Dietary Guidelines Advisory Committee Meeting 4

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Meeting Summary

Wednesday, November 4 (1:00 p.m.)

Participants

Dietary Guidelines Advisory Committee (DGAC): Dr. Linda V. Van Horn (Chair), Dr. Naomi K. Fukagawa (Vice-Chair), Dr. Cheryl Achterberg, Dr. Lawrence J. Appel, Dr. Roger A. Clemens, Dr. Miriam E. Nelson, Dr. Sharon (Shelly) M. Nickols-Richardson, Dr. Thomas A. Pearson, Dr. Rafael Pérez-Escamilla, Dr. Xavier Pi-Sunyer, Dr. Eric B. Rimm, Dr. Joanne L. Slavin, Dr. Christine L. Williams

Executive Secretaries: Ms. Carole Davis, Ms. Kathryn McMurry, Ms. Shanthy Bowman, Ms. Holly McPeak

Others: Dr. Rajen Anand, RADM Penelope Slade-Sawyer, Dr. Robert Post, CAPT Sarah Linde-Feucht

Welcome and Opening Remarks

Dr. Rajen Anand, Executive Director of the Center for Nutrition Policy and Promotion (USDA), called the meeting to order at 1:00 p.m. He welcomed the participants and those attending by Webinar to the fourth meeting of the DGAC, recognizing the Committee and USDA's partners, HHS. He reviewed the Committee's charge: informing the Secretaries of warranted changes to the *Dietary Guidelines* that are based on current science published since the last *Dietary Guidelines;* emphasizing food-based over nutrient-based recommendations; and avoiding attempts to translate any recommendations into policy or communications pieces. The Committee will submit their recommendations in the form of a technical report to the Secretaries of USDA and HHS. Dr. Anand reviewed information related to Federal Advisory Committee Act (FACA) compliance, including requirements to publish announcements of each DGAC meeting in a Federal Register notice in support of open, transparent meetings. The public was invited to provide written comments at www.dietaryguidelines.gov.

Capt. Sarah Linde-Feucht, Deputy Director of the Office of Disease Prevention and Health Promotion (HHS), gave welcoming remarks on behalf of Rear Admiral Slade-Sawyer. She expressed appreciation to the members, staff, and participants.

Dr. Robert Post, Deputy Director of the Center for Nutrition Policy and Promotion, welcomed the Committee and commented on the success of using the Webinar technology. The meetings have allowed for a large and widespread reach across the internet audience and have made it possible to maintain an archived recording of each meeting. He provided the internet audience with information on how to obtain technical assistance if needed.

Dr. Linda V. Van Horn (DGAC Chair), greeted all the meeting attendees and explained how much work the Committee and USDA/HHS staff had been doing on the research questions since the last meeting. Among the seven Subcommittees, there are several families of research questions and nearly 180 subquestions that have been developed. Proposed conclusions will be discussed for the questions where the evidence has been reviewed. Conclusions on the remaining research questions will be addressed at the fifth meeting. Due to the amount of information to be covered, there will be a sixth meeting in the spring of 2010. Dr. Van Horn reminded the public that the details of the evidence reviews will be made available on USDA's Nutrition Evidence Library (NEL) database after the DGAC advisory report is released. NEL ensures that the scientific review is well-documented, transparent, and reproducible. The process reduces bias and standardizes the approach across Subcommittees. Dr. Van Horn provided some general information on how the scientific literature was searched, sorted, and reviewed. This process was applied across all Subcommittees.

She explained that for questions that could be answered with a brief update of a substantial source of existing evidence, such as previous *Guidelines* or an Institute of Medicine (IOM) report, a full NEL review was not done. For some questions, food pattern modeling was used to evaluate the diet and identify the amounts of different foods that can be consumed to achieve adequate nutrient intake. An overview of the modeling process was provided. Other data analyses considered by the Subcommittees included dietary intake data from the National Health and Nutrition Examination Surveys. Public comments were also taken into consideration.

Before calling for the first Subcommittee report, Dr. Van Horn explained that the Subcommittees would be providing succinct presentations consisting of their proposed conclusions and supporting evidence. She noted that each Subcommittee developed research questions that were put through an extensive review of the scientific literature and grading process prior to the development of the proposed conclusion. She reminded the public that everything being presented in the meeting is still in draft form and that, although agreement will be reached on many conclusions, further discussions will still be required after the meeting before consensus can be formally reached at a later meeting.

Nutrient Adequacy Subcommittee
Chair: Shelly Nickols-Richardson, Ph.D., R.D.

Shelly Nickols-Richardson, Chair of the Subcommittee, recognized the Subcommittee members and staff. The Subcommittee addressed four research topics: nutrients of concern, folic acid fortification, B12 fortification/supplementation, and food pattern modeling. The food pattern modeling questions included realignment of vegetable subgroups, adequacy of USDA food patterns, and USDA patterns with "typical choices." In looking at the questions, the Subcommittee's principles were that nutrients should come primarily from food and that the *Dietary Guidelines* should provide guidance on achieving nutrient needs by age and sex groups.

Under nutrients of concern, the question was, "What nutrients are most likely to be consumed by the general population in amounts low enough and are of pubic health significance to be of concern?" First, shortfall nutrients were identified, using dietary intake data. Second, the public health significance of shortfall nutrients was determined, using biochemical data and disease prevalence. Third, the Subcommittee looked at the likelihood of a shortfall nutrient requirement being met by following food intake guidelines. Shortfall nutrients were identified with data from NHANES (National Health and Nutrition Examination Survey) and compared to Dietary Reference Intakes (DRI). Data on biochemical indices indicating public health concern were used from CDC, NHANES, and other peer-reviewed sources. The likelihood of achieving DRIs was considered in relation to the 2005 *Dietary Guidelines for Americans*.

The review of intake evidence indicated that, for adults, shortfall nutrients are vitamins A, C, D, E, and K and choline, calcium, magnesium, potassium, and dietary fiber. For children, the shortfall nutrients are vitamins A, C, D, and E and calcium, magnesium, phosphorus, potassium, and dietary fiber. Phosphorus is a shortfall nutrient in adolescent females. A review of biochemical evidence showed that only five to seven percent of the U.S. population has low serum concentrations of vitamins A, C, and E. Vitamin K deficiency is also rare.

One report indicated that more than 55 percent of individuals residing in lower latitudes in the United States had low serum vitamin D. However, using the current IOM cutoff values, only about ten percent of non-Hispanic whites over the age of 60 years have low vitamin D levels. The proportion of older adults with low levels of vitamin D increases as the cutoff values increase. Vitamin D will be reviewed more thoroughly and presented at the next meeting.

Due to rates of osteoporosis and osteopenia in women over 50, calcium is a concern. The high rate of hypertension and prehypertension makes potassium important for its role in lowering blood pressure and dietary fiber important for its role in reducing risk of coronary heart disease (CHD). The food pattern modeling indicates that the DRIs for vitamins A, C, and K can be easily met by meeting the recommendations for fruit and vegetable intake. For both adults and children, the nutrients of concern are vitamin D, calcium, magnesium, potassium, and dietary fiber. Vitamin B12, folate, choline, iron, and phosphorus are of concern for certain subgroups. Magnesium is under review.

Member Nelson presented on folic acid fortification. Mandatory compliance for folic acid fortification began in 1998, based on the U.S. Public Health Service's recommendation that all

women of childbearing age consume 400 micrograms of folic acid per day, to reduce the risk of neural tube defects in infants. The Subcommittee looked at peer-reviewed literature from 1999-2009. The first research question was, "What effect has folic acid fortification policy had on serum, plasma, and RBC folate status?" The draft conclusion with Grade I evidence was that, "There is clear and consistent evidence that serum, plasma, and red blood cell (RBC) folate concentrations increased in the U.S. and Canada following mandatory folate fortification." The evidence is from 11 cross-sectional studies. Since mandatory fortification, serum folate more than doubled, and RBC folate increased about 57 percent. There is still a small group of women at risk for low folate concentrations.

The second research question was, "What impact has mandatory folic acid fortification had on the incidence of neural tube defects (NTD)?" The proposed conclusion, with the Grade I evidence, was: "Clear and consistent evidence shows that the incidence of children born with NTD has been reduced following mandatory folic acid grain fortification in the U.S. and Canada." This was supported by 13 studies. In the U.S., there was a 23 to 54 percent reduction in spina bifida incidence and a 31 percent reduction in anencephaly incidence.

The next research question was, "What effect has mandatory folic acid fortification had on the incidence of stroke?" The proposed conclusion, with Grade III evidence, was that there is "limited evidence that stroke mortality has declined in the U.S. and Canada following folic acid fortification policy." One study looked at the small decline in stroke mortality in the U.S. and Canada, compared to England and Wales, which did not mandate fortification and have seen no change.

For the next research question, "What impact has mandatory folic acid fortification had on the incidence of colon cancer," the proposed conclusion, with Grade III evidence, was that there's "limited evidence that mandatory folic acid fortification has resulted in a transient increase in the incidence of colon cancer in the U.S. and Canada." The evidence was from two trend studies, one in the U.S. and Canada, the other in Chile. The U.S. and Canada study showed that rates of colorectal cancer started rising in 1996, when voluntary fortification began. That increase peaked in 2000. Chile also saw a small increase in the rates of hospital discharge due to colorectal cancer following fortification.

