



August 12, 2020

Mr. Brandon Lipps  
Deputy Under Secretary for Food, Nutrition & Consumer Services  
U.S. Department of Agriculture  
1400 Jefferson Drive, S.W.  
Washington, D.C. 20024

CAPT Paul Reed, M.D.  
Deputy Assistant Secretary for Health, Medicine & Science  
Office of the Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Lipps and CAPT Reed,

On behalf of the Distilled Spirits Council of the United States (DISCUS), I am submitting the following comments in response to the 2020 Dietary Guidelines Advisory Committee's (DGAC or "the Committee") Scientific Report ("the Report") published July 15.

DISCUS is the national trade association representing leading producers and marketers of distilled spirits products. The U.S. distilled spirits industry supports more than 1.6 million American jobs, adds \$190 billion to the economy, and contributes nearly \$32 billion in federal, state, and local taxes annually.

As noted throughout the DGAC process, DISCUS supports the Dietary Guidelines for Americans (DGA) as an important source of helpful and practical information for healthcare professionals and for adult Americans who choose to consume alcohol. However, the 2020 DGAC Report reflects serious methodological and analytical flaws that undermine the scientific rigor and objectivity of its conclusions on alcohol consumption and all-cause mortality.

In particular, the 2020 DGAC proposal to change the U.S. definition of moderate drinking deviates significantly and unjustifiably from long-standing, evidence-based U.S. dietary guidelines and contradicts decades of independent research findings.

The proposal is not based on a preponderance of scientific evidence as required by law and the DGAC Charter<sup>1</sup>, and contradicts evidence in the DGAC's published systematic review protocol. The proposal also violates standards for transparency, as the DGAC failed to present any data or outcomes of its review until June 15 and did not fully reveal its proposal to change the definition of moderate drinking until July 17. Accordingly, the proposal should not be included in the 2020 DGA, which should retain the United States' long-standing, evidence-based definition of moderate drinking.

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<sup>1</sup> The DGAC must base its recommendations on the "preponderance of scientific and medical knowledge which is current at the time the report is prepared" as mandated by Public Law 101-445 (7 U.S.C. § 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III) and summarized in the DGAC Charter.

## Executive Summary

The DGAC scientific review and DGA development process, led by your agencies, must be characterized by full transparency and scientific rigor. The Committee's consideration of alcohol and all-cause mortality has violated many key parameters established by your agencies for transparency and the scientific review process.

As a result, the Report's conclusions on moderate alcohol consumption are seriously flawed, inadequately supported by evidence, and fail to address critical research questions (like the relationship between alcohol consumption and cardiovascular disease – the leading cause of death for Americans), while deviating into topics outside the scope of Dietary Guidelines.

We have identified significant issues with the proposal to change the definition of moderate drinking, which can be summarized as follows.

With regard to Chapter 11, Part D<sup>2</sup>, the Report:

1. Violates the Committee's published systematic review protocol that established rules for inclusion and exclusion of evidence;
2. Lacks proper, transparent, and convincing citations and evidence to support its proposal to change the definition of moderate drinking; and
3. Misrepresents information on alcohol consumption trends and exceeds the purview of the Dietary Guidelines.

Since the issuance of the first DGA in 1980, and in every iteration since, the federal government has advised adults who choose to consume alcohol to do so in moderation. The definition of moderate drinking included in the most recent 2010 and 2015 DGA<sup>3</sup> is based on a comprehensive and robust body of scientific studies, is widely referenced in U.S. and global health research and guidance, including by the National Institutes for Health<sup>4</sup>; and is an important reference point for healthcare providers and practitioners. The 2015 DGAC report concluded that moderate drinking "was identified as a component of a healthy dietary pattern associated with some health outcomes, which reaffirms conclusions related to moderate alcohol consumption by the 2010 DGAC."<sup>5</sup>

The 2020 DGAC indeed reaffirms that moderate drinking is associated with little health risk<sup>6</sup> and is specifically associated with reduced risk of all-cause mortality compared to never drinking.<sup>7</sup> While the Report characterizes this evidence as "limited," the Committee's systematic review found that "[a]pproximately half of the studies reported significant findings that low average alcohol consumption ... was associated with reduced risk of all-cause mortality compared with never

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<sup>2</sup> Page numbers in this comment refer to Chapter 11, part D, unless otherwise stated.

