

# Nutrition and Your Health: Dietary Guidelines for Americans



## Dietary Guidelines Advisory Committee Meeting

Sponsored by the
U.S. Department of Health and Human Services (HHS)
U.S. Department of Agriculture (USDA)

Held at the Holiday Inn Select Bethesda, MD May 26-27, 2004

## **Meeting Summary**

Wednesday, May 26

(8:40 a.m.)

### **Participants**

**Dietary Guidelines Advisory Committee:** Dr. Janet C. King (Chair), Dr. Lawrence J. Appel, Dr. Yvonne L. Bronner, Dr. Benjamin Caballero, Dr. Carlos A. Camargo, Dr. Fergus M. Clydesdale, Dr. Vay Liang W. Go, Dr. Penny M. Kris-Etherton, Dr. Joanne R. Lupton, Dr. Theresa A. Nicklas, Dr. Russell R. Pate, Dr. F. Xavier Pi-Sunyer, Dr. Connie M. Weaver

**Co-Executive Secretaries:** Ms. Carole Davis, Ms. Kathryn McMurry, Dr. Pamela Pehrsson, Dr. Karyl Thomas Rattay

Others: Dr. Cristina Beato, Dr. Eric Hentges, Capt. Penelope Royall, Dr. Carol Suitor

#### Welcome and Introductions

**Dr. Janet C. King, Chair, Dietary Guidelines Advisory Committee,** welcomed Committee members, staff, and observers to the fourth meeting of the Advisory Committee and turned the floor over to Dr. Beato and Dr. Hentges.

**Dr. Cristina Beato, Acting Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS),** acknowledged that the Committee had been working hard and was close to completing its recommendations. She noted that the Committee had requested an additional meeting to complete its task and that the Departments had agreed this would be

warranted. Dr. Beato stated that the Committee's recommendations would be submitted to the Secretaries after the final meeting and that the timeline for the release of the Guidelines would not be altered.

Dr. Beato thanked the Committee members on behalf of the Secretaries for volunteering their time and expertise to assist the Departments in developing the 2005 *Dietary Guidelines*. She reminded Committee members and observers that the Committee operated under the Federal Advisory Committee Act (FACA) and that questions should be referred to Ms. Kathryn McMurry at HHS, who is the Designated Federal Officer for the Committee. Dr. Beato noted that the FACA process was designed to ensure independent review in an open, public process, with opportunities for public participation. She stated that the public comment period for the Committee had passed, but that the public would have an opportunity to submit comments to the departments prior to the final release of the *Dietary Guidelines*.

Dr. Beato reminded the Committee that its charge was to independently review the science and to make recommendations about what constitutes a healthy diet. She reiterated that the Dietary Guidelines would serve as the foundation for federal nutrition policy and as such, would impact many education and health initiatives. Dr. Beato emphasized that the Committee's task was to focus on the science and that the Departments would develop the policy statements and consumer education materials. She encouraged the Committee to aim high and to provide the best science-based advice possible.

Dr. Beato again thanked the Committee members for their valuable time and expertise and commended Dr. King for her leadership as chair of the Committee.

**Dr. Eric Hentges, Director, Center for Nutrition Policy and Promotion, U.S. Department of Agriculture (USDA)** thanked the Committee members on behalf of the Under Secretaries of Agriculture for their hard work and the time they had devoted to their task. He stated that he was looking forward to the next two days of deliberations and the outcome of the meeting.

**Dr. King** acknowledged that the Committee had undertaken a challenging task last September. She noted that the Committee's charge to undertake a comprehensive review of the scientific literature that provides a basis for the *Dietary Guidelines* differed from the charges to previous Committees. She stated that the Committee had completed that task and had drafted a number of conclusive statements and implications from its review of the literature. Dr. King informed the Committee and observers that the first day of this meeting would be devoted to reviewing those conclusive statements and implications. On the second day, the Committee would begin the process of developing dietary guidance statements stemming from the conclusive statements.

Dr. King stated that the goal of the first day was to review the full draft of the technical section of the report in order to identify gaps or inconsistencies and to ensure that all Committee members were comfortable with the scientific rationale for each conclusive statement. The Committee would work into the evening to accomplish that goal.

Dr. King noted that the Committee would know by the end of the day whether an additional meeting would be needed. She thanked Committee members and staff for their hard work and turned the floor over to Dr. Weaver and the Nutrient Adequacy Subcommittee.

### Nutrient Adequacy C. Weaver, Lead

After thanking Dr. King and the staff, Dr. Weaver reminded Committee members that the Subcommittee had focused on dietary patterns to meet the recommended intake of nutrients, with a goal of trying to achieve the Adequate Intake (AI) or Recommended Daily Allowance (RDA) recommended by the Institute of Medicine (IOM). She then presented the Subcommittee's conclusive statements pertaining to each of its research questions.

Q1: What nutrients are most likely to be consumed in amounts low enough to be of concern?

- Based on the CSFII 1994-96 database, the prevalence of adequacy for the following nutrients are of concern:
  - For adults: Vitamins A, C, E and folate, calcium, magnesium, zinc, potassium and fiber.
  - For children: Vitamin E, folate, calcium, magnesium, potassium, and fiber.

Q2: What dietary patterns are associated with achieving recommended nutrient intakes?

- Two major elements contribute to dietary patterns that meet nutrient intake recommendations:
  - They are based on the basic food groups (fruits, vegetables, grains, low-fat milk products, and lean meat and meat alternates) and
  - They include a variety of food commodities within and among each of those food groups.

Dr. Weaver presented several graphs that illustrated how the proposed patterns developed by USDA to meet nutrient adequacy goals, differed from current food consumption patterns. She noted that the proposed food patterns would require significant increases in consumption of fruits, vegetables, and milk products. Total grain consumption would not change greatly, but the proportion of whole grains to refined grains would increase. Consumption of meats and beans would not change significantly, compared to other food groups. Consumption of fats and sugars would need to decrease in order to stay within calorie limits. Within the vegetable group, consumption of dark green and orange vegetables would need to increase substantially, consumption of starchy vegetables would decrease, and consumption of other vegetables would increase slightly, especially for females. Dr. Weaver noted that the Fatty Acids Subcommittee would address the recommended amounts and proportions of various types of fats in the diet.

Q3: What factors related to diet or physical activity may help or hinder achieving recommended nutrient intakes?

• A sedentary lifestyle limits the amount of calories needed to maintain one's weight; careful food selection is needed to meet recommended nutrient intakes within this calorie limit. Incorporating foods with high nutrient density into dietary patterns increases nutrient intake and the likelihood of meeting

recommended nutrient intakes without exceeding calorie needs. The consumption of foods or beverages that are high in calories but low in nutrients may result in insufficient intake of important micronutrients and fiber, especially for sedentary rather than more active individuals.

Dr. Weaver noted that the Subcommittee was also concerned about the effects of added sugars on vitamin and mineral intake. She then turned the floor over to Dr. Nicklas to discuss the issue of nutrient density and the scientific basis for this statement.

Dr. Nicklas stated that after careful review of the literature, the Subcommittee concluded that there was a lack of consensus regarding the definition of nutrient density. Some studies looked at nutrition intake per 1000 kcal; others looked at percent of RDA/DRI/EAR (Estimated Average Range), consumption or omission of food groups, or ratio of recommended to restricted food groups. Other studies used an index, such as the Calories for Nutrient Index, the Diet Quality Index, or the USDA Healthy Eating Index.

Summarizing some of the results, Dr. Nicklas stated that studies had shown that individuals who consume energy dense, nutrient poor foods may have increased energy intake or decreased nutrient density, and they may be less likely to meet the RDA for several nutrients or to eat the recommended servings of foods from all food groups. Studies also showed that consumption of foods from all food groups resulted in the most adequate nutrient intake. One study found that dietary diversity within the vegetable group was negatively associated with energy intake and body fatness. Dr. Nicklas stated that the Subcommittee had based its conclusive statement on these and other published studies.

Q4: How can flexibility of food patterns be increased?

Dr. Weaver stated that the Subcommittee had asked USDA staff to develop various iterations of the proposed patterns to see if substitutions could be made for certain foods that people may not consume due to personal preferences or dietary restrictions. These models helped the Subcommittee identify nutritionally adequate substitutions for a number of food groups and eating patterns, which was reflected in its proposed conclusive statement regarding flexibility:

• Substitutions can be used to increase flexibility of food group choices while still achieving recommended nutrient intakes.

Grains
Legumes
Milk and milk products
Fruits and fruit juices
Vegetarian patterns

Dr. Weaver stated that the proposed food patterns came close to meeting the AI or RDA for almost all nutrients. She noted that the patterns had been revised to meet the new AI for potassium that was published in a recent IOM report. Dr. Weaver stated that vitamin E was the only nutrient for which the proposed food patterns would not meet the RDAs. She noted that the Subcommittee would present options to meet this goal in the rationale for this statement and would include a list of foods rich in vitamin E.

Q5: Are special nutrient recommendations needed for certain subgroups?

Dr. Weaver noted that most of her presentation in this area would focus on Vitamin D because the Subcommittee's proposed recommendations were substantially different from the 1997 IOM report and because this issue had not been covered extensively in previous meetings. Before turning to that subject, she presented the Subcommittee's proposed conclusive statements regarding other nutrients.

Dr. Weaver stated that the Subcommittee's conclusive statement regarding adults over age 50 reinforced the IOM recommendations for this group:

• Individuals over the age of 50: A substantial proportion of individuals >50 may have reduced ability to absorb naturally occurring vitamin B12. Consuming vitamin B12 in its crystalline form, either by consuming foods fortified with vitamin B12 or taking crystalline B12 supplements, may lead to improved absorption of the vitamin.

The Subcommittee also adopted the IOM's recommendations for women capable of becoming pregnant and pregnant women and for adolescent females and women of childbearing age:

- Women Capable of Becoming Pregnant and Pregnant Women: A large body of evidence indicates that folic acid reduces the risk of neural tube defects in infants.
- Adolescent Females and Women of Childbearing Age: A small percentage of these females do not meet their iron requirements. However, they need enough good sources of iron to keep up their iron stores.

Dr. Weaver then presented the Subcommittee's conclusive statement regarding vitamin D:

• Individuals unable to maintain a serum 25 hydroxy vitamin D (25(OH)D) level of 80 nmol per liter: To achieve a serum 25(OH)D level of 80 nmol per liter may take 25 mcg (1000 IU) of vitamin D per day—substantially more than the AI of 15 mcg (600 IU). Many individuals in at-risk groups for vitamin D inadequacy are unable to maintain serum 25(OH)D at 80 nmol per liter. These at-risk groups include the elderly, individuals with dark skin, and those not exposed to sufficient UVB radiation.

Dr. Weaver stated that the Subcommittee's proposed intake of vitamin D could be achieved through three cups of vitamin D-fortified milk per day, which would provide 300 IU, plus increased consumption of vitamin-D fortified foods and/or supplements. She noted that multivitamin supplements typically contain 400 IU of vitamin D.

Dr. Weaver summarized the process that the Subcommittee had followed in developing its recommendation and presented the scientific evidence supporting the conclusions it reached at each step. The Subcommittee's first task was to determine the optimal or target serum level for vitamin D status. Dr. Weaver stated that there was a consensus that the serum 25 (OH) vitamin D level was the appropriate status indicator for vitamin D, but there was no documented consensus regarding the optimal level. She noted that it was generally agreed that levels below 25 nmol represented overt deficiency, but that there was less agreement

regarding the transition between sub-optimal and normal levels. Dr. Weaver stated that it was important to determine this threshold because sub-optimal vitamin D status was associated with osteoporosis and many other disorders. She then presented data supporting the Subcommittee's conclusion that 80 nmol per liter was the optimal level, including evidence that this was the cutoff for fractional calcium absorption as well as for desirable levels of parathyroid hormone (PTH), which accelerates bone resorption. Another study showed that serum 25 (OH) D levels near 80 nmol per liter were linked with reduced risk of fracture through suppressed PTH.

The next step in the process was to determine the relationship between vitamin D intake and change in serum vitamin D level. Dr. Weaver stated that the Subcommittee had reviewed two major and several smaller studies in this area and she presented data showing the dose response relationship between intake of vitamin D and serum 25 (OH) D levels. Based on the evidence, the Subcommittee determined that a dose of 1,000 IU of vitamin D would be required for those at risk of not being able to achieve adequate levels of vitamin D through skin production.

Dr. Weaver then presented data and summarized studies showing that the ability to produce vitamin D through the skin decreased with age. She noted that NHANES III data showed that 60 percent of older adults were deficient in vitamin D at serum levels of 62 nmol per liter, which was approximately 25 percent lower than the Subcommittee's proposed optimal level. She presented data from a study showing the differential ability of light skinned and dark skinned individuals to generate vitamin D and a study documenting the prevalence of vitamin D deficiency in African Americans over Caucasians. She also presented evidence showing that limited exposure to the sun due to time of day or latitude could affect vitamin D formation.

Dr. Weaver stressed that since the Subcommittee's proposed level was higher than both the current AI and Upper Limit (UL), it was important to address the issue of safety. She presented data from recent dose response studies showing no risk of toxicity at doses of up to 100,000 IU, which was many times higher than the proposed level.

Dr. Weaver summarized the main messages of the Nutrient Adequacy Subcommittee's proposed conclusive statements as follows:

- Eat a variety of foods within and among the five basic food groups while maintaining appropriate energy intake.
- Incorporate nutrient dense foods into dietary patterns.

Dr. Weaver stressed the importance of promoting variety within food groups and noted that recent studies had shown that this could contribute to the probability of meeting nutrient adequacy. She then opened the floor for discussion.

#### Discussion

In response to questions from Dr. King and Dr. Kris-Etherton, Dr. Weaver stated that it would be too cumbersome to include a definition of "variety within food groups" in the conclusive

statement but that the Subcommittee would provide examples in the translation section of the report.

Dr. Caballero asked whether the cutoff for vitamin D deficiency might be lower for dark-skinned individuals. Dr. Weaver replied that this would be a good area for research because studies regarding optimal serum 25 (OH) D levels did not specify race and studies linking vitamin D status and health outcome had not been conducted specifically with dark-skinned individuals. She noted that the Subcommittee's proposed intake of 1,000 IU was based on studies that used supplements, in which race was not a factor. She stated that a new study had shown a higher instance of prostate cancer linked with vitamin D deficiency in African Americans, and another report regarding vitamin D had just been published in Scandinavia.

Dr. King noted that the Subcommittee's recommendation of 25 mcg of vitamin D per day for at-risk groups was a major change from the current RDA of 5 mcg per day for individuals aged through 50 years (including infants and children), 10 mcg per day for ages 50 to 70, and 15 mcg per day above age 70. She urged the Committee to consider the issue carefully before adopting the proposed recommendation.

