

Comments to Dietary Guidelines Committee

Given the obvious difficulty in convincing Americans to follow the Dietary Guidelines for Americans, it is absolutely essential that the 2010 Guidelines establish credibility as the product of a rigorous scientific review. This will require changes in the way the DGAC conducts its review. We commend an “evidence-based” methodology as invented by the prestigious Cochrane Collaboration and promoted within HHS by the U.S. Preventive Services Task Force. In this, we reiterate our recommendations for the preparation of the 2005 Dietary Guidelines and remind the Advisory Committee of the Institute of Medicine’s 2007 “lessons learned” assessment of the development of the DRIs that were the basis of the last Guidelines, an assessment that confirmed our warnings.¹

In the run-up to the development of the 2005 Dietary Guidelines, Mr. Richard Hanneman of the Salt Institute wrote on several occasions to the Department of Health and Human Services emphasizing the need to critically consider a number of fundamental issues^{2, 3}. In all his communications, he stressed the paramount importance of employing evidence-based data rather than expert opinion in drawing conclusions upon which public policy would be established. He used the internationally respected Cochrane Collaboration as an example of evidence-based study that was internationally acceptable. Mr. Hanneman also cautioned against the use surrogate or proxy endpoints (e.g. blood pressure) rather than definitive health outcomes (e.g. mortality) as a basis upon which to render conclusions for broad population-based policy recommendations.

In the IOM assessment, referring to the DRI, Professor George Beaton embraced these same concerns: “However, in terms of its current application, particularly to individuals, we have gone far beyond the data. We must retreat a bit and ensure that we ground ourselves in science.” He went on to say: “It also depends on how far we are prepared to abandon science in favor of opinion and judgment. We must temper our theories, approaches, desires, and dreams with reality. We must always remember that the whole purpose of any DRI process must be to come up with evidence-based information that can be applied to real life.”

At the same meeting, Dr. Peter Greenwald, Director of the Division of Cancer at the National Cancer Institute (NCI) stated: “The first task related to the use of research to inform public policy is whether there are enough research data to even begin... It is important to note that the most definitive studies are randomized controlled clinical trials (buttressed by basic nutritional science), followed by non-randomized controlled trials. The studies become weaker from that point, with cohort or case-control studies and ecologic studies appearing as one moves down the pyramid. At the very bottom of the list are the opinions of respected authorities.... Little research of the most useful type (randomized clinical trials) is available, whereas there is an enormous amount of information that is not very meaningful. This needs to be reversed.”

Dr. Greenwald went on to say: “Regarding efforts to establish the impacts and risks/benefits of nutrient substances, the following points are worth noting:

- Efficacy data based on sound scientific evidence must be present before making public health recommendations regarding nutrients.
- Many existing data are not sufficient, not sound, and even contradictory; these need to be sorted through using systematic approaches.
- Confidence in nutrient–disease relationships can change, often in unexpected directions.
- Large randomized trials have the greatest impact in changing the level of confidence in a nutrient–disease relationship. Although these trials have an enormous cost, they are necessary.

To underscore the importance of “getting the science right,” we need only turn to a recent article in the *New York Times Magazine* written by a respected science reporter. It was entitled “Why can’t we trust much of what we hear about diet, health and behavior-related diseases?” (Taubes, 2007). The reporter includes several examples, many in nutrition epidemiology, where there is so much conflicting evidence that people do not believe it. Clearly, we have a serious problem, and we must push for the conduct of definitive studies before we make pronouncements on public health.”

It is clear that an inordinate number of conclusions that found their way into previous versions of the Dietary Guidelines were not based upon high quality evidence, but rather upon expert opinion. Recommendations relating to the consumption of salt (sodium chloride) are an example of this. Both the recommended level of 1500 mg sodium/day and the upper limit of 2300 mg/day for sodium were based upon expert opinion, rather than experimentally derived data. Furthermore, this expert opinion was almost exclusively driven by concerns for a single CVD risk factor - hypertension - to the virtual exclusion of all other risk factors and biomarkers. The assumption was made that by driving down this risk factor we were accomplishing some good. We cannot continue to presume we are doing good when we have not, at the same time, looked at other risk factors or negative biomarkers that result as a consequence of adhering to recommended salt intakes. The ACCORD (Action to Control Cardiovascular Risk in Diabetes) and the ADVANCE (Action in Diabetes and Vascular Disease) trials to reduce serum glucose levels both succeeded in achieving their primary risk factor reduction goals, but had to be terminated early because an unexpected number of individuals died. The strategy of focusing on a single risk factor to the exclusion of all other health impacts is simply not sound⁴.

Recent research carried out indicated that there may indeed be very negative consequences if the diet limits sodium to the range of 1500 – 2300 mg Na/day as recommended in the dietary guidelines^{5, 6}.

While the 2005 Dietary Guideline recommendations may provide a minor reduction (2-5 mm HG) in blood pressure for less than 1/3 of the population, the negative consequences of stimulating the renin-angiotensin-aldosterone system (RAAS) in terms of arterial stiffness and a cascade of metabolic syndrome effects far outweigh any possible benefits of adherence to this recommendation for the population in general.

We hope the Dietary Guidelines Advisory Committee will endeavor to address the above concerns. We should not be driven by a compulsion to recommend or regulate. In the absence of quality data, and in the presence of conflicting evidence, we must have the discipline to forego recommendations that may end up doing the population harm if followed. We can no longer afford to base conclusions on single risk factors to the exclusion of a range of other possible risk factors and negative biomarkers. Finally, we should venture to use the Cochrane Collaboration as an example of rational evidence-based medicine⁷.

The Salt Institute is grateful for the opportunity of presenting these comments to the 2010 *Dietary Guidelines* revision process.

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¹ Food and Nutrition Board, Institute of Medicine, “The Development of DRIs 1994-2004: Lessons Learned and New Challenges,” The National Academies Press, 2008.

² Letters to Kathryn McMurry, HHS, July 14, 2003; September 9, 2003; March 15, 2004; April 6, 2004; April 28, 2004.

³ Statement to HHS/USDA Hearing on the Dietary Guidelines Advisory Committee Report, September 21, 2004.

⁴ Krumholz, H. M. and T. H. Lee, “Redefining Quality — Implications of Recent Clinical Trials,” *NEMJ*, 2008, June 12, 358:2537-2539.

⁵ Shapiro, Y., Boaz, M., Matas, Z., Fux, A., & M. Shargorodsky, “The association between the renin-angiotensin-aldosterone system and arterial stiffness in young healthy subjects,” *Clinical Endocrinolog.*, 2008 Apr;68(4):510-2.

⁶ Edna R. Nakandakarea, Ana M. Charfa1, Flávia C. Santosa1, Valéria S. Nunesa, Katia Ortegab, Ana M.P. Lottenberga, Décio Mion Jr.b, Takamitsu Nakanoc, Katsuyuki Nakajimac, Elbio A. D’Amicod, Sergio Catanozia, Marisa Passarellia, Eder C.R. Quintãoa, “Dietary salt restriction increases plasma lipoprotein and inflammatory marker concentrations in hypertensive patients,” *Atherosclerosis*, 2008 October; 200 (2):410-16.

⁷ In 2008, the Cochrane Collaboration reissued its 2004 report reiterating that there was no population-wide benefit established for sodium reduction recommendations. See: Hooper L, Bartlett C, Davey Smith G, Ebrahim S. Advice to reduce dietary salt for prevention of cardiovascular disease. Cochrane Database of Systematic Reviews 2004, Issue 1. Art. No.: CD003656. DOI: 10.1002/14651858.CD003656.pub2.