due to a substantial evolution in the accepted standards of "evidence" and how to grade such evidence since the DGA process began in 1980. A member of the 2010 DGAC wrote, "The process under which they [the Guidelines] were developed clearly needs enhancing to ensure that Americans are being provided the strongest, most accurate recommendations based on the most rigorous science available," and elaborated shortcomings that included a reliance on weak evidence, inconsistent inclusion of studies, and an inability to "take the long view" on how a field of science might have shifted over time (18). Another 2010 DGAC member wrote, "Despite our evidence-based review lens where we say that food policies are "science based," in reality we often let our personal biases override the scientific evidence" (19). Members from both the 2005 and 2010 DGACs also expressed concern about the DGA's reliance on weak data and inconsistent methods (20, 21).

"A call for higher standards of evidence for dietary guidelines," was also the title of a 2008 paper published in the *American Journal of Preventive Medicine*, which pointed out the problem of unintended consequences when "high-quality evidence is missing" (22).

Most recently, in 2020, three previous DGAC members, including the chair of the 2005 Committee, argued in a "State of the Art Review" in the *Journal of the American College of Cardiology* (JACC), that there was insufficient rigorous evidence to support limits on saturated fats as a measure of protection against heart disease (23). Their assessment was based on the evolving accrual of evidence in the field, summarized in more than 20 review papers by independent teams of scientists from around the world that have now challenged the scientific basis for this advice (24-28). The JACC authors also pointed out that the few papers arguing to the contrary on saturated fats have mistakenly included data from nonrandomized trials or excluded long-term outcome data on mortality (29).

Reassessments of DGA recommendations

As described below, recent reassessments of some key DGA recommendations have reflected contemporaneous updates based on the advancing science. By contrast, some changes appear to suggest a breakdown in the scientific process.

The changing advice on trans fats is an example of the DGA evolving with the science. The food industry created industrial trans fatty acids (iTFA) in 1902 when Wilhelm Normann in Germany patented a process to harden oils by hydrogenation. This process was considered a breakthrough, since it gave a needed stability and solidity to vegetable oils, such as cottonseed, soybean, and corn. Hydrogenated oils were initially embraced by

the food industry as an inexpensive option for packaged foods and starting in the 1960s, with the advent of the diet heart hypothesis, (i.e. that lower dietary saturated fat reduces heart disease risk) were increasingly employed as a replacement for saturated fats. The DGA at first implicitly favored iTFA, because they were mostly comprised of unsaturated fats, which the guidelines had long favored over saturated fats. In the early 1990s, however, researchers discovered that iTFA raised total and LDL-cholesterol, lowered HDL-C, and were associated with increased risk of CHD (30). The 1995 DGA acknowledged this risk, yet still recommended iTFA, finding them less threatening than the cholesterol raising effects of saturated fats (31). In 2000, the DGA issued its first formal advice to avoid intake of trans fats while still continuing to recommend margarine over butter, due to margarine's lower saturated-fat content (32). Based appropriately on the evolving science in this area, DGA iterations since that time have ultimately led to zero tolerance of iTFA in hydrogenated oils.

Similarly, in 2015, after 35 years of advising the public to limit its intake of dietary cholesterol, the DGAC report dropped its numerical cholesterol cap of 300 mg/day, stating that the committee would "not bring forward this recommendation because available evidence shows no appreciable relationship between consumption of dietary cholesterol and serum cholesterol. . ." and "[c]holesterol is not a nutrient of concern for overconsumption" (33). A total of 2 years earlier, the American Heart Association had also dropped its cap on dietary cholesterol (34), presumably due to an evolution in the available evidence. Nonetheless, the 2015 DGA policy distributed to the public stated that the elimination of a cap on cholesterol did not suggest that dietary cholesterol was no longer an important consideration and referred instead to a report by the Institute of Medicine (IOM) stating that "individuals should eat as little dietary cholesterol as possible while consuming a healthy eating pattern" (35).