Dr. Pate noted that the conclusive statement regarding the third research question referred to the impact of a sedentary lifestyle on nutrient intake but did not mention that higher levels of physical activity could increase the likelihood of meeting nutrient adequacy goals by increasing caloric intake. Dr. Weaver replied that the Subcommittee had considered language to that effect but was concerned that it might be misinterpreted as permission to overeat. Dr. King noted that this was related to the issue of caloric limits and choosing a variety of foods.

Dr. King suggested that the Committee focus its discussion and asked for comments regarding the statement regarding nutrients that are most likely to be consumed in amounts low enough to be of concern.

Responding to questions, Dr. Weaver stated that iron was not identified as an area of concern because the IOM approach indicated that the probability of iron deficiency was relatively low for the general population, although it was prevalent among certain groups. She noted that the Subcommittee had addressed this issue by including recommendations for iron in its conclusive statements regarding special subgroups.

Responding to another question, Dr. Weaver stated that vitamin D was not included as a nutrient of concern because it was one of several nutrients that had not been evaluated using the IOM approach. She noted that the Subcommittee had added a statement specifying the nutrients that were not addressed in the IOM report, including vitamin D.

The Committee then engaged in a lengthy discussion regarding the Subcommittee's vitamin D statement. Given the significant difference between the proposed level and the current AI for children plus the lack of clinical trials in children and dark-skinned individuals, Dr. Bronner suggested that it might be wise to adopt a step down approach until data was available. Dr. Weaver replied that the American Academy of Pediatrics (AAP) was recommending vitamin D supplementation for infants; Canada had issued an alert to pediatricians for rickets; and rickets had been identified in dark-skinned children. She stated that there was no evidence to support a particular age cutoff for vitamin D supplementation.

Dr. Weaver stated that the increased prevalence of rickets in children was due primarily to vitamin D deficiency in breastfeeding mothers. She stressed that the Subcommittee did not wish to discourage breastfeeding and that the problem could be corrected by improving the vitamin D status of either the infant or the mother through supplementation. Dr. Bronner urged the Committee to refrain from making specific recommendations regarding supplementation levels for dark-skinned individuals until more data was available regarding dose response relationships.

In response to a question from Dr. King, Dr. Weaver replied that the Subcommittee had reviewed data on differential ability to synthesize vitamin D by skin and on the prevalence of vitamin D deficiency between African American and Caucasian individuals. She acknowledged that it was not possible to determine whether the optimum serum level would be different for dark-skinned versus lighter-skinned individuals because such studies had not been conducted.

Dr. Weaver stated that although a consensus vote had not been taken at the NIH conference last fall, evidence presented at that conference consistently supported 80 nmol per liter as the optimal level and experts meeting in Switzerland in May 2003 had overwhelmingly approved 80 nmol per liter as the optimal level. She also noted that the Subcommittee was recommending 1000 IU per day for older adults, regardless of skin color.

Dr. Nicklas asked whether enough vitamin-D fortified foods were available to justify emphasizing food sources rather than supplements. Dr. Weaver replied that the vitamin D in fortified foods and in supplements might be of equal quality and that the availability of fortified foods varied greatly.

Dr. Appel asked whether professional groups in other countries had issued recommendations regarding vitamin D intake. Dr. Weaver replied that the Dietary Guidelines Advisory Committee (DGAC) was the first group to address the issue because the most convincing data regarding outcome measures and safety had only recently become available.

In response to several questions, Dr. Weaver stated that one glass of fortified milk provided 100 IU of vitamin D. Committee members discussed whether milk was fortified with D2 or D3 and whether the form of vitamin D would affect its viability.

Dr. King noted that a dose of 25 mcg did not seem to have a significant impact on serum levels of vitamin D. Dr. Weaver acknowledged that although the recommended level was many times higher than the current AI, it would be difficult to correct a serious deficiency with 1000 IU per day. Dr. Weaver stated that the recommended level may not be enough for some people but it was an appropriate long-term preventive dose.

Dr. Caballero noted that vitamin D was among the first Dietary Reference Intakes (DRIs) to be issued by the IOM in 1997 and that updating the DRIs was a complex process. He felt it would be important to ensure that any changes the Committee may recommend would not conflict with the ongoing work of the standing committee. He also expressed concern that while there was convincing DRI evidence that a substantial proportion of the population fell short of 80 nmol, there was no data showing how many were meeting the current DRI. Dr.

Weaver replied that there were good studies supporting the target level of 80 nmol per liter and the dose needed to achieve that level, as well as NHANES data showing that many people were currently below that target. She noted that three members of the DRI panel were in the literature proposing a daily intake of 1000 IU and that this level was a reasonable interim approach until the DRI and IOM committees could deliberate together. She further stated that Vitamin D was an important reason to ask the IOM to review bone-related nutrients.

Dr. King noted that vitamin D appeared to be among the nutrients for which more research was needed. She suggested that it might be appropriate to treat vitamin D as an emerging issue rather than going forward with a conclusive statement and a dietary recommendation. Dr. Pi-Sunyer stated that given the prevalence of osteoporosis, he did not see the downside of recommending 25 mcg per day. Dr. Go concurred, since toxicity levels were much higher than the proposed level.

Several members suggested eliminating the reference to supplements and focusing instead on foods and fortified foods. Dr. Weaver acknowledged that the proposed intake could be met through fortified foods such as milk, orange juice, breakfast cereals, and some pasta. Dr. Camargo noted that the Committee was comfortable recommending supplements for vitamin B12, and Dr. Weaver reiterated that the AAP was recommending vitamin D supplements for infants. She suggested that supplements could be included in the list of sources of vitamin D, along with foods and fortified foods.

Dr. Camargo suggested that physicians could be encouraged to perform blood tests to help high-risk individuals determine whether they were vitamin D deficient. Dr. King cautioned that the Committee needed to be careful about making policy recommendations of that nature.

Dr. King proposed changing "the AI of 15 mcg (600 IU)" in the conclusive statement to "the current AI," since the AI varied by age. She reminded the Committee that the only other quantitative recommendation was for 14 grams of fiber and noted that the Committee had required a full literature review to support that recommendation, despite the fact that it was the same level recommended by the IOM. She stated that she was uncomfortable proposing a level for vitamin D that was higher than the AI without sufficient data. Other Committee members felt that it was important to specify what was meant by "substantially more than the current AI."

After discussing a number of changes, the Committee approved the following revised version of the conclusive statement regarding vitamin D:

• For individuals unable to maintain a serum 25(OH)D level of 80 nmol/L: To achieve a serum 25(OH)D of 80 nmol/L may take substantially more (e.g., 25 mcg/day from dietary sources) than the current AI. Many individuals in at-risk groups for vitamin D adequacy are unable to maintain serum 25(OH)D at 80 nmol/L at current intake levels. These at-risk groups include the elderly, individuals with dark skin and those not exposed to sufficient UVB radiation.

Dr. King called a break.

(Break)

Dr. King reconvened the meeting and the Committee discussed the conclusive statement regarding nutrients most likely to be consumed in amounts low enough to be of concern. The wording of the first bullet was revised to include a reference to the IOM approach and other minor changes. The Committee approved the revised conclusive statement as follows:

- Using the IOM approach and the CSFII database, the following nutrients are consumed in amounts low enough to be of concern:
  - o For adults: Vitamins A, C, E and folate, calcium, magnesium, zinc, potassium and fiber.
  - o For children: Vitamin E, folate, calcium, magnesium, potassium, and fiber.

The Committee then discussed the conclusive statement regarding dietary patterns. After some discussion, the phrase "meat and meat alternates" was changed to "meat and other protein sources." References to "low-fat" milk products and "lean" meat were removed, and the statement was condensed into one paragraph. The Committee approved the revised conclusive statement as follows:

• A wide variety of foods within and among the basic food groups (fruits; vegetables, grains; milk products; and meat and other protein sources) contribute to meeting nutrient recommendations.

The Committee then considered the conclusive statement regarding physical activity and nutrient adequacy. The statement was reworded to focus on the benefits of a physically active lifestyle, as opposed to the limitations of a sedentary lifestyle, and the overall text was simplified. The Committee approved the revised conclusive statement as follows:

 A physically active lifestyle and selection of nutrient dense foods help to achieve nutrient adequacy without exceeding energy needs. Selection of low nutrient density foods or beverages may result in insufficient intake of important micronutrients and fiber, especially for sedentary individuals.

The Committee discussed the conclusive statement regarding flexibility. The statement was modified to include specific foods for which substitutions could be made and to remove references to fruits and fruit juices, which would be discussed in the section of the report on fruits and vegetables. The Committee approved the revised conclusive statement as follows:

• Comparable nutrient adequacy can be achieved by substituting other foods for refined grains; legumes; lactose-containing milk; and meat, poultry, and fish.

The Committee then addressed the conclusive statement regarding special nutrient requirements for certain groups (aside from the vitamin D statement approved before the break). The conclusive statements regarding iron and folic acid were revised slightly and were approved as follows:

• Adolescent Females and Women of Childbearing Age: Since adolescent females and women of childbearing age have an increased iron requirement, they are advised to regularly consume foods rich in iron.

• Women Capable of Becoming Pregnant and Pregnant Women: Since folic acid reduces the risk of neural tube defects, a daily intake of 400 mcg of synthetic folic acid from supplements and/or fortified foods is recommended.

The conclusive statement regarding vitamin B12 in individuals over age 50 was approved as originally presented.

Dr. King thanked the Nutrient Adequacy Subcommittee for its work and introduced Capt. Penelope Royall, Deputy Assistant Secretary for Health, Disease Prevention and Health Promotion. She noted that Capt. Royall would be working with the Committee to assist it in completing its process in a timely manner. Dr. King then adjourned the meeting for lunch.

(Lunch, 12:35-1:45)

Dr. King reconvened the meeting and reminded the Committee that when it approved the conclusive statements it was also approving the rationale behind those statements. She then turned the floor over to Dr. Pi-Sunyer and the Energy Balance and Macronutrients Subcommittee.

# Energy Balance and Macronutrients X. Pi-Sunyer and B. Caballero, Lead

Dr. Pi-Sunyer acknowledged the Subcommittee members who worked on developing the conclusive statements and thanked the staff member for her assistance. He then presented the Subcommittee's proposed conclusive statement pertaining to the first research question.

Q1: What is the relationship of physical activity to body weight and other nutrition-related aspects of health?

- Regular physical activity reduces risk for the development of chronic diseases and is essential to the maintenance of a healthy weight. Thirty minutes of at least moderate physical activity per day provides important health benefits. More than 30 minutes of moderate to vigorous physical activity daily provides added health benefits, and many adults may require up to 60 minutes of moderate to vigorous physical activity per day to prevent unhealthy weight gain.
- Children and youth require 60 minutes of regular moderate to vigorous physical activity for maintenance of good health and fitness and for healthy weight during growth. Decreased sedentary behavior is associated with decreased BMI in children.
- Vigorous intensity physical activity (e.g., jogging or other aerobic exercise)
  provides greater benefits to physical fitness than does moderate physical activity.
  Also, vigorous physical activity burns calories more rapidly than moderate
  physical activity. Vigorous physical activity performed for at least 20 minutes on
  three or more days per week can promote health and fitness as well as contribute
  to the maintenance of a healthy weight.

• All individuals, especially youth, should limit their sedentary behaviors. Specifically, the combination of television and video viewing should be limited.

Dr. Pi-Sunyer reminded the Committee that Dr. Pate and an expert from the CDC had presented the rationale for this conclusive statement at a previous meeting. He stated that the recommended amount of physical activity was based on extensive data, including doubly labeled water studies conducted by the IOM, 16 observational studies related to prevention of weight gain, and other studies.

Dr. Pate noted that the conclusive statement was intended to integrate physical activity guidelines that had previously been regarded as inconsistent, including recommendations in the Surgeon General's report and the work of the IOM, the CDC, the World Health Organization, and other groups.

#### Discussion

Dr. King asked if it would be appropriate to state that some physical activity was better than none. Dr. Pate replied that the conclusive statement acknowledged the dose response relationship above 30 minutes, but not below that level. Dr. Pi-Sunyer stated that the Subcommittee did not want to perpetuate low levels of physical activity. Dr. Caballero noted that the fourth part of the conclusive statement addressed sedentary behavior.

Committee members proposed using the term "adolescents" as opposed to "youth" in the second part of the statement and specifying that the recommendations in other sections were aimed at adults. Committee members also suggested that the statement should recommend "daily" as opposed to "regular" physical activity and should specify that reduction of sedentary behaviors was associated with lower BMI in overweight children.

Committee members expressed no major concerns regarding the section of the statement pertaining to the benefits of vigorous physical activity. Minor modifications were proposed in order to specify a recommended amount and frequency of vigorous physical activity. Dr. Pate noted that "daily," which implied seven days per week, was inconsistent with the literature and would create problems for surveillance. Committee members agreed to use the phrase "on most days" in this section of the statement and in the section on children.

The final section of the statement, which pertained to sedentary behaviors, generated significant discussion. Committee members agreed that the statement should specify that sedentary behaviors should be limited during leisure time, given the reality that most Americans are quite sedentary at work or school. Committee members agreed that although the statement was based on studies in children, it should include individuals of all ages.

The Committee reviewed and approved the revised conclusive statements, as follows:

Regular physical activity reduces risk for the development of chronic diseases and
is essential to the maintenance of a healthy weight. Thirty minutes of at least
moderate physical activity on most days provides important health benefits. More
than 30 minutes of moderate to vigorous physical activity on most days provides
added health benefits in adults, and many adults may require up to 60 minutes of

moderate to vigorous physical activity on most days to prevent unhealthy weight gain.

- Children and adolescents require 60 minutes of moderate to vigorous physical
  activity on most days for maintenance of good health and fitness and for healthy
  weight during growth. In overweight children, reducing sedentary behaviors has
  been shown to lower BMI.
- Vigorous physical activity performed for at least 20 minutes on three or more days
  per week provides important health benefits. Vigorous intensity physical activity
  (e.g., jogging or other aerobic exercise) provides greater benefits for physical
  fitness than does moderate physical activity. Vigorous physical activity burns
  calories more rapidly than does moderate physical activity.
- During leisure time, all individuals, especially children and adolescents, should limit their sedentary behaviors, such as television watching and video viewing.

Q2: How much physical activity is needed to avoid weight regain in weight-reduced persons?

• While the contribution of physical activity to weight loss usually is modest, acquiring a routine of regular physical activity will greatly help an individual to maintain a stable body weight after successful weight loss. The amount of physical activity that weight-reduced adults require to avoid weight regain is estimated to be from 60 to 90 minutes daily at a level of brisk walking.

Dr. Pi-Sunyer noted that Dr. Caballero had presented data supporting this recommendation at the previous meeting. Dr. Caballero stated that data from many sources—including the IOM report, the National Registry of Weight Loss, doubly labeled water studies, and expert panels—consistently showed that people who had lost weight required higher levels of physical activity than those who were never obese. He noted that these findings applied only to adults and that comparable data did not exist for children.