<sup>3</sup> 2015-2020 Dietary Guidelines for Americans: "...up to one drink per day for women and up to two drinks per day for men" (p 93).

<sup>4</sup> National Institute on Alcohol Abuse and Alcoholism (NIAAA), "Overview of Alcohol Consumption: Drinking Levels Defined," available at <https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking> (last accessed on August 7, 2020).

<sup>5</sup> United States Department of Agriculture and Department of Health and Human Services, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, (p 212), available at <https://health.gov/sites/default/files/2019-09/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf> (last accessed on August 7, 2020).

<sup>6</sup> "In the absence of binge drinking, low volume alcohol consumption...has low risk for most adults" (p 3).

<sup>7</sup> "Limited evidence suggests that low average alcohol consumption, particularly without binge drinking, is associated with a lower risk of all-cause mortality compared with never drinking alcohol" (p 15).

drinking alcohol” and “only 2 studies reported that low alcohol consumption was significantly associated with greater all-cause mortality compared to never drinking alcohol.<sup>8</sup>” Remarkably, the Committee cited just **one** study that examined differences in risk amongst men consuming two drinks per day as compared to one drink per day—a study that has methodological problems (*see* page 6 of this comment).

The Report’s claim that this exceedingly limited evidence base represents a “preponderance of evidence” sufficient to justify changing the longstanding, evidence-based definition of moderate drinking defies logic. As noted above, the DGAC is required to base its recommendations on the “preponderance of scientific and medical knowledge,” and particularly when considering a significant departure from prior Dietary Guidelines there should be a clear showing that scientific and medical evidence has undisputedly shifted to support that change. In this case, not only has the Committee failed to meet that standard, most of the studies included in the protocol support retaining the guidance from the prior DGAC Reports.

The Dietary Guidelines are revisited every five years and the 2020 DGAC has had ample time to develop systematic review protocol, execute that protocol, and develop a recommendation based on the review of that body of scientific studies. Although the protocol narrowed down the body of studies for consideration to 60, the DGAC Report references more than 160 studies. Even taking into consideration these numerous studies that were not included in the protocol, the DGAC has failed to provide adequate support to justify their recommended departure from the longstanding definition of moderate drinking.

## **Detailed discussion of flawed arguments and conclusions in Chapter 11, Part D<sup>9</sup>**

### ***1. The Report violates the Committee’s published systematic review protocol that established rules for inclusion and exclusion of evidence.***

At the most basic level, the Committee has failed to uphold its own published parameters for inclusion and exclusion of evidence.<sup>10</sup>

Examples include:

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<sup>8</sup> “Twenty-five studies compared those who consumed alcohol with never drinkers. Approximately half of the studies reported significant findings that low average alcohol consumption (particularly without binge drinking) was associated with reduced risk of all-cause mortality compared with never drinking alcohol, approximately half of the studies indicated no significant relationship, and 2 studies reported that low alcohol consumption was significantly associated with greater all-cause mortality compared to never drinking alcohol” (p 16).

<sup>9</sup> Note that the Committee’s flawed analysis and conclusions in Chapter 11, Part D, about which we raise detailed and significant concerns, have also been used to inform the Report’s conclusions on dietary patterns (*see* Chapter 8, Part D, pp 37-38), despite evidence in Chapter 8 that some healthy dietary patterns, such as the Mediterranean diet, include moderate alcohol consumption. The detailed concerns about Chapter 11, Part D presented here should also be addressed in the context of the Committee’s conclusions on dietary patterns and all flawed conclusions should be corrected in the 2020 DGA.

<sup>10</sup> Nearly two-thirds of the references in Chapter 11 rely on sources outside the systematic review, compared to Chapter 9, for example, where just ten percent of the references were not part of the systematic review. Chapter 11 is the only chapter to introduce this large amount of additional research AND in opposition to the evidence in the systematic review. Other chapters do include a small number of references to other research, but in a supporting role.