In the next iteration of the guidelines, the 2020 DGAC conducted a formal systematic review of the evidence on dietary cholesterol and concluded that there was "insufficient evidence" to support a relationship between cholesterol in the diet and cholesterol in the blood (36). However, the 2020 DGAC generated some confusion by sidelining its own systematic review and instead reverting to the less current 2015 report, which advised keeping dietary cholesterol "as low as possible" within the context of a nutritionally adequate diet (37). This 2015 report had, in some analyses found only "moderate" evidence for health benefits from dietary patterns "lower. . .in cholesterol." For unclear reasons, the grade of "moderate" was upgraded to "strong" by the 2020 DGAC without any additional analyses. Discrepancy between the results of the 2020 systematic review and the conclusions of the expert report suggests a breakdown in the scientific review process as well as the process by which the agencies translate science into policy.

Another long-standing pillar of DGA advice, "to avoid too much fat," has evolved in ways that are contradictory and appear to elicit confusion. In 1990, total fat was given a specific (and arbitrary) numeric cap of 30% of calories based exclusively on observational data, which provide a lower standard of evidence than do randomized trials, because causality cannot be assigned from such data (38). The recommended proportion of calories from fat was later revised to a range of 20% to 35%, and this guidance remained in place until 2010, when, without any clear explanation of the scientific rationale, the Dietary Guidelines discontinued any top-level recommendation on reducing total fat (39). Indeed, as far back as 2000, the DGAC expressed concern about the government's low-fat advice, because it "could engender an overconsumption of total calories in the form of carbohydrates, resulting in the adverse metabolic consequences of high-carbohydrate diets." The DGAC report added, "Further, the possibility that overconsumption of carbohydrates may contribute to obesity cannot be ignored" (40). In 2015, the DGAC report explained that dietary advice should not emphasize reducing total fat (41), because low-fat "diets are generally associated with dyslipidemia (hypertriglyceridemia and low HDL-C concentrations)" (42), which are indicators of increased risk for heart disease. For this reason, the DGAC Vice Chair noted that ". . .there is no conventional message to recommend low-fat diets" (43).

Subsequent systematic reviews and other assessments have concluded that rigorous clinical trial evidence did not support the advice to eat a low-fat diet when the Guidelines were first issued (44) or subsequently (45-50). Nevertheless, adding to potential public confusion, the 2015 and 2020 DGAs adopted macronutrient standards defined by the National Academies of Sciences, known as the "Acceptable Macronutrient Distribution Ranges" (AMDR), which allow dietary fat to range between 20% and 35% of calories. In other words, despite eliminating the words "low-fat" and any formal low-fat recommendation, the text of the DGA paradoxically continues to advise a range of dietary fat intake that has historically been understood in the scientific literature as a low-fat diet.

Congressional Action and a report by the National Academies of Science

In 2015, stakeholder concerns about both the process of determining the DGA and reversals in some of its recommendations prompted a 2-hour hearing of the House Committee on Agriculture, which oversees the DGA, at which both the Secretaries of USDA–HHS testified (51). "Have these guidelines failed?" questioned panel member Representative Glenn Thompson, a Republican from Pennsylvania. "They don't seem like they're accomplishing their objective." The panel's top Democrat, Collin C. Peterson of Minnesota, echoed the sentiment: "I just want you to understand from my constituents, most of them don't believe this stuff anymore . . . and so that's why I say I wonder why we're doing this". Among other issues, members of Congress questioned whether science had been inappropriately excluded, whether a single set of guidelines was appropriate for America's diverse population, and whether the process had strayed from its original Congressional mandate.

Emerging from this hearing was a mandate by Congress, in 2015, for the National Academies of Sciences, Engineering, and Medicine (NASEM) to review the DGA process, funded by an appropriation of one million dollars (52). In the report accompanying the bill, Congress issued a "directive," which stated:

> "Questions have been raised about the scientific integrity of the process in developing the dietary guidelines and whether balanced nutritional information is reaching the public. The entire process used to formulate and establish the guidelines needs to be reviewed before future guidelines are issued. It is imperative that the guidelines be based upon strong, balanced science and focus on providing consumers with dietary and nutritional information that will assist them in eating a healthy and balanced diet. At a minimum, the process should include: full transparency, a lack of bias, and the inclusion and consideration of all of the latest available research and scientific evidence, even that which challenges current dietary recommendations" (53).