#### Discussion

Committee members proposed a number of minor revisions, such as deleting the word "greatly" and changing "brisk walking" to "moderate intensity." The Committee approved the revised conclusive statement as follows:

• Although the contribution of physical activity to weight loss usually is modest, acquiring a routine of regular physical activity will help an adult to maintain a stable body weight after successful weight loss. The amount of physical activity that weight-reduced adults require to avoid weight regain is estimated to be from 60 to 90 minutes daily at a level of moderate intensity.

Dr. Lupton asked whether any of the Subcommittee's conclusive statements referred to resistance training. Subcommittee members stated that resistance training was discussed extensively in the rationales and the translation section but that the data did not seem to support a conclusive statement on that topic. After some discussion, the Subcommittee

agreed that a conclusive statement on resistance training would be appropriate and offered to draft a statement during the next break.

Q3: What are the optimal proportions of dietary fat and carbohydrate to maintain BMI and to achieve long-term weight loss?

The Committee approved the conclusive statement regarding macronutrient distribution and weight maintenance as presented:

• Weight maintenance depends on a balance of energy intake, regardless of macronutrient distribution and energy expenditure.

Dr. Pi-Sunyer then presented the conclusive statement on macronutrient distribution and long-term weight loss:

Long-term, there is evidence that well-planned weight loss diets that are consistent
with the acceptable macronutrient distribution ranges for fat, carbohydrate, and
protein are safe and can be efficacious. Regardless of the macronutrient
composition, weight loss occurs when calorie intake is less than calorie
expenditure.

#### Discussion

Dr. Caballero proposed changing "calorie intake" and "calorie expenditure" to "energy intake" and "energy expenditure" to make it consistent with the previous statement. The Committee approved the statement with that revision. The final statement read as follows:

Long-term, there is evidence that well-planned weight loss diets that are consistent
with the acceptable macronutrient distribution ranges for fat, carbohydrate, and
protein are safe and can be efficacious. Regardless of the macronutrient
composition, weight loss occurs when energy intake is less than energy
expenditure.

Q4: What is the relationship between energy density and BMI?

Available data are insufficient to determine the contribution of energy dense foods
to unhealthy weight gain and obesity. Consuming energy dense foods may
facilitate excess caloric intake by packing many calories in a small amount of food
and by delaying the sensation of fullness or satiety after a meal. Conversely,
consuming foods of low energy density may help keep caloric intake down in
people trying to maintain or lose weight.

#### Discussion

Committee members suggested a number of revisions to simplify this statement. They stressed that most studies on satiety looked at the impact of energy-dense meals rather than single foods and that the data was stronger for solid foods than for beverages. Some Committee members noted that many energy-dense foods were also nutrient dense. After

considering a number of modifications, the Committee approved the revised conclusive statement as follows:

Available data are insufficient to determine the contribution of energy dense foods
to unhealthy weight gain and obesity. Consuming energy dense meals may
facilitate excess caloric intake. Conversely, solid foods of low energy density may
be used to reduce energy intake in people trying to maintain or lose weight.

Q5: Does the intake of added sugars contribute to excess intake of calories and weight gain?

 The evidence evaluating the association between added sugars and body weight or BMI is insufficient. However, when individuals consume foods or beverages that are high in added sugars but low in other nutrients, there is strong documentation that they also consume more calories than those who consume low amounts of added sugars.

#### Discussion

Dr. Pi-Sunyer turned the floor over to Dr. Lupton to lead the discussion since she had done the literature review regarding this question. Dr. Lupton began by stating that while increased intake of added sugars was associated with increased caloric intake in most studies, the evidence associating increased caloric intake and body weight or BMI was inconsistent. Two prospective studies and one intervention trial found a positive relationship, but many cross-sectional studies found a strong negative correlation. Dr. Lupton stated that it was incorrect to state that the evidence regarding the association between added sugars and BMI was insufficient when in fact there was a great deal of cross-sectional data showing a negative relationship.

The Committee then engaged in an extensive debate about how to word this statement. Several Committee members argued that prospective studies and intervention trials provided more credible data because causal relationships could not be established through cross-sectional studies. Dr. Lupton stated that this would be acceptable if the same standards were applied to all of the conclusive statements. She also clarified that the prospective studies and the intervention trial that found positive associations between added sugars and BMI had been based on soft drinks and not foods. Committee members proposed that the sentence regarding added sugars and body weight or BMI be modified to state, "limited prospective evidence suggested a positive relationship ..." and to clarify that the statement referred to sugar-sweetened beverages.

At the request of Dr. King, Dr. Pi-Sunyer described the prospective studies and intervention trial on which the statement was based. A study conducted in the U.S. by Ludwig and others examined the association between consumption of sugar-sweetened drinks and differences in measures of obesity, adjusted for potentially confounding variables. The researchers found that for each additional serving of sugar-sweetened drink both BMI and frequency of obesity increased after adjusting for other variables. A ten-year study by Philips and others published in March of this year, found that soda was the only energy-dense snack food that was significantly related to BMI-Z score over the study period, though it was not related to percent body fat. And, a recently published intervention trial conducted in New Zealand by James and others found that a school-based educational program produced a modest reduction

in the number of carbonated drinks consumed, which was associated with a reduction in the percentage of overweight and obese children.

The Committee debated the merits and limitations of these studies. Ms. McMurry reminded the Committee that its charge was to make recommendations based on the preponderance of the scientific and medical knowledge. After extensive discussion and proposed revisions to the statement, the Committee was unable to reach a consensus. The Committee agreed that the Energy Subcommittee would provide copies of the studies to those who wished to review them and that the issue would be tabled until the following day.

*Q6:* What is the relationship between portion size and energy intake?

• The amount of food offered to a person influences how much he or she eats and, in general, more calories are consumed when a large portion is served rather than a small one. Higher calorie intake is even more likely when the portions are high in energy density.

Dr. Caballero noted that the statement did not make any reference to BMI. In response to a question, he clarified that the statement was based on short-term studies.

The Committee approved the statement as presented.

#### Other Issues

Dr. Pi-Sunyer stated that the Subcommittee had also reviewed the literature pertaining to breakfast and BMI. The Subcommittee felt that the evidence was inconclusive and decided to classify this as an unresolved issue requiring more research. Committee members had no objections to that decision.

Dr. Pi-Sunyer noted that the Subcommittee had also drafted a statement for the supplementary information on discretionary calories:

• Discretionary calories from added sugars, fats, and alcohol impact the macronutrient density of the diet. This is of particular concern for sedentary individuals with low energy intakes. As persons become more physically active, they will have available to them more discretionary calories.

Dr. King suggested, and Dr. Pi-Sunyer agreed, that this statement could be addressed later, as part of the discussion of flexible calories.

#### Resistance Exercise

Dr. Pate presented the new draft conclusive statement regarding resistance exercise:

• Resistance exercise training increases muscular strength and endurance, promotes bone health, and maintains or increases lean weight. These benefits are seen in youth, adults, and older adults who perform eight to 10 resistance exercises two or more days per week.

Dr. Pate noted that he had not included children in the statement because it was unclear whether the evidence for some of the benefits would extend down below the adolescent age range. Responding to suggestions, he agreed that it would be acceptable to replace "youth" with "adolescents." He stated that he had included a specific reference to older adults to emphasize the benefits of resistance exercise for this age group. In response to a question from Dr. Weaver, Dr. Pate acknowledged that weight-bearing exercise was better than resistance exercise for bone health. After some discussion, he suggested that bone health could be addressed in a separate statement. The statement was revised as follows and approved by the Committee:

• Resistance exercise training increases muscular strength and endurance maintains or increases lean weight, and can prevent falls in the elderly. These benefits are seen in adolescents, adults, and older adults who perform one or more sets of eight to 10 resistance exercises two or more days per week.

Dr. King noted that the issues of added sugars and flexible calories would be addressed the following morning and called a break.

(Break)

Dr. King reconvened the meeting and reviewed the agenda. She stated that although the meeting was behind schedule, she would like the Committee to review the conclusive statements for fatty acids, carbohydrates, fluids and electrolytes, ethanol, and food safety before adjourning for the evening. Remaining issues pertaining to added sugars and flexible calories would be discussed the following morning, along with the conclusive statements on selected food groups. The afternoon of the second day would be devoted to developing dietary guidelines stemming from the conclusive statements. Dr. King stressed the importance of voting on the proposed guidelines by the end of the meeting so that the accompanying materials could be drafted. She then turned the floor over to Dr. Kris-Etherton.

# Fatty Acids P. Kris-Etherton, Lead

Dr. Kris-Etherton acknowledged the members of the Fatty Acids Subcommittee and thanked the staff members for their assistance throughout the process. She then presented the Subcommittee's first proposed conclusive statement:

*Q1:* What are the relationships between total fat intake and health?

• Evidence indicates increased risk of inadequate intakes of vitamin E, alphalinolenic acid (ALA), and linoleic acid (LA) and increased risk factors for coronary heart disease (CHD) at low intakes of fat (less than 20 percent of energy) and high intakes of carbohydrates, and increased risk for obesity and its complications, including coronary heart disease with high intakes of fat (greater than 35 percent of energy).

Dr. Kris-Etherton noted that this recommendation was consistent with the IOM Macronutrient Report. She stated that the science behind the lower limit was related to nutrient adequacy, specifically that diets with total fat intake of less than 20 percent of energy do not meet RDAs for vitamin E and the AI for ALA and LA. She added that low-fat diets aggravated some lipid risk factors in the North American population and that evidence from the Nurse's Health Trial showed that it was difficult for individuals to follow diets that had 20 percent calories from fat.

The upper end of the recommendation was based on CSFII data showing that higher fat diets were associated with a risk of increased caloric intake and higher saturated fat intake, especially with current consumption patterns.

#### Discussion

Dr. Appel suggested that the statement should be more specific about the types of risk factors. He proposed replacing "increased risk factors for coronary heart disease" with "adverse changes in High Density Lipoprotein-cholesterol (HDL-C) and triglycerides." Dr. Pate suggested that the second part of the statement should list CHD as a separate risk, rather than as a complication of obesity. The Committee approved the revised statement with those proposed changes:

• Evidence indicates increased risk of inadequate intakes of vitamin E, alphalinolenic acid, and linoleic acid and adverse changes in HDL-C and triglycerides at low intakes of fat (less than 20 percent of energy) and high intakes of carbohydrates, and increased risk for obesity and coronary heart disease with high intakes of fat (greater than 35 percent of energy).

*Q2*: What are the relationships between saturated fat intake and health:

• There is a positive dose response relationship between intake of most saturated fatty acids and Low Density Lipoprotein (LDL) cholesterol concentrations, and, therefore, with risk of coronary heart disease (CHD) and mortality from coronary heart disease.

Dr. Kris-Etherton stated that the scientific basis for this statement was the demonstrated positive linear relationship between most saturated fatty acids and LDL cholesterol, which is a major risk factor for coronary heart disease.

Dr. Kris-Etherton then presented the implications for the general population:

- Saturated fat consumption should be as low as possible while consuming a nutritionally adequate diet, within 20 to 35 percent of calories from fat and recommendations for LA and ALA.
  - o For individuals who have an LDL cholesterol of less than 130 milligrams per deciliter, less than 10 percent of calories from saturated fat is recommended.
  - For individuals with an elevated cholesterol greater than or equal to 130 milligrams per deciliter, less than seven percent of calories from saturated fat is recommended.

O To establish healthy eating patterns and reduce risk of developing coronary heart disease, less than 10 percent of calories from saturated fatty acids is recommended for children.

Dr. Kris-Etherton summarized the scientific rationale for the recommendations of seven percent and ten percent. She noted that decreasing saturated fat from the current average of 12 percent of calories to nine percent would reduce CHD risk in individuals with an LDL cholesterol of less than 130 by six percent. Decreasing saturated fat to less than seven percent of calories would be expected to decrease CHD risk in individuals with an elevated cholesterol by about eight to 10 percent.

#### Discussion

Responding to a question, Dr. Kris-Etherton stated that the word "most" in the conclusive statement was included to acknowledge the fact that stearic acid had a neutral effect on blood cholesterol levels and, as such, was clinically different from the majority of saturated fatty acids in the diet. She noted that the IOM Macronutrient Report had not made that distinction.

A number of Committee members suggested that stearic acid should be explicitly mentioned in the conclusive statement, while others disagreed. Subcommittee members stated that they had considered including stearic acid in the conclusive statement but decided that it would be more appropriate to discuss stearic acid in the rationale.

Several Committee members noted that saturated fats were associated with ischemic stroke and atherothrombotic events, in addition to coronary heart disease, and proposed replacing "coronary heart disease" with "cardiovascular disease" in the first part of the statement.

Committee members proposed several other modifications, including replacing the term "saturated fatty acid" with "saturated fats," removing the phrase "mortality from CHD," and removing the word "most." The Committee approved the following revised statement:

- There is a positive dose response relationship between intake of saturated fats and LDL cholesterol concentrations, and, therefore, with risk of cardiovascular disease (CVD).
- Saturated fat consumption should be as low as possible while consuming a nutritionally adequate diet, within 20 to 35 percent of calories from fat and recommendations for LA and ALA.
  - For individuals who have an LDL cholesterol of less than 130 milligrams per deciliter, less than 10 percent of calories from saturated fat is recommended.
  - For individuals with an elevated LDL cholesterol greater than or equal to 130 milligrams per deciliter, less than seven percent of calories from saturated fat is recommended.
  - To establish healthy eating patterns and reduce risk of developing coronary heart disease, less than 10 percent of calories from saturated fatty acids is recommended for children.

*Q3:* What are the relationships between trans fat intake and health?

- There is a positive linear trend between *trans* fatty acid intake and LDL concentration, and, therefore, with risk of coronary heart disease.
- *Trans* fatty acids either have no effect or lower HDL cholesterol concentrations, especially at the higher levels evaluated. The net result is a higher total cholesterol (or LDL cholesterol):HDL cholesterol ratio. This higher ratio has led to concern that dietary *trans* fatty acids are more deleterious with respect to CHD than saturated fatty acids.

Dr. Kris-Etherton presented a slide illustrating the linear relationship between *trans* fatty acid intake and LDL concentration. She then presented the implications statement:

• *Trans* fatty acid consumption should be kept very low for all population groups. In particular, *trans* fatty acid intake should be less than one percent of energy.

Dr. Kris-Etherton stated that the dose response relationship was the scientific basis for the conclusive statement. The implications statement was based on a thorough review of the evidence and consultation with experts. Based on that information, the Subcommittee determined that the lowest achievable level would be less than one percent of energy. Dr. Kris-Etherton stated that it would not be possible to eliminate all *trans* fatty acids even if manufactured sources were removed, because naturally occurring *trans* fats provide approximately 0.5 percent of energy. She noted that current intake of *trans* fatty acids was 2.6 percent of energy.

