

**MINUTES OF THE NUTRITION COORDINATING COMMITTEE (NCC)
MEETING, NATIONAL INSTITUTES OF HEALTH (NIH)
Rockledge 2, Conference Room 9112, Bethesda MD
February 5, 2004, 2:00-4:00 PM**

WELCOME

Dr. Van Hubbard, Director, Division of Nutrition Research Coordination (DNRC), convened the NCC Meeting at 2:00 PM and welcomed the participants. The agenda for this meeting is provided as Appendix A, and the list of attendees is provided as Appendix B. Dr. Deborah Galuska, Centers for Disease Control and Prevention (CDC) participated via teleconference.

APPROVAL OF MINUTES FROM THE NOVEMBER 6, 2003 NCC MEETING

Minutes from the November 6, 2003, NCC Meeting had previously been sent to NCC members via email. Dr. Hubbard asked if there were any corrections to the minutes. There were none. Dr. Paul Coates, NIH Office of Dietary Supplements (ODS), made a motion to approve the minutes, and Dr. Sooja Kim, Center for Scientific Review, seconded the motion. The minutes were thus approved and will be posted on the DNRC website, <http://www.dnrc.nih.gov> along with the minutes from previous NCC Meetings.

COMMUNITY HEALTH AND NUTRITION EXAMINATION SURVEY

Dr. Sue Krebs-Smith, NCI, provided the NCI vision about a Community Health and Nutrition Examination Survey (HANES). Dr. Krebs-Smith said that NCI is planning to submit a proposal to the National Center for Health Statistics (NCHS) for a Community HANES, with a particular emphasis on energy intake, weight status, and physical activity.

The National Health and Nutrition Examination Survey (NHANES) is the major source of data for tracking these factors among the general population, as it is the only survey with a nationally representative sample and state-of-the-art measures relating to diet, physical activity, body size, weight status, nutritional biomarkers, and other measures related to energy balance. These unique features stem from the design of the survey, which involves mobile exam centers (MECs) that travel to different areas of the country for interviews and examinations. However, the NHANES sample is constrained by operational concerns of the MECs, and the sample of about 5000 persons per year is insufficient to make precise estimates about many population subgroups of interest. The most cost-effective and efficient way of gathering information about these subgroups may be to conduct targeted surveys. Population subgroups of interest might include populations defined by race/ethnicity, such as Native Americans, various Latino communities, Asian American communities, and country areas such as Appalachia.

Because these groups would be concentrated geographically, NCI is proposing a surveillance system to incorporate scaled-down MECs that could travel to identified areas and capture the most basic information related to diet, physical activity, body size and composition, and physiological mechanisms

related to energy balance. In addition to these measures, taken at the individual level, this geographically-concentrated surveillance system would allow for the assessment of community-level variables, such as access to food stores, availability of sidewalks, common modes of transportation, and policies and other local level initiatives that may be influencing these factors. As this surveillance system would include linguistically, as well as culturally, diverse populations, the survey instruments will need to be translated into multiple languages and tested for cross-cultural equivalency.

This surveillance system would provide much needed information on diet, weight status, physical activity, and related measures among groups of people about whom very little information is available. The timing is critical, as numerous subgroups of the population may be facing dramatic increases in chronic disease if the current patterns of increasing obesity, poor diet, and lack of physical activity continue. To date, systematic surveillance of targeted at-risk groups using state-of-the-art assessments has not been available.

These estimates will contribute to the public health aims of surveillance, health promotion/disease prevention objectives, health policy, program evaluation, and health disparities:

- Several of the Healthy People 2010 objectives relate to food and nutrient intake, physical activity, weight status, and other measures related to energy balance.
- Subgroup-level estimates on these factors will optimize the tracking of these objectives among the population.
- This surveillance system will also allow assessment of how well various subgroups are following the 10 Dietary Guidelines for Americans.
- The environmental level data collected as part of this will help inform public policies in those areas, and public health campaigns such as the 5 a Day for Better Health Program would benefit by the inclusion of data for selected subsets of the population.
- Finally, this proposal is directly responsive to the government's health disparities initiative which calls for collecting risk factor data for small populations and methodological research to ensure cross-cultural equivalence in survey research.

Dr. Krebs-Smith plans to submit a budget request within NCI to contribute to the costs of this effort; however, this effort will not likely to go forward unless other agencies are able to contribute.

Ms. Vicki Burt, who is Chief of the Planning Branch for NHANES at NCHS, CDC, noted that NHANES has four trailers (one in use) that could potentially be used for Community HANES. To outfit them as an examination center with a laboratory would require the purchase of freezers, centrifuges, stadiometer, scales, and computer equipment. The costs for these would not be enormous relative to the cost of the trailer and the software to collect data. If a component like DXA (for measuring bone density) was undertaken, the costs would be extremely high for that one piece of equipment. It would also occupy considerable space in the exam center.

NCHS collaborated on the sample design and developed software to be used in the New York City (NYC) HANES. The software that was developed has potential to be used in other Community HANES. Statistics Canada is planning a health measurement survey, and they are likely to use single trailers and/or fixed sites for this effort. NCHS hopes to learn from their efforts. To collect data for a Community HANES in Fiscal Year 2006, planning needs to begin now.

Dr. Rachel Ballard-Barbash, NCI, commented that efforts to collect health monitoring data for specific at-risk populations (data which are not available in nationally representative efforts such as NHANES), has become a priority for many federal agencies involved in national health monitoring. These types of health monitoring efforts are very relevant to several priorities described in the NIH Obesity Research Strategic Plan, and the NCC may want to be sure that as this effort develops, it addresses priorities within the strategic plan. Addressing those priorities may also increase the priority for funding.

UPDATE FROM THE DHHS OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION (ODPHP)

Ms. Kathryn McMurry, ODPHP, made several announcements:

- On Wednesday, February 11, the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences will release the report *Dietary Reference Intakes for Electrolytes (Potassium, Sodium, Chloride) and Water*. The report was sponsored by various groups, including the DHHS Office of Public Health and Science and the National Institutes of Health, with some additional funding from the US Department of Agriculture (USDA), Environmental Protection Agency, Health Canada, and the International Life Sciences Institute. There will be a press conference at 11 AM on February 11th at the National Academy of Sciences Auditorium on Constitution Avenue in Washington DC. It is expected that this event will attract media attention.
- DHHS is preparing for the second national summit for *Steps to a HealthierUS*, to be held on April 29-30, 2004, in Baltimore, Maryland. There was an enthusiastic response to the first summit, and it is hoped that its success will be repeated. The summit will focus attention on chronic disease prevention and health promotion and will feature presentations on asthma, obesity, diabetes, heart disease and stroke, and cancer, as well as lifestyle choices, including nutrition, physical activity, and tobacco use. You may register online at the website, www.healthierus.gov/steps. Early registration closes on April 1, 2004.
- The *Shaping America's Youth* initiative addressing childhood overweight and