The next research question was, "What effect does folic acid supplementation (with or without additional B vitamin supplementation) have on risk of stroke in those with or without preexisting vascular disease?" The proposed conclusion was, with Grade III evidence, that there is "inconsistent evidence that supplementation with folic acid reduces risk of stroke in adults." The evidence was from two meta-analyses, one showing no significant difference in risk between those treated with folic acid and the control. The smaller meta-analysis showed an 18 percent reduction of risk. However, this analysis included regions without grain fortification.

The last research question was, "What effect does folic acid supplementation (with or without additional B vitamin supplementation) have on the risk of CHD in those with or without preexisting vascular disease?" The proposed conclusion, with Grade I evidence, was that "folic acid supplementation does not appear to reduce risk of CHD, particularly in countries with folic acid fortification." The supporting data came from two randomized controlled trials (RCT) and

one meta-analysis, all showing no reduction in cardiovascular events. The overarching question was "What is the relationship between folic acid intake in the U.S. and Canada, post fortification era, and health outcomes?" Overall, there was a substantial reduction in NTDs, a small decrease in stroke, and a transient increase in colon cancer.

Member Fukagawa addressed the question of vitamin B12. The overarching question was, "Are special nutrient recommendations needed for certain subgroups?" Specifically, there was the research question, "Is there evidence to recommend B12 supplementation or fortification?" NHANES data showed that daily B12 intake in all age and gender groups exceeded the Recommended Daily Allowance (RDA). However, there was concern about pernicious anemia and neurovascular deficits in pregnant women and senior citizens. The proposed conclusion was, "Individuals over the age of 50 appear to be meeting their RDA for vitamin B12 and should continue doing so by eating foods naturally rich in B12 and fortified with B12 or by taking the crystalline form of B12 supplements." Because there was little new evidence, this was supported by an update to the literature review since the 2005 DGAC report.

Member Nickols-Richardson opened the floor for discussion, which included absorption of B12 in elderly populations. It was mentioned that elderly individuals actually seem to absorb crystalline vitamin B12 more easily than naturally-occurring B12. The Subcommittee decided to revisit the topic of folate and its relationship to stroke, CHD and blood pressure, and reconsider the grading of the evidence for folate and stroke. Possible excessive nutrient intakes, such as with sodium and phosphorous, were discussed. Phosphorus was only a shortfall nutrient in adolescent females. The Subcommittee will look at abundance nutrients next. Concern with nutrient databases that can have misleading data was mentioned. Food sources of nutrients are often underreported. A concern regarding indiscriminant supplement use and a risk of over-nourishment was also mentioned. The Subcommittee previously looked at this and discourages high-level B vitamin supplementation.

Member Achterberg spoke on food pattern modeling, discussing the effectiveness of the current food group categories and how to adjust them. The questions discussed were addressed by modeling, rather than a literature review. The question was, "What revisions to the vegetable subgroups may help to highlight vegetables of importance and allow recommendations for intake levels that are achievable, without compromising the nutrient adequacy?" Part of the rationale was the size discrepancy between the Other Vegetables subgroup and the Orange Vegetables subgroup, the latter of which is under-consumed. Tomatoes alone make up 22.3 percent of vegetable consumption, and the rationale for examining potential changes in the vegetable subgroups structure was four-fold: 1) to decrease the wide discrepancy between the largest vegetable subgroup, Other Vegetables, and the smallest vegetable subgroup, Orange Vegetables; 2) to provide more focus on tomatoes; 3) to facilitate development of food intake patterns that meet nutritional recommendations, are within calorie needs, and are realistic; and 4) to encourage increased vegetable consumption and selection of a variety of vegetables to meet nutrient needs through guidance that is both understood and achievable by consumers.

The vegetable subgroups were realigned so that Orange Vegetables became Red-Orange Vegetables and butterhead lettuce and bok choy shifted to the dark green subgroup. By adding tomatoes to the new Red-Orange Vegetables subgroup, consumption within the subgroup is

substantially increased. The overall vegetable recommendation does not change. With the realignment, the new recommendations are within the 95th percentile of usual intake for almost all age and sex categories, making the recommendations more achievable. The change is isocaloric, and nutrient adequacy does not change. The proposed conclusion is that "The proposed revision of the vegetable subgroups results in expanding to the new Red-Orange Vegetables subgroup, with only minor changes in the Dark Green (leafy greens and broccoli) subgroup. These proposed new intake amounts from this realignment meet nutrient adequacy while staying within an individual's calorie needs and make recommendations more achievable than existing recommendations."

Member Nickols-Richardson addressed the question, "How well do USDA food intake patterns, using updated food intake and nutrient data, meet DRIs and potential 2010 *Dietary Guidelines* nutrient recommendations?" This was the next logical question after realigning the vegetable subgroups. The USDA food patterns were also used for modeling analyses for the 2005 *Dietary Guidelines.* Development of the patterns included identifying appropriate energy levels for food intake patterns, based on the DRI formulas for estimated energy requirements. The next step was to set the nutritional goals for nine vitamins, eight minerals, six macronutrients, and the Acceptable Macronutrient Distribution Range for five macronutrients, based on age and sex groups. Food groups were established; amounts of nutrients obtained by consuming various combinations of foods were determined; and nutrient levels in each pattern were evaluated against nutritional goals.

To update the modeling analysis for the 2010 *Dietary Guidelines*, more recent and detailed food consumption and nutrient content data were used. The foods reported consumed in the 2003-2004 NHANES were assigned to food item clusters in an ideal, nutrient-dense form. Nutrient profiles for each food group or subgroup were calculated, using a representative food from each cluster. For all food patterns, when using the nutrients and calories from ideal representative foods, the sum of the calories from recommended amounts of each food group was less than the caloric goal for the pattern. The remaining calories were assigned to the discretionary calorie allowance. Therefore, the 12 USDA food patterns meet almost all of their nutritional goals for adequacy, with many nutrients above the RDA or Adequate Intake (AI). Three nutrient adequacy goals are not met: vitamin E, choline, and potassium at lower calorie levels. However, the patterns meet almost all nutrient goals for moderation. If the USDA patterns are followed, nearly all nutrient needs and goals for moderation can be met, with discretionary calories remaining. The proposed conclusion is that "nutrient needs can be met by consuming the USDA pattern of eating that includes a defined energy intake level for an individual."

The next food pattern modeling question was, "What is the impact on caloric and nutrient intake, if the USDA food patterns are followed, but typical, rather than the ideal representative choices are made?" In contrast to the previous modeling, in which ideal representative foods are used, this question looked at typical food choices, as identified by the 2003-04 NHANES. Calorie, sodium, cholesterol, and saturated fatty acid levels in most food groups increased, usually due to processed foods, methods of preparation (such as added sugar or frying), and inclusion of full fat foods. With typical food choices, moderation goals are not met. The proposed conclusion was that "typical food choices from all food groups in the USDA food pattern result in a diet that is too high in energy, total fat, saturated fat, sodium, and dietary cholesterol. Consumers must be

encouraged to select nutrient-dense forms of foods from each food group and subgroup, as well as achieve moderation goals."

The next steps for the Subcommittee are to address food groups of concern; food components that are overconsumed; nutrients of concern; vitamin D; breakfast intake and meeting nutrient needs; emphasizing foods first and the use of supplements only for specific intake patterns and for specific age and gender groups; and additional modeling to look at whole versus enriched grains, vegan patterns, milk and milk products, nutrients from starchy vegetables compared to grains, and additional food patterns and nutrient adequacy.

Discussion

The need for lower-energy modeling was emphasized in light of the obesity epidemic. Addressing potential choline inadequacies was suggested; however, this discussion should include the accuracy and importance of the choline recommendation. It was pointed out that choline is most important in women of childbearing age and in the older population. A request was made to make the "Dark Green Vegetables" "Green Vegetables." The issue was described that the nutrient profile on some green vegetables, particularly green beans and some lettuces, do not align with the Dark Green Vegetables. It was expressed that the subgroups can be confusing, and some clarification would be beneficial. There was support for the move to distinguish best practices from common practices when following the food groups and significant calorie differences were noted. The point of the comparison was to differentiate between healthy and unhealthy diets; it is impossible to compare diets of ideal foods to diets of typical foods isocalorically. The spread between the ideal intake and the typical intake, even while following the *Guidelines*, is 400 calories, so the representative food items are not representative. However, the 400 calories is a modeled number, not intake data. It was pointed out that the typical model was of someone who followed the *Guidelines*, but without choosing nutrient-dense foods. Most Americans not eating nutrient-dense foods are also not following the *Guidelines*, so total intake is inflated in this model. After the *Guidelines* are released, USDA will formulate a new set of food plans, including a thrifty plan. It was noted that an increase in fruits and vegetables would address the shortfall nutrients of concern. As modeling continues, USDA should look for ways to enhance nutrient density without increasing calories with the goal of meeting nutrient RDAs and countering obesity.

Carbohydrates and Protein Subcommittee
Chair: Joanne Slavin, Ph.D., R.D.

Joanne Slavin, Chair of the Subcommittee, acknowledged the Subcommittee members and staff. The Subcommittee addressed three issues, with NEL searches for each one: glycemic index/load (GI/GL), dietary protein patterns, and food groups.