#### Discussion

In response to a question, Dr. Kris-Etherton stated that the recommended level was based on practical considerations and was in line with recommendations from other groups. She also noted that clinical trials have not been conducted at levels lower than 0.5 percent of energy.

Dr. King suggested that the implications should be part of the conclusive statement because it set forth the recommended amount. Dr. Lupton expressed concern that the statement was recommending a specific amount that was based on practical considerations rather than scientific evidence, which was a different standard than had been used for other recommendations. Dr. Caballero noted that the IOM recommended that *trans* fatty acid intake should be "as low as possible," which the Subcommittee had shown would be less than one percent. Dr. Camargo stated that a quantitative recommendation would help people plan diets and emphasized that this recommendation was supported by a dose response relationship.

Committee members suggested changing "LDL concentration" to "LDL cholesterol," changing "has led to concern" to "suggests," and changing "very low" to "as low as possible." The Committee approved the revised conclusive statement as follows:

• There is a positive linear trend between *trans* fatty acid intake and LDL cholesterol, and, therefore, with risk of coronary heart disease. Moreover, *trans* fatty acids either have no effect or lower HDL cholesterol concentrations,

especially at the higher levels evaluated. The net result is a higher total cholesterol (or LDL cholesterol): HDL cholesterol ratio. This higher ratio has led to concern that dietary *trans* fatty acids are more deleterious with respect to CHD than saturated fatty acids.

• *Trans* fatty acid consumption should be kept as low as possible for all population groups. In particular, *trans* fatty acid intake should be less than one percent of energy.

Q4: What is the effect of cholesterol intake on cardiovascular disease?

• There is a positive dose response relationship between cholesterol intake and LDL cholesterol concentration; and therefore, with risk of coronary heart disease.

Dr. Kris-Etherton showed a figure from the IOM report that illustrated the dose response relationship between cholesterol intake and LDL cholesterol concentration. She then presented the Subcommittee's recommendations for cholesterol intake:

- Cholesterol consumption should be as low as possible while consuming a nutritionally adequate diet.
  - o For individuals with an LDL cholesterol of less than 130 milligrams per deciliter, less than 300 milligrams of cholesterol per day is recommended.
  - For individuals with an elevated LDL cholesterol (greater than or equal to 130 milligrams per deciliter), less than 200 milligrams of dietary cholesterol per day is recommended.
- To establish healthy eating patterns and reduce risk of developing coronary heart disease, less than 300 milligrams of dietary cholesterol per day is recommended for children.

Dr. Kris-Etherton stated that this recommendation was based on the National Cholesterol Education Program ATP III Expert Panel, which stated that dietary cholesterol intake of less than 200 milligrams (mg) per day was expected to lower LDL cholesterol by three to five percent and, in turn, reduce risk of heart disease by the same amount. She noted that current cholesterol consumption was 331 mg per day in men and 213 mg per day in women. She further noted that 100 mg of dietary cholesterol per 1,000 calories changed total cholesterol by 10 grams per liter. A man with LDL cholesterol below 130 who reduced his dietary cholesterol by 31 mg per day could therefore decrease his total cholesterol by 3 mg per deciliter and would achieve an even greater decrease in total cholesterol by consuming less than 200 mg of cholesterol per day.

#### Discussion

At the request of Dr. King, the dietary recommendations were incorporated into the conclusive statement so that it would be consistent with other statements. Committee members debated whether "coronary heart disease" should be changed to "cardiovascular disease." After some discussion, the Committee agreed that the evidence was strongest for coronary heart disease. The language of the statement remained as drafted, but the wording of

the title was modified slightly to replace "cardiovascular disease" with "coronary heart disease."

Before voting on the conclusive statement, the Committee discussed the potential implications of the recommendations for children. Some Committee members questioned whether the data would support the statement that consuming the recommended amount of dietary cholesterol would reduce risk of developing coronary heart disease later in life. After some discussion, it was generally agreed that this implication was not supported by the data and that the phrase should be removed from the statement. The Committee agreed that the phrase, "to establish healthy eating patterns" was more appropriate. Dr. Nicklas stated that she had studies to support that statement and agreed to provide the references for inclusion in the rationale.

The Committee then approved the revised statement as follows:

What is the effect of cholesterol intake on coronary heart disease?

- There is a positive dose response relationship between cholesterol intake and LDL cholesterol concentration; and therefore, with risk of coronary heart disease.
- Cholesterol consumption should be as low as possible while consuming a nutritionally adequate diet.
  - o For individuals with an LDL cholesterol of less than 130 milligrams per deciliter, less than 300 milligrams of cholesterol per day is recommended.
  - For individuals with an elevated LDL cholesterol (greater than or equal to 130 milligrams per deciliter), less than 200 milligrams of dietary cholesterol per day is recommended.
- To establish healthy eating patterns, less than 300 milligrams of dietary cholesterol per day is recommended for children.

The Committee also agreed that the phrase "and reduce the risk of developing coronary heart disease" should be deleted from the recommendations for children in the conclusive statement on saturated fat, and that language about establishing healthy eating patterns in children should be incorporated into conclusive statements for other nutrients, as appropriate.

Q5: What are the relationships between n-6 polyunsaturated fatty acid (PUFA) intake and cardiovascular disease risk?

• An n-6 PUFA intake between five percent to 10 percent of energy confers beneficial effects on coronary artery disease mortality.

Dr. Kris-Etherton stated that the IOM recommendation for linoleic acid, an essential fatty acid that constitutes about 90 percent of PUFA consumed, was five to 10 percent of energy. She noted that the lower end of the range was the amount required to prevent nutrient deficiency, and she presented three sources of data supporting the upper end of the range, including epidemiological evidence and clinical trials. Dr. Kris-Etherton stated that the conclusive

statement was also consistent with ATP III and recommendations from the American Diabetes Association.

The Committee approved the conclusive statement as presented.

Q7: What are the relationships of omega-3 fatty acids with health?

 Omega-3 fatty acids have been shown in epidemiologic and clinical trials to reduce the incidence of cardiovascular disease. The literature shows that the intake of fish, which contains EPA and DHA, reduces the incidence of cardiovascular disease, whereas the literature for ALA is less definitive.

Dr. Kris-Etherton presented evidence supporting the conclusive statement, including data from the Nurses Health Study showing the inverse relationship between ALA and fatal coronary heart disease and non-fatal MI and epidemiological data showing that 500 mg of EPA and DHA per day was associated with the lowest risk for CHD. She noted that clinical trial evidence and intervention studies also showed beneficial effects of EPA and DHA. Based on the evidence, the Subcommittee made the following dietary recommendation:

• ALA intake in the range of 0.6 to 1.2 percent of calories is recommended, along with the consumption of fish, particularly fish rich in omega-3 fatty acids, twice per week.

Dr. Kris-Etherton stated that the recommended intake of ALA, which is an essential nutrient, was based on the IOM recommendation. The lower end of the range was the AI for ALA, which was based on median intake in the U.S. The upper end of the range corresponded to the highest ALA intakes from foods consumed by individuals in the U.S. and Canada. Dr. Kris-Etherton noted that the IOM acknowledged that higher intakes of ALA than the AI had been shown to afford some degree of protection against coronary heart disease, but the studies were not specifically conducted to test the effects of ALA.

Dr. Kris-Etherton stated that the recommendation of two servings of fish per week was intended to ensure beneficial intake of EPA and DHA. The Subcommittee utilized a modeling exercise conducted by the USDA's Center for Nutrition Policy and Promotion, which showed that eight ounces of high n-3 fish per week would provide between 186 and 652 mg of EPA and DHA per day. She noted that two servings of fish per week was consistent with the recommendations of many other groups, including the World Health Organization (WHO), the Euro Diet Report, the American Heart Association, the American Diabetes Association, and the U.K. Scientific Advisory Committee. Dr. Kris-Etherton pointed out that the recommended amount was twice the average fish consumption in the U.S., which was one serving per week. The recommendation did not specify a total amount of eight to nine ounces, because serving sizes would be different for children.

Dr. Kris-Etherton noted that the IOM Report recommended 0.6 to 1.2 percent of calories as ALA, of which 10 percent could come from EPA and DHA. Consuming 500 grams of EPA and DHA per day would represent 20 percent of ALA, or twice the amount in the IOM report. Dr. Kris-Etherton stated that 500 grams of EPA and DHA per day provided many beneficial effects and that adverse effects were unlikely unless intake was greater than 3 grams per day.

#### Discussion

In response to a question about mercury in fish, Dr. Kris-Etherton stated that the Subcommittee would recommend following the FDA recommendations, which would allow up to twelve ounces of low-mercury fish per week, even for high-risk groups. She noted that this issue would be discussed in detail in the section on food safety.

Dr. Lupton asked whether the Subcommittee was recommending increased consumption of EPA and DHA, independent of fish. She noted that the recommendation did not specify an amount of EPA and DHA, which could be met through fish oil supplements. Dr. Kris-Etherton stated that after careful consideration of this issue, the Subcommittee had decided to limit its recommendation to fish because fish provides many other nutrients in addition to EPA and DHA. Dr. King asked if the Subcommittee's rationale would include alternative sources for those who could not or would not eat fish. Dr. Kris-Etherton replied that this would require a quantitative recommendation.

A lengthy discussion followed regarding whether to recommend a specific amount of EPA and DHA and, if so, what amount to recommend, and whether to base the recommendation exclusively on fish or to include supplements. Committee members noted that there were no dose response studies regarding EPA and DHA and that the recommended amounts of EPA and DHA were extrapolated from epidemiological studies regarding fish consumption, plus secondary prevention studies and clinical trials using fish. They also noted that the IOM and AHRQ reports did not make a specific recommendation for EPA and DHA. Some committee members expressed concern about the lack of standardization in supplements.

Committee members discussed the nature of the cardiovascular benefits of n-3 fatty acids and debated whether the statement should specify coronary heart disease, coronary artery disease, cardiovascular disease, or cardiovascular death. After some discussion, Committee members agreed that the conclusive statement should refer to benefits for cardiovascular disease, as originally drafted.

Committee members suggested basing the recommendation on fish, but including a statement on equivalent EPA and DHA and providing guidance regarding alternative dietary sources for those who would prefer not to eat fish. Committee members also proposed specifying a total amount of fish to consume per week, but indicating that a smaller amount would be more appropriate for children. Dr. Kris-Etherton agreed to prepare a revised version of the conclusive statement incorporating these modifications. Dr. King deferred a vote until the revised version was ready for review.

Q7: What are the relationships of monounsaturated fatty intake with health?

Although monounsaturated fatty acids (MUFA) are not biologically required in the
diet, very low MUFA diets could result in intakes of SFA and n-6 PUFA that
would exceed desirable levels of intake. There is a negative linear trend between
MUFA intake and total cholesterol (TC):HDL cholesterol (HDL-C) concentration
ratio. If equal amounts of MUFA are substituted for saturated fatty acids, LDL-C
decreases.

Dr. Kris-Etherton noted that this statement came from ATP III. The implications would be:

• After accounting for SFA and PUFA, MUFA provide fatty acids to achieve the total fat goal.

#### Discussion

In response to a question, Dr. Kris-Etherton clarified that MUFA were not biologically required in the diet because they could be synthesized in the body.

After some discussion regarding the role of MUFA in replacing saturated fats and PUFA in the diet, Committee members proposed a number of revisions to clarify and simplify the statement. Dr. Kris-Etherton agreed that the first sentence could be removed and that "inverse relationship" could replace the term "negative linear trend." Committee members also suggested incorporating the implications into the body of the statement and reiterating the recommended range of calories from fat. The Committee approved the revised statement as follows:

There is an inverse relationship between MUFA intake and total cholesterol (TC):
 HDL cholesterol (HDL-C) concentration ratio. If equal amounts of MUFA are
 substituted for saturated fatty acids, LDL-C decreases. After accounting for SFA
 and PUFA, MUFA provide fatty acids to achieve the total fat goal (20-35% of
 total calories).

Dr. King postponed the discussion of the conclusive statements on carbohydrates and asked Dr. Clydesdale to present the conclusive statements on food safety following a break.

(Break)

## Food Safety F. Clydesdale, Lead

Dr. Clydesdale acknowledged the members of the Subcommittee and thanked the staff member for her assistance. He then presented the Subcommittee's first proposed conclusive statement:

Q1: What acts are most likely to cause food safety problems?

• The four basic "FightBAC!" messages: "clean—separate—cook—chill," continue to address behaviors in the home that are most likely to cause problems with food borne illness.

Dr. Clydesdale stated that the Subcommittee had reviewed the literature regarding behaviors that caused foodborne illness, a viewpoint from the CDC, and a study that found the ""FightBAC!"!" approach was effective in changing behaviors. He also presented statistics to emphasize the prevalence of food-borne diseases in the U.S.

Dr. Clydesdale stated that additional guidance was needed to make the "FightBAC!" Messages more actionable, including directions for hand washing, cleaning raw fruits and

vegetables, not washing meat or poultry to reduce risk of cross contamination, and chilling perishable foods at any stage where food is not being cooked and cleaned.

Dr. Clydesdale stated that the Subcommittee had reviewed five papers on hand washing, including a double blind, placebo-controlled study. He noted that the Subcommittee would prescribe a detailed technique for hand washing developed by the CDC and described in the literature.

The Subcommittee reviewed ten relevant articles on cleaning fruits and vegetables that provided evidence that bacteria can survive on fresh produce, that fresh produce supports pathogen growth, and that some people practice unsafe handling practices. Dr. Clydesdale described the protocol for washing fruits and vegetables that the Subcommittee adopted from the scientific literature.

Dr. Clydesdale stated that a study conducted for the "FightBAC!" Partnership found that the most commonly observed food preparation practice that can lead to cross contamination and pathogen exposure was washing meats and poultry. He stressed the importance of emphasizing this recommendation in the guidelines.

The Subcommittee also recommended adding one or more additional chill steps in the "FightBAC!" sequence, based on its literature review and discussions with food safety experts.

#### Discussion

The Committee discussed whether the additional guidance should be included in the conclusive statement or provided in Section E of the report. Some members questioned whether the general public would be familiar with "FightBAC!" A proposal was made to remove the references to the program from the conclusive statement and provide a clear description of the recommended behaviors. It was also suggested that the title of the conclusive statement should reflect the fact that it focused on behaviors that were most likely to prevent food safety problems rather than acts that were likely to cause those problems.

After discussing these and other modifications, the Committee approved the revised conclusive statement as follows:

What behaviors are most likely to prevent food safety problems?