Congress was, in effect, mandating the first-ever outside peer review of the DGA process. Somewhat surprisingly, Congress then

Table 1. NASEM report recommendations.

Part 1: **Optimizing the process for establishing the DGA**

1. The Secretaries of USDA and HHS should employ an external third-party to review and narrow the candidate pool to a list of primary and alternate nominees. Criteria against which nominees are screened should be developed by USDA and HHS for use by the third-party.
2. The Secretaries of USDA and HHS should make a list of provisional appointees open for public comment-including short biographies and any known conflicts-for a reasonable period prior to appointment.
3. The Secretaries of USDA and HHS should disclose how provisional nominees' biases and COI 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 COI; and by
   d. Documenting how COI were managed in the DGAC report.
4. The Secretaries of USDA and HHS should adopt a system for continuous process improvement to enhance outcomes and performance of the DGAC selection process.

Part 2: **"Redesigning the process for establishing the Dietary Guidelines for Americans"**

1. The Secretaries of the US Department of Agriculture (USDA) and the US Department of Health and Human Services (HHS) should redesign the DGA process to prioritize topics to be reviewed in each DGA cycle, and redistribute the current functions of the DGAC to three separate groups:
   a. Dietary Guidelines Planning and Continuity Group to monitor and curate evidence generation, to identify and prioritize topics for inclusion in the DGA, and to provide strategic planning support across DGA cycles;
   b. Technical expert panels to provide content and methodological consultation during evaluation of the evidence; and
   c. Dietary Guidelines Scientific Advisory Committee to interpret the scientific evidence and draw conclusions.
2. The Secretaries of USDA and HHS should provide the public with a clear explanation when the DGA omit or accept only parts of conclusions from the scientific report.
3. The Secretary of USDA should clearly separate the roles of USDA Nutrition Evidence Library (NEL) staff and the Dietary Guidelines Scientific Advisory Committee (DGSAC) such that:
   a. The NEL staff plan and conduct systematic reviews with input from technical expert panels, perform risk-of-bias assessment of individual studies, and assist the DGSAC as needed.
   b. The NEL systematic reviews are externally peer reviewed prior to being made available for use by the DGSAC.
   c. The DGSAC synthesizes and interprets the results of systematic reviews and draws conclusions about the entire body of evidence.
4. The secretary of USDA should ensure all Nutrition Evidence Library (NEL) systematic reviews align with best practices by:
   a. Enabling ongoing training of the NEL staff,
   b. Enabling engagement with and learning from external groups on the forefront of systematic review methods,
   c. Inviting external systematic review experts to periodically evaluate the NEL's methods, and
   d. Investing in technological infrastructure.
5. The Secretaries of USDA and HHS should enhance food pattern modeling to better reflect the complex interactions involved, variability in intakes, and range of possible healthful diets.
6. The Secretaries of USDA and HHS should standardize the methods and criteria for establishing nutrients of concern.
7. The Secretaries of USDA and HHS should commission research and evaluate strategies to develop and implement systems approaches into the DGA. The selected strategies should then begin to be used to integrate systems mapping and modeling into the DGA process.

allocated control of the appropriation to the same USDA office, the Center for Nutrition Policy and Promotion (CNPP), which directly oversees the DGA. No one at the time seemed to identify this apparent COI. According to USDA officials with knowledge of the process, CNPP wrote the contract for the NASEM, defined the scope of the report, and was allowed to chair the opening meeting for the NASEM review. Notably, CNPP did not urge NASEM panel members to review the DGA with an eye toward ensuring the inclusion of evidence that "challenges current dietary recommendations," as Congress had encouraged.

In 2017, NASEM issued a two-part report, with the first section focusing on the selection process for the DGAC expert committee, and the second section addressing the process for reviewing the science (54, 55). The top-level recommendations included a need for the DGA process to "improve transparency" and "strengthen scientific rigor." "To develop a trustworthy DGA," the report states, "the process needs to be redesigned" (56).

