June 10, 2020

Barbara Schneeman, PhD
Chair, 2020-2025 Dietary Guidelines Advisory Committee
c/o Eve Stoody, PhD
Designated Federal Officer
Center for Nutrition Policy and Promotion, Food and Nutrition Service
U.S. Department of Agriculture
3101 Park Center Drive, Room 1034
Alexandria, VA 22301

Re: Dietary Guidelines: Draft Conclusions, Scientific Rigor, and the Need for Transparency

Dear Dr. Schneeman:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the 2020 Dietary Guideline Advisory Committee (DGAC or the “Committee”) regarding outstanding issues with the applicability and relevance of the Guidelines and the Draft Conclusions1 prior to the Committee’s issuance of its forthcoming scientific report “outlining its science-based recommendations and rationale”2 for the 2020-2025 Dietary Guidelines for Americans (the “Dietary Guidelines,” “Guidelines,” or DGAs). Representing more than 107,000 registered dietitian nutritionists (RDNs), nutrition and dietician technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals committed to accelerating improvements in global health and well-being through food and nutrition. Our members have helped conduct, review, and translate nutrition research for the DGAs since their inception, and will work to help consumers, industry, and schools choose meal patterns in accordance with the final recommendations of the Secretaries of the U.S. Department of Agriculture and the U.S. Department of Health and Human Services (collectively the “Departments”).

The Academy recognizes the enormous task before it in developing the 2020-2025 DGAs and the newly-required guidelines for Americans from birth to two-years-old. Below, we respectfully offer comments and recommendations related to the following issues:

- Newly issued Draft Conclusions and the DGAC’s process developing them.
- The need for enhanced transparency throughout the DGA development process, including work by the Departments after issuance of the scientific report.

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• The need to ensure the DGAs are relevant to the majority of Americans, recognizing the prevalence and variety of overweight, obesity, and other nutrition-related chronic diseases in the U.S. population.

I. **Fundamentals**

A. Importance of Quality Guidelines

The Academy has full confidence that, if provided with sufficient time, the Committee can fulfill its charge to “provide independent, science based advice and recommendations to be considered by USDA and HHS in the development of the 2020-2025 Dietary Guidelines for Americans.” We look forward to a transparent and collaborative process for reviewing and translating the best available “science into succinct, food-based guidance that can be relied upon to help Americans choose foods that provide a healthy and enjoyable diet.” We also look forward to ongoing engagement with the Committee as they update and finalize their conclusions and present their findings to the public.

We reiterate the need specified in the Academy’s June 2, 2020 comments seeking sufficient time to ensure that the Committee and the Departments can complete their work in a manner consistent with the highest scientific standards. **The critical work of developing, reviewing, and drawing conclusions from systematic reviews should not sacrifice quality for alacrity. Systematic reviews should not be developed with less-transparency or more limited engagement of experts than was previously used. The Dietary Guidelines for Americans are simply too important to be rushed unnecessarily.**

Fortuitously, the DGAC’s charter provides the Committee until October to prepare and issue its Scientific Report before disbanding. We are grateful for the contributions of Committee members and committed staff members from the Departments working diligently under atypical timelines and highly unusual circumstances. **Because it is critical that health care professionals, researchers, and the public can continue to have confidence in the Dietary Guidelines, we offer the comments below in an effort to allay procedural concerns.**

B. Elements of Quality Guidelines

Americans should be able to have confidence in well-developed, quality guidelines as the gold standard of evidence-based information that reduce bias and have a systematic approach to recommendation development. A well-designed process means that the studies included in the work are selected based on an understanding of the body of literature (through a scoping review), an a priori development of a comprehensive systematic review protocol and clearly delineated results in tabular format, and use of an

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‘evidence-to-decision’ framework to write recommendation statements that are both evidence based and implementable by their target population.

The comprehensive systematic review protocol should describe in detail the population being studied, the search plan for finding studies and the inclusion/exclusion criteria used to gather studies for analysis, and the methods for analysis (which includes an analysis of the quality of each study included and pooled or meta-analysis of the data). An important part of systematic review—which is important if a meta-analysis is to be conducted—is determining the outcome of interest and having homogeneity among the studies in regard to the outcome. The results of this process are then exhibited in a clear outcome-focused table detailing the studies included and their quality. This results table serves as the foundation of the narrative output—a conclusion statement. The advisory group, made up of content experts, is tasked with developing the systematic review protocol, assisting with drafting the conclusion statements and leveraging the evidence to decision framework to develop the final recommendation statement.