- The most important food safety problem is microbial foodborne illness. The behaviors in the home that are most likely to prevent a problem with foodborne illnesses are:
  - Clean hands, contact surfaces, and fruits and vegetables. (This does not apply to meat and poultry, which should not be washed.)
  - o Separate raw, cooked, and ready-to-eat foods while shopping, preparing, or storing.
  - o Cook foods to a safe temperature.
  - o Chill (refrigerate) perishable foods promptly.

Q2: What topics, if any, need attention even though they are not an integral part of the "FightBAC!" campaign?

- Unsafe food may look and taste fine.
- Those at risk of listeriosis (pregnant women and their fetuses, elderly, and the immunocompromised) should avoid high-risk foods including deli meats and frankfurters that are not reheated.
- The risk of methylmercury exposure from fish may be minimized by following the FDA/EPA 2004 methylmercury consumer advisory.

Dr. King suggested that the bullet on unsafe food should specify that perishable foods could be refrigerated for three to four days. Other committee members suggested that it was more realistic to state that risk of methylmercury exposure from fish could be "lowered" rather than "minimized." It was also suggested that the specific reference to the 2004 FDA/EPA advisory should be removed because the advice changed frequently. The Committee then approved the revised statement as follows:

- Do not refrigerate perishable food more than 3 to 4 days because it may become unsafe and still look and taste fine.
- Those at risk of listeriosis (pregnant women and their fetuses, elderly, and the immunocompromised) should avoid high-risk foods including deli meats and frankfurters that are not reheated.
- Consumer advisories can help individuals lower their risk of methylmercury exposure from fish.

Dr. King called a break, following which Dr. Camargo would present the conclusive statements on ethanol.

(Break)

## Ethanol C. Camargo, Lead

Dr. Camargo acknowledged the Subcommittee members and staff. He noted that the Subcommittee had reviewed the literature and developed proposed conclusive statements regarding several research questions, from which it had developed the following implication:

- Those who choose to drink alcoholic beverages should do so in moderation, where moderation is defined as a maximum of one drink per day for women and a maximum of two drinks for men.
- One drink is equivalent to 12 ounces of regular beer, 5 ounces of wine (12% alcohol), 1.5 ounces of 80-proof distilled spirits.

Dr. Camargo noted that this statement was similar to the 2000 *Dietary Guidelines*. The key differences were that the new statement defined moderation and specified equivalent amounts of various types of alcoholic beverages.

Dr. Camargo proposed that this statement might be better as a conclusive statement than an implication. He suggested that the Committee review each of the Subcommittee's conclusions regarding each of its research questions before voting on the first statement.

Q1: Among persons who consume four or less alcoholic beverages per day, what is the dose response relationship between alcohol intake and health?

- Epidemiologic studies suggest that the lowest total all cause mortality occurs at one to two drinks per day.
- The relationship between alcohol consumption and coronary heart disease mortality follows a J-shaped curve with the lowest risk at one to two drinks per day.
- Compared with non-drinkers, women who consume one drink per day appear to have a 10 percent higher risk of breast cancer.

Dr. Camargo emphasized that the conclusive statement was based on epidemiologic studies and not randomized trials. He noted that the literature consisted of dozens of studies in many different settings and that the Subcommittee had prepared tables summarizing the evidence supporting each of these health outcomes.

- Q2: What is the relationship between consuming four or fewer alcoholic beverages per day and macronutrient profiles, micronutrient profiles, and overall diet quality?
  - Consuming one to two alcoholic beverages per day is not associated with macronutrient or micronutrient deficiencies, nor overall dietary quality.

Dr. Camargo noted that there was no evidence to indicate that the diets of moderate drinkers were compromised in any way. Although caloric intake increased slightly in most studies, BMI did not increase.

- Q3: What is the relationship between consuming four or fewer alcoholic beverages daily and caloric intake, physical activity, and body weight?
  - There is no apparent association between consuming one or two alcoholic beverages per day and obesity.

Dr. Camargo noted that this was consistent with the conclusion of the NIAAA report.

Supplementary Information

• Evidence reviewed in the NIAAA Report highlights the importance of including information regarding adverse effects of moderate alcohol consumption.

Specifically, some people should not drink alcohol, and in some situations, alcohol should be avoided.

Dr. Camargo stated that the groups of people who should not drink alcohol included those who cannot control their drinking, children, adolescents, those on medications that might interact with alcohol, and those with certain diseases. Situations in which drinking should be avoided would include before driving or handling heavy machinery, during pregnancy, and while breastfeeding. He noted that this level of detail was not provided in the 2000 *Dietary Guidelines*.

#### Discussion

Dr. Camargo proposed that the reference to the NIAAA Report in the final conclusive statement should be removed and that the statement should read: "Studies suggest adverse effects at even moderate consumption levels in specific individuals and situations."

Some Committee members suggested that the statement should specify the groups of people who should not drink and the situations in which alcohol should be avoided. There were varying opinions regarding the level of detail that would be appropriate for the conclusive statement, as opposed to an implications statement.

Dr. Nicklas asked if any studies showed that excessive drinking above moderate levels had any adverse effects on nutrition. Dr. Camargo stated that the Subcommittee had reviewed the data for up to four drinks, which was four times the maximum number of drinks for women, and had found no evidence of poor nutrition. He noted that while causality could not be inferred from epidemiological studies, there seemed to be sufficient evidence to support this conclusion.

In response to a question, Dr. Camargo stated that the caloric impact of alcoholic beverages, and especially mixed drinks, would be addressed in the section on discretionary calories.

The Committee then reviewed and voted on each of the conclusive statements in turn:

- <u>Implications</u>: This statement was changed to an overarching conclusive statement on ethanol and was approved by the Committee as drafted.
- <u>Health outcomes</u>: Responding to a question, Dr. Camargo confirmed that total allcause mortality was lower for moderate drinkers than for those who consumed no alcohol. He reiterated that the Subcommittee had data tables to support the conclusive statement and that the evidence was consistent in studies conducted in many different cultures. The Committee approved the statement as drafted.
- <u>Impact on diet quality</u>: Dr. Camargo noted that this statement was based on crosssectional studies and that prospective studies or clinical trials were unlikely to be conducted in this area. The Committee approved the statement as drafted.
- <u>Body weight and obesity</u>: Dr. Camargo acknowledged that the evidence was puzzling and agreed with Committee members who suggested that there was a

need for more research in this area. The Committee agreed to treat this as an emerging issue rather than a conclusive statement.

- <u>Adverse effects of alcohol consumption</u>: The Committee approved the revised statement as follows:
  - Studies suggest adverse effects at even moderate alcohol consumption levels in specific individuals and situations.
  - o Some people should not drink alcohol are (e.g., children) individuals who cannot restrict alcohol, individuals who are taking medications that can interact with alcohol, and individuals with specific medical conditions.)
  - o In some situations, alcohol should be avoided (e.g., women who may become or are pregnant, women who are breastfeeding, individuals who plan to drive, operate machinery, or take part in other activities that require attention, skill, or coordination.)

Dr. King then turned the floor over to Dr. Lupton and the Carbohydrates Subcommittee.

# Carbohydrates J. Lupton, Lead

Dr. Lupton acknowledged the Subcommittee members and staff. She noted that several of the Carbohydrates Subcommittee's research questions were now incorporated into other sections of the report. She then presented the Subcommittee's proposed conclusive statements pertaining to the remaining research questions, plus a conclusive statement pertaining to a new question on the relationship between sugar intake and dental caries.

Q1: What is the relationship between fiber intake and coronary heart disease?

• Diets rich in dietary fiber can reduce the risk of coronary heart disease.

Dr. Lupton presented the implications of this statement:

• Individuals should consume 14 grams of dietary fiber per 1,000 calories.

The message to be conveyed by the Dietary Guidelines was: "Good sources of fiber are whole grains, fruits, vegetables, and legumes."

Dr. Lupton stated that the conclusive statement was based on a complete review of the literature on dietary fiber in coronary heart disease in the IOM macronutrient report plus a review of studies published since that time. The literature included prospective epidemiological studies, a large number of small clinical intervention trials with lower LDL cholesterol or blood pressure as the endpoint, and a variety of cross sectional data. The quantitative recommendation was based on fiber intake in the highest quintiles of three well-designed prospective cohort studies: the Health Professionals Follow-up Study, the Nurses Health Study, and the Finnish Men's Study.

#### Discussion

In response to questions, Dr. Lupton stated that the relationship between fiber intake and blood pressure was discussed in the supporting text but was not included in the conclusive statement. She also stated that the conclusive statement was not the same as the health claims for fiber that had been approved by the FDA, and she confirmed that all of the studies published since the IOM Report supported the recommendations of that report.

Dr. Lupton suggested that the feasibility of this recommendation in children should be added to the list of topics for future research.

The Committee approved the conclusive statement as drafted.

*Q2:* What is the relationship between fiber intake and laxation?

Dr. Lupton noted that the Committee had decided at the last meeting that laxation should be addressed separately from coronary heart disease risk. She then presented the Subcommittee's conclusive statement on this issue:

• Diets rich in dietary fiber promote normal laxation.

The implications for the general population would be the same as for heart disease.

Dr. Lupton stated that constipation was one of the most common disorders in Western countries. She noted that the IOM macronutrient report for fiber intake had reviewed all of the existing human studies on fiber and its relationship to laxation, including epidemiological studies, experimental studies, and many intervention trials. Despite the extensive data on this topic, laxation could not be used as an endpoint because the amount of fiber required to produce a good laxative effect varied widely among individuals. The recommended amount of fiber was therefore the same as for coronary heart disease.

Dr. Lupton noted that chronic constipation was one of the most common causes of morbidity in childhood. Studies showed that up to ten percent of children are chronically constipated and that those children consume approximately half as much fiber as those who are not constipated. For that reason, the Subcommittee felt it was important to recommend the same amount of fiber per 1,000 calories for children as for adults.

Dr. Lupton stated that constipation was also higher in the elderly than in the general population and appeared to have a greater impact on quality of life.

#### Discussion

Committee members agreed that the conclusive statement was well documented.

Committee members noted that the recommended amount of fiber was the same for coronary heart disease risk and laxation. After some discussion, the Committee agreed that the implication statement should be incorporated into the body of the conclusive statement on

coronary heart disease risk so that it would be clear that there was only one recommended amount.

In response to a question, Dr. Lupton stated that it was difficult to be more specific about what would constitute "normal" laxation because it varied among individuals and involved several factors. She agreed that it would be acceptable to replace "normal" with "healthy."

Dr. Nicklas expressed concern that some elderly individuals might have difficulty eating enough food to meet the fiber recommendation. The Committee discussed whether to recommend fiber supplements as an alternative for those who could not consume enough fiber through dietary sources. After some discussion, the Committee agreed that supplementation should not be part of the conclusive statement and could be addressed in Section E of the report.

The Committee approved the revised conclusive statement as follows:

• Diets rich in dietary fiber promote healthy laxation.

Q3: What are the relationships between total carbohydrate intake and the incidence of either Type 1 or Type 2 diabetes?

Dr. Pi-Sunyer presented the Subcommittee's conclusive statement:

• Total dietary carbohydrates are consumed of starches, sugars and fiber. There is no evidence of a relationship between carbohydrate intake and the incidence of either Type 1 or Type 2 diabetes. However, fiber, whole grains and vegetables have been reported to lower the incidence of type 2 diabetes in observational studies.

Dr. Pi-Sunyer stated that the conclusive statement was supported by data from four longitudinal prospective observational studies and an analysis of NHANES III cross-sectional data. In all of these studies, there was no association between increased carbohydrate intake and the development of diabetes. He noted that some prospective longitudinal studies also showed no association between total sugar intake and development of diabetes.

#### Discussion

Responding to a suggested revision, Dr. Pi-Sunyer agreed that the second sentence could be modified to refer to "total carbohydrate intake."

After some discussion, the Committee agreed that the reference to observational studies should be removed from the last sentence for consistency with other conclusive statements. The sentence was also modified to state that carbohydrates were "associated with lower incidence of type 2 diabetes in adults."

Committee members agreed that the specific types of carbohydrates listed in the first sentence should be incorporated into the second sentence in parentheses.

The Committee approved the revised conclusive statement as follows:

• There is no evidence of a relationship between total carbohydrate (starches, sugars, and fiber) intake and the incidence of either type 1 or type 2 diabetes. However, fiber, whole grains, and vegetables have been associated with lower incidence of type 2 diabetes in adults.

Q4. Would use of the glycemic index, response and load be useful for providing dietary guidance for Americans?

Dr. Lupton stated that the Subcommittee recommended that this be treated as an unresolved issue. Dr. Pi-Sunyer stated that there was conflicting evidence and that the Subcommittee felt more research in normal populations was needed. Committee members accepted the Subcommittee's recommendation.

Carbohydrates and Dental Caries

Dr. Lupton presented the conclusive statement that had been drafted the previous evening regarding this issue:

• Although both sugar and starch-containing foods that adhere to the teeth can contribute to dental caries, the primary factors in protecting against caries are good oral hygiene and fluoridation.

Dr. Lupton then presented the implications for the general public:

• Oral hygiene, water fluoridation, fluoride supplementation, and fluoride toothpaste are all important factors to protect against dental caries. To protect against dental caries it is important to use fluoride either in the water or as a supplement, to brush after meals, and to minimize the frequency of exposure of fermentable carbohydrates, sugars, and starches to teeth.

Dr. Lupton stated that the conclusive statement and implications were based primarily on the IOM Macronutrient Report. An additional literature review had identified a good review article that supported the conclusion of the Macronutrient Report, plus a few smaller studies on sugar alcohols.

#### Discussion

Dr. Nicklas stated that she had heard concerns about fluoridation in children. After some discussion, she was comfortable including fluoride if it was not singled out as a means of preventing dental caries. Other Committee members felt it would be important to include fluoridated water because many people were drinking bottled water that was not fluoridated and many communities were no longer fluoridating their water supply. Dr. Weaver noted that an IOM report had identified fluoride as a bone-related nutrient.

Dr. Pate asked if dietary factors had an independent effect on dental caries, after controlling for oral hygiene and fluoridation. Dr. Lupton was unaware of any such studies. Dr. Clydesdale stated that the key issue was the fact that sugars and starch provide fermentable substrates for the bacteria that cause tooth decay.

Dr. Camargo expressed concern that the proposed statement was less direct than the 2000 *Dietary Guidelines*, which stated: "Foods containing sugars and starches can promote tooth decay." Dr. Lupton replied that the wording of the new conclusive statement was based on the IOM Macronutrient Report issued in 1992, which recognized that oral hygiene and fluoridation were more important factors in dental caries. Committee members agreed that it would be important to emphasize the dietary behaviors that influence dental caries, while acknowledging the important protective role of oral hygiene and fluoridation.

After reviewing several modifications, the Committee approved the revised conclusive statement as follows:

• Foods containing sugars and starches provide fermentable substrates for bacteria that cause dental caries. However, good oral hygiene and fluoridation protect against caries.