Member Pi-Sunyer addressed the questions on glycemic index/load, "What is the relationship between glycemic index/load and body weight, cancer, type two diabetes mellitus (T2D), and cardiovascular disease (CVD)? The search looked at literature between 2004 and 2009 for

bodyweight and cancer and 2000 to 2009 for CVD and T2D. Only original research articles were reviewed. For body weight, the proposed conclusion, with Grade I evidence, was that "GI/GL are not associated with weight and do not lead to greater weight loss or better weight maintenance. There was no difference between high and low GI/GL diets (greater than eight week duration) in facilitating weight loss." The evidence review included 22 articles: 13 RCTs, two prospective cohort trials, and seven cross-sectional studies. The RCTs showed no difference between high and low GI/GL diets in weight loss or maintenance. The observational studies validated that finding.

For cancer, the proposed conclusion, with Grade I evidence, was that "The epidemiological evidence for an association between GI or GL and cancer is overwhelmingly negative." There were 26 articles reviewed. Of 17 prospective studies on GI and cancer, 15 found no association, one found an inverse association with colorectal cancer, and one found a weak positive association with all cancers. Of 19 prospective studies on GL and cancer, 16 found no association, one found a weak positive association, and one found an inverse association. Three case control reports found GI to be significantly associated with cancer, as did three for GL. No other associations were observed. The cancers were prostate, gastric, and thyroid.

For diabetes, the proposed conclusions were that at a Grade II "There is mixed evidence as to whether there is an association between a high GI and T2D," and with Grade I "There is little evidence to suggest that a high GL is associated with T2D." There were 10 longitudinal prospective studies reviewed. For GI, five reports (two of the same cohort) found a positive association, one an inverse association, and four no association. For GL, seven found no association, two found an inverse association, and one found a positive association. For CVD, the proposed conclusion was, with Grade III evidence, "The evidence for an association between high GI or high GL and CVD is more negative than positive. The evidence available is inadequate to come to a firm conclusion regarding this question." Eight articles were reviewed, and the outcomes were inconsistent. However, three studies reported a relationship between GI and GL and CVD in women with a body mass index (BMI) over 23 or 25. The overall proposed conclusion, with Grade I evidence, was that "Current evidence predominantly shows no relationship of GI and weight or cancer and no relationship of GL and weight, T2D, or cancer. The evidence for GI and T2D is mixed, but more strongly negative than positive. The evidence for the relationship of either GI or GL and CVD is inadequate to come to any conclusion."

Member Slavin presented on the questions related to dietary protein patterns, which was a new topic for the Committee to address: "What is the association between consumption of various dietary patterns (e.g., plant-based, animal-based, and vegan) and health outcomes? How did the health outcomes of a plant-based diet compare to that of an animal-based diet? How did the health outcomes differ between those who follow a vegan, non-animal protein diet, and those who consume animal products?" For these questions, the Subcommittee defined an animal-based diet as a pattern that includes regular consumption of animal products; a plant-based diet as a pattern that includes the occasional consumption of animal products, with most dietary intake coming from plant foods; and a vegan diet as a dietary pattern that does not include animal products. Inclusion criteria were articles from 2000 through 2009 and included children and adults. To broaden the search, health outcomes were not identified.

In comparing health outcomes of a plant-based diet to those of an animal-based diet, the proposed conclusion, with Grade III evidence, was that "Using the current NEL process, intake of a plant-based diet is associated with lower BMI and blood pressure. No protective properties of vegetarian diets against cancers were found in the EPIC-Oxford cohort. Differences in eating patterns among countries are great and affect the results of this question." The NEL review included 18 observational studies (five longitudinal cohort, two case control, and 11 cross-sectional studies). They represented data from nine different countries, and six articles were from the same EPIC-Oxford (European Prospective Investigation into Cancer and Nutrition) cohort in the UK. The studies are limited by small sample sizes and inconsistent classification of plant-based diets. For the question of vegan diets, the proposed conclusions, with Grade III evidence, were that "Few studies are available that compare vegan diets to animal-based diets. Limited data suggests that vegans have lower BMIs than meat-eaters. Vegans may also have lower blood pressure than meat-eaters. Vegans have significantly lower intakes of calcium than meat-eaters. Therefore, vegan eating patterns may improve biomarkers, but are associated with low intakes of calcium." For this question, there were five observational studies (two longitudinal cohorts and three cross-sectional). Of these, four were based on the EPIC-Oxford cohort. The studies were limited by the small number of vegans and semi-vegetarians in the cohorts.

The Subcommittee has developed a number of research recommendations. There is a need for well-defined cohort studies of populations consuming plant-based diets, compared to animal-based diets; studies of potential limitations of plant-based diets for key nutrients (calcium, iron, B12, and protein quality), especially in children and the elderly; better assessment tools to classify vegetarian dietary patterns in epidemiologic studies; identification of cohorts that include a significant number of vegan subjects compared to matched protein eaters; and intervention studies with calorie-controlled vegan diets to determine if lower BMIs and positive biomarkers are linked to diet composition rather than calorie intake.

Research recommendations on effects of essential amino acids and types of protein versus total protein intake on health outcomes were suggested. Because lifestyle differences between vegetarians and non-vegetarians may confound the studies, randomized trials are needed. It was noted that, due to the small number of vegetarians in the U.S., it is difficult to have an adequate vegetarian population. Since the vegetarian population is so small, a related field of study might be comparing abundant meat-eaters to moderate meat-eaters. Blood pressure in vegetarians was discussed and whether it was linked to BMI, which apparently it was. The DASH (Dietary Approaches to Stop Hypertension) diet was based on the understanding that vegetarian diets lower blood pressure. A suggestion to broaden the search terms was made in order to avoid missing data.

Member Achterberg spoke on food groups. The food groups the Subcommittee addressed were Fruits, Vegetables, Milk and Milk Products, and the subgroup, Dry Beans and Peas. The first question was, "What is the relationship between the intake of fruits and vegetables and body weight and cardiovascular outcomes?" The review looked at literature from 2004 to 2009 for adults, including individual studies, systematic reviews, and meta-analyses. Intake of juice was not considered, as it is being covered by a question in the Energy Balance Subcommittee. The proposed conclusion on body weight was, "Using the NEL search process, the evidence for an

association between increased fruit and vegetable intake and lower body weight is modest, with a trend toward decreased weight gain over five or more years in middle adulthood. No conclusions can be drawn from evidence of increased fruit and vegetable intake on weight loss." The evidence was Grade III. There were 11 studies, including three RCTs, three prospective cohort studies, one case-control and four cross-sectional studies. In the RCTs, small weight loss was observed over short time periods. Prospective cohort studies showed a weak inverse relationship between fruit and vegetable consumption and long term weight gain. However, due to differing methodologies, it was difficult to quantify the fruits and vegetables in any given study.

On the question of CVD, the proposed conclusion was, "Using the current NEL search process, there is moderate to strong evidence supporting an inverse relationship between fruit and vegetable consumption and cardiovascular/coronary heart disease in U.S. populations, with larger effects noted above five fruit and vegetable servings per day." This was Grade II evidence. There were 10 studies reviewed, including six prospective cohort studies, two case control studies, and two meta-analyses. They showed a correlation between increased fruit and vegetable intake and a decrease in CVD. For blood pressure, the proposed conclusion, with Grade III evidence, was, "Using the current NEL search process, there's limited evidence to suggest any association between fruit and vegetable intake and blood pressure." The evidence included four studies: one prospective cohort study and three cross-sectional studies. The prospective cohort study found no association between the intake of fruits, vegetables, or fruits and vegetables and hypertension. The cross-sectional studies had mixed and conflicting results.

For blood cholesterol, the question was, "What is the relationship between the intake of fruits and vegetables and blood cholesterol?" The proposed conclusion was that "Using the current NEL search process, the evidence for relationship between fruit and vegetable intake and blood lipids is limited but appears to show a trend between increased consumption of fruits and vegetables, with lower total and low density lipoprotein (LDL) blood cholesterol levels." The evidence was Grade III. There were only three studies: one trial and two cross-sectional studies. The trial added three servings of cherries per day for 28 days, finding no effect on plasma lipids. Cross-sectional studies found an inverse association between fruit and vegetable consumption and total and LDL cholesterol between extreme quintiles. The work on fruits and vegetables is still under review.

The question of serving sizes was raised. Because serving sizes differ by country and by study, and different fruits and vegetables are used, making comparisons is difficult. It also should be considered that any benefit may be due to fruits and vegetables replacing something else in the diet.

Member Slavin presented on the Milk and Milk Products food group. The Subcommittee's questions were, "What is the relationship between the intake of milk and milk products and body weight, bone health, cardiovascular outcomes, metabolic syndrome (MetS) and T2D?" Because there had been a search for the 2005 DGAC report, this search went from 2004 to 2009 in children and in adults. Body weight was not looked at in children. On body weight, the proposed conclusion was that "There is little convincing evidence that milk and milk products have any unique role in regulation of body weight and body adiposity." The evidence was Grade

I. There were 18 studies: one systematic review, one randomized control trial, four prospective cohort studies, eight cross-sectional studies, three crossover trials with energy intake as the outcome, and one prospective cohort study on pregnancy. The conclusion was strongly supported by the systematic review and intervention study and four prospective cohort trials.