- The published systematic review protocol<sup>11</sup> on the question of the relationship between alcohol consumption and all-cause mortality states that the Committee will exclude articles published prior to January 2010. Yet, of the 168 studies cited in the Report, 33 were published before 2010 (*see* citations 7, 15, 18, 20, 22, 23, 26, 27, 29, 32, 35, 37, 43, 104, 105, 108, 109, 118, 120, 121, 122, 129, 130, 131, 132, 141, 150, 152, 154, 155, 156, 160, and 164).
- The Report cites six references that were specifically excluded in the published review protocol (*see* citations 115, 140, 109, 32, 13, and 25, which correspond to exclusions in the published review protocol cited as 222, 154, 112, 195, 239, and 284, respectively).
- The Report cites eight papers authored or co-authored by a DGAC member (citations 17, 106, 110, 118, 123, 131, 133, and 136), none of which were included in the published review protocol. These studies should be excluded from consideration due to the conflict of interest inherent in a member of the DGAC reviewing and including his own work in a government document.
- The Report includes a lengthy discussion of the merits of a type of study known as a “Mendelian randomization” (MR). Yet, the single Mendelian randomization study included in the published review protocol (citation 45 in the Report) is not relevant to the Committee’s central proposal to change the definition of moderate drinking, as it did not address gradations of consumption. Further, the well-documented methodological weaknesses of Mendelian randomization studies in alcohol research are not addressed by the Report (*see* section 2 below).
- The published review protocol specifically excluded meta-analysis studies from its search algorithm, yet the Report references 17 meta-analyses, two of which are co-authored by a DGAC member.
- The Report cites and discusses several modelling studies that were not included in the published systematic review protocol. These studies model hypothetical outcomes based on drinking patterns specifically calibrated to other countries, for example, the United Kingdom and Australia, which have different drinking patterns, demographics, and underlying lifestyles and health profiles. Accordingly, these models and their conclusions are not applicable to the United States.
- The Report freely admits the Committee’s conclusions were reached by reviewing evidence that was either not reviewed or was specifically excluded from the review protocol, providing no justification as to why it has violated the methodological and transparency requirements for the scientific review process. The Report notes, “[t]his additional evidence is drawn from traditional meta-analyses, studies of mortality based on composite condition-specific risk curves for alcohol-associated outcomes, MR studies about leading causes of mortality, and relevant literature published before 2010” (p 21).

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<sup>11</sup>U.S. DGAC, “What is the relationship between alcohol consumption and all-cause mortality? Systematic Review Protocol,” available at [https://www.dietaryguidelines.gov/sites/default/files/2020-04/Alcohol-ACM-Final\\_Protocol\\_4.20.20.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-04/Alcohol-ACM-Final_Protocol_4.20.20.pdf) (last accessed on August 7, 2020).

## ***2. The Report lacks proper, transparent, and convincing citations for evidence to support its proposal to change the definition of moderate drinking.***

In addition to violating the published review protocol's parameters for inclusion and exclusion of evidence, the Report repeatedly fails to properly, transparently, and convincingly cite evidence to support its conclusions. Examples include:

### Improper Citations

Contrary to proper scientific writing, the Report fails to adequately elaborate sourcing and citation. For example, the Report states:

Sixty studies that met the inclusion criteria for this systematic review addressing alcohol consumption and all-cause mortality were identified through the literature search from January 2010 to March 2020.<sup>25,45-103</sup>

It is extremely unorthodox to cite 60 studies at once and not elaborate each study's relevance and applicability. In addition, of the 60 studies included in the systematic review protocol, several suffer from flawed methodology, are the subject of independent scientific critiques, focus on social or economic aspects outside the purview of the DGAC review, and/or have results that are not generalizable to other populations or even to other population segments in the same country.<sup>12</sup>

### Missing Citations

The following is a non-exhaustive list of the Report's statements presented without any citation at all; these are only a handful of the most relevant and egregious examples. Without citations, it is impossible to fully evaluate these statements.