Dr. Camargo asked if there would be a conclusive statement regarding the acceptable amount of added sugar in the diet, preferably quantified. Dr. Lupton stated that this would be addressed in the section on flexible calories.

Dr. King called a break.

(Break)

# Fluid and Electrolytes L. Appel, Lead

Dr. Appel acknowledged the Subcommittee members and staff and presented the first proposed conclusive statement:

- *Q1.* What amount of fluid is recommended for health?
  - The combination of thirst and normal drinking behavior, especially the consumption of fluids with meals, is sufficient to maintain normal hydration.

Dr. Appel noted that the conclusive statement was consistent with the recent IOM Report and was based on NHANES data showing that stable serum osmolality was independent of total water consumption.

Responding to a question, Dr. Appel clarified that "normal drinking behavior" referred to normal, spontaneous behavior, including fluids with and between meals. He stated there was evidence that tangent fluid deficits over time were of no physiological consequence because fluids were replenished at meals.

Committee members expressed concern about possible dehydration among elderly individuals, especially in hot weather. Dr. Appel replied that this would be addressed in the implications for the general public:

• 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.

#### Discussion

Dr. Weaver noted that the Subcommittee had found no evidence to support a quantitative recommendation regarding a specific amount of water to drink each day.

Dr. Appel noted that there was insufficient evidence to make a recommendation regarding prevention of chronic disease and that this would be one of the Subcommittee's research recommendations.

Committee members discussed whether the implications statement should include a specific reference to older persons exposed to heat stress. Dr. Appel replied that there was no evidence that the elderly were more susceptible to heat stress than younger individuals.

Dr. Pi-Sunyer expressed concern that people may not know what was meant by "normal drinking behavior." He proposed changing the phrase to "usual drinking behavior." Dr. Appel accepted the change, and the Committee approved the revised conclusive statement as follows:

• The combination of thirst and usual drinking behavior, especially the consumption of fluids with meals, is sufficient to maintain normal hydration.

What are the effects of sodium intake on health?

Dr. Appel stated that it would probably be necessary to merge the conclusive statement and implications, because the implications contained the quantitative recommendations. He noted that this issue had been discussed extensively at the last meeting and that there was no disagreement about the relationship between sodium and blood pressure. The key issues were what the recommended threshold should be and how to deal with the interactive effects of potassium and sodium in the diet.

Dr. Appel presented the Subcommittee's conclusive statement regarding those issues:

• The relationship between salt (sodium chloride) intake and blood pressure is direct and progressive without an apparent threshold.

He then presented the implications for adults:

- In view of the high and increasing prevalence of elevated blood pressure and of the magnitude of blood pressure-related cardiovascular-kidney disease in the U.S., adults should consume less than 2300 milligrams of sodium per day.
- Many persons will benefit from further reductions in salt intake, including hypertensive individuals, African Americans, and middle- and older-aged adults.
- Because a diet rich in potassium blunts the effect of salt on blood pressure, individuals should concurrently increase their consumption of potassium.

Dr. Appel noted that the 2300 mg of sodium per day was the upper limit in the IOM report.

#### Discussion

Dr. King suggested that the implications should be incorporated into the conclusive statement.

Committee members suggested removing the references to specific conditions in the first bullet of the implications, for consistency with other conclusive statements.

Responding to a question, Dr. Appel noted that the rationale included a disclaimer that individuals who were engaged in vigorous physical activity may need more sodium.

Dr. Appel noted that the recommended intake of sodium was consistent with the IOM Report and with recommendations issued by other groups. Committee members expressed concern that the statement was recommending the UL when the literature showed a clear dose response relationship as sodium intake decreased. After some discussion, the Committee agreed to keep the recommendation of less than 2300 mg but to specify that this was the upper limit and to indicate that this would require many individuals to decrease their salt intake.

The Committee approved the revised conclusive statement as follows:

- The relationship between salt (sodium chloride) intake and blood pressure is direct and progressive without an apparent threshold.
- In view of the high levels of salt intake, adults should decrease consumption to less than 2300 milligrams (UL) of sodium per day. Many persons will benefit from further reductions in salt intake, including hypertensive individuals, African Americans, and middle- and older-aged adults
- Because a diet rich in potassium blunts the effect of salt on blood pressure, individuals should concurrently increase their consumption of potassium.

Dr. Appel then presented the implication for children:

• To establish a healthy eating pattern, children should reduce their intake of salt.

#### Discussion

Dr. Appel stated that this statement was supported by the available data. Responding to a comment, he agreed that it should be incorporated into the body of the conclusive statement.

The Committee approved the statement as presented.

At the suggestion of a Committee member, the title of this conclusive statement was revised to: "What are the effects of salt (sodium chloride) on health?"

What are the effects of potassium intake on health?

Dr. Appel presented the Subcommittee's proposed conclusive statement and implications regarding potassium:

- Diets rich in potassium can lower blood pressure, lessen the adverse effects of salt on blood pressure, reduce the risk of developing kidney stones, and improve bone health.
- In view of the health benefits of potassium and its low intake by the general population, individuals should consume at least 4700 milligrams per day of potassium from foods. African Americans are likely to derive a special benefit from an increased intake of potassium.
- To establish a healthy eating pattern, children should increase their intake of potassium.

#### Discussion:

Responding to a question, Dr. Appel stated that there were no human studies regarding independent effects of potassium. He noted that this was an important topic that could also apply to salt.

Dr. Weaver suggested that it would be more consistent with the evidence to state that potassium "may" improve bone health.

Responding to a question, Dr. Appel stated that the dose response relationship was not as strong for potassium as for salt.

Committee members suggested several revisions to the second bullet to clarify that it pertained to adults and to stress that the recommended level was the AI for potassium. Dr. Appel stated that there was clear evidence to support a statement that African Americans would derive special benefit from meeting the AI.

The Committee approved the revised conclusive statement as follows:

- Diets rich in potassium can lower blood pressure, lessen the adverse effects of salt on blood pressure, reduce the risk of developing kidney stones, and may improve bone health.
- To achieve these benefits, adults should consume at least 4700 milligrams (AI) potassium per day from foods. African Americans are likely to derive a special benefit from meeting the potassium AI.
- To establish a healthy eating pattern, children should increase their intake of potassium from foods.

Dr. King thanked the Subcommittee and staff and turned the floor over to Dr. Weaver for the conclusive statement on physical activity and weight-bearing exercise.

## Physical Activity and Weight-Bearing Exercise C. Weaver

Dr. Weaver presented the new proposed conclusive statement and implications regarding physical activity and weight-bearing exercise for bone health:

- Physical activity, especially weight-bearing exercise, has been associated with increased bone mass accrual in childhood.
- In adults, regular weight-bearing exercise can help protect against bone loss and maintain muscle strength, important for their forces on the skeleton as well as preventing falls.

#### Discussion

Dr. Weaver stated that there were multiple lines of evidence to support this statement; including intervention trials and a white paper on peak bone mass. She noted that there was not enough evidence to recommend a specific duration or frequency of weight-bearing exercise.

Responding to questions, Dr. Weaver described what was meant by "applying forces on a skeleton" and explained that weight-bearing exercise helped to maintain the muscle tone necessary to protect against bone loss and prevent falls.

After discussing various minor changes, the Committee approved the revised conclusive statement as follows:

- Physical activity, especially weight-bearing exercise, increases bone mass accrual in childhood.
- In adults, regular weight-bearing exercise protects against bone loss by applying forces to the skeleton and by helping to maintain muscular strength.

Dr. King noted that the remaining issues pertaining to Omega-3s, added sugars, food groups, and flexible calories would be addressed the following day. She then recessed the meeting.

(10:01 p.m.)

## Thursday, May 27

(8:40 a.m.)

Janet C. King welcomed Committee members and observers to the second day of the meeting and reviewed the agenda for the day. She noted that the morning would be devoted to reviewing the remaining conclusive statements on omega-3 fatty acids fish, flexible calories, food groups (whole grains, fruits and vegetables, and dairy), and added sugars. The Committee would then discuss the overarching issue of tracking healthy dietary patterns from childhood into adulthood. Following a review of the conclusive statements, the Committee would begin translating those statements into guidance. Dr. King noted that the goal for the

day was to identify the messages that the Committee would put forth as recommendations for the next set of *Dietary Guidelines*. She then turned the floor over to Dr. Kris-Etherton.

# Omega-3 Fatty Acids/Fish P. Kris-Etherton, Lead

Dr. Kris-Etherton stated that she would start with the conclusive statement on ALA so that the Committee could discuss it separately from EPA, DHA, and fish. She reiterated the conclusive statement that she had presented the previous day:

• ALA intake in the range of 0.6 to 1.2 percent of calories is recommended.

Dr. Kris-Etherton reminded the Committee that this was the recommendation of the IOM Committee. The lower boundary reflected the AI for ALA, which was based on median intakes of ALA in the U.S., and the upper boundary corresponded to the highest ALA intakes from foods consumed by individuals in the U.S. and Canada. Dr. Kris-Etherton noted that higher intakes of ALA than the AI had been shown to afford some degree of protection against coronary heart disease.

The Committee approved the conclusive statement as presented. Dr. Kris-Etherton then presented the conclusive statement for fish:

• Recommend consumption of two servings of fish per week, particularly fish rich in n-3 fatty acids (8-9 ounces total for adults, smaller amount for children.)

Dr. Kris-Etherton reiterated that this recommendation was supported by the recently released Agency on Healthcare Research and Quality (AHRQ) report, which concluded that consumption of omega-3 fatty acids from fish, or from supplements of fish oil, reduced all cause mortality and various cardiovascular disease outcomes. The statement also was consistent with recommendations from many other groups, including the American Heart Association and the World Health Organization (WHO).

Dr. Kris-Etherton presented data showing that two servings of fish per week would provide approximately 20 percent of energy from ALA as EPA and DHA, which was twice the IOM recommendation of 10 percent of ALA from omega-3s. She clarified that the IOM recommendation was based on current fish consumption of approximately one serving per week.

#### Discussion

Responding to questions, Dr. Kris-Etherton stated that there would be no toxic or adverse effects to increasing consumption of EPA and DHA and that doubling current consumption of fish or EPA and DHA would not interfere with meeting nutrient requirements for ALA.

The Committee discussed whether EPA and DHA should be substituted for part of ALA or whether it could be additive. Dr. Kris-Etherton noted that the WHO recommendation was one to two percent of calories from omega-3s, and the IOM recommendation was 0.6 to 1.2 percent. She also noted that there was no UL for ALA and that toxicity levels were far higher

than the proposed intake. Dr. Nicklas recommended that EPA and DHA should be additive because the food patterns were based on consuming a certain amount of vegetable oil to meet ALA requirements. Committee members calculated that adding 500 mg EPA and DHA onto ALA would increase the upper range of omega-3 intake to approximately two percent of calories. The 500 mg of EPA and DHA, added to 1.2 percent of calories from ALA, would represent 1.4 percent of calories, which was within the range recommended by WHO.

Committee members discussed the question of equivalent sources of EPA and DHA for those who did not eat fish. Several Committee members reiterated their concerns about recommending supplements due to lack of standardization; others felt that supplementation should be presented as an option. Dr. Clydesdale noted that technology was now available to add EPA and DHA to foods in fairly stable form. Committee members suggested that recommending "dietary sources of EPA and DHA" would address this issue without mentioning supplements directly. Some committee members felt that this section of the statement should not specify an amount since dose response studies on DHA and EPA independent of fish were unavailable.

Dr. King noted that the Committee's charge was to establish dietary guidelines and not nutrient recommendations. She emphasized that the statement would need to be worded carefully so that the Committee would not be seen as having set the standard for EPA and DHA intakes.

Committee members suggested that one way to address the issue would be to state that 500 mg of EPA and DHA was roughly equivalent to the amount found in two servings of fish high in n-3, which had been shown in studies to provide cardiovascular disease benefit in adults.

The Committee agreed that references to dose response studies in fish should appear in the rationale and not in the conclusive statement.

The Committee approved the full conclusive statement as follows:

- ALA intake in the range of 0.6 to 1.2 percent of calories is recommended.
- Recommend consumption of two servings of fish per week, particularly fish rich in n-3 fatty acids (8-9 ounces total for adults, smaller amount in children).
- Studies support CVD benefit in adults at the amount found in consumption of two servings/week of fish high in n-3, which is roughly equivalent to 500 mg of EPA + DHA per day.
- For those individuals who choose not to eat fish, dietary sources with EPA+DHA are available.

# Flexible Calories B. Caballero, Lead

Dr. Caballero presented the proposed conclusive statement on flexible or discretionary calories that had been developed through joint discussions of the Energy, Carbohydrates, and Macronutrients Subcommittees:

• Discretionary calories from added sugars, fats, (and alcohol) impact the micronutrient density of the diet. This is of particular concern for sedentary individuals with low energy intakes.

Dr. Caballero stated that while the term used to describe these calories was still to be decided, the definition was clear: flexible or discretionary calories were determined by subtracting the amount of energy required to fulfill nutrient needs from the maximum energy needs to maintain a stable healthy body weight. Dr. Caballero noted that the initial calculation of flexible calories was based on the recommended food patterns, including non-fat milk products and lean meats. He stressed that when nutrient needs were met using the foods that are typically consumed, which are not usually the lowest fat choices within each group, flexible calories disappeared, especially at the lower end of energy requirements.

Dr. Caballero identified two important communication messages related to this issue. The first would be to promote physical activity, emphasizing that as people become more active, they have more available calories. The second would be to promote the use of flexible calories to improve the quality of the diet by consuming foods that may be more energy-dense but provide important nutrients, such as low-fat milk instead of non-fat milk.

#### Discussion

After a brief discussion, the Committee agreed that the term "discretionary calories" was preferable to "flexible calories."

Committee members agreed that it would be important to include a table in the translation section of the report to illustrate the range of discretionary calories that would be available to sedentary people versus active people. The Committee proposed revisions to the conclusive statement that would more clearly convey the relationship between physical activity and discretionary calories. After some discussion, the Committee decided that the conclusive statement should focus on meeting nutrient requirements to maintain weight, but that the question of whether discretionary calories would be available to those who wished to lose weight should be discussed in the translation section.

Dr. Camargo suggested that the conclusive statement should specify "excessive intake of alcohol," since the Committee had approved a conclusive statement that consumption of one to two drinks had no impact on micronutrient density. After some discussion, he agreed to retain the original language but to remove the parentheses so that it would be clear that calories from alcohol were the same as those from added sugars and fats.

The Committee approved the revised conclusive statement as follows:

Discretionary calories from added sugars, fats, and alcohol impact the
micronutrient density of the diet. To meet nutrient requirements without gaining
weight, a sedentary person may have very few discretionary calories. As persons
become more physically active, they will have available to them more
discretionary calories.