For bone health, the proposed conclusion was, for children "Intake of milk and milk products is associated with improvements in bone health in children." For adults, the proposed conclusion was, "Results in adult trials are more mixed and inconsistent. There is inconsistent support for the role of milk and milk products on bone health." Both were supported by Grade II evidence. There were nine articles: one systematic review, two meta-analyses, three trials, one longitudinal study, one case control, and one cross-sectional study. Studies reported that children who are milk avoiders have poorer markers of bone health. There is a meta-analysis of this question in adult populations with less clear results. However, low intake of calcium was not associated with increased fracture risk. Another meta-analysis concluded that a low intake of calcium, as judged by intake of milk, does not confer a substantial increase in fracture risk, and the intervention studies are supportive of a role for milk and milk products in bone health.

For CVD, the proposed conclusion was that "Recent studies find that intake of milk and milk products is protective against CVD." The evidence was Grade II. There were three articles: one systematic review, one systematic review with a meta-analysis, and one case control study. An inverse association was consistently reported for outcomes including stroke, myocardial infarction (MI), ischemic heart disease, and acute coronary syndrome.

For metabolic syndrome, the proposed conclusion was that "Limited milk and milk product consumption is not generally linked to metabolic syndrome and may even be protective in certain population groups." The evidence was Grade III. There were five articles: one systematic review with a meta-analysis, one prospective cohort study, and three cross-sectional studies. The meta-analysis showed a reduction in risk associated with the highest level of milk consumption. Dairy consumption was not associated with any metabolic variables in an elderly Dutch population. In a French study, intake of dairy products was associated with lower probability of insulin resistance. NHANES data found that each serving of dairy products increased risk of metabolic syndrome by eight percent among men; no significant associations between whole milk, low-fat milk or skim milk and metabolic syndrome were observed.

For blood pressure, the evidence was Grade III. The proposed conclusion was that "Using the current NEL search process, there is limited evidence that supports a relationship between the intake of milk and milk products and blood pressure." There were 13 articles: one systematic review, one trial, six prospective cohort studies, and five cross-sectional studies. The results of the articles are mixed and conflicting. The data are complicated by types of milk products consumed, calcium intake from other sources, and the relationship of blood pressure to weight loss.

For blood cholesterol, the proposed conclusion was that "Intake of milk and milk products in recent studies does not show increases in total blood cholesterol, but may be linked to increased high density lipoprotein (HDL) cholesterol." The evidence was Grade II. There were three articles: one randomized trial, one prospective cohort study, and one cross-sectional study. In

one study, intake of milk products was associated with lower blood cholesterol, but that was associated with weight loss in the study. In another study, baseline dairy consumption was not associated with change in lipid levels over 6.4 years. The NHANES dataset associated more frequent cheese consumption with higher HDL and lower LDL cholesterol in women. In men, more frequent cheese consumption was associated with higher BMI, waist circumference, HDL cholesterol, and LDL cholesterol.

The proposed conclusion for T2D was that "In a recent systematic review with a meta-analysis, relative risk for T2D was estimated to be ten percent lower in people who had a high milk intake." The evidence was Grade II and consisted of one systematic review with a meta-analysis which included four prospective cohort studies.

A number of cross-cutting issues were discussed including data on HDL cholesterol from the Carbohydrates and Protein Subcommittee as well as the Fatty Acids and Cholesterol Subcommittee. The possibility of comparing high, medium, and low dairy consumers was raised. It was urged that the emphasis be on patterns rather than single food groups and nutrient outcomes, particularly with an emphasis on food patterns and modeling. Grading issues were discussed, and it was suggested to expand the search window to increase the number of studies considered. It was acknowledged that many studies are not designed to show the mechanism of health effects.

Member Slavin discussed the research questions on dry beans and peas, which are important sources of protein, fiber, vitamins, and minerals but are underutilized in the U.S. diet. They may also slow carbohydrate absorption. The questions were, "What is the relationship between intake of dried beans and peas and body weight, cardiovascular outcomes, and T2D?" The literature search included studies, reviews, and meta-analyses from 2000-2009. Children and adults were included. The proposed conclusion on the question of body weight was that there is "Limited data that intake of dry beans and peas is related to body weight." The evidence was Grade III. There were nine articles: one meta-analysis, two systematic reviews, four trials, one prospective cohort study, and one cross-sectional study. While the cross-sectional analyses suggest that the consumers of beans had better nutrition, lower weight, and lower waist circumference, the randomized trials did not show diets with beans and peas to cause a greater weight loss than the control. The low consumption of beans and peas in the country make it difficult to link their consumption to disease outcomes.

On the question of cardiovascular outcomes, the proposed conclusion was that "The soluble fiber content of beans contributes to lipid-lowering benefits. There is limited evidence that dried beans and peas have any unique abilities to lower serum lipids." The evidence was Grade III. There were thirteen articles: one meta-analysis, six trials, three prospective cohort studies, one longitudinal study, one case control study and one cross-sectional study. In intervention studies, dried beans and peas lowered serum lipids, due to their high content of soluble fiber. Soy may lower serum lipids in hypercholesterolemic subjects, but not in normal subjects. The small number of subjects who consume dried peas and beans makes it difficult to determine protectiveness.

The proposed conclusion for the question of T2D was that "Consumption of legumes may be inversely associated with the risk of T2D." The evidence was Grade III. There was one prospective cohort study, and it associated consumption of soybeans and other legumes with decreased risk for T2D.

Because the largest consumers of legumes are likely to be vegans and vegetarians, this might be a confounding factor. It was also noted that, because protein in legumes is hard to digest, the protein has low utilization rates.

Member Slavin listed the remaining research topics for the Subcommittee: whole grains, animal protein products, vegetable protein, fiber, carbohydrate type, liquids versus solids, non-calorie sweeteners, satiety, and modeling. Food pattern modeling will explore adjusting the percent of plant and animal protein intake and macronutrient proportions, both scenarios including an evaluation of nutrient adequacy.

General Discussion

Chairperson Van Horn said that the importance of obesity should be emphasized throughout the *Guidelines*. Primary prevention of obesity will address children. Member Fukagawa stated that there is a need for an integrated view on the total diet for health and well-being rather than focusing on specific questions. Member Nickols-Richardson thanked the Carbohydrates and Protein Subcommittee for its analyses, which will aid the Nutrient Adequacy Subcommittee. Chair Van Horn thanked the participants and audience and concluded the meeting for the day.

(Recess 4:38 p.m.)

Thursday, November 5 (8:00 a.m.)

Remarks from the Chair

Chair Van Horn called the meeting to order and reiterated that the presentations and proposed conclusions are drafts.

Sodium, Potassium, and Water Subcommittee
Chair: Larry Appel, M.D., M.P.H.

Larry Appel, Chair of the Subcommittee, acknowledged the members and staff. The Subcommittee has completed reviews and drafted conclusions for water; sodium and blood pressure (BP) in children; and sodium and BP in adults. Work on potassium, dietary patterns and BP in children and adults, and sodium/potassium interaction are ongoing. There may be interaction with the Nutrient Adequacy Subcommittee on dietary patterns.

The first research question was, "What amount of water is recommended for health?" Though the Subcommittee did a literature search, there were no major studies published since the last *Dietary Guidelines* that would affect the recommendations. The Subcommittee spoke with Dr. Michael Sawka, an outside expert, who agreed with the Subcommittee that there were no major studies that would affect recommendations. The draft conclusion is that "Consumption of water is necessary to maintain health. However, there is no evidence of dehydration or other problems relating to inadequate water intake in the general population." Due to the lack of recent literature, the Subcommittee has not graded the conclusion. The combination of thirst and usual drinking behavior, especially consumption of fluids with meals, is sufficient to maintain normal hydration. Healthy individuals who have routine access to fluids and who are not exposed to heat stress consume adequate water to meet their needs. Purposeful drinking is warranted for individuals who are exposed to heat stress or who perform sustained vigorous activity. The new implications are that no quantitative recommendation for minimum water consumption can or should be set and that, in view of the obesity epidemic, individuals should select water or fluids with few or no calories.

Member Appel spoke on the Subcommittee's work on sodium. The DRIs set by the IOM identify the Upper Limit of 2,300 milligrams of sodium and an Adequate Intake at 1,500 milligrams. There is a relationship between salt intake and BP, and BP is linked to CVD and stroke. There is probably a relationship between salt and gastric cancer, and there are reasons to suspect a relationship between salt and increased risk of osteoporosis and left ventricular mass. There are hypotheses of a relationship between salt and overweight and obesity. High BP is serious, because CVD (including CHD and stroke) is the leading cause of death worldwide, and 62 percent of strokes and 49 percent of coronary events are attributed to BP. Twenty-six percent of all adults have hypertension. The lifetime risk of developing hypertension is 90 percent. Lowered BP lowers the risk of CVD, even in those without hypertension, and there are benefits

even to relatively small reductions in BP. However, only 42 percent of U.S. adults have normal blood pressure, and there is a trend of higher BP in the U.S. population.