- “Among studies that examined finer gradations of consumption, the lowest levels of risk for men were generally up to 1 or 1.5 drinks per day on average” (p 13).
- “Meta-analyses of average alcohol consumption and all-cause mortality find that, based on continuous risk curves, risk starts to increase above the equivalent of one-half U.S. standard drink per day on average for women, above one-half to 1 drink per day on average for men, and above 1 drink per day on average for both women and men” (p 14).
- “Although a woman has a higher risk than a man of most harms (including all-cause mortality) at all levels of alcohol consumption, at lower levels of consumption the risk differences between men and women are considerably less than those observed at higher levels of consumption such that different sex based recommendations are not supported” (p 25).<sup>13</sup>

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<sup>12</sup> The methodological flaws in the studies are too numerous to list here. To provide two examples: the results from reference 71 (Licaj et al., *BMJ* 2016) are not generalizable because the study included only young women and the results from reference 80 (Pan et al., *J Gerontol A Biol Sci Med Sci* 2019) are not generalizable even to Chinese populations living in other areas because of different distributions of lifestyle factors and population structure and characteristics.

<sup>13</sup> It is worth noting this contradicts basic knowledge and U.S. guidance about physiological differences in alcohol metabolism by men and women. For example, the NIAAA states that women will have higher blood alcohol concentration from drinking the same amount of alcohol over the same time period compared to men (NIAAA, “Women and Alcohol,” available at <https://www.niaaa.nih.gov/sites/default/files/women-and-alcohol-fact-sheet.pdf> (last accessed on August 7, 2020)).

### Inadequate support and citations

The Report admits that its proposal to dramatically alter the long-standing definition of moderate drinking and halve the maximum daily alcohol guideline for men is based on shockingly little evidence. The Report states, without citation: “**Only 1 study examined differences among men comparing 1 vs 2 drinks**” (p 15). The only study included in the published review protocol that fits this description is Ricci, et al. (citation 85), which was specifically tailored to influence the DGA.<sup>14</sup>

If just one study examined differences among men comparing 1 vs. 2 drinks, it is therefore incomprehensible how the Committee can claim “... the **preponderance of evidence** indicates that consuming 2 drinks per day among men is associated with a modest but meaningful increase in risk compared to consumption of lower amounts, including 1 drink per day” (emphasis added).

Furthermore, by examining only differences *amongst* those who consume alcohol, the Committee has made a serious analytical error. Comparing groups with differing levels of exposure only to each other violates standard scientific protocol which calls for comparing experimental groups (in this case, those who consume alcohol) to control groups (those who do not consume alcohol).

The Report admits the Committee’s justification for “tightening” the consumption guideline for men is supported almost entirely by studies not addressed by or specifically excluded from the Committee’s published systematic review protocol: “[a]lthough they **were not included in the Committee’s systematic review**, precise estimates of effect sizes at finer gradations of consumption are best addressed by meta-analyses and modeling [sic] studies” (p 14).

The Report further states:

Evidence that drinking 2 drinks per day has increased all-cause mortality risk compared to 1 drink per day among men is more specifically supported by studies with designs that better identify narrower consumption strata or continuous risk functions including traditional meta-analyses,<sup>107-111</sup> survival analyses,<sup>25</sup> and modeling studies using weighted composite risk curves based on multiple alcohol-related causes of death<sup>24,107,115,116,125</sup> (p 24).<sup>15</sup>

None of the studies referenced in this claim are included in the Committee’s review protocol. The “additional evidence” so heavily relied on by the Committee was excluded from the published review protocol for good reason. Meta-analyses were specifically excluded from the Committee’s review protocol because all epidemiological studies, including the ones used for meta-analyses, rely on self-reported alcohol consumption, which is notoriously inaccurate. In addition, meta-analyses compare studies with major differences in cohort size and methodology.