Dr. King called a break, to be followed by a discussion of selected food groups.

(Break)

## Selected Food Groups B. Go, Lead

Dr. Go stated that this new Subcommittee had been created after the March meeting to address three questions. He acknowledged the other Subcommittee members, including Drs. Lupton, Pi-Sunyer, Appel, Weaver, and King, and thanked USDA and HHS staff for their support.

Dr. Go stated that the Subcommittee had been charged with addressing three questions:

- What are the relationships between whole grain intake and health?
- What are the relationships between fruit and vegetable intake and health?
- What are the relationships between dairy product intake and health?

Dr. Go noted that the full Committee would be reviewing this information for the first time and turned the floor over to Dr. Lupton.

What are the relationships between whole grain intake and health?

Dr. Lupton presented the Subcommittee's proposed conclusive statement on whole grains:

- Diets rich in whole grains can reduce the risk of diabetes and coronary heart disease, and may help with weight maintenance.
- Implications for the general population: Aim for at least three servings of whole grains per day, preferably by substituting whole grains for refined grains.

Dr. Lupton noted that whole grains, whole cereal grains, and foods made from them consisted of the entire grain seed, which is made up of three components: bran; the germ; and the endosperm. She stated that in the grain refining process, most of the bran and some of the germ was removed, resulting in the loss of dietary fiber, vitamins, minerals, phytoestrogens, and phenolic compounds. Once these have been removed, refined grains are then enriched with thiamin, riboflavin, iron, and niacin. Dr. Lupton noted that refined grains were also fortified with folic acid, which was not present in whole grains.

Dr. Lupton informed the Committee that the conclusive statement was based on 46 published papers and the recommended servings were based on the highest quintile in 12 prospective studies. She noted that whole grain intake was consistently associated with reduced risk of coronary heart disease and risk of Type-2 diabetes among both men and women in large prospective studies. Dr. Lupton stated that while the evidence for whole grains and weight was not as strong as for coronary heart disease and diabetes, it was sufficient to conclude that whole grain consumption may help with weight maintenance.

Discussion

In response to a question, Dr. Lupton confirmed that three servings of whole grains was the amount consumed in the highest quintile of all major prospective studies.

Referring to the rationale for the conclusive statement, Dr. Weaver stated that there was no evidence in the text of a biological basis for the relationship between whole grain intake and decreased risk of diabetes. Dr. Lupton agreed to revise that section of the rationale.

Committee members suggested that the first bullet should state that diets rich in whole grains "are associated with reduced risk," since the statement was based on observational data. Dr. Lupton agreed that this change would be appropriate.

Committee members proposed adding a statement regarding recommended intake in children, using the standard sentence, "To promote a healthy eating pattern ..." Dr. Lupton stated that the recommended amount for children would be at least three servings.

The Committee discussed whether folic acid intake would be jeopardized in people consuming 1000 calories or less, for whom three servings of whole grains would represent the entire daily intake from that food group. Committee members noted that some of the whole grains could come from fortified breakfast cereals and agreed that this issue should be addressed in the translation section.

What are the relationships between fruit and vegetable intake and health?

## Cardiovascular disease

Dr. Appel presented the Subcommittee's proposed conclusive statement regarding fruits and vegetables and cardiovascular disease:

 A greater consumption of fruits and vegetables is associated with a reduced risk of stroke and perhaps other cardiovascular diseases.

Dr. Appel described the evidence on fruit and vegetable intake and cardiovascular disease, which consisted of observational studies with endpoints of stroke, coronary heart disease, and total CVD. Six of seven cohort studies showed a significant inverse relationship between fruit and vegetable intake and stroke, one of three showed a significant inverse relationship between fruit and vegetable intake and coronary heart disease, and both studies showed a significant inverse relationship between fruit and vegetable intake and total CVD. Dr. Appel presented data by quartiles from the NHANES Follow-Up I study showing that relative risk of stroke mortality, IHD mortality, and CVD mortality decreased as frequency of fruit and vegetable intake increased.

Dr. Appel stated that the results tended to be similar for fruits and vegetables. He noted that there was an appearance of a dose response relationship, although it was difficult to detect thresholds in observational studies and this was not tested in most settings.

### Discussion

Dr. Kris-Etherton asked whether the conclusive statement should specify a quantity.

Dr. Weaver noted that the Nutrient Adequacy Subcommittee would be making specific recommendations regarding intake of fruits and vegetables. She stated that the text in the rationale would be stronger if it included information on the intake of fruits and vegetables by quartile for each study. Dr. Appel replied that he could review the studies to determine whether it would be possible to identify an optimal level of intake. Dr. Go stated that the Subcommittee would present an overall recommendation for fruit and vegetable intake after it had presented its conclusive statements regarding the effects of fruits and vegetables on various aspects of health.

Dr. Lupton suggested that since she and Dr. Appel had based their conclusive statements on the same studies, it would be possible to identify the amount of fruits and vegetables and whole grains to get into the highest quintile within each cohort group. This would also be consistent with how the rationale for the recommended intake for fiber had been presented.

## Weight Loss

Dr. Appel presented the Subcommittee's proposed conclusive statement regarding fruit and vegetable intake and weight loss:

- Available data, albeit sparse, suggests that increased consumption of fruits and vegetables is a useful component of programs designed to achieve and sustain weight loss.
- An even more limited body of evidence suggests that greater consumption of vegetables may prevent weight gain in the first place.

Dr. Appel noted that these were similar to the conclusions that Dr. Rolls had reached based on her research.

#### Discussion

Dr. King asked whether there was any evidence that fruits and vegetables had a diluting effect on calories. Dr. Appel replied that this could be part of the biological rationale for the observed effects. He noted that when options are restricted, people lose weight.

Responding to a question, Dr. Appel clarified that "limited body of evidence," meant that the statement was based on a small number of studies; most of these studies showed weight loss was achieved. He then presented a brief overview of the literature in this area.

### Cancer

Dr. Go presented the proposed conclusive statement regarding fruit and vegetable intake and cancer:

• Evidence, although limited, suggests that greater consumption of fruits and vegetables is associated with reduced risk of cancers in certain sites (oral cavity and pharynx, larynx, esophagus, stomach, and colon-rectum).

Dr. Go stated that the conclusive statement was based on expert panels convened by the National Cancer Institute (NCI), the International Agency for Research on Cancer (IARC), and the World Cancer Research Fund and American Institute of Cancer Research (WCRF/AICR). Dr. Go informed the Committee that prospective studies were underway for which data had not yet been published, including a European prospective investigation into cancer and nutrition and the Winn study at NCI. The Subcommittee also reviewed information provided by the American Cancer Society and the Produce for Better Health Foundation.

Dr. Go presented the NCI's evidence-based criteria for its Physician Data Query (PDQ) database and used this framework to classify the evidence for this conclusive statement:

- <u>Level 1</u>: Evidence obtained from at least one well-designed and conducted randomized control trial
- <u>Level 2</u>: Evidence obtained from well-designed and conducted non-randomized control trial
- <u>Level 3</u>: Evidence obtained from well-designed and conducted cohort or casecontrol studies, preferably from more than one center or research group
- <u>Level 4</u>: Ecologic (descriptive) studies (e.g., international patterns studies, migration studies)
- <u>Level 5</u>: Opinions of respected authorities based on clinical experience or reports of expert committees.

Dr. Go stated that the ongoing NCI study would provide Level 1 evidence when it becomes available. Most of the data reviewed by the Subcommittee was at Level 3. As a basis of comparison, Dr. Go noted that most of the evidence was at Level 5 prior to the 1980s.

Dr. Go presented a table summarizing the findings of case control studies of fruit or vegetable consumption and their cancer preventive effect from the recently published report of the WHO expert panel (*WHO Handbook of Cancer Prevention*). He noted that the panel had reviewed a wide range of literature from many countries; it took into account compounding factors such as culture, sex, age, smoking, and drinking; and it developed a confidence rating to indicate the relative strength of the evidence supporting the panel's conclusions. The panel also separated fruits and vegetables for the purposes of its data analysis.

The WHO panel concluded that fruits and vegetables did have a protective effect with respect to cancer in the oral cavity, larynx, esophagus, stomach, and colon-rectum. This was consistent with the findings of the NCI and WCRF/AICR. Dr. Go noted that the definitive evidence that would emerge from various randomized studies would determine whether this conclusion could be confirmed.

Dr. Go noted that there was insufficient data to support a conclusive statement regarding lung, prostate, or brain cancer.

Dr. Go stated that the major organizations had issued comparable recommendations regarding optimal fruit and vegetable consumption. WRCF/AICR recommended year-round consumption of a variety of vegetables and fruits, for a total of 400-800 grams (five or more portions) daily. WHO recommended 400 grams per day or more, not including tubers. ACS recommended five or more servings per day, and NCI recommended five to nine servings per day.

### Discussion

Committee members discussed whether the term "limited evidence" should be removed from the conclusive statement. Some members stated that they thought the evidence was very strong. Dr. Go replied that he had used the term "limited" because the evidence did not meet NCI criteria for Levels 1 or 2.

Dr. Lupton expressed concern that the evidence did not include any prospective studies and noted that the findings of case-control studies often did not reflect those of prospective and intervention studies. Committee members then debated the merits and limitations of prospective studies for cancer research. Dr. King proposed that the conclusive statement could be revised to indicate that it was based on case control studies. At Dr. Lupton's request, Dr. Go agreed to review the Nurses' Health Study, the Health Professionals Follow-Up study, and others to determine whether they contained any evidence pertaining to this issue. Dr. Go agreed that colorectal cancer could be removed from the conclusive statement and discussed in the rationale, due to inconsistent evidence.

Dr. Weaver noted that the recommended intake of fruits and vegetables by other groups was a significant increase over the previous recommendation of five servings per day. She acknowledged that nine servings per day could be justified on the basis of nutrient adequacy, but she stated that the Subcommittee had not presented any data regarding the relationship of fruits and vegetables to health that would support this recommendation. Dr. Go stated that the recommendations were based on the IOM Macronutrient Report. Dr. Weaver noted that the new IOM report for potassium was not available at the time of the Macronutrient Report. Dr. King proposed that the issue of quantities of fruits and vegetables could be discussed after reviewing the conclusive statement on diabetes.

#### Diahetes

Dr. Pi-Sunyer presented the Subcommittee's proposed conclusive statement regarding fruits and vegetables and diabetes:

• There is some evidence that greater consumption of fruits and vegetables is associated with a reduced risk of Type 2 diabetes.

Dr. Pi-Sunyer stated that there was limited data on this topic, most of it observational. The evidence for vegetables was much stronger than the evidence for fruits, but reduced risk had also been found in studies in which fruits and vegetables were analyzed together. Dr. Pi-Sunyer then summarized the major studies that formed the scientific basis for the conclusive statement.

Before presenting the implications of the four conclusive statements on fruits and vegetables, Dr. Go presented current consumption data for fruits (1.5 servings per day) and vegetables (about 3.3 servings). He noted that consumption of fruits and vegetables had not improved much since tracking was introduced in 1989. In light of that, the Committee had drafted the following conclusive statement:

- Individuals should increase their consumption of fruits and vegetables.
- Because available evidence is insufficient to identify any one specific fruit, vegetable, or nutrient as responsible for their protective effects, individuals should consume a variety of fruits and vegetables.

#### Discussion

Dr. King suggested that all four fruit and vegetable statements should be grouped together. She noted that the Subcommittee was not recommending any amount of fruits or vegetables for these disease end points, although specific amounts would be recommended to meet nutrient requirements.

Dr. Pi-Sunyer noted that the diabetes literature compared five or more servings with less than five servings. Dr. Go stated that the cancer literature ranged from five to ten, depending on the country in which the study was conducted. Some subjects consumed as few as two or three servings of fruits and vegetables per day. Dr. Appel stated that while few of the cardiovascular studies provided such information, it appeared that the highest quintiles consumed between nine and ten servings per day. Committee members noted that current consumption of fruits and vegetables was five servings per day, although Dr. Go stated that French fries accounted for 1.4 of those servings.

Committee members debated whether the implications statement should be more specific with regard to the recommended amount of fruits and vegetables. Dr. Pate noted that although most studies did not show a dose response relationship, it was likely that the dose response relationships for the various disease endpoints would not be the same. He suggested that it would be prudent to let the Nutrient Adequacy Subcommittee make the recommendations regarding amounts of fruits and vegetables. Other Committee members noted that fruits and vegetables were also important sources of fiber and potassium.

Responding to a question from Dr. King, Dr. Weaver stated that the Nutrient Adequacy Subcommittee was recommending a total of nine servings of a combination of fruits and vegetables for 2000 calories and above, based on the proposed food patterns. At 1000 calories the recommended amount was four servings of fruits and vegetables, and at 3200 calories it was 13 servings. Committee members noted that these amounts were consistent with the implications statement for fruits and vegetables. The Committee agreed that the implications statement should avoid specifying a quantity and should cross-reference the Nutrient Adequacy section by recommending that adults who increased their fruit and vegetable consumption to meet nutrient needs could decrease their risk of chronic disease.

After considering a number of changes, the Committee approved the modified conclusive statement on fruits and vegetables as follows:

- Greater consumption of fruits and vegetables is associated with a reduced risk of stroke and perhaps other cardiovascular diseases.
- There is some evidence that greater consumption of fruits and vegetables is associated with a reduced risk of Type 2 diabetes.
- Available data, albeit sparse, suggests that increased consumption of fruits and vegetables is a useful component of programs designed to achieve and sustain weight loss. A limited body of evidence suggests that greater consumption of vegetables may prevent weight gain.
- Case control studies suggest that greater consumption of fruits and vegetables is associated with a reduced risk of cancers in certain sites (oral cavity and pharynx, larynx, esophagus, stomach).
- Adults who increase their fruit and vegetable consumption to meet their nutrient needs will achieve the levels associated with decreased risk of chronic disease.

Dr. King called for a brief break, to be followed by a working lunch.

(Break)

Dr. King reconvened the meeting and noted that the Committee had three items to cover: the conclusive statement on dairy products, development of potential guidelines, and the conclusive statement on added sugars. She then turned the floor over to Dr. Weaver.

What are the relationships between dairy product intake and health?

Dr. Weaver noted that the Nutrient Adequacy Subcommittee had conducted the literature review on this topic. She presented the Subcommittee's proposed conclusive statement:

• Diets rich in dairy products can reduce the risk of low bone mass and may help with insulin resistance syndrome. While the evidence is inconclusive that milk products help manage body weight, there is no evidence that consuming three servings of low-fat milk products daily increases body weight. Therefore, adults and children should not avoid milk products because of concerns that these foods are "fattening."