C. Outlining Challenges in Developing the Dietary Guidelines

The Dietary Guidelines are a seminal document for strategies to prevent chronic disease and promote health for Americans, with many challenges that have been previously delineated, including but not limited to:

- Who is the target audience? Is it only healthy Americans or also those living with chronic conditions?
- Is it best to only have the questions determined in advance versus determined by the workgroup?
- How many questions can be managed in a reasonable timeframe? And is a five year update a reasonable timeframe in which to “redo” each question?
- How and when can external systematic reviews be used to broaden the capacity of the research?

The work of the 2020-2025 DGAC is ably supported by the National Evidence Systematic Review (NESR) group of the USDA who have done a tremendous amount of work both for the more traditional areas and for the new guidelines for the Birth to 24 months demographic. The initiation of the 2020 guidelines were preempted by 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. We are pleased to note that some of the

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recommendations have been fulfilled and we understand that other recommendations were impracticable to accomplish in the available timeframe, but we reemphasize the rationale for mandating the NASEM reports and the value of their reports’ recommendations.

Currently the Committee is at a crucial inflection point in the DGA development process—the review of the Draft Conclusion statements for the six areas being included: dietary patterns, pregnancy and lactation, birth to 24 months, beverages and added sugars, dietary fats and seafood, and frequency of eating. Public input into this process is essential. It ensures all avenues have been investigated and that the public can have confidence how the evidence was developed and it clarifies which are the outcomes of interest and how these were used in the formation of the conclusion statement. The Academy continues to be very supportive of the NESR work, the process as initially published, and the mission of the Dietary Guidelines. We believe it is imperative to highlight a few areas of serious concern that we urge the NESR and the Committee to consider. Our concerns are focused strongly around transparency and rigor.

II. Methodologic Rigor and Transparency in Developing Draft Conclusions

A. National Academies Recommendations

We are concerned that the USDA has not fully adopted recognized, “state-of-the-art systematic review methods”\(^5\) to “maximize scientific rigor,”\(^6\) which was one of NASEM’s “five values to improve the integrity of a process to develop credible and trustworthy guidelines.”\(^7\) 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.”\(^8\) 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.”\(^9\) The report concludes, “Current methods need to be strengthened to better support the development of credible and trustworthy DGA.”\(^10\) We agree.

B. Additional Concerns

The Academy of Nutrition and Dietetics has specific concerns about certain aspects of the rigor of the scientific method employed. The issue of methodological rigor is raised when

\(^{5}\) NASEM, part 2, p. 14.
\(^{6}\) NASEM, part 2, p. 49.
\(^{7}\) NASEM, part 2, p. 6.
\(^{8}\) NASEM, part 2, p. 5.
\(^{9}\) NASEM, part 2, p. 185
\(^{10}\) NASEM, part 2, p. 96.
information is not fully available as it would be in a typical published journal article of a systematic review. For example, in reviewing questions that start with almost 7,000 potentially relevant articles resulting in fewer than four articles that are ultimately included (dietary patterns and sarcopenia), it is critically important to transparently report the Committee’s reasons for exclusion. However, these are not reported.

The Academy questions when, in multiple dietary pattern questions, results from manual searches are repeatedly reported as zero. The Committee should make clear—to scientists and stakeholders seeking to replicate the methodology—whether this means that no manual searches happened. If manual searches did happen, it is necessary to specify who conducted the searches and how; if not, the Committee should make clear why not.

The Academy also notes that in some instances, the arithmetic in the PRISMA charts appears incorrect and reduced reliability upon review. For example, as seen below, 59+52 does not equal 112. More importantly, 52 articles are shown as finally included, but the breakdown sums up to 25+26+8+8=67 (which is different than 52). Perhaps there is an obvious explanation for these discrepancies; perhaps they may have been prepared in haste and can be easily rectified, but overt errors cast immediate doubt on methodologic rigor.
The 2010 Institute of Medicine (IOM) report on the use of biomarkers as surrogates for disease outcomes examined LDL and HDL as case studies and concluded unequivocally that they were not suitable for use as surrogates for the impact of diet on heart disease.\textsuperscript{11} The IOM concluded that, "lowering LDL-C does not always correlate with improved patient outcomes,"\textsuperscript{12} and described the evidence from the ILLUMINATE trial (in which a drug therapy that successfully evidenced decreased LDL-C levels and increased HDL-C in fact caused an increase in cardiovascular events and death).\textsuperscript{13} Due to this and other studies' demonstration of a disconnect between lipoprotein modulation therapies and the expected improvements in cardiovascular disease outcomes, the IOM concluded that “data supports use of LDL as a surrogate endpoint for some cardiovascular outcomes for statin drug interventions, but not for all cardiovascular outcomes or other cardiovascular interventions, foods, or supplements” and that "current data does not support use [of HDL] as a surrogate endpoint.”\textsuperscript{14} \textbf{We seek clarification as to the extent to which specific recommendations may rely on DRIs that are outdated, overly or inappropriately reliant upon surrogate endpoints, or otherwise ripe for an update.}