One recommendation, to disclose the list of DGAC nominees, should in our view, be broadened to bring transparency to the entire DGAC selection process by also making public the names of the officials at USDA–HHS involved in the process, the criteria used to guide these decisions, and an explanation according to predefined public criteria as to why certain candidates are accepted and others rejected.

Part one of the report also made four recommendations (Table 1) focused on the need for the agencies to publicly disclose "biases and conflicts of interest" of the DGAC nominees and, among other things, to "document how those conflicts of interest were managed" in the expert report. While it is important to emphasize that potential COI are not evidence of actual COI, potential conflicts are clearly an important issue. A recent paper found that 95% of the 2020 to 2025 DGAC members had at least one relationship with industry and that a majority had 20 connections or more with industry (57). (Relationships were defined as employment, consultancy, or board membership with or research funding from industry; editor of a publication run by industry; any payment to participate in or organize an industry event; or any award or prize from industry. Such relationships may have been equally likely among previous DGACs, when disclosure was less common. Today, disclosure of such potential conflicts is the common practice in scientific journals, and in 2011, the IOM issued a standard that "no more than a minority" of an expert group

developing clinical practice guidelines should be allowed to have a COI (58). This expectation should apply to any expert advisory group yet can only be objectively verified if COIs are publicly disclosed. Additionally, members of expert groups may have strong intellectual biases, such as previously published positions. Nutrition experts in particular should also consider disclosing personal dietary preferences as relevant COIs (59). The NASEM report recommended that all "financial and nonfinancial biases and conflicts" of the DGAC should be "explicitly disclose[d]" and managed (60).

The USDA responded to the NASEM report, in a 2019 written statement to Congress (In a 2019 appropriations bill, Congress mandated that the Secretary of Agriculture shall "submit a report to the Committees on Appropriations of both Houses of Congress that includes. . .an explanation with respect to the decision to incorporate or exclude in [the next] Dietary Guidelines for Americans recommendations from the report by the National Academies of Science, Engineering, and Medicine entitled "Redesigning the Process for Establishing the Dietary Guidelines for Americans'" and issued September, 2017."), (61, 62) stating that it chose not to publicly disclose the COIs of provisional nominees, "in concern of the provisional appointees' privacy" and "the potential of public slander" (63). As later explained by a USDA official at a public meeting, the agency did not have the capacity to report on such a large number of potential nominees and feared that such disclosure could have a chilling effect on people who might consider applying (64). However, the USDA's response to Congress does not consider the possibility that even if provisional nominees were excluded from public disclosure, the NASEM recommendation might have implied that there be disclosures for the selected nominees, i.e. those who were appointed. These appointees possess significant decision-making authority over the scientific report that forms the basis of US nutrition policy. The USDA stated that it would not follow this interpretation of the NASEM recommendation, however. By contrast, the 2020 DGAC, in its advisory report, noted that it planned to post the financial disclosure forms of its members' COI on the DGA official website ("a copy of Form 450 was posted on DietaryGuidelines.gov") (65), yet at the time of this writing, those COI reports could not be found. The advisory report did document how conflicts were managed, yet the description is vague, without mentioning any specific COI, and therefore, cannot be externally evaluated or verified.

Part two of the report makes seven recommendations (Table 1), several of which aim to improve the scientific process (66). The introduction to this part of the report states that reform of the Guidelines process can "improve transparency, promote diversity of expertise and experience, support a deliberative process, promote independence in decision making, and strengthen scientific rigor. If successfully implemented, these modifications collectively have the potential to help improve the credibility of the *DGA* and trustworthiness of the process" (67).

The scientific issues that the NASEM emphasizes are that the "scientific rigor needs to be maximized" and that the "process by which the science is evaluated can be strengthened," by using "validated, standardized processes, and methods." This idea is iterated: "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," and "Current methods need to be strengthened to better support the development of credible and trustworthy DGA."