Dr. Weaver noted that the rationale for this statement had been discussed extensively at the previous meeting. She then presented the implications:

Americans need to increase their intake of dairy products. This is especially
important for children and adolescents who are building their peak bone mass and
developing lifelong habits. For calorie needs above 1600 kilocalories per day, aim
for three cups of milk or equivalent.

Dr. Weaver stated that the recommendation of three cups per day was based on nutrient adequacy, especially in light of the new IOM potassium report, and that it was also consistent with the recommendations of several other groups. She noted that it would be difficult to

achieve the AI for potassium with less than three cups of milk. She also presented slides showing that milk was an important source of other important nutrients, including vitamin D, phosphorus, protein, riboflavin, and magnesium.

Dr. Weaver presented data regarding milk as a marker for nutrient adequacy. In one study, 53 percent of the women with low calcium intakes had "poor" diets overall, versus only ten percent of women with adequate calcium intake. She noted that most of the poor diets would have become adequate with only a single serving of milk.

Dr. Weaver presented data from the CARDIA study, which found that dairy consumption was inversely associated with hypertension and with development of all components of the insulin resistance syndrome (obesity, hyperinsulinemia, and insulin resistance). Each daily dairy serving lowered the odds ratio of developing the syndrome by 21 percent, with the best results achieved at three or more servings of dairy per day. Dr. Weaver also presented data from a recent prospective study showing that dairy intake was inversely associated with stroke, and she summarized DASH-I data showing that dairy provided additional benefits over fruits and vegetables alone in lowering blood pressure.

Dr. Weaver stated that the strongest evidence for a relationship between dairy and health was with bone. The Subcommittee reviewed seven randomized control trials and 32 observational studies in a wide range of ages that related dairy intake to bone, without use of supplements or fortified foods. All of the randomized controlled trials showed a positive relationship between dairy consumption and at least one or more skeletal sites. Twenty-five of the observational studies showed this positive relationship. Eight of the observational studies used hip fracture as the outcome, which Dr. Weaver stated was the strongest measure that could be used in an observational study; five of those studies showed a significantly positive relationship between dairy and bone. Moreover, an in-depth review of NHANES III data showed that Caucasian women with low milk intake during childhood doubled their risk of fractures.

Dr. Weaver presented a graph showing that while Americans drank more than four times as much milk as carbonated soft drinks in 1945, in 2001 they drank nearly two and a half times more soda than milk. She stated that the impact of this substitution in children was discussed in the rationale for this conclusive statement.

### Discussion

Committee members discussed whether the effect of dairy on insulin resistance syndrome (IRS) might be due to its effect on blood pressure or insulin resistance and not the whole syndrome. Dr. Weaver noted that each of the components of IRS was reported separately. Dr. Appel stated that there was not a strong relationship between calcium and blood pressure. He was not sure whether there was a relationship between dairy and blood pressure because he had not reviewed the literature. Dr. Weaver stated that concerns such as these were why the statement said that dairy "may help" with insulin resistance syndrome. After extensive discussion, the Committee agreed that the relationship between dairy and insulin resistance syndrome should be removed from the conclusive statement and treated as a research recommendation.

Dr. Appel asked whether there was sufficient data to state that dairy could help to reduce the risk of fractures, in addition to the risk of low bone mass. Dr. Weaver replied that the bone mass data was from both randomized control trials and observational studies, while the evidence on hip fracture was limited to observational studies. She agreed that fractures could be discussed in the rationale.

Committee members suggested that the conclusive statement should acknowledge the importance of dairy throughout the lifecycle and they proposed revised wording regarding the relationship between dairy and body weight.

Committee members suggested that "dairy products" could be changed to "milk and milk products." Dr. Weaver stressed that it would be important to acknowledge the importance of variety, in light of a recent study in which choosing a variety of foods within the dairy group was strongly associated with meeting nutrient adequacy for 15 nutrients. After some discussion, the Committee agreed that the proposed change would convey variety and would also be consistent with other conclusive statements. Committee members also agreed that the implications statement should specify non-fat or low-fat milk and milk products.

Committee members asked whether people who did not drink milk could substitute calciumfortified products such as orange juice. Dr. Weaver emphasized that fortified products were not nutritionally equivalent to milk, which was a source of many other essential nutrients.

After considering several other minor edits, the Committee approved the revised conclusive statement as follows:

- Diets rich in milk and milk products can reduce the risk of low bone mass throughout the lifecycle.
- Americans need to increase their intake of non/low-fat milk and milk products. This is especially important for children and adolescents who are building their peak bone mass and developing lifelong habits. For people who require 1600 kcal/day or more: aim for three cups of non/low-fat milk or equivalent.
- While the evidence is inconclusive that milk products help manage body weight, studies indicate that consuming three servings of low-fat milk products daily does not increase body weight.

Dr. King thanked the Subcommittee members and turned to a discussion of the report. She proposed that the introduction to the report should include a detailed statement of the key disease risks that would be addressed by the Dietary Guidelines. She noted that a description of hypertension had been drafted and that Committee members would be invited to help draft descriptions of obesity, diabetes, cardiovascular disease, coronary artery disease, cancer, and osteoporosis.

Dr. King stated that some consideration had been given to including a summary at the end of Section D that would tie together issues, such as sugar, that were discussed in many different places of the report. The purpose of this summary would be to pull together the science before moving into the translation section.

Dr. King then turned to a discussion of potential dietary guidance that would stem from the conclusive statements.

## Translation of Scientific Conclusions

Dr. King asked the Committee members to keep the conclusive statements in mind as it considered key messages to translate the science into dietary guidance. She presented a list of seven potential guidelines that had been drafted to date:

- 1. You have a daily calorie limit, choose foods wisely.
- 2. Maintain energy balance. (Or: Be physically active every day.)
- 3. Increase intake of fruits and vegetables, whole grains, and non-fat or low-fat milk and milk products.
- 4. Decrease saturated fat, trans fat, and cholesterol.
- 5. Decrease sodium/salt intake.
- 6. If alcohol is consumed, keep intake moderate.
- 7. Keep food safe to eat.

Dr. King noted that all of these messages were open for discussion. The Committee then considered each in turn.

You have a daily calorie limit, choose foods wisely.

Dr. Weaver expressed concern that the proposed guideline did not convey the importance of eating a variety of foods. She noted that the Nutrient Adequacy Subcommittee's main message was, "Eat a variety of food within and among the basic food groups, while maintaining appropriate energy intake."

Committee members suggested that these messages could be combined and simplified and discussed whether physical activity should be referenced in the guideline. After considering various alternatives, the draft guideline was revised as follows:

• Choose a variety of foods within and among the basic food groups, while not exceeding your daily calorie limit.

*Maintain energy balance. (Or: Be physically active every day.)* 

Committee members agreed that "Be physically active every day," was easier to understand and would be more likely to influence behavior that "Maintain energy balance." The Committee discussed whether the guideline should specify duration or types of activities. It was generally agreed that the guideline should be as simple as possible. After discussion, the Committee agreed to the alternate draft guideline, "Be physically active every day," without changes.

• Be physically active every day.

Increase intake of fruits and vegetables, whole grains, and non-fat or low-fat milk and milk products.

Committee members discussed whether the term "increase intake" should be defined or quantified. It was generally agreed that the guideline should be as simple as possible and that detailed definitions could be provided in the accompanying text. The Committee agreed that it would be acceptable to state, "Increase *daily* intake..."

• Increase daily intake of fruits and vegetables, whole grains, and non-fat or low-fat and milk products.

Committee members agreed that this message should be separate from the first guideline, since these three food groups had been singled out as requiring special attention because of their links to chronic disease, as well as nutrient adequacy.

Responding to a question, Dr. King clarified that the guidelines would capture the key messages from the conclusive statements and that there would not be a guideline for each conclusive statement.

Decrease saturated fat, trans fat, and cholesterol.

Committee members agreed that the guideline should include a recommendation to increase intake of n-3 and ALA and should also include a reference to fish.

There was some discussion as to whether the guideline should also recommend increasing unsaturated fat or substituting oil for solid fat. Dr. Kris-Etherton stated that this would not be consistent with the evidence, as Americans are consuming the right amount of polyunsaturated fats.

After discussion, the draft guideline was revised as follows:

• Decrease intake of saturated fat, trans fat, and cholesterol, while increasing intake of foods rich in omega-3 fatty acids (fish).

Decrease sodium/salt intake.

Dr. Appel expressed concern that consumers could interpret this to mean they should use less table salt, when 75 to 80 percent of sodium was present in foods.

Committee members agreed that the word "sodium" should be removed from the guideline. Various alternatives were proposed to convey the message that the guideline would apply to packaged foods as well as those prepared at home. After some discussion, the Committee proposed a revised version:

• Choose and prepare foods with less salt.

Dr. Appel suggested that this could serve as a working draft for the purposes of developing the report and offered to work on refining it further prior to the Committee's final meeting.

If alcohol is consumed, keep intake moderate.

Dr. Camargo noted that this was similar to the previous guideline regarding ethanol, which was: "If you drink alcoholic beverages, do so in moderation."

Some Committee members expressed concern that this message could be seen as promoting moderate drinking, as opposed to smaller amounts. Others suggested that the term "moderate" should be defined, as in the conclusive statement. Dr. Camargo stated that detailed information would be provided in the text. Although Committee members proposed a number of revisions, the current guideline was approved.

• If alcohol is consumed, keep intake moderate.

Keep food safe to eat.

Committee members suggested that "food" should be changed to "foods." No other revisions were proposed.

• Keep foods safe to eat.

Committee members agreed that a guideline should be added to address the importance of maintaining a healthy weight. The Committee discussed the importance of counting calories, but a consensus emerged that it was easier to monitor weight. After considerable discussion, the Committee members agreed to the following wording as a first draft:

• Monitor your weight to achieve health.

The Committee agreed that this should be the third guideline in the list, because it followed naturally from the guidelines on nutrient adequacy and physical activity. The Committee then reviewed the revised list of key messages and determined which Subcommittee would be responsible for developing the text regarding each guideline that would appear in the translation section of the report:

- 1. Choose a variety of foods within and among the basic food groups, while not exceeding your daily calorie limit.
- 2. Be physically active every day.
- 3. Monitor your body weight to achieve health.
- 4. Increase daily intake of fruits and vegetables, whole grains, and non-fat or low-fat milk and milk products.
- 5. Decrease intake of saturated fat, trans fat, and cholesterol, while increasing intake of foods rich in omega-3 fatty acids (fish).

- 6. Choose and prepare foods with less salt.
- 7. If you drink alcohol, do so in moderation.
- 8. Keep foods safe to eat.

Dr. King emphasized that the purpose of this section of the report was to translate the science into food guidance. She reminded the Committee that it was not writing a document for the public and was not making policy recommendations. Responding to a question, Dr. King noted that the translation section could include some of the boxes and tables that had been prepared to accompany the conclusive statements, such as the list of foods rich in vitamin E.

Capt. Royall suggested that Part E of the report should be considered a blueprint for the development of the policy and consumer documents. She noted that this was the first time the Committee had been asked to translate nutrient research into food guidance and that some uncertainty about how to do that was to be expected.

Dr. King stated that between this meeting and the final meeting, the responsibilities of the Subcommittees were to finish Part D and to develop the key messages for part E. She recommended that they focus on part E first so that a full draft could be prepared while they made their revisions to Part D, including research recommendations.

Ms. McMurry stated that this section of the report should include any information that would clarify the messages the Committee felt were important to convey. It should explain very clearly and succinctly what the Committee's guidance means, including any limitations or qualifications there may be based on the level of research.

Dr. Hentges stated that section E should present the science in lay language that would enable the Departments to develop consumer messages and policy statements. Dr. Suitor suggested that the Subcommittees send her the messages in whatever language they were comfortable with, and she would translate them into lay language.

Dr. King stated that the Subcommittees' deadline for completing part E was June 15. She then discussed the date for the final meeting. She stated that August 10 and 11 presented conflicts for the fewest Committee members. The Subcommittees would meet on August 10, with a full Committee meeting on August 11. She noted that it might be possible to arrange a conference call to include members who were out of town. Dr. King then turned to a discussion of added sugars.

# Added Sugars/Sugar-Sweetened Beverages J. Lupton, Lead

Dr. King informed observers that the Committee had been unable to reach agreement during the first day of the meeting regarding the association of added sugars to body weight or BMI. She noted that the Committee had reviewed the references for this information and had received copies of the papers to read overnight. Dr. Lupton added that the Committee had received copies of two tables from the IOM Macronutrient Report that morning: Table 6-10 on sugar and energy intake, and Table 6-11 on sugar intake and body mass index. Both tables

included literature on the effects of total sugars and added sugars. Dr. King asked her to summarize the issues and the information in those tables.

Dr. Lupton stated that the discussion was centered on the effect of added sugars on calories and on either weight or body mass index. There was strong evidence that an increase in added sugars contributed to added caloric intake, as shown in Table 6-10; the Committee had agreed to a conclusive statement on that issue the previous day. The question that remained unresolved was whether the increase in caloric intake resulted in increased weight or body mass index.

Dr. Lupton stated that the cross-sectional studies on added sugars and body weight presented in Table 6-11 found that individuals who consumed high levels of added sugars tended to weigh less than those who consumed moderate amounts. Based on that evidence, Dr. Lupton was not comfortable inferring that the increased calories from added sugars resulted in increased body weight or BMI.

Dr. Lupton noted that since the IOM Report, data had become available from an intervention trial and two prospective studies that looked at a variety of added sugar sources. These studies, which the Committee had reviewed overnight, did find an association between added sugars and BMI, but only for soft drinks.

The Committee then engaged in an extensive debate regarding the design and methods of various studies. Committee members agreed that there was strong evidence that sugar-sweetened beverages tended to increase caloric intake and that added calories from liquids appeared to be more difficult to regulate than those from solid foods. They also agreed that additional research was needed regarding the association between added sugars and BMI. After further discussion, the Committee members approved revised wording for the second bullet of the conclusive statement on added sugars.

The Committee approved the revised conclusive statement on added sugars as follows:

- When individuals consume foods or beverages that are high in added sugars, there is strong documentation that they also consume more energy than those who consume low amounts of added sugars.
- There is evidence that sugar-sweetened beverages are not as well regulated as calories in the solid form.

## Next Steps

The Committee reviewed a list of steps to be accomplished prior to the meeting in August. The first step was to identify the key messages to be included in Part E. Dr. King stated that conference calls would be scheduled for that purpose and asked the Subcommittees to submit their key messages to Dr. Suitor so she could begin to draft that section of the report. Dr. King confirmed that June 15 was the deadline for this task.

The remaining tasks were to revise Part D, prepare the research recommendations, and identify terms for the glossary. Dr. King noted that each Subcommittee should submit a

maximum of three research recommendations, with a short description of why that research would be important. Dr. King set June 30 as the deadline for these tasks.

Dr. King then thanked the Committee members for their hard work and adjourned the meeting.

(3:08 p.m.)