For the scientific question asking “What is the relationship between dietary patterns consumed and risk of certain types of cancer,”\textsuperscript{15} there were repeatedly studies that had some risks of bias. However, the results of the risk of bias tool analysis for each study are unavailable thus it is difficult provide comment on this. This information would be provided in a typical systematic review peer-reviewed publication. One Committee member highlighted concerns similar to those raised above with the results table and the need for risk of bias results:

> "And I think it’s just concerning sometimes, where you have maybe one or two randomized control trials and maybe 15 or 20 observational studies, and I think at times, some subcommittees may rate those a bit differently than other subcommittees. And so, it’s just interesting to me that sometimes, with these, we’ll get a moderate rating versus a limited.”\textsuperscript{16}

Accordingly, to avoid conflict with the National Academies’ explicit recommendations and consistent with the need for an evidence-to-decision framework, the public should expect that the agencies will provide a detailed rationale for criteria in the development of

\begin{itemize}
  \item \textsuperscript{12} Id. at 165
  \item \textsuperscript{14} IOM 2010. Evaluation of biomarkers and surrogate endpoints in chronic disease. Washington, DC: The National Academies Press at 133.
  \item \textsuperscript{16} Transcript of March 12, 2020 Afternoon Meeting of Dietary Guidelines Advisory Committee at 54; Leidy. Available at https://globalmeetwebinar.webcasts.com/viewer/landing.jsp?ei=1289829&tp_key=62557ab93c
\end{itemize}
protocols, systematic reviews, and Draft Conclusions. Overall, it is not be acceptable that parts of methodology that would be essential in a written scientific paper are not part of the open information. Published protocols and Draft Conclusions should provide sufficient detail to enable independent replication; at present, they do not.

In addition to providing rationale, beyond time, for not addressing all questions initiated, the Academy recommends that the NESR publish the results tables for each conclusion statement draft, including the Risk of Bias results, its validity, and how the grade labels were assigned. This will allow a more transparent dialog on the extent the individual conclusion statements are appropriate or not and identify specific ways to strengthen the presented results.

III. **Need for Enhanced Transparency throughout the Process**

The public must have confidence that the Guidelines are indeed “based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared”\(^\text{17}\) that has not been “influenced by politics or other factors” that were noted by the National Academies.\(^\text{18}\) We strongly agree with the National Academies that, “In the steps of the process where public participation would be inappropriate, such as decision making for the DGA recommendations themselves, it will be critical for the agencies responsible for the DGA to explain to the public why key decisions were made.”\(^\text{19}\)

A. **Committee Members Note Concerns**

During the March DGA meeting, some of the DGA committee members presented on alterations to the inclusion and exclusion criteria of the search plans, the questions which would be addressed and the ability to do the work as was originally laid out. Committee members frequently 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.”\(^\text{20}\) The input below highlights some major areas of concern in the public’s ability to trust the evidence which informs the DGAs without specific additional clarity or research:

- As 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.”\(^\text{21}\) However, 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-

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\(^{18}\) NASEM 2 at 129.
\(^{19}\) NASEM 2 at 43.
\(^{21}\) 2010 DGAs at 58.
2025 DGAC members noted that many of the public comments had been focused on the need to address obesity, 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.”

**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.**

- “We recognize that we have not evaluated evidence related to these topics, so we’re—they’re not part of our conclusions and recommendations, but certainly, I note, and I think we can note, that in the National Academies report on the Dietary Guidelines process, there was a specific recommendation to the Secretaries of USDA and HHS to commission research and evaluate strategies to develop and implement a systems approach into the Dietary Guidelines, and that the selected strategies should then begin to be used to integrate systems mapping and modeling into the DGA process.”

- “There are a lot of issues swirling around that sort of—in orbit around the Dietary Guidelines, and people come to me and ask me about, and I’ll just give you a few examples. The environmental impact of the foods we eat and grow, things like that seem to be coming center-stage now. Things like high-versus low-carbohydrate diets, keto diets, time-restricted feeding, these are all issues that we didn’t deal with, at least in the committee I was on, two committees I was on, and I just wonder, I know you don’t want to take up a lot of space in that document, but I think these are topics that are hard to ignore, and I think a lot of people in the public are interested in them.”