Specific recommendations included advice to create technical expert panels both "to provide content and methodological consultation during evaluation of the evidence" and to help the USDA office that conducts systematic reviews "to perform risk of bias assessment of individual studies, and assist the [DGAC] as needed." The NASEM also recommends that the USDA's "systematic reviews are externally peer reviewed prior to being made available for use" by the DGAC.

The USDA explained in its report to Congress that it did not create technical expert panels for the 2020 process "due to time and resource constraints." By contrast, the agency did accept the NASEM recommendation to change the process for selecting scientific questions, moving it to prior to the selection of the DGAC (68). While this change provided a new opportunity for public participation, it effectively shifted decision-making authority regarding the scientific questions from the DGAC to agency officials, which could be seen as contrary to the FACA rules requiring that the committee maintain control over the scientific process, as cited above.

The USDA also introduced added rigor to the DGA process by introducing "external" peer review of the systematic reviews, as recommended. However, one must again question the appearance of potential COI, since the reviewers were neither fully independent nor "external," as they were all employees of the federal government, including many from the agencies, HHS and USDA, which issue the DGA (69). (That said, none of the reviewers came from the USDA office directly involved in the DGA process, according to a paper coauthored by 2020 DGAC members.) (70).

Regarding the process of systematic reviews of the science, which are performed by a USDA office called the Nutrition Evidence Systematic Review (NESR), the NASEM report states that it assessed this process and identified "several opportunities to advance and align. . .with existing best practices for systematic reviews." The NASEM's heightened concern about the scientific reviews is made evident by the fact that it devotes three out of its seven process recommendations to focus on the need for the USDA to be "strengthening and adopting appropriate and strategic methodologies so as always to align with current best practices." The NASEM specifically recommends that the USDA "follow state-of-the-art methods" and lists several of these, "such as the GRADE approach and the AHRQ Evidence-based Practice Centers Program approach," but does not specify which specific method to adopt. All of these approaches use rigorous systems for grading scientific evidence.

The USDA responded:

> "When appropriate and feasible, refinements to the NESR methodology are carefully planned, tested, and adopted. Examples of process improvements that NESR has made as part of this effort to support the 2020 Advisory Committee relate to (1) tools and processes for assessing risks of bias of primary research; (2) criteria for grading the strength of evidence underlying the conclusion drawn in NESR systematic reviews; and (3) technology to support efficient and accurate searching for and screening of studies, as well as data extraction."

Despite these assurances, the NESR's actual methodology contains only vague descriptions about how it "generally" "might" grade different types of studies and concludes:

> ". . .the NESR systematic review process included a number of steps in which study design was considered, ensuring that the conclusions drawn and the strength of evidence grades assigned reflected a thorough assessment and consideration of the strengths and limitations of various study designs."

The NESR does not specify what steps are taken in considering study design, what it considers to be "strengths and limitations" of various types of evidence or the specific rules regarding how it grades evidence (71). The lack of detail or definition of the specific procedural and analytical steps in the NESR methodology would not be considered acceptable by any objective scientific body.

A presentation by USDA officials at the first meeting of the 2020 DGAC confirmed that the NESR's "grading rubric" does not include standards for prioritizing data from high-quality RCTs over evidence from observational studies. This aspect of grading evidence is a crucial feature of the "state-of-the-art" methodologies listed above; They all initially rank data from randomized controlled clinical trials as of higher quality than those from observational, or epidemiological, studies. It is notable that the USDA did not adopt this basic criterion. Indeed, for the crucial task of grading the strength of the body of evidence for reaching a recommendation, the NESR left this decision up to the discretion of each DGAC subcommittee (72). As a result, the 2020 subcommittees differed in their evaluation of the evidence, with observational evidence considered of "moderate" strength by some DGAC members, while others had differing views (73). By omitting a consistent approach for differentiating the quality and strength of varying types of scientific evidence, the USDA–HHS systematic reviews cannot be viewed as meeting internationally recognized methodological standards in the field, nor can they be considered as meeting the NASEM's recommendations to improve the rigor of NESR's scientific review methodology.

