February 14, 2025

Janet M. de Jesus, MS, RD
HHS/OASH/ODPHP
101 Wootton Parkway, Suite 420S
Rockville, MD 20852

Submitted electronically at www.regulations.gov (Docket HHS-OASH-2024-0019)

RE: Request for Public Comments on Reports on Alcoholic Beverages and Health to Inform the Dietary Guidelines for Americans, 2025-2030 (Docket HHS-OASH-2024-0019)

Dear Ms. de Jesus:

Wine Institute is the public policy advocacy association representing over 1,000 California wineries and affiliated businesses responsible for 81 percent of the nation's wine production and more than 95 percent of U.S. wine exports. Our members, the vast majority of which are small, family-owned businesses, produce some of the most highly value-added agricultural products in the country, while creating 1.1 million jobs. We appreciate the opportunity to provide the following comments in response to Docket HHS-OASH-2024-0019: Request for Public Comments on Reports on Alcoholic Beverages and Health to Inform the *Dietary Guidelines for Americans, 2025-2030* ("Request for Comments"). In the Request for Comments, Health and Human Services ("HHS") and US Department of Agriculture ("USDA") invite comments on two reports: (1) The Interagency Coordinating Committee on the Prevention of Underage Drinking ("ICCPUD") Alcohol Intake and Health draft report, and (2) The National Academies of Sciences, Engineering, and Medicine's ("NASEM") Review of Evidence on Alcohol and Health report. Both reports will inform *Dietary Guidelines for Americans, 2025-2030* ("DGAs").

The responsible and sustainable production, marketing, and consumption of wine has been at the very heart of Wine Institute's existence throughout our 90-year history. As such, our members have always recognized the importance of the DGAs and the need to ensure consumers have accurate, science-based information to guide their decisions about alcohol consumption. Accordingly, we support the DGAs as helpful and practical guidance for healthcare professionals and adult Americans who choose to consume alcohol.

Since the first edition of the DGAs in 1980—and every iteration since—the U.S. government has advised adults who choose to consume alcohol to do so in moderation. Wine Institute's website contains the following statements based on the 2020-2025 DGAs:

- If alcohol is consumed, it should be in moderation – no more than one drink per day for women and up to two drinks per day for men – and only by adults of legal drinking age, preferably at mealtime.
- There are some people who should not consume beverage alcohol at all. Those who are under 21, women who are pregnant, or have a medical or family history of concern for example. Any person who has concerns about consuming alcohol should consult with their healthcare provider. [1]

The DGAs have long since been the result of a transparent and thoughtfully prescribed process that provides for public input and accountability at every turn. That framework ensures public confidence, more widespread adoption, and industry promotion of the resulting DGAs. Accordingly, we have serious concerns with ICCPUD's draft report and the process underlying it. We share many of those concerns with others including at least 113 members of Congress. In contrast, NASEM's process and resulting report represent what we expect for informing the DGAs and to ensure they are "based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared"—as the law requires.[2] We elaborate on these points in our comments below.

1. **Repeated Concerns Regarding ICCPUD's Process and Draft Report**

This is not the first time we have submitted comments expressing concerns about ICCPUD's involvement in the DGAs and its approach. ICCPUD playing any role in the DGA process came as a surprise for Wine Institute and many others. As we explain more fully in Section 3 below, members of Congress wrote to the Secretaries for HHS and USDA—which jointly publish the DGAs every five years—expressing concerns about ICCPUD's newly discovered role in the DGA process, asking questions, and requesting relevant documents.

Tellingly, after those initial congressional letters were issued, HHS published a request for public comments on the methodology for ICCPUD's Study on Alcohol Intake and Health.[3] But HHS provided only a 30-day comment period and published the notice one day before the July 4 holiday. In contrast, all other DGA public comment opportunities of which we are aware provided at least 60 days. Additionally, and in another departure from the usual course, HHS did not make the submitted comments publicly available on regulations.gov.[4] Instead, and after continued inquiries from Congress and increased public scrutiny,

[1] *See* https://wineinstitute.org/our-work/responsibility/social/
[2] *See* 7 U.S.C. § 5341(a)(2) (part of National Nutrition Monitoring Act).
[3] *See* 89 Fed. Reg. 55274, July 3, 2024.
[4] *See* "Privacy" FAQ at https://www.regulations.gov/faq ("Does Regulations.gov publicly disclose my Comments? Yes, most participating agencies post public Comments on Regulations.gov."

ICCPUD eventually released its own four-page summary version of the purported 66 comments it received.[5]

Despite the brief comment period, Wine Institute submitted five pages of written comments which we hereby incorporate by reference and attach to these comments. In sum, our previous comments detail concerns that (1) ICCPUD's activity on the DGAs is beyond its statutory purpose, scope, and funding; (2) ICCPUD's process lacks transparency and public input; (3) there are potential conflicts of interest and biases within ICCPUD's Scientific Review Panel (SRP); and (4) ICCPUD's methodology appears flawed. Those concerns remain true and have grown since that time.

Once again, this process for public comment seems rushed. ICCPUD released its draft report on January 15, 2025, and that same day HHS published notice for only a 30-day comment period.[6] This time, however, HHS also compounds issues: the same 30-day comment period applies to NASEM's Review of Evidence on Alcohol and Health report *and* ICCPUD's draft report. Two large reports, one brief comment period.

To be clear, ICCPUD's draft report is 81 pages of complex and scientific information that include charts, citations, source material, and more. NASEM's report is 230 pages of similar complexity. A 30-day period is insufficient to review those two documents and provide meaningful feedback. Moreover, collapsing ICCPUD's draft report and NASEM's report into a single notice-and-comment period risks conflating the two documents and any comments received. For those reasons, Wine Institute and others submitted timely requests to extend the comment period. We were disappointed that HHS ignored those requests.

2. <u>New Concerns Regarding ICCPUD's Process and Draft Report</u>

Potential Conflicts of Interest and Biases

In our previous comments we expressed concern over certain members of ICCPUD's SRP —selected without any public notice, vetting, or input and without disclosing any selection criteria—for several reasons including potential conflicts of interests and biases. We mentioned the following concerns:

- Panelist Dr. Tim Naimi's financial ties to known temperance movement groups like the International Organization of Good Templars, a fraternal organization now called Movendi. These organizations have a long history of promoting the notion that there is "no safe level" of alcohol consumption with little regard for what the preponderance of current and sound scientific evidence shows.
- ICCPUD's decision not to provide a financial conflict disclosure for one of the panelists, Dr. Kevin Shield.
- Leading roles that several panelists played in efforts to severely reduce government drinking guidelines in the U.S. and Canada only to see those governments reject their recommendations.

[5] *See* https://www.stopalcoholabuse.gov/media/pdf/Tab-A-RFI-Comment-Summary.pdf.
[6] *See* 90 Fed. Reg. 3883, January 15, 2025.

- Panelist Dr. Priscilla Martinez's comments at a May 2024 conference that public health messaging should say any amount of drinking increases health risk. Her public comments suggested a clear bias towards "no safe level" messaging even before the SRP finalized a methodology or review of current science.

Since that time, a media outlet reported that "ICCPUD's study on alcohol is overseen by Alicia Sparks, a project director who has ties to anti-alcohol campaigning—including the US Alcohol Policy Alliance, which aims to reduce alcohol consumption in the US."[7] Alicia Sparks was the Chair of the US Alcohol Policy Alliance and remains on its board according to its website.[8] That organization has called for a reduction in the DGA recommendations for alcohol consumption and encouraged the public to contact Congress and provide comments for ICCPUD's draft report to inform the DGA process.[9]

At the same time, Alicia Sparks is a Senior Principal at the company Synergy Enterprises, Inc.[10] Synergy funded a self-published manuscript of the protocol ICCPUD's SRP members proposed for their review.[11] And the SRP members thanked Alicia Sparks for helping with that proposed protocol.[12]

It is troubling that someone helping run the US Alcohol Policy Alliance that is calling for a specific outcome in the DGAs, is also working as a contractor who helped with and is potentially overseeing ICCPUD's study, which is intended to inform the DGAs. If true, we have not seen any of this information disclosed on ICCPUD's webpage regarding its draft study.[13] Nor has ICCPUD explained how it identified or resolved conflicts of interest.

Lack of Transparency

While ICCPUD disclosed the names of the six SRP members, it has never disclosed who comprises the Technical Review Subcommittee. This raises questions given ICCPUD's statement that "[a]ny disparities in COI [conflicts of interest] assessments will be resolved by the Scientific Review Panel and Technical Review Subcommittee." Nor did ICCPUD share the identities of any other contributors—other than the six SRP members—to the draft report such as data analysts, peer reviewers, or unnamed "experts" it references several times in the draft report and with whom the SRP members apparently consulted. The public is entitled to know whether and how ICCPUD will meet the transparency, scientific rigor, and conflict-free standards that govern the DGA process.

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[7] *See* https://www.dailymail.co.uk/health/article-14149239/canadian-scientists-drinking-policy-limits-advising-biden-white-house.html.

[8] *See* https://www.alcoholpolicy.org/about-us.

[9] *See* https://www.prnewswire.com/news-releases/us-alcohol-policy-alliance-calls-for-reduced-alcohol-intake-in-dietary-guidelines-for-americans-302350966.html.

[10] *See* https://www.seiservices.com/leadership.

[11] *See* https://www.researchsquare.com/article/rs-4224612/v1 ("Funding for this manuscript was provided by Syergy Enterpises Inc.").

[12] *Id*. ("We would like to thank Dr. Alicia Sparks for her contributions to the protocol and her feedback on the revised protocol.").

[13] *See* https://www.stopalcoholabuse.gov/research-resources/alcohol-intake-health.aspx.

Concerns with the Methodology

We have several concerns about the methodology in ICCPUD's draft report. For example, in their draft report, the SRP claims that its initial search yielded 7,294 publications and that it then excluded 7,003 of those publications. Notably absent is any rationale, explanation, or criteria used to exclude those publications. They then state that a total of 56 unique systematic reviews were included in the current review. Reviewing Table 2 in the draft report, however, shows only 16 unique systematic reviews. The draft report does not address that discrepancy. In fact, it does not address Table 2 at all. Moreover, of the 16 publications the SRP used, more than one-third of them (5 of the 16) were authored in part by members of the SRP. Given these issues, it is difficult to understand how the draft report meets the standards governing the DGA process.

3. Congressional Concerns with ICCPUD go Unanswered

Congress has taken an active interest in the DGA since the enactment of the National Nutrition Monitoring and Related Research Act in 1990, establishing the statutory mandate for HHS and USDA to publish the DGAs every five years. It is hardly a surprise then that Congress would raise questions when the agencies announced in spring of 2022 that they were removing recommendations on alcohol from the Dietary Guidelines Scientific Advisory Committee (DGAC) process for the first time ever.

While it rarely happens, it is not unprecedented for consideration of a particular topic to be removed from the DGAC process. However, it is unprecedented to do so without establishing a clearly defined transparent and rigorous process that will take the place of the DGAC process. Congress has raised repeated concerns about the decision to shift consideration of adult alcohol intake from the DGAC to ICCPUD, as well as the failure to provide even basic information about how the ICCPUD work was to be conducted. As an initial response to the agencies' unprecedented steps, Congress appropriated $1.3 million in December 2022 to fund the NASEM Review of Evidence. Since that time, dozens of members of the House and Senate have raised significant concerns about the ICCPUD process.[14]

On April 4, 2024, the House of Representatives Committee on Oversight and Government Reform announced that it was conducting oversight of the DGA process with respect to alcohol and the decision to launch the ICCPUD Adult Alcohol Intake study. In a letter to HHS Sec. Xavier Becerra, Chairman James Comer (KY-1) and Rep. Lisa McClain (MI-9), Chairwoman of the Subcommittee on Health Care and Financial Services stated, "We are alarmed that HHS appears to be removing alcohol review from the DGAC and 'delegating' it to ICCPUD, despite the statute directing the Secretaries of HHS and the U.S. Department of Agriculture (USDA) to issue the Dietary Guidelines."[15] They asked the agency to provide information in response to specific questions about the origin and work on the ICCPUD Adult Alcohol Intake study. Nearly six months later, on October 1, 2024, the Committee

[14] *See* https://www.politico.com/newsletters/politico-pulse/2024/09/25/hhs-study-brews-controversy-on-the-hill-00180850.

[15] *See* https://oversight.house.gov/release/comer-mcclain-probe-formulation-of-alcohol-consumption-guidelines%EF%BF%BC/.

subpoenaed both HHS and USDA seeking the requested information and noting that either agency had fully complied with the Committee's request.[16] In response to the release of the ICCPUD report, Chairman Comer issued a statement on January 15, 2025 stating, "rather than examine all available science, the Biden Administration's public health apparatus is once again cherry-picking data and operating in secrecy...."[17]

On April 14, 2024, Sen. Bill Cassidy, MD (R-LA), Chairman of the Senate Committee on Health, Education, Labor and Pensions, and Sen. John Boozman (R-AR), Chairman of the Senate Committee on Agriculture, sent a letter to HHS and USDA raising specific questions about the DGA process and the lack of transparency around the review of alcohol.[18] In questions posed to the agencies, the Senators highlighted specific areas where there was a lack of information and clarity available on both the NASEM and ICCPUD processes.

These concerns have been amplified and expanded on by a broad cross section of the Congress. In response to the agencies' failure to address these concerns, 113 members of the House of Representatives wrote to the agencies on October 7, 2024, calling for work on the ICCPUD study to be suspended until the work on the NASEM evidence review was completed. The letter noted, "the secretive process at ICCPUD and the concept of original research on adult alcohol consumption by a committee tasked with preventing underage drinking, jeopardizes the credibility of ICCPUD and its ability to continue its primary role of helping the nation prevent underage drinking."[19] To date, the agencies have failed to address Congress' many questions regarding ICCPUD's role and the manner in which its work has been conducted.

4. NASEM Review of Evidence is the Product of Rigorous, Transparent Process

The NASEM systematic review of current science closely followed the standards set forth for the DGA aimed at ensuring a rigorous and transparent process. This process stands in stark contrast to that of the ICCPUD study in several important areas.

Transparency was built into the NASEM process at numerous important points throughout. At the outset, NASEM convened an expert committee of fourteen scientists who were all subject to a public nomination and vetting process that included the opportunity for public comment. This open process allowed NASEM to adjust the make-up of the committee in response to public input and ensured the committee included participants with a diverse range of expertise and medical knowledge. The NASEM systematic review process also included opportunities for public participation during an open meeting and provided a portal

[16] *See* https://oversight.house.gov/release/comer-issues-subpoenas-to-hhs-and-usda-for-docs-related-to-development-of-alcohol-consumption-guidelines%EF%BF%BC/.
[17] *See* https://oversight.house.gov/release/comer-issues-statement-on-biden-administrations-failed-effort-to-shape-alcohol-consumption-guidelines/.
[18] *See*https://www.help.senate.gov/imo/media/doc/2024414_final_help_and_ag_letter_on_dietary_guidelines_for_americanspdf.pdf
[19] *See* https://www.forbes.com/sites/patrickgleason/2024/10/10/congress-demands-greater-transparency-for-dietary-guidelines-review/.

for public submissions and feedback throughout the process. Additionally, the origin, purpose and funding of the NASEM review were clearly established by Congress.

The NASEM review of evidence also stands apart from the ICCPUD study due to its adherence to methodologies that are closely aligned with well-established DGA protocols. The NASEM committee explained its methodologies in detail and its protocols were registered in the PROSPERO international database for systematic reviews as well as posted on the study website. While the report did provide graded conclusion statements, these statements were only made when there was sufficient evidence to evaluate a topic, and the report acknowledges the limits of observational data. Most importantly, the NASEM report went through a rigorous independent peer review prior to publication. The ten members of the review panel were chosen for their scientific and technical expertise and were all publicly identified in the NASEM report.

5. Conclusion

We urge the agencies to fully consider and weigh the significant flaws in the ICCPUD process that are now reflected in the draft Alcohol Intake and Health study—a lack of transparency, conflict of interest and bias, and a flawed methodology. These flaws are more glaring when reviewing the ICCPUD study together with the NASEM Review of Evidence. We are concerned that a failure to acknowledge these flaws will lead to recommendations included in the 2025-2030 DGA that are not supported by a clear preponderance of the scientific evidence as the National Nutrition Monitoring and Related Research Act requires. This will, in turn, erode public trust and confidence in the DGA.

Thank you for your consideration of these comments.

Sincerely,

Robert P. Koch
President and CEO

Attachment

August 2, 2024

Mr. Robert Vincent
SAMHSA Reports Clearance Officer
Center for Behaviors Quality and Statistics
Substance Abuse and Mental Health Services Administration, HHS
Submitted via email

RE: 89 FR 55274 - Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) request for comment on Alcohol Intake and Health methodology

Dear Mr. Vincent:

Wine Institute is the public policy advocacy association representing over 1,000 California wineries and affiliated businesses responsible for 81 percent of the nation's wine production and more than 95 percent of U.S. wine exports. Our members, the vast majority of which are small, family-owned businesses, produce some of the most highly value-added agricultural products in the country, while creating 1.1 million jobs. We appreciate the opportunity to provide the following comments for Federal Register Docket 2024-14650 entitled The Interagency Coordinating Committee on the Prevention of Underage Drinking ("ICCPUD") Requests for Public Comments. As explained more fully below, Wine Institute has serious concerns about the flawed process that is underway at ICCPUD for the purpose of informing the *Dietary Guidelines for Americans, 2025-2030* (DGA) as noted in the Federal Register notice.

First know that the responsible and sustainable production, marketing, and consumption of wine has been at the very heart of Wine Institute's existence throughout our 90-year history. As such, our members have always recognized the importance of the DGA and the need to ensure consumers have accurate, science-based information to guide their decisions about alcohol consumption. Accordingly, we support the DGA as helpful and practical guidance for healthcare professionals and adult Americans who choose to consume alcohol.

Since the first edition of the DGAs in 1980—and every iteration since—the U.S. government has advised adults who choose to consume alcohol to do so in moderation. Wine Institute's website contains the following statements based on the *Dietary Guidelines for Americans, 2020-2025*:

- If alcohol is consumed, it should be in moderation – no more than one drink per day for women and up to two drinks per day for men – and only by adults of legal drinking age, preferably at mealtime.
- There are some people who should not consume alcohol at all. Those who are under 21, women who are pregnant, or have a medical or family history of concern for example. Any person who has concerns about consuming alcohol should consult with their healthcare provider. [1]

The 2025 Dietary Guidelines Advisory Committee's (DGAC) Charter—formed pursuant to federal law—gets filed with Congress before the Advisory Committee can meet or take any action.[2] Transparency and publicly established guardrails underly the charter to help protect the validity of the committee's activities and findings and, in turn, consumer acceptance of the DGA. For example, the charter provides that specific scientific questions the Advisory Committee examines *must* be discussed in a public forum.[3] The Departments of Health and Human Services (HHS) and Agriculture (USDA) also *must* appoint a Designated Federal Officer to "ensure efficient and transparent committee operations."[4] We are unaware of any similar charter or other publicly established guardrails to ensure the new ICCPUD process meets the same high standards set for the DGA.

Moreover, there are significant flaws in this ICCPUD process and apparent conflicts of interest within the Scientific Review Panel (SRP) that ICCPUD established to conduct this DGA work. We are concerned that this will lead to recommendations included in the 2025-2030 DGA that are not supported by a clear preponderance of the scientific evidence as required by the National Nutrition Monitoring and Related Research Act (NNMRRA). This will, in turn, erode public trust and confidence in the DGA.

I. ADULT ALCOHOL INTAKE IS BEYOND THE MANDATE AND SCOPE OF ICCPUD

In April 2022, it was announced that for the first time in the history of the DGAs the alcohol research review would be conducted "through efforts separate from the 2025 Dietary Guidelines Advisory Committee."[5] More than a year after the announcement that alcohol would be reviewed outside of the normal DGA process, we learned that ICCPUD would be studying adult alcohol intake to inform the DGA. The Sober Truth on Preventing Underage Drinking Act (STOP Act) established ICCPUD with a narrowly tailored congressional mandate to focus on underage drinking. Specifically, the STOP Act provides that ICCPUD's only duties are that it "shall guide policy and program development across the Federal Government ***with respect to underage***

[1] Available at: https://wineinstitute.org/our-work/responsibility/social/

[2] Available at https://www.dietaryguidelines.gov/sites/default/files/202301/2025_DGAC_Charter_Final_12.09.2022.pdf

[3] *See id.* under the heading: "Objectives and Scope of Activity."

[4] *See id.* under the heading: "Designated Federal Officer."

[5] U.S. Departments of Health and Human Services & Agriculture (2024). Related Projects: Alcohol Beverages and Health. Retrieved June 7, 2024, available at https://www.dietaryguidelines.gov/related-projects#uswds-text-2587.

drinking, provided, however, that nothing in this section shall be construed as transferring regulatory or program authority from an agency to the Committee [i.e., ICCPUD]."[6]

ICCPUD, tasked specifically and exclusively with the issue of underage drinking, is clearly an inappropriate body to review adult alcohol consumption. This process is outside of the statutory framework the National Nutrition Monitoring and Related Research Act sets forth. The methodology presented by the ICCPUD scientific review panel is primarily focused on adult alcohol consumption. There has been no explanation to date as to why ICCPUD should be leading original research around the adult consumption of alcohol. Further, no explanation has been given on why ICCPUD's limited resources have been diverted from its critical primary mission to conduct work that is duplicative of efforts already underway at the National Academy of Sciences, Engineering and Medicine (NASEM) and other agencies including the Centers for Disease Control (CDC) and the Institute for Health Metrics and Evaluation (IHME).

II. ICCPUD PROCESS LACKS TRANSPARENCY AND PUBLIC INPUT

The ICCPUD process for considering adult alcohol intake has lacked even the most basic level of transparency from the outset. What little information has been shared has been done largely after the fact and in response to Congressional inquiries. Again, this is a departure from the 2025 DGAC's Charter, practices, and approach. This consistent theme of operating behind closed doors without public input has been present throughout this process and applies to the Technical Review Subcommittee (TRS) that ICCPUD established as well as the SRP.

The following facts demonstrate the lack of transparency and public engagement to date:

a. The TRS was established at some point in the spring or summer of 2023 (date unknown), yet no information has been shared about any of the subcommittee's meetings including meeting dates or agendas.
b. None of the TRS meetings have included any public component to observe or provide input.
c. The individuals participating in the TRS have never been identified.
d. There was zero public engagement or opportunity for comment on the appointment of the SRP participants.
e. The SRP contract was awarded without any public process or competitive bidding.
f. Financial disclosure information has not been shared for all SRP participants.
g. The current comment period on the proposed methodology lacks transparency because none of the comments will be publicly available as is normally required with the U.S. regulatory process on Regulations.gov.

This consistent, intentional lack of transparency will only serve to undermine ICCPUD's work on alcohol intake and ultimately weaken the effectiveness of the DGA.

[6] 42 U.S.C.S. § 290bb-25b(c)(1)(D) (emphasis added).

III. CONFLICTS OF INTEREST AND BIAS WITHIN SCIENTIFIC REVIEW PANEL

In addition to a lack of transparency around how the SRP panelists were appointed, we also have serious concerns about apparent conflicts of interest and bias among some of the participants. We were alarmed to see that some of the panelists, including Dr. Tim Naimi, have financial ties to known temperance movement organizations like the International Organization of Good Templars (IOGT), now known as Movendi. These organizations have a history of promoting the notion that there is "no safe level" of alcohol consumption with little regard for what the preponderance of current and sound scientific evidence shows. Without any explanation, ICCPUD has chosen not to provide any financial conflict disclosure for one of the SRP panelists, Dr. Kevin Shield.

Several of the panelists have also played leading roles in efforts to severely reduce government drinking guidelines only to see them rejected by those governments. Dr. Naimi was a member of the 2020 DGAC and a member of the Subcommittee on Beverages. He was responsible for the DGAC recommending a reduction in the guidance on moderate consumption that was later rejected by USDA and HHS due to the fact it was not supported by a clear preponderance of the current scientific evidence.[7] Drs. Naimi and Shield were both directly involved in leading work by the Canadian Center on Substance Use and Addiction (CCSA) which recommended significantly reducing Canada's daily alcohol intake guidelines in 2023. The Canadian government declined to adopt those recommendations. These instances show a consistent pattern and suggest that Dr. Naimi's work is guided more by a predetermined objective (i.e., "no safe level") as opposed to an unbiased review of current scientific evidence.

Similarly, at a U.S. Alcohol Policy Alliance conference in May 2024, Dr. Priscilla Martinez, another SRP panelist, argued that public health messaging should say that any amount of drinking increases health risk. Her public comments suggest a clear bias towards "no safe level" messaging even before the SRP has finalized a methodology or conducted any review of the latest science.

IV. THE PROPOSED METHODOLOGY IS FLAWED

In addition to the concerns raised above, the proposed methodology raises a number of additional questions and concerns. It does not adhere to statutory requirements, as outlined by the National Nutrition Monitoring and Related Research Act which in relevant part states 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."[8] The current methodology proposes conducting original research rather than using the best and most current existing scientific evidence. There is no explanation given as to how this research could be conducted in time for the ICCPUD work to be concluded by the end of this year. Additionally, no information has been provided on the cost of this research or which other ICCPUD activities targeting underage drinking may be negatively impacted.

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[7] https://www.dietaryguidelines.gov/about-dietary-guidelines/related-projects/usda-hhs-response-national-academies-sciences-engineering

[8] *See* 7 U.S.C.S. §§ 5341(a)(2) available at https://www.dietaryguidelines.gov/about-dietary-guidelines/process/monitoring-act.

Specific aspects of the methodology also raise concerns. While not an exhaustive list, we would note the following. The original research outlined would use statistically insignificant study sizes and modeling with cherry-picked inputs rather than the preponderance of sound scientific evidence. The methodology also outlines a proposal for nominal group interviews with researchers that have received no public vetting or scrutiny to pick the studies that are included in their review of health impacts of alcohol. In other words, the panel has opted to cherry-pick studies without public review and completely at odds with the DGA process outlined by law.

The process for developing the methodology and sharing it for public comment has also been deeply flawed. The ICCPUD work on adult intake commenced in April of 2022 according to SAMHSA, and the TRS and SRP were both formed well over a year ago, though the exact dates have not been publicly disclosed. It is concerning that the public is only now seeing a methodology—barely five months before the work is scheduled to be completed. It will also be impossible to see what, if any, impact the public comments have on the final methodology due to the fact that none of the comments will be publicly available. All of this contributes to a perception that this comment period is a performative step meant to "check the box" and not a serious effort to ensure the Adult Intake and Health study is based on the best available science.

The ICCPUD process stands in stark contrast to the NASEM review which Congress mandated to review the latest science on alcohol and health to inform the 2025-2030 DGAs. Congress directed NASEM to look at the eight questions related to adult alcohol consumption and health outcomes which the 2020 DGAC was supposed to address, but only ended up addressing one of the eight questions. The NASEM review aligns with DGA methods, has held open meetings, allowed for ongoing public comment and stakeholder input, and received an appropriate level of public scrutiny of committee membership and statement of task. To date, there has been no justification for ICCPUD to take on this duplicative work. Without a transparent process that prioritizes sound science over biased agendas, the ICCPUD Adult Intake and Health study will not meet the preponderance of scientific evidence standard long held by the DGA.

Sincerely,

Robert P. Koch
President and CEO

cc: RDML Paul Reed, MD, Deputy Assistant Secretary for Health