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<sup>14</sup> Study objectives included: “In addition, we evaluate the adequacy of the current alcohol recommended limits according to the 2015-2020 US Dietary Guidelines for Americans (USDGA),” *Am J Clin Nutr.* 2020; (p 1).

<sup>15</sup> The Committee uses two of the same citations, neither included in the review protocol, to claim: “[i]n addition, among those who do not necessarily consume alcohol on most days, available evidence indicates that for any given amount of total consumption, consuming fewer alcoholic drinks per drinking day is generally associated with lower mortality risk than consuming more drinks per drinking day.<sup>107,125</sup>” Citation 125 has the same authors as citation 107 and uses the same theoretical model, not actual data. The weaknesses of modelling studies are discussed at the top of page 7 in this comment.

Modelling studies are based on hypotheticals, not evidence, and the modelling studies referenced are based on drinking patterns and conditions in other countries that are not relevant to the U.S. population. As these studies were not included in the Committee's review protocol, they should not be considered in the Committee's discussion and should not have influenced the Committee's conclusions; nor should they be reflected in the final DGA.

The Report further justifies changing the definition of moderate drinking by claiming that "for a variety of 'acute' conditions (e.g., injuries from motor vehicle crashes, falls, drownings, violence), the number of drinks consumed per drinking day or per drinking occasion is the primary determinant of risk as mediated through blood alcohol concentration; although these risks increase exponentially at higher levels of consumption, risk increases above zero drinks<sup>124,157,159,160</sup>" (p 24). These citations are not included in the review protocol, and these "acute harms" do not fall within the purview of the Dietary Guidelines (*see* section 3 below).

The Report claims without citation that "emerging evidence suggests the magnitude of risk associated with low volume alcohol consumption may have been underestimated" (p 24). Also without citation, the Report questions the widely-recognized body of scientific evidence showing moderate alcohol consumption is related to reduced all-cause mortality compared to never drinking (commonly known as a "j-curve"), claiming "... more recent observational studies and meta-analyses that focus on mitigating confounding and selection bias find reduced protection or no risk reduction for all-cause mortality compared with previous studies" (p 24).

In actuality, the j-curve has been repeatedly and robustly confirmed (including in most of the studies included in the DGAC's published systematic review protocol on this research question). The j-curve persists after adjustment for multiple confounders and is observed for both all-cause mortality and mortality from cardiovascular disease. The Committee's review protocol includes, and yet the Report does not discuss or emphasize, multiple studies that confirm this finding. Of particular note is a large and robust study published in the *Journal of American Cardiology* in 2017 by Xi et al. which analyzed the relationship between alcohol intake and risk of all-cause, cardiovascular, and cancer mortality (citation 103). The study covered 333,247 American adults from 13 waves of U.S. National Health Interview data.

Xi et al. found that compared with lifetime abstainers (people who have never consumed alcohol), light-to-moderate alcohol consumption (defined as between 3 and 14 drinks per week, so consistent with the 2015 DGA definition)<sup>16</sup> was associated with **significantly** reduced risk of all-cause mortality (21 percent decreased mortality for light consumption; 22 percent for moderate) and CVD mortality (26 percent decrease for light consumption; 29 percent for moderate), respectively. In contrast, heavy alcohol consumption<sup>17</sup> significantly increased risks of all-cause (11 percent) and cancer mortality (27 percent).

Xi et al. concluded that their study "re-emphasized the existence of a J-shaped curve in the alcohol-mortality association." In a commentary accompanying publication of the study, Dr. Giovanni de Gaetano found that the Xi et al. study confirms the j-curve as "a robust scientific conclusion" and

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<sup>16</sup> Light alcohol consumption was defined as 3 drinks per week. Moderate alcohol consumption was defined as between 3 and 14 drinks per week for men and between 3 and 7 drinks per week for women.