The lack of a uniform NESR methodology is evidenced in other ways. One subcommittee "updated" previous NESR systematic reviews by using "evidence scans" to add new evidence to the previously conducted systematic reviews (74), yet "scans" are not accepted practice in the field. To achieve a systematic outcome, a new review must be conducted, incorporating the totality of all the available evidence, old and new. Another inconsistency among subcommittees in the 2020 process was that several subcommittees excluded clinical trials shorter than 4 weeks, while the Subcommittee on Dietary Patterns excluded all trials shorter than 12 weeks (75). If this evidentiary standard had been used previously when reviewing the Dietary Patterns, all the trials on the so-called DASH diet (Dietary Approaches to Stop Hypertension) would have been excluded (76). As it stands, the DASH trials comprise a large part of the evidence base for the "US Style" Dietary Pattern (77, 78).

In addition, several bodies of scientific evidence were omitted from consideration. One of these was the scientific literature on weight loss (79), a questionable decision given that at least two-thirds of Americans are overweight or obese and also that weight loss is widely considered an important intervention to reduce risk for type 2 diabetes and other health conditions. Another omission was the near-entirety of the scientific literature on low-carbohydrate diets. At least one outside group submitted formal public comments alerting the USDA to this oversight, with lists of some 65 clinical trials of these diets (80). In addition, a 2019 review commissioned by the American Diabetes Association recognized this diet as having "demonstrated the most evidence for improving glycemia [blood sugar control]," a critical issue for the management and prevention of type 2 diabetes (81). An abundance of literature suggests that low-carbohydrate diets are safe and effective for the prevention of obesity, type 2 diabetes, and heart disease (82). The omissions of this and other bodies of scientific literature potentially contribute to the DGA's limited ability to address populations diagnosed with diet-related diseases, as discussed below.

Such methodological shortcomings have played at least a part in the reversal of several key DGA recommendations as described above, as well as the continuation of some recommendations despite ample scientific evidence to the contrary, such as advice to consume three servings of refined grains per day, the continued cap on saturated fat (83), and the introduction of a vegetarian "Dietary Pattern" to protect against obesity, type 2 diabetes, heart disease, and cancer. (For the vegetarian diet, the systematic reviews for the 2015 DGAC found only low-quality evidence that this diet could protect against these diseases.)

Overall, the USDA did not adopt a majority of the NASEM process recommendations, particularly those that would enhance transparency and scientific rigor of the process. Despite this, the 2020 DGA process did not generate high levels of concern, compared to the previous iteration. A number of groups noted the undisclosed COI at USDA and on the DGAC (84-89). One or more members of the DGAC came forward to anonymously express concerns about the scientific process (90, 91), and the influential Academy of Nutrition and Dietetics, among other groups, called for a delay in the issuance of the DGAC report due to unfinished, incomplete or inconsistent reviews (92, 93, 94). Also asking for a delay of the expert report was a member of Congress, in a letter to the Secretaries of USDA–HHS, in which he further urged the agencies to adopt more fully the NASEM recommendations" (95). It seems clear that greater alignment of the DGA process with the NASEM report is still needed.

DGA compliance with Congressional statute

The National Nutrition Monitoring and Research Act (NMMRA), the Congressional statute authorizing the DGA, sets forth several requirements, as mentioned above, to which the USDA–HHS have only partially adhered in recent years. For example, the statute requires that the DGA should address the "general public" (96). In 1980, when the DGA was first launched, adult obesity rates were under 15%, and the population was mostly healthy. Thus, to address the general public, the DGA focused exclusively on this healthy population by providing advice for the prevention of chronic diseases. Treatment of these diseases has been considered beyond the scope of the DGA, according to USDA officials, who have explained that although studies of individuals with chronic diseases may be included in the NESR systematic reviews, primary outcome data of these studies are not examined (97).