Member Williams presented on sodium and BP in children. The research question was, "What is the effect of sodium intake on blood pressure in children from birth to 18 years?" In the U.S., BP rises with age, and BP during childhood exhibits significant tracking phenomena. Over the past 20 years, mean BP in children has increased, leading to increased risk of CVD in adult life. High BP in children is associated with cardiovascular abnormalities in childhood and early atherosclerotic lesions, and can be attributed to increased obesity and dietary intake of sodium and potassium. Most children and adolescents exceed the recommended sodium intake and do not meet recommended levels of potassium. The evidence review was prompted by the increase in high BP, hypertension, and pre-hypertension in children; evidence that the BP elevation is associated with immediate and future adverse effects; and evidence that sodium influences childhood BP as it does adult BP. The literature review went back to 1970. It included 19 studies: 15 clinical trials (14 RCTs) and four prospective cohort studies. In 12 of the 15 clinical trials, a decrease in systolic and/or diastolic BP was reported on lower sodium diets. In eight of those 12, the difference was statistically significant. Ten of the 15 clinical trials achieved contrasts in sodium intake of 40 percent between treatment groups or periods. Three trials reported no change in blood pressure on a low sodium diet. Of the four prospective cohort studies, three found evidence that lower sodium intake was associated with lower BP. The evidence review indicated that sodium reduction modestly lowers BP in children, but that reduction, if sustained, can reduce BP in adults and perhaps blunt the age-related risk of increased BP. Most studies were limited by sample size, duration, or inadequate reduction in sodium intake. The evidence was Grade II. The draft conclusion was, "A lower sodium intake appears to reduce blood pressure in infants and children." This implies that, among children and adolescents, lower sodium intake has beneficial effects on BP and that reduced BP early in life should translate to benefits later in life.

Member Appel addressed the research question, "What is the effect of sodium intake on blood pressure in adults?" Because the 2005 IOM report and other meta-analyses on the topic provided so much evidence, the NEL review only went back to 2004. The final review included 13 studies, of which 12 were clinical trials (nine RCTs). Five of the studies were U.S. studies. Of the 12 clinical trials, nine reported a statistically significant decrease in systolic BP on a lower sodium intervention; six reported a statistically significant decrease in diastolic blood pressure. The systemic review of 34 trials showed statistically significant reductions in systolic and diastolic BP on lower sodium interventions. This evidence was Grade I and supported the 2005 *Dietary Guidelines* recommendation. The draft conclusion was that "The relationship between salt (sodium chloride) intake and BP is direct and progressive without an apparent threshold." The implications of these conclusions are that people should reduce their salt intake. A daily sodium intake of no more than 2,300 milligrams has been recommended for the general adult population, 1,500 milligrams for hypertensive individuals, blacks, and middle-aged and older adults. However, this subgroup actually constitutes the majority of Americans, and a goal of 1,500 milligrams could be applied to all Americans. Because this goal is difficult to meet with the current food supply, the goal should be incrementally reduced to 1,500 milligrams. Individuals should also increase their consumption of potassium-rich foods, since a diet rich in potassium blunts the effects of sodium on BP.

While the 2005 *Dietary Guidelines* recommended 2,300 milligrams as the upper limit for the general population and 1,500 milligrams for hypertensives, blacks, middle-aged and older adults, the World Health Organization's recommendation is 2,000 milligrams. Recently Canada recommended 1,000 milligrams for children one to three and 1,500 milligrams for adults. However, NHANES data shows average sodium intake at nearly 2,300 milligrams at three years old with a continual increase until adulthood. Sodium intake does not decrease until middle age. Males have much higher sodium intakes, due to higher caloric intake. A 2009 study in the *American Journal of Health Promotion* estimated the benefits of reducing sodium intake in the population to 2300 milligrams or 1500 milligrams at billions of dollars in healthcare savings and hundreds of years in Quality-Adjusted Life Year (QALY) savings. One question the Subcommittee discussed was whether or not the recommendations on sodium and potassium should be calorie adjusted; the Subcommittee had discussions with outside experts. The reasons to calorie-adjust are that sodium intake is linked to calorie intake, people naturally adjust by caloric intake, and clinical trials tend to adjust sodium and potassium by calorie level. However, there is no clear biological rationale to adjust sodium and potassium intake by caloric intake.

Public comments urged both more and less restrictive recommendations, adding a separate guideline for children, updating the methodology for assessing the guideline (which has been done), and linking sodium to disease outcomes and medical costs. For overall diet, some comments suggested a focus on associating dietary patterns with health improvements, overall improvement in dietary quality and strategies to reduce BP, and recommending eating more foods high in potassium. The public also commented on stores and restaurants, urging ways to make the public aware of sodium levels in prepared, preserved, and restaurant foods. Discussion occurred on salt sensitivity. Groups associated with salt sensitivity include African Americans, middle-aged and older adults, and individuals with hypertension, but there is significant variability within the groups. Given the scope of the BP and CVD problem, salt sensitivity is irrelevant to public health. Dietary therapies to lower BP include weight loss, reduced sodium intake, increased potassium intake, dietary patterns (DASH or vegetarian diets) and moderation of alcohol intake.

Though many food manufacturers are reducing sodium levels, this is not uniform. There are large increases in sodium sources that the public is not aware of, such as transition foods in infants and meats augmented with sodium-containing solutions.

Next steps include looking at dietary patterns and BP in children and adults, potassium, the sodium/potassium interaction, and food pattern modeling.

Chair Van Horn said looking at children will be a new and valuable feature of the *Guidelines*. She supported reducing the sodium guidelines incrementally. Member Pi-Sunyer noted that cutting calories cuts sodium, so this can be emphasized for children. Member Pearson said calorie adjustment is an issue in other Subcommittees as well. Member Appel suggested a unified approach to calorie adjustment. Calorie-adjusted values could be used in illustrative menus. He added that immediate reduction to the lower sodium recommendation is not likely to succeed, so the *Guidelines* must acknowledge practical reality. Chair Van Horn recommended partnering with industry to address the sodium problem. She noted that many other dietary

recommendations grow out of the need to compensate for the high sodium intake problem. Dr. Rob Post noted that IOM released a report in October that suggests reducing sodium in school meals gradually in two-year increments.

Energy Balance and Weight Management Subcommittee
Chair: Xavier Pi-Sunyer, M.D., M.P.H.

Xavier Pi-Sunyer, Chair of the Subcommittee, acknowledged the Subcommittee members and staff and provided an overview of the topics to be presented: energy density, childhood overweight, gestational weight gain, and physical activity. Member Pérez-Escamilla addressed dietary energy density (ED) associated with body weight and highly prevalent chronic diseases, including T2D, CVD, and cancer. Dietary energy density was defined as total food consumption in the diet divided by the corresponding calorie amount. The literature search went back to 2004 and looked at body weight, BMI, and various disease outcomes and risk factors in adults. The first question was, "To what extent is dietary energy density associated with body weight?" The preliminary conclusion was that "Low energy density diets improve body weight outcomes among male and female adults." The studies estimated energy density based on foods, excluding caloric and non-caloric beverages. The evidence was Grade I. There were 17 studies: four randomized controlled trials, five prospective cohort studies, five cross-sectional studies, and three literature reviews. The cross-sectional and prospective observational studies showed a consistent positive relationship, and the randomized controlled trials indicated that the relationship was likely to be causal. The implications of this evidence is that a low ED dietary pattern that is associated with beneficial body weight outcomes is higher in fruits, vegetables, whole grains, and fiber and lower in total and saturated fat. Research supports low ED of the total diet; however, not necessarily of individual foods.

During discussion member Pérez-Escamilla clarified that the diets were not isocaloric, noting the issue is likely satiety related to food volume. Chair Van Horn noted that for a dietary pattern to work towards promoting a healthy body weight, one has to be satisfied and adhere to the diet within proper calorie intake.

Member Pérez-Escamilla presented on the second research question, "To what extent is dietary ED associated with type 2 diabetes mellitus?" The proposed conclusion was that "In agreement with the association between ED and body weight outcomes, the few available studies find a consistent association between ED and risk for T2D or its risk factors. Promoting lower ED dietary intakes may be associated with lower risk of T2D, although the results need confirmation as further evidence becomes available." The evidence was Grade III. There were three studies: two cohort studies and one cross-sectional study. The two cohort studies found a relationship between ED and T2D, which was confirmed by cross-sectional findings. On the research question, "To what extent is dietary ED associated with cancer?" the proposed conclusion was that "Evidence for ED and cancer is indirect and extrapolated from ED and body weight studies." The main evidence source was the 2007 World Cancer Research Fund report; studies directly examining the relationship between energy density and cancer were not found.

Member Williams addressed questions related to childhood overweight and obesity. The first question was, "To what extent is dietary ED associated with childhood overweight and obesity?" The literature search went back to 1980 and looked at studies that calculated ED and included objective measures of adiposity in children. The proposed conclusion was that "Energy-dense diets increase adiposity and the risk of overweight and obesity in children." The evidence was Grade III. There were seven studies reviewed: two cross-sectional and five longitudinal cohort studies. Five studies found a positive association between ED and adiposity, and most excluded all or most beverages.