<sup>17</sup> Heavy alcohol consumption was defined as more than 14 drinks per week for men and more than 7 drinks per week for women.

disproved debate wherein the j-curve is “frequently discussed as a problem on beliefs rather than scientific data.”<sup>18</sup>

The Report admits:

The 2010 Dietary Guidelines Advisory Committee conducted a review on the topic of alcohol intake and coronary heart disease, and concluded that “strong evidence consistently demonstrates that compared to non-drinkers, individuals who drink moderately have lower risk of coronary heart disease.”<sup>134</sup> Since that time, observational studies and metaanalyses [sic] of observational studies have affirmed that the “J-shaped curve” for coronary heart disease and ischemic stroke demonstrates higher risk among those who do not consume alcohol compared with those who consume low volumes of alcohol, followed by higher risk among those consuming progressively higher amounts of alcohol<sup>135,136</sup> (p 17).

Yet, the Committee proposes to disregard this robust body of evidence along with the conclusions of previous DGACs, once again apparently on the basis of flawed MR studies:

However, a relatively new type of study design, referred to as MR<sup>19</sup> or genetic randomization studies, has resulted in evidence that challenges previous conclusions about the protective association between low average consumption and CVD<sup>137-140</sup> (p 18).<sup>20</sup>

Despite the fact that the Committee failed to conduct a systematic review on the relationship between alcohol consumption and cancer, the Report cites the 2020 American Cancer Society Guideline on Diet and Physical Activity for Cancer Prevention conclusion that “it is best not to drink alcohol,” but does not note that the ACS guideline retains the same recommended daily guidelines as the 2015 DGA’s definition of moderate drinking: “[p]eople who do choose to drink alcohol should limit their consumption to no more than 1 drink per day for women and 2 drinks per day for men.”<sup>21</sup>

Finally, and as noted previously, the Report’s discussion of Mendelian randomization studies (pp 18-20) does not include a comprehensive, objective review of the relative merits and weaknesses of these studies. Aside from violating the Committee’s published review protocol (which includes only one Mendelian randomization study), the discussion fails to consider the many well-known limitations on the use of Mendelian randomization studies in alcohol research.<sup>22</sup>

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<sup>18</sup> de Gaetano G, Costanzo S. Alcohol and Health: Praise of the J Curves. *J Am Coll Cardiol*. 2017;70(8):923-925. available at <https://www.sciencedirect.com/science/article/pii/S0735109717387326?via%3Dihub> (last accessed on August 7, 2020).

<sup>19</sup> Only one study (citation 45) in the published systematic review protocol is an MR (Almeida, et al. *Addict. Biology*, 2017).

<sup>20</sup> Citation 139 referenced here is the Holmes, et al. study which was widely discredited (*see* <https://www.bmj.com/content/349/bmj.g4164/rapid-responses> (last accessed on August 7, 2020)). And, citation 140 refers to Millwood et al. *Lancet* 2019 393(10183):1831-1842, which suffers from the same shortcomings as Holmes et al.

<sup>21</sup> Rock CL, Thomson C, Gansler T, et al. American Cancer Society guideline for diet and physical activity for cancer prevention. *CA Cancer J Clin*. 2020.

<sup>22</sup> For example, MR studies erroneously use genetic variants to infer causality due to alcohol, where in fact the same diseases can occur without drinking. Furthermore, about half of the MR studies cited draw from Southeast Asian populations only, which introduces an important limitation on generalizability to the United States. A number of researchers (for example, Costanzo, de Gaetano et al. 2019) have criticized the application of MR for research on alcohol and health. The shortcomings of MR studies as applied to alcohol research have also been elaborated, for example by Davey Smith et al, *Eur. J. Epidemiol* 2020 35:99–111 and Mukamal et al, *Eur. J. Epidemiol* 2020 35:93-97.

### ***3. The Report misrepresents information on alcohol consumption trends and exceeds the purview of the Dietary Guidelines.***

The mandate of the DGAC and the DGA are quite clear. The DGA provide “advice on what to eat and drink to promote health and reduce risk of chronic disease.” The 2020 DGAC Charter further specifies that “[s]ubcommittees must **limit their review and advice to dietary guidance for human nutrition on the topics and scientific questions specified by the Departments.**”<sup>23</sup>

Despite this clear instruction, Part D Chapter 11 significantly exceeds the Committee’s mandate. The Committee is not the appropriate nor qualified body to address social or economic impacts of alcohol consumption, nor is it charged with assessing non-dietary considerations such as “depression, child abuse and neglect, fetal alcohol spectrum disorder, motor vehicle crashes, domestic violence, sexual assault, vandalism and other property crimes, and nuisance violations” (p 2). While these serious issues are indeed worthy of extensive attention, including analysis of the harmful use of alcohol, they fall clearly outside the purview of dietary guidelines. Nor are these issues likely to arise from the moderate levels of drinking practiced by the large majority of American adults who do choose to consume alcohol.

The Committee claims, without citation, that binge drinking is increasing and “[m]any U.S. adults consume alcohol excessively,” (p 21) despite substantial evidence from federal data that the United States is experiencing significant, measurable, and continuing progress in reducing the harmful use of alcohol.

Remarkably, alcohol use disorders have decreased by 20 percent since 2010,<sup>24</sup> the same time period during which the DGA have defined moderate alcohol consumption as up to two drinks per day for men and up to one drink per day for women. In fact, the National Survey on Drug Use and Health shows that slightly over 26 percent of American adults have consumed more than 4 drinks in one occasion at any time in the past month, remaining steady from 2015 to 2018. Heavy drinking (five or more drinks on the same occasion on 5 or more days in the past month) among adults decreased slightly from 2015 to 2018 and affects fewer than 7 percent of American adults.

The Report makes several unjustifiably sweeping statements about alcohol that call into question the objectivity of the Committee’s review. Statements like “[o]verall, alcohol is an unhealthy substance,” (p 26) and “alcohol is a potentially harmful substance with minimal nutritional value” (p 24) are highly subjective, used without citations, are not supported by the evidence in the Committee’s review protocol, and reveal a predisposition amongst the report authors toward negative conclusions on even moderate alcohol consumption.

### **Conclusion**

The distilled spirits industry acknowledges that beverage alcohol products can be abused and may result in harm. It is for these reasons that, throughout the decades, we have focused upon and pursued solutions that effectively address and combat the harmful use of alcohol.

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<sup>23</sup> U.S. DGAC Charter, available at <https://www.dietaryguidelines.gov/sites/default/files/2019-03/DietaryGuidelinesAdvisoryCommitteeCharter-10-05-18.pdf> (last accessed on August 7, 2020).

<sup>24</sup> SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, available at <https://www.samhsa.gov/data/release/2018-national-survey-drug-use-and-health-nsduh-releases> (last accessed on August 7, 2020).

We fully support the public health objective of combating alcohol abuse in all forms and, for individuals of legal drinking age who choose to drink, encouraging moderate alcohol consumption. Some individuals should not consume alcohol at all<sup>25</sup>, and we support that decision.

It is for these reasons that we support the DGA in its efforts to provide evidence-based information that assists American adults in making responsible choices about alcohol and to foster discussions with healthcare professionals about the potential risks and benefits of consuming alcohol. Together, they can determine what is best for that person based on individual risk factors, such as family history, genetics and lifestyle.

In sum, we reaffirm our serious concerns about the integrity of this process and the many flaws reflected in the DGAC's proposal to change the longstanding, evidence-based definition of moderate drinking. The proposal does not reflect the preponderance of evidence and, therefore, should not be included in the 2020 DGA. We thank you for your attention to this important issue and are available at your convenience to provide further information.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Samir Zakhari". The signature is fluid and cursive, with a large initial "S" and "Z".

Samir Zakhari, Ph.D.  
Chief Scientific Advisor  
Distilled Spirits Council

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<sup>25</sup> Many individuals should not consume alcohol, including individuals who are taking certain over the counter or prescription medications or who have certain medical conditions, those who are recovering from alcoholism or are unable to control the amount they drink, and anyone younger than age 21 years. Individuals should not drink if they are driving, planning to drive, or are participating in other activities requiring skill, coordination, and alertness. Women who are or who may be pregnant should not drink. Women who are breastfeeding should consult with their health care provider regarding alcohol consumption.