Today, the situation is quite different, with some 60% of American adults diagnosed with one or more diet-related disease (98), reflecting a general public in which the majority of individuals is no longer healthy. The DGA, therefore, no longer serves the general public, an issue the NASEM report identified when it stated "Given the prevalence of chronic disease and risk for chronic disease in the population, this National Academies committee believes it will also be essential for the *DGA Policy Report* to include all Americans whose health can benefit by improving their diet based on the scientific evidence. Without these changes, present and future dietary guidance will not be applicable to a large majority of the general population" (99). At least some members of the 2020 DGAC appear to be confused about the issue and in an article state that the DGA "are relevant to the American population as a whole, including people at-risk of diet-related diseases," while at the same time contradicting themselves a sentence later by noting that the DGA "do not address recommendations for treatment or management of diet-related chronic diseases, which are not within the scope of the DGA" (100). The stronger language appears

to favor the latter statement, implying that the DGA recommendations cannot address or resolve diet-related diseases.

The US population is indeed now so diverse that there is arguably no single "normal" anymore (101), challenging the continuation of a DGA with a single set of dietary principles. Underserved groups are particularly vulnerable, including Black and Latino populations, which have higher rates of chronic diseases than those of European ancestry. The 2020 DGAC recognized this disparate impact of chronic disease and repeatedly expressed concern that the DGAs "may not be completely generalizable to the US population as the result of differing participant characteristics" (102).

The NMMRA also requires that the DGA "shall be based on. . .knowledge which is current at the time the report is prepared." Many of the 2020 DGA reviews met this "current" standard, covering the science through 2019 or even early 2020. However, 43 of the reviews on pregnancy and "Birth to 24 Months" examined evidence through no later than July 2017, with the majority looking at data only as far as July 2016 (103). In some cases, the reviews were "updated" by a subjective inspection of the more recent data, but new systematic reviews were not undertaken.

Other reviews not based on the most current science are those on the Dietary Patterns, which comprise the cornerstone of the DGA recommendations. The 2020 Subcommittee on Dietary Patterns topic did not conduct new systematic reviews of these patterns with relation to heart disease, type 2 diabetes or obesity. Reviews covering these three diseases contain statements similar or identical to the following one found in the cardiovascular disease review: "[b]ased on results from the systematic evidence scan, the 2020 Committee determined that the newly published evidence was generally consistent with the body of evidence from the existing review, and a full systematic review update was not needed at this time. Therefore, the conclusion statement and grade from the existing review were carried forward" (104, 105, 106). The "existing" reviews refer to those published by the NESR in 2015, covering science through 2012 in the case of obesity, and 2013 in the case of heart disease and diabetes (107). Thus, the evidence base for the USDA's recommended Dietary Patterns for these major diet-related diseases was 8 to 9 years out of date at the time of the 2020 DGA publication.

DGA compliance with FACA regulation

As noted above, DGAC members have historically chosen the scientific questions to be asked and led the evidence reviews addressing these questions, with help from the USDA–HHS staff. However, since the creation of the USDA Nutrition Evidence Library in 2008, now called NESR (108), an increasing number of systematic reviews have been conducted without DGAC oversight. Given that each DGAC undertakes an enormous task, without compensation, the NESR's work could be seen as an effort to increase efficacy in the process. Yet, the NESR may have overstepped. For instance, the reviews of the Dietary Patterns and their relationship to obesity, type 2 diabetes, and cardiovascular disease, were published in 2014, without participation in or oversight from any DGAC (109). Since, as noted above, the Dietary Patterns form the backbone of the DGA, it is worrisome that these core recommendations were made without outside review. The NESR did have a "Technical Expert Collaborative" on the project that included five outside scientists, but these individuals were consultants to NESR, not independent DGAC members; in addition, peer review was conducted by USDA employees (excluding those in the office directly overseeing the DGA).

The NESR, as mentioned above, conducted 43 systematic reviews, including the conclusion statements, as part of the "Pregnancy and Birth to 24 Months Project," before the 2020 DGAC was publicly convened (110). These reviews were published in a USDA-funded supplement to an academic journal, authored by USDA–HHS officials directly involved in the DGA (111), a process that may at least give the appearance of a COI. The 43 systematic reviews (112) on these topics undertaken by USDA employees, without DGAC oversight, can be contrasted to 11 reviews (about one-fourth of the reviews on these topics) conducted with DGAC involvement (113, 114). Many of the 43 reviews conducted outside the DGAC process were used to answer questions in the 2020 DGAC expert report (115).