On the question, "Is intake of fruits and vegetables (not including juice) associated with adiposity in children?" the proposed conclusion was that "Intake of fruits and vegetables, especially fruit, is inversely associated with adiposity in children." The evidence was Grade II. The review was based on the combined results of two independent systematic literature reviews, the American Dietetic Association's (ADA) Evidence Analysis Library review from 2004, and the current NEL review. Combined, there were 24 articles: one RCT, six longitudinal studies, and 17 cross-sectional studies. Ten studies found an inverse protective association between fruit and vegetable intake and adiposity; 12 found no association; one found a positive association for increased recent intake but none for usual intake, and another saw no association between a vegetarian diet and adiposity. Increasing consumption of fruits and vegetables in childhood is an important public health goal, not only from the perspective of increasing the intake of shortfall nutrients, but also to lower dietary ED, improve energy balance, and prevent obesity.

The next research question was, "Is intake of 100 percent fruit juice associated with adiposity in children?" The proposed conclusion was that "For most children, intake of 100 percent fruit juice is not associated with increased adiposity, unless consumed in large quantities (at or above 12 ounces a day). However, intake of 100 percent fruit juice has been prospectively associated with increased adiposity in children who are overweight or obese. Thus, 100 percent fruit juice can be a healthy part of a child's diet when consumed in moderation, as part of a nutrient rich, energy-balanced diet." For this question, the conclusion was based on the combined results of an ADA review from 2004 and the current NEL review. Combined, there were 25 articles included in the review: 12 longitudinal cohort studies and 13 cross-sectional studies. Of these, 16 studies found no association between fruit juice and adiposity; five found a positive association between fruit juice and adiposity; two found differing results by gender; and two found no association in normal weight children but a positive association for children who were at risk of overweight or obese. While 100 percent fruit juice can be a healthy part of a child's diet when consumed in moderation as part of a well-balanced diet, consumption of whole fruits rather than 100 percent juice is likely to confer greater health benefits. Since about one-third of U.S. children are currently overweight or obese, it is important to control calorie intake and choose nutrient dense foods and beverages for daily consumption.

Chair Van Horn noted the draft report of the expert panel on pediatric CVD clinical guidelines recommended no more than 4 ounces of 100 percent fruit juice per day for children. Member Williams noted that, in moderation, juice can still be nutritious. Member Achterberg noted people may not be considering beverages in the context of diet. Member Pérez-Escamilla pointed out that many consumers, especially low-income consumers, are confused as to what really is 100 percent fruit juice.

Member Pérez-Escamilla spoke on the question of weight gain during pregnancy. The research question was, "How does gestational weight gain impact short and longer term (e.g., childhood obesity) pregnancy outcomes?" The evidence source was the 2009 IOM report, Weight Gain During Pregnancy. This report was a revision of the 1990 IOM recommendations, taking into account the needs of specific populations, based on pre-pregnancy BMIs and other demographics. American women are now more diverse, having more twins and triplets, and having children later in life. Two thirds of women of reproductive age are now overweight or obese. The IOM committee's new approach to the guidelines considered outcomes for the mother and the infant and the tradeoffs between them. The IOM recommendations for underweight, normal weight, and overweight women based on pre-pregnancy BMI have not changed from 1990. For obese women, there is a range of recommended gestational weight gain. There is much work to do to improve adherence to gestational weight gain guidelines among overweight and obese women. The IOM concluded that the resulting guidelines in the 2009 IOM report, Weight Gain During Pregnancy, themselves were not very different from the previous version. However, it will take a different way of thinking about how to improve the BMI at which women become pregnant, to promote better gestational weight gain and issues related to post conception and postpartum weight retention.

Member Pérez-Escamilla noted there is little data on dietary intake patterns during pregnancy and gestational weight gain, and information broken down by trimester is needed. Research does not show primary care providers addressing weight gain or dietary advice. Women should not be losing weight during pregnancy, so the message should be expressed very carefully. Chair Van Horn suggested that early healthy lifestyle interventions are needed to support the need for weight control before getting pregnant. Member Slavin added that obese women often have poor diets, contributing to the incidence of low birth weight. Member Nickols-Richardson mentioned that there is a MyPyramid for Moms, and the IOM recommendations are important to justify it. Member Pérez-Escamilla said access to dietitians, nutritional counseling, proper foods, and physical activity opportunities are crucial.

Member Nelson spoke on physical activity, as related to health and body weight. The 2010 *Dietary Guidelines for Americans* should reference the 2008 *Physical Activity Guidelines for Americans* (PAG) that were issued by HHS. The overall question is, "How is physical activity related to body weight and other nutrition-related aspects of health? In particular, how much physical activity is needed to maintain a healthy body weight, lose body weight if overweight or obese, and avoid regain in weight-reduced persons?" For the overarching question, the proposed conclusions are that "There is clear and consistent evidence that physically active people have higher levels of health-related fitness, a lower risk profile for developing most chronic disabling medical conditions, and lower rates of various chronic diseases than do people who are inactive. Physically active people are at reduced risk of becoming overweight and obese. Adults of all body weight classifications gain health and fitness benefits by being habitually physically active." The proposed conclusions for the three sub-questions come directly from the 2008 *Physical Activity Guidelines for Americans*.

For the question, "How much physical activity is needed to maintain a healthy body weight?" the proposed conclusion was that "There is clear and consistent evidence that physical activity

provides benefit for weight stability. For children, 60 minutes per day is recommended. For adults, 150 minutes to 300 minutes per week of moderate intensity physical activity or 75 to 150 minutes of vigorous-intensity physical activity, or an equivalent combination of the two is recommended. There is a great deal of inter-individual variability with physical activity and weight stability. Some adults may need more physical activity to maintain body weight. Achieving energy balance and a healthy weight depends on both energy intake and expenditure." For the question, "How much physical activity is needed to lose weight if overweight or obese?" the proposed conclusion is that "Clear and consistent research shows that a large dose of physical activity is needed for substantial weight loss. Adults who are most successful at achieving weight loss combine calorie restriction with increased physical activity participation. A combination of caloric restriction with participation in 150 to 300 minutes per week of moderate-intensity physical activity or 75 to 150 minutes per week of vigorous physical activity or an equivalent combination of the two is recommended. More may be needed to achieve substantial weight loss." On the question, "How much physical activity is needed to avoid regain in weight reduced persons?" the proposed conclusion is that there is "Limited evidence for the effectiveness of physical activity alone in preventing weight regain following substantial weight loss. Adults who are successful at long-term weight maintenance following weight loss appear to limit caloric intake in addition to maintaining a high level of physical activity. To prevent substantial weight gain over six or more months, adults may need more than 300 minutes per week of moderate- or 150 minutes per week of vigorous-intensity physical activity or an equivalent combination of the two." The Subcommittee will update the 2005 DGAC report content on caloric intake.

Member Rimm compared the idea of dietary patterns to physical activity patterns, indicating that detailed physical activity patterns could lead to better outcomes. Member Pérez-Escamilla commented that low income Latinos have high occupational physical activity levels, but low levels of recreational physical activity; the stress of these jobs might negate the benefits of the physical activity. Member Nelson said the physical activity shows a benefit, but the stress effect had not been taken into account. Member Nelson said people can become more active through a better built environment.

Member Nelson said the Subcommittee's remaining research topics are macronutrient proportions, additional topics on childhood overweight and obesity, dietary behaviors, environmental factors, and population subgroups.

Food Safety and Technology Subcommittee
Chair: Roger A. Clemens, Dr.PH.

Roger Clemens, Chair of the Subcommittee, thanked the Subcommittee, staff, and the public commenters. Member Pérez-Escamilla spoke on in-home food safety practices. The research question was, "To what extent do consumers follow proper techniques for food storage, preparation, and handling?" Foodborne illness affects over 76 million Americans annually, and the proportion of outbreaks attributable to unsafe food safety practices is believed to be substantial. The literature search went back to 2004 and looked at both healthy populations and

those at elevated risk of adverse outcomes, two years old or older. The proposed conclusion was that "U.S. consumers do not follow proper food storage, preparation, and cleaning/sanitation techniques at home." The evidence base was not yet given a grade and included 20 studies: one meta-analysis, one systematic review, one quasi-experimental study, and 17 observational studies, as well as a secondary analysis of the 2006 Food and Drug Administration (FDA) and Food Safety Inspection Service (FSIS) Food Safety Survey. The conclusion is based on strong epidemiological observational evidence. This implies that risky food safety behaviors at home are likely to translate into home-based foodborne illness outbreaks, and consumers are often not translating their food safety knowledge into safe practices.

In studies among pregnant participants in the Women, Infants, and Children (WIC) program, risky behaviors included eating hot dogs without properly heating them and eating soft and blue-veined cheeses. Proper refrigeration, thawing, and meat thermometer use was not practiced. College students also showed risky behaviors related to cross contamination, hygiene, cooking temperatures, food storage, and consumption of risky foods. Older adults are at a higher risk for foodborne illness, as many left food on counters, did not wash their hands before eating, did not keep refrigerators at proper temperatures, and showed other unsafe practices.

Although U.S. consumers are aware of the importance of food safety, they do not believe the home kitchen is an important source of food outbreaks. They perceive industry and government to have the power and ability to affect food safety outcomes.

Member Nelson asked if there is data on the specific risk for food safety behaviors at home causing foodborne illness. Member Pérez-Escamilla said the conclusions are inferred, and more data are needed to assess this risk more directly. Member Pérez-Escamilla said future studies should go into households using microbial indicators to assess risk.