- “[T]he process has changed, and a few things are being developed as we go.”

- “It’s just really hard to measure the diet, and we’re seeing that in a lot of papers are limited by they’re only measuring one aspect and not others. So, moving forward,

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we need to be better as a research community at trying to capture this complexity in our work.”

- “I think it’ll be very important for us to talk about the methods that we’ve used versus others, where there might be discordant conclusions from what we publish versus what people have been publishing over the last year or year and a half.”

- “I think there are two themes that are repeated in the many comments that we received from the general public, and I think they are of great interest for Americans right now, and it would be a missing opportunity if we don’t address them with a little bit of detail and the reasons why they were not taken into consideration in this iteration of the Dietary Guidelines. One is the issue of the low-carb diets and obesity, given that a big segment of the American public is obese, and this is an issue that is of high interest. And the other one is the issue of the sustainability. We can recommend ways to eat, but I’m saying if these are not sustainable, then probably in the long range, is not going to work.”

- “We have very few studies to look at. So, I’m echoing what Steve just said, and hopefully through the report, we’ll be pretty candid in terms of the recommendations of the types of studies and study designs that are really required to make definitive conclusions.”

- “Well, there could be many reasons why [RCTs and cohort studies] don’t align. So, what I think would be useful is, in the report, to make some comment about that and potential explanations for, if they’re not in good alignment, to consider what the potential explanations for that might be.”

In addition, the evidence base for many analyses came from studies predominantly on white, upper middle class individuals; moreover these studies failed to be adjusted for important “potential confounders such as race/ethnicity[and] socioeconomic status.”

- For example, one DGAC member, regarding one review undertaken by the Subcommittee on Pregnancy and Lactation, noted "Most of the participants...were
white, or the race/ethnicity was not reported. And most were mid- to high-socioeconomic status.”32

- “The reported outcomes varied across the studies, and the study populations often did not fully represent the race or ethnic and socioeconomic diversity of the US population.”33

**B. Gaps in Transparency**

The process currently has major gaps in transparency. While the conclusion statements are available, the results of the systematic reviews which are the foundation of the conclusion statements are not. Due to this lack of results of each step of the systematic reviews, there is no satisfactory way of determining the quality or strength of the evidence, one lacks the ability to understand where the grades “low and moderate” originated from, and one cannot tell whether any pooled or meta-analysis was done prior to when the conclusion statement was drafted. We urge the Committee to rectify these issues and offer this information for public input before issuing its Scientific Report.

The lack of information makes it very difficult to have a meaningful dialog on the evidence and on the grading of the conclusion statements. The public needs information on why the inclusion and exclusion criteria were changed for key questions, why 20 percent of the scientific questions will no longer be addressed and the implications of these decisions on the quality and trustworthiness of the forthcoming Guidelines.

For example, only one of the eight research questions on alcohol are being answered. The current pandemic and corresponding quarantine have amplified the need to have evidence-based recommendations related to alcohol consumption and its impact on health. Another example is that for the added sugars topic, a mere one of five assigned scientific questions will actually be addressed. It is essential to explain why such fundamental questions such as “What is the relationship between added sugars consumption and growth, size, body composition, and risk of overweight and obesity” are not being addressed when over 50 percent of the United States population is overweight or has obesity.34

The public needs to understand that the impact of the decision to artificially truncate the time allotment to complete the Committee’s work has prevented the Committee from reviewing the full body of evidence, thus making the scientific process less rigorous and the eventual output less valid.

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32 Public Meeting, March 12, Morning, at 2:19. Regarding a separate review by the same Subcommittee, she states, “They [the subjects] were predominantly non-Hispanic white and well-educated.” Public Meeting, March 12, Morning, minute 48

33 Transcript of March 12, 2020 Afternoon Meeting of Dietary Guidelines Advisory Committee at 45; Heymsfield. Available at https://globalmeetwebinar.webcasts.com/viewer/landing.jsp?ei=1289829&tp_key=62557ab93c

IV.  FOCUS ON PRIMARY PREVENTION AMID PREVALENCE OF CHRONIC DISEASE

For 35 years, the DGAs have provided the best available scientific advice to consumers seeking to prevent or reduce their risk of diet-related diseases. This advice has never been more critical. As the most recent iteration makes clear, the DGA’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.”\textsuperscript{35} While appropriate, the Academy notes this focus on primary prevention of diet-related chronic diseases and conditions is not uniformly applicable to most Americans. Two out of three American adults and one out of three children are overweight or have obesity.\textsuperscript{36} Nearly half of adults have diabetes or prediabetes, and roughly half of adults have high blood pressure, a major risk factor for heart disease and stroke. Furthermore, 13 cancers, including breast, colorectal, esophageal, and uterine, are linked to overweight or obesity.\textsuperscript{39} In total, 60 percent of Americans in 2014 “had at least one chronic condition, and 42 percent had multiple chronic conditions.”\textsuperscript{40}

We note that traditionally underserved populations are experiencing even higher rates of these diseases. Currently nearly 50 percent of non-Hispanic blacks and 45 percent of Hispanics have obesity.\textsuperscript{41} These diet-related chronic diseases also have been consistently shown to increase morbidity and mortality risk from COVID-19, with 90 percent of worsened outcomes accompanied by a co-morbidity of one these diseases.\textsuperscript{42} 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.

\textsuperscript{35} Ibid.


Given the extremely high prevalence of co-morbidities and overweight/obesity, the DGAs need to go beyond mere prevention and equally focus on amelioration of these conditions by leveraging a healthy food environment and food choices.

A. Target Audience(s)

The charter for the 2020 DGAC reminds us that the National Nutrition Monitoring and Related Research Act of 1990 (Section 301 of Public Law 101-445 codified at 7 U.S.C. 5341) instructs that [the DGAs] shall contain nutritional and dietary information and guidelines for the general public. This creates a significant tension when the general public has obesity, overweight, or one or more other chronic diseases. The DGAC must make clear if and when its dietary recommendations are appropriate for (1) a general population in which more than two-thirds of the adult population is overweight or instead (2) prevention for obesity and other chronic diseases.

The Academy strongly recommends the DGAC and Departments reconcile that instruction with the 2015-2020 DGAs’ statement that its “primary audiences are policymakers, as well as nutrition and health professionals, not the general public,” or otherwise explain whether there has been a change in the primary audience since the 2015-2020 DGAs were published.

We recognize the value in directing guidelines at the entities and individuals most able to effect the respective changes on both micro and macro levels, including registered dietitian nutritionists. At the same time, there is a potentially competing value in the guidelines being written in approachable, concise language that is easy for consumers to apply. As there are evidence-based dietary recommendations for many diet-related chronic diseases that do not match the DGAs, confusion can develop among professionals and the public about which dietary recommendations to follow if it is not clear who the DGAs target in terms of nutritional needs.

To promote understanding of the Scientific Report and the subsequent Guidelines, we encourage the DGAC to reiterate that the DGAs do not apply to people with certain health statuses and are not meant to replace medical advice or individualized recommendations based on health assessment and disease status. In addition, recommendations may differ across the lifecycle—particularly for older adults—making the current age-related approach appropriate. In short, the DGAs should indicate when certain recommendations may differ for a significant proportion of Americans and should explicitly detail its rationale for making differing recommendations.


B. Health Equity

The Academy’s strategic plan encourages a shift in focus toward health equity, social determinants of health, and transparent involvement of broader constituencies throughout the DGA process. Racial and ethnic minorities experience unique health and wellness challenges and are at a greater risk of having food insecurity as well as obesity.\textsuperscript{45, 46} In a recent statement, Academy President Linda T. Farr, RDN, CSOWM, LD, FAND, made clear that “The Academy of Nutrition and Dietetics believes American society, leaders and organizations must commit to doing more to address systemic racism and pervasive inequities across all facets of society.”\textsuperscript{47} The Academy believes that the DGAs and the Departments’ other initiatives to improve the nutritional status of Americans, reduce obesity and other diet-related chronic diseases, and increase food security must include efforts to achieve health equity and reduce health disparities. We urge the Committee to include in its scientific report strategies for achieving health equity, including how collaboration across all sectors and levels of government to implement policies can improve public health and provide equitable access to healthy and affordable food, clean water, and effective nutrition care services.

V. Conclusion

The Academy appreciates the opportunity to comment on the evidence analysis process and other issues of concern for the DGAC. We are happy to discuss these recommendations in greater detail in the near future. Please contact either Alison Steiber at 202-775-8277 ext. 4860 or by email at asteiber@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

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\textsuperscript{45} Vaccaro JA, Huffman FG. Sex and Race/Ethnic Disparities in Food Security and Chronic Diseases in U.S. Older Adults. \textit{Gerontol Geriatr Med.} 2017;3:2333721417718344. Published 2017 Jun 30. doi:10.1177/2333721417718344 (“Although the national average of household food insecurity is 14%, it is 22.4% for Hispanic households and 26% for African American households as compared with 11% for White non-Hispanics.” (Internal citations omitted.)).