The USDA–HHS appears to be driving DGAC scientific decisions in other ways as well, rather than the other way around, as FACA regulation intends. For example, as noted above, the agencies selected the topics to be addressed by the DGAC. Previously, the DGAC had chosen its own topics to investigate. This change was questioned several times by DGAC members during the committee's first 2 days of public meetings. For instance, one member asked, ". . .if a new question arises, something new comes out in the literature, for whatever reason, another question arises, I'm assuming that we can discuss that and include that" (116). An HHS officer rejects this idea, replying, "As far as the evidence review process, we ask that the committee really focus on the topics and questions that are provided. . ..I mean you're welcome to discuss any of these topics in the scientific report, there just won't be like the scientific evidence review behind that." The point that no new systematic reviews could be requested by the DGAC was repeatedly confirmed by other agency officials during the first meeting. A recent paper by Harvard nutritionists questions "the entire process for developing [the guidelines]" and urges, as one of five recommendations, to reinstate the "voice" of the DGAC in the process of selecting questions for scientific review (117).

Indeed, one might now consider the DGAC to be of marginal relevance to the development of the DGA. In the 2020 process, the USDA–HHS determined the scientific questions; the NESR evaluated and graded the evidence. The NESR was even responsible for "developing conclusions and advice based on the evidence," according to a recent paper by six 2020 DGAC members (118). This paper also expresses the opinion that the role of the DGAC was confined to developing analytical protocols for some of the systematic reviews. However, as noted above, even this function is limited, since the majority of the reviews in 2020 were conducted outside of the 2-year period when the DGAC was convened. We argue that this approach is the opposite from what both statute and the FACA regulation intend. The expert committee should be driving the scientific process, not marginalized in a process now overtaken by potentially conflicted federal agencies.

The decisions and procedures described above by USDA–HHS officials, therefore, appear to be inconsistent with the FACA requirement that "the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority. . .but will instead be the result of the advisory committee's independent judgment" (119).

Conclusion

The US DGA has been in existence for more than 40 years now, during which time this policy has provided largely consistent nutritional advice for the nation. At the same time, the DGA has been insufficient to stem the rising tide of diet-related chronic diseases, which now afflict a majority of the country. As one former

DGAC member wrote, "It is extremely difficult to reverse or change public policy, once enacted, without causing consumer confusion. There are few mechanisms available to regulators and policymakers to make adjustments that reflect new science and understanding" (120). Certainly it is a challenge for policy makers to adjust to new science for fear of losing the public trust.

Nevertheless, a policy that is certain and unchanging can never reflect the evolving nature of science itself. It is imperative that the DGA evolve with the most recent evidence, for its own sake and also to comply with its governing statute.

We suggest that the USDA–HHS be encouraged to adopt the NASEM recommendations to increase transparency and enhance scientific rigor of the process. We believe it is important for the USDA–HHS to bring full transparency and public disclosure to the DGAC selection process, the COIs and biases on the DGAC, and the management thereof. The DGAC should follow IOM guidelines, with no more than 50% of committee members having ties to industry. The USDA–HHS should also fully adopt one of the state-of-the-art methodologies mentioned by the NASEM, in order to ensure reliability of the systematic review process. The DGA process needs a reliable, reproducible and rigorous scientific methodology that prevents the omission of scientific data and ensures consistent evaluation of the evidence. We further believe it is important to reinstate the independence and the authority of the DGAC. These outside experts should select the scientific questions to be considered and direct the entire systematic review process. Finally, measures should be adopted to ensure that the DGAC's science-based advice is reliably translated into policy. The adoption of these reforms will be critically important to enhance the scientific credibility of the DGA and ensure its ability to serve its role in advancing the nation's health by combatting diet-related diseases.

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All data are included in the manuscript and/or supporting information.

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