Member Pérez-Escamilla addressed the research question, "What are the benefit-risk ratios for different levels and frequencies of seafood consumption?" In 2004, the Environmental Protection Agency (EPA) and the FDA jointly issued an advisory that women (who are pregnant, may become pregnant, or are lactating) and young children follow species-specific limitations on fish consumption to limit risks from mercury in seafood. Shark, swordfish, king mackerel, and tile fish were to be avoided; albacore tuna limited to six ounces per week, and other cooked seafood limited to 12 ounces per week. Currently, the public, including the medical community, is confused about fish. There is still uncertainty on the risks, and there is not a recommendation for groups other than those covered by the 2004 EPA/FDA advisory.

The NEL literature search looked from 2007 to 2009 in both healthy populations and those at risk, ages two and older. The proposed conclusion was that "Health benefits derived from the consumption of recommended levels of a variety of seafood in the U.S. outweigh the risks associated with methyl mercury exposure, even among pregnant and lactating women and young children." The implications are that seafood is a healthy food choice that can be safely promoted, provided that the types and sources of seafood to be avoided are clearly communicated to consumers. The evidence is Grade II. The conclusion is based on three quantitative risk/benefit assessments, one systematic review, and the 2007 IOM report, Seafood Choices (a qualitative risk/benefit assessment). A qualitative analysis in the U.S. advised

avoiding shark and swordfish; however, other seafood could be consumed frequently. The qualitative analyses demonstrate that a variety of seafood should be recommended with different fat content. Both systematic reviews looked at omega-3 fatty acids and methyl mercury for CVD and neurological development. The IOM report endorsed the 2004 EPA/FDA advisory for the same target groups, but extended the recommendations to other Americans, due to the benefits of omega-3 fatty acids. The other systematic review concluded that the benefit/risk ratio is substantially in favor of recommending consumption of a variety of cooked seafood, with the benefits of consuming fish on CVD outweighing the risk for cancer.

Chair Van Horn asked if there are pockets of methyl mercury toxicity in the parts of the country with the highest seafood consumption. Member Rimm noted the effects of toxicity are subtle and develop over time.

Member Clemens said the remaining research topics are: in-home practices and recommended techniques for washing hands, utensils, equipment, and surfaces used in food preparation, serving, cooking, and eating; and washing of foods. Also remaining are consumer practices for consumption of undercooked or raw foods; and the risks and benefits of different seafood sources. Consumer food technologies that are effective in reducing pathogen exposure, decreasing risk of foodborne illness, and increasing food shelf life will also be reviewed in context of accessibility, cost-effectiveness, and acceptability to consumers. The Subcommittee will address other topics through text in the report, including food allergy, organic foods, and non-microbial contaminants other than methyl mercury.

Discussion

Member Appel asked about the dissemination of food safety information through the schools. Member Pérez-Escamilla mentioned the Fight-BAC!® campaign as a government/industry partnership to raise awareness, which includes a focus on school-aged children. Member Nickols-Richardson mentioned the Cooperative Extension Service, which is facing budget cuts, but which educates on food safety, farming, and food supply in relation to health and wellness. Member Pérez-Escamilla seconded the importance of that program toward making consumers understand their roles in food safety. Member Nelson asked if there should be a recommendation on wild versus farmed fish. Member Rimm pointed out that there are contaminants in all foods. Fish contaminants are just better-known, though there is less in fish than in other foods.

Fatty Acids and Cholesterol Subcommittee
Chair: Thomas Pearson, M.D., Ph.D., M.P.H.

Thomas Pearson, Chair of the Subcommittee, acknowledged the Subcommittee members and staff. While mortality is decreasing, the incidence of heart disease among Americans is not. Serum cholesterol levels correlate with CHD. Despite the use of effective lipid-lowering drugs, cholesterol levels have been stable since 1990. The relationship between saturated fat (SFA) and cholesterol and CHD is well-known, and there is little evidence that dietary saturated fat and

cholesterol intakes have changed since the 1990s. The Subcommittee asked, "How did intakes of fat and cholesterol by Americans change between 1977-78 and 2005-06, according to national surveys?" According to NHANES, dietary intake of total fat, saturated fat, polyunsaturated fat (PUFA), and monounsaturated fat (MUFA) and cholesterol have remained stable in men and women. Energy intake increased during that time period.

The first research topics addressed were, "What is the influence of dietary fat on cardiovascular disease and other health outcomes for saturated fat and cholesterol?" The literature search went back to 2004 for saturated fat and to 1999 for cholesterol, looking at healthy individuals, those with elevated chronic disease risk, as well as disease subgroups. The search focused on RCTs or clinical controlled studies, prospective cohort studies, meta-analyses, and systemic reviews.

The first research question under this topic was, "What is the effect of SFA intake on risk of cardiovascular disease, T2D, and intermediate markers such as lipid and lipoprotein levels, measures of insulin resistance, and inflammation?" For CVD, there were 12 studies: 10 RCTs, one non-randomized clinical trial, and one meta-analysis of 11 pooled cohorts. For T2D, there were 10 studies: seven RCTs, one prospective cohort study, and two systematic reviews. This question of association between SFA intake and T2D risk was not included in the 2005 DGAC report. The proposed conclusion, with Grade I evidence, was that "Dietary saturated fat is positively associated with intermediate markers and endpoint health outcomes for two chronic diseases: 1) increased serum total and LDL cholesterol and increased risk of CVD and 2) increased markers of insulin resistance and increased risk of T2D. Conversely, decreased SFA intake improves measures of both CVD and T2D risk. The evidence shows that five percent energy decreases in SFA, replaced by MUFA or PUFA, decreases risk of CVD and T2D in healthy adults and improves insulin responsiveness in insulin resistant T2D subjects."

The second research question under this topic was, "What is the effect of cholesterol intake on increased risk of cardiovascular disease, including intermediate health outcomes such as lipid and lipoprotein levels and markers of inflammation?" Member Pearson proposed a question as to how cholesterol should be expressed, as mg/d, mg/d by level of caloric intake, or mg/1000 kcal? There were 16 studies reviewed (all since 1999): eight RCTs, five prospective cohort studies, one meta-analysis, and two systematic reviews. Eggs remain the largest source of cholesterol in the studies. At least two studies showed an elevation of LDL and HDL in hyper-responders, but no change in hypo-responders, raising the issue of genetic predispositions. However, six studies showed improvement or no change in serum lipoprotein cholesterol with high egg consumption. A meta-analysis of 17 studies of high intake of cholesterol indicated there were no changes in total/HDL or LDL/HDL cholesterol ratios when SFA was taken into account. Overall, these results on dietary cholesterol are consistent with the IOM report. In prospective cohort studies, it was shown that egg consumption of up to six eggs per week was not associated with increased all-cause mortality. Egg consumption of more than seven eggs per week showed less consistent results, with one study showing an increased risk of mortality and one study showing no association with all-cause mortality. Three studies looking at T2D subgroup showed egg consumption was related to increased risk of CVD in patients with T2D. Other than the T2D finding, this was consistent with the IOM report. The proposed conclusion for CVD was that "There is a lack of consistency in epidemiologic studies relating dietary cholesterol to clinical CVD endpoints. However, many studies on dietary cholesterol use eggs as the dietary source.

Independent of other dietary factors, evidence suggests that there is no association between consumption of one egg per day and risk of CHD or stroke in healthy adults, although consumption of greater than seven eggs per week may increase risk. An important exception is that dietary cholesterol has been associated with CVD risk in individuals with Type 2 diabetes." The evidence was Grade II.

The next research topic evaluated the impact of specific dietary fats on plasma LDL, HDL, and non-HDL cholesterol. One question was, "What are the effects of dietary stearic acid on LDL cholesterol?" There were three studies: two RCTs and one systematic review. Stearic acid intake has been increasing, especially from red meat. It is a sizable contribution to calories, and whether or not it is a cholesterol-raising fat is a concern. The proposed conclusion, with Grade II evidence, was that "Based on randomized controlled trials, replacement of energy from carbohydrates with stearic acid has a neutral effect on LDL-cholesterol. The potential impact of stearic acid on cardiovascular disease risk in general remains unclear." It was noted that stearic acid does not have a cholesterol-raising effect like other saturated fats.

The next question was, "What effect does consuming natural versus synthetic (industrial) *trans* fatty acids (TFA) have on LDL-cholesterol, HDL-cholesterol, and non-HDL-cholesterol?" The daily intake of natural or ruminant (rTFA) is small in the average adult population, approximately 1.2 grams and 0.5 percent of total daily energy intake. There were four studies: three prospective cohorts and one case-control study. The proposed conclusion, with Grade II evidence, was that "It is well documented that industrial (iTFA) adversely affect the LDL, HDL and non-HDL cholesterol levels, but evidence is very limited that rTFA levels typically consumed have any effect on CVD or CHD risks. Based on the results of two small, well-designed crossover studies, high intakes of rTFA (10.2 g-12 g per day) do not show consistent and different effects from iTFAs. One study found rTFA intake compared to iTFA intake increased both LDL-cholesterol and HDL-cholesterol in women, but not in men." There was no suggestion that rTFAs were safer than iTFAs. "Three prospective cohort studies and one case-control study using CHD endpoints showed no significant difference in associations between rTFA and iTFA, corroborating the studies evaluating their effect on lipids and lipoproteins." The overall conclusion was that "Total TFA intake should be considered the target for dietary change." However, it was reiterated that the recommendation to reduce TFA intake remains in place.

