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CC:

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Re: Comment on Proposed Systematic Review Protocol Regarding the Relationship between Types of Dietary Fat Consumed and Risk of Cardiovascular Disease (Docket No. FNS-2019-0001)

Dear Members of the 2020 Dietary Guidelines Advisory Committee:

We, the undersigned, urge the DGAC to amend its <u>proposed protocol</u> to answer the question: What is the relationship between types of dietary fat consumed and risk of cardiovascular disease?

The proposed protocol would only include a literature search of studies published since 2000. We urge the DGAC to amend the protocol to ensure that the highest-quality randomized controlled trials with CVD or LDL-cholesterol endpoints conducted before 2000 are included either individually or as part of a meta-analysis or systematic review.

The results of numerous pre-2000 randomized controlled trials are invaluable because few post-2000 trials have had cardiovascular endpoints, and few post-2000 RCTs with LDL-cholesterol endpoints have been conducted in metabolic wards. Omitting these RCTs would exclude much of the most crucial evidence needed to answer the DGAC's question.

Other expert committees that have answered this question have relied heavily on pre-2000 RCTs. For example, a 2017 advisory from the <u>American Heart Association</u> concluded that "taking into consideration the totality of the scientific evidence, satisfying rigorous criteria for causality, we conclude strongly that lowering intake of saturated fat and replacing it with unsaturated fats, especially polyunsaturated fats, will lower the incidence of CVD." A key underpinning of that conclusion was that "randomized controlled trials that lowered intake of dietary saturated fat and replaced it with polyunsaturated vegetable oil reduced CVD by $\approx 30\%$, similar to the reduction achieved by statin treatment." Those RCTs were published long before 2000.

Similarly, in 2016, the WHO published a <u>systematic review and regression analysis</u> on the effects of saturated fatty acids on serum lipids and lipoproteins. The vast majority of the RCTs included in that review were published before 2000. Likewise, the 2018 <u>WHO draft guidelines</u> on saturated and trans fats included numerous RCTs that were published before 2000.

According to <u>USDA</u>, the decision to exclude existing SRs and MAs was made because it was "suggested" by the National Academies' report on the Dietary Guidelines. In fact, the Academies' <u>report</u> noted that "with limited resources, it would be advantageous to leverage existing systematic reviews, meta-analyses, and reports to minimize unnecessary replication of efforts," and the report concluded that the use of high-quality existing SRs and MAs "is generally appropriate and encouraged."

We understand that it would be impractical to review all evidence on dietary fats and CVD published since the 1960s. However, the DGAC cannot conduct a scientifically rigorous review of the evidence on dietary fats and CVD if it excludes all high-quality pre-2000 RCTs with CVD or LDL-cholesterol endpoints.

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