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CC:  
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**Re: Comment on Proposed Protocols for questions to be answered by the Dietary Guidelines Advisory Committee (Docket No. FNS-2019-0001)**

Dear Members of the 2020 Dietary Guidelines Advisory Committee:

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on several key protocols posted by the Dietary Guidelines Advisory Committee (DGAC) on July 8. CSPI is a nonprofit health advocacy organization with approximately 500,000 members and subscribers to *Nutrition Action Healthletter*. CSPI is a co-signer of two additional comments to the DGAC.<sup>1</sup> The recommendations below apply to the following protocols (though they may also be applicable to others):

**Dietary patterns**—all posted protocols

**Dietary fats and seafood**—all posted protocols on dietary fats

**Beverages and added sugars**—growth, size, body composition, risk of overweight and obesity

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<sup>1</sup> The Center for Science in the Public Interest (CSPI) has co-signed two additional comments on these protocols. One urges the DGAC to include systematic reviews (SRs) and meta-analyses (MAs) other than those conducted by USDA's Nutrition Evidence Systematic Review (NESR) team. A second comment recommends that the protocol on dietary fats and cardiovascular disease either (a) include randomized controlled trials with cardiovascular disease or LDL-cholesterol endpoints published before 2000 or (b) include SRs or MAs that include those pre-2000 trials.

**Exclude non-randomized controlled trials.** Several protocols—including those for dietary fat and cardiovascular disease (CVD), and for dietary patterns and CVD, type 2 diabetes, obesity, and all-cause mortality—include “non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies.” Non-randomized trials, which are considered a lower level of evidence than RCTs, are not typically included in reviews by the DGAC or other expert panels. For example, the AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk<sup>2</sup> did not include non-randomized trials, and the AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults<sup>3</sup> used only randomized trials to compare the effectiveness of weight-loss diets. Similarly, the 2015 DGAC relied on systematic reviews (SRs) and meta-analyses (MAs) that did not include non-randomized trials when the committee reviewed (a) dietary patterns and risk of CVD, type 2 diabetes, and body weight, (b) saturated fat and CVD, and (c) added sugars and body weight and type 2 diabetes. We see no reason to include non-randomized trials when adequately powered RCTs with similar endpoints are available. Unless the DGAC provides a strong rationale for including non-randomized trials, we urge the committee to exclude them from the protocols listed above.

**Exclude retrospective studies.** Several protocols—including those for dietary fat and CVD, and for dietary patterns and CVD, type 2 diabetes, obesity, and all-cause mortality—include retrospective cohort studies and unspecified (i.e., both retrospective and prospective) nested case-control studies. Retrospective nested case-control or cohort studies, which are considered a lower level of evidence than prospective studies, are not typically included in reviews by the DGAC or other expert panels. We see no reason to include retrospective studies when prospective studies are available. Unless the DGAC provides a strong rationale for including retrospective studies, we urge the committee to exclude them from the protocols listed above.

Finally, we note that the USDA has provided inadequate time for the protocols to be thoroughly evaluated. On July 8, 2019, USDA announced that the 2020 Dietary Guidelines Advisory Committee subcommittees had posted the first 40 protocols for reviewing the evidence on the 80 questions that the DGAC will answer. The public was given until July 24 to submit comments on those 40 protocols. Although this request for comments appears to improve transparency and public involvement in the DGAC process, the short time frame makes it difficult for the protocols to be thoroughly vetted by the scientific community.

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<sup>2</sup> Eckel RH, Jakicic JM, Ard JD, de Jesus JM, Houston Miller N, Hubbard VS, Lee IM, Lichtenstein AH, Loria CM, Millen BE, Nonas CA, Sacks FM, Smith SC Jr, Svetkey LP, Wadden TA, Yanovski SZ; American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2014 Jul 1;63(25 Pt B):2960-84. doi: 10.1016/j.jacc.2013.11.003. Epub 2013 Nov 12.

<sup>3</sup> Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; Obesity Society. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *J Am Coll Cardiol*. 2014 Jul 1;63(25 Pt B):2985-3023. doi: 10.1016/j.jacc.2013.11.004.