Remaining research topics are the influence of dietary fat on CVD and other health outcomes, including MUFAs and n-6 PUFAs; the relationship between consumption of n-3 fatty acids and health outcomes, looking at plant and marine sources; the affect of a maternal dietary intake of n-3 fatty acids on breast milk and infant health outcomes; health benefits related to consumption of fats from specific foods (nuts, fish, and chocolate); genetic polymorphisms affecting the association between dietary components and plasma LDL cholesterol; and food pattern modeling. Food pattern modeling will explore the impact on food choices and nutrient adequacy of limiting cholesterol-raising fat, limiting cholesterol intake to less than 200 milligrams per day, and of increasing n-3 fatty acids. Dr. Pearson welcomed the public comments the Subcommittee had received, especially from students.

Discussion

Member Nelson asked for the rationale behind keeping cholesterol under 200 milligrams per day, considering the egg data. Member Nelson said the cholesterol content in eggs has gone down. The 200 milligrams recommendation is being considered for hyperlipidemic, CHD, and diabetic subgroups. The 2005 recommendation was for 300 milligrams as an upper limit for most individuals and 200 milligrams as upper limit for high risk subgroups.

Member Pi-Sunyer commented on the data on substituting saturated fat with carbohydrate. Ideally, the substitution should be fiber for a high energy density food like saturated fat. However, the detrimental effect on HDL and triglyceride is troubling. Member Pearson said the biggest benefit for health is from substituting MUFAs and PUFAs for saturated fats, rather than carbohydrates. The American Heart Association guidelines addressed a diet with 20 to 35 percent of calories from fat rather than very low fat diets. Member Slavin said soluble fiber keeps HDL levels up. Member Pearson noted that there are good and bad fats and good and bad cholesterols. Member Slavin pointed out that the Committee does not want to discourage egg consumption.

Member Appel asked if there is enough power in the RCTs on cholesterol. He suggested looking at cholesterol in egg eaters and non-egg eaters to get an understanding of where cholesterol is coming from, since cholesterol comes from other sources than only eggs. Member Pearson noted that 25 percent of dietary cholesterol comes from eggs, so the math does not match the recommendation. People eating one egg a day should watch their other intakes. Older consumption data should be reexamined. Many of the RCTs were small, short-term, and industry-funded.

Member Pérez-Escamilla pointed out that zero *trans* fats on food labels does not mean there are no *trans* fats in the food, and this should be considered. Member Clemens said that is an issue of FDA definitions and isomers. Member Pérez-Escamilla said the primary concern is hydrogenated oil. Discussion occurred on whether there is the evidence to lower the cholesterol limit to 200 milligrams. Several members contributed to the discussion indicating that the evidence shows a benefit for reduction in consumption in the subgroups, but there are many large subgroups. Modeling can be used to look at cholesterol and a nutrient-rich diet, which should address the competing risks and benefits, since this is not Grade I evidence.

Member Williams noted that expressing cholesterol as milligrams per 1000 calories would eliminate eggs from young children's diets, which is not an intended outcome. It should also be considered that foods with cholesterol may be replaced by foods high in saturated fat.

Ethanol Subcommittee
Chair: Eric Rimm, Sc.D.

Eric Rimm, Chair of the Subcommittee, said the Subcommittee would address four topics: alcohol beverage consumption, ethanol and weight gain, ethanol and cognitive

function/dementia, and ethanol and CHD/stroke. He acknowledged the Subcommittee members and staff.

The 2005 *Dietary Guidelines for Americans* included a chapter on alcohol. The key recommendations for the public included that "those who choose to drink alcoholic beverages should do so in moderation – defined as the consumption of up to one drink per day for women and up to two drinks per day for men." The Subcommittee first looked at general information on alcohol use in the U.S., using NHANES data from 2003 to 2006. According to NHANES, among those 21 years and over, 32.8 percent of men and 17.4 percent of women drank alcohol on a given day, and beer was the beverage most frequently consumed. Although beer generally has more calories than distilled beverages, most distilled spirits were consumed as mixed drinks, and the mixer has a caloric content. Most adults (76.3 percent of men and 65.3 percent of women) drank alcoholic beverages at least once per year. On a given day, 65.9 percent of men did not consume alcohol; but among those who drank, 15.1 percent drank two drinks or fewer. Nineteen percent of men drank in excess of two drinks on a given day. Nearly 81 percent of women did not drink on a given day. Ten percent of women drank one drink, while nine percent consumed more than one drink. There is a clear issue of excess consumption in a small portion of the population.

Looking at average consumption over a year, 60 percent of men consume an average of one drink daily, 7.7 percent two drinks, and 8.6 percent exceed two drinks per day. For women, 3.8 percent consume an amount, on average, that exceeds one drink per day. On days when they do drink, many men and women exceed two drinks and one drink, respectively; though excess drinking declines after age 65. To address binge drinking, one question for further consideration is, "Is it more important to provide a recommendation for average consumption or patterns of consumption?" Member Rimm suggested three options for framing guidelines: recommending an average consumption level, a daily upper limit, or a weekly limit with a recommendation against binge drinking. This last option occurs in the National Institute of Alcohol Abuse and Alcoholism (NIAAA) Rethinking Drinking 2009. He asked the full committee for guidance.

For weight gain, the research question was, "Among persons who consume alcoholic beverages, what is the relationship between patterns of intake and weight gain?" The literature search went back to 1994 and included only observational prospective studies and randomized clinical trials. The evidence included eight studies, and was assigned a Grade II. The draft conclusions were that "Evidence predominantly from observational prospective studies suggests that among free living populations moderate drinking is not associated with weight gain. There is insufficient evidence to determine the relationship of drinking patterns or frequency of consumption to weight gain. Heavier consumption over time is associated with weight gain."

The next topic, cognitive function/dementia, was not addressed in the 2005 *Dietary Guidelines*. The research question was, "Among persons who consume alcoholic beverages, what is the relationship between patterns of alcohol intake and cognitive decline with age?" The literature search went back to 1995 and focused only on long-term effects (i.e. not acute effects). Twenty-four studies, with Grade II evidence, supported the conclusion. The draft conclusion was that "The evidence in observational prospective studies suggest that compared to non-drinkers,

individuals who drink moderately have reduced cognitive decline with age. There was insufficient evidence to determine if drinking patterns were important, although there was a suggestion that heavy or binge drinking was detrimental to age-related cognitive decline."

On the topic of alcohol and CHD/stroke, a new research question looking at drinking patterns was, "Among persons who drink alcoholic beverages, what is the relationship between patterns of alcohol intake and CVD?" Due to the volume of literature on alcohol and CHD, the Subcommittee focused on eight meta-analyses. For alcohol and stroke, the Subcommittee reviewed 15 prospective cohort studies and one case control study. The proposed conclusion, with Grade II evidence, was that "The evidence from observational prospective studies strongly suggests that compared to non-drinkers, individuals who drink moderately have lower risk of CHD and modestly lower risk of stroke. There was insufficient evidence to determine if drinking patterns were equally predictive of risk, although there was a suggestion that heavy or binge drinking was detrimental, especially for stroke."

Discussion

Member Rimm noted cancer would be discussed within the chapter text, but would not undergo a comprehensive NEL review since the World Cancer Research Fund report was published only recently.

Chair Van Horn noted that drinking leads to lowered inhibition, which affects diet. Also, people who drink may underreport alcohol consumption the same way overweight people underreport caloric intake. Member Rimm agreed that alcohol calories are completely discretionary calories. The loss of inhibition may contribute to weight gain among those who drink; however, data generally show that moderate drinkers do not gain weight. Member Rimm emphasized that the number of drinks represents a maximum, not a target. Member Rimm pointed out that the papers summarized in the 2005 *Guidelines* were based on average consumption, not daily consumption data. Awareness of the caloric content of food and beverages through labelling information is a cross-cutting theme.

Meeting Wrap-up

Chair Van Horn congratulated everyone involved in the meeting for their efforts and progress made. The next step is to reprioritize the key questions. Member Appel said Subcommittees should look at contextual ancillary issues that affect the discussion. Member Rimm reminded the Subcommittees to rely on the best evidence, not only the largest quantity evidence. Chair Van Horn seconded the idea of looking at the methodology and value of a study or trial, reminding the Committee that they have the expertise to show good judgement in the absence of studies.

Chair Van Horn summarized next steps. Each Subcommittee will finish drafting its proposed conclusion statements for the remaining research questions. The Subcommittees will present the

remaining proposed conclusions at the next meeting. The meeting's focus will be to come to consensus on the science and to begin integrating the conclusions into food-based recommendations. The sixth meeting will be held by Webinar after the report has been drafted. The Committee will discuss and approve the report and then it will undergo final formatting prior to submission to the Secretaries of USDA and HHS, who will then post it for public comment.

Dr. Anand thanked the DGAC members, co-executive secretaries, staff, and the USDA Graduate School, and the Economic Research Service for their contributions.

(Adjournment 3:26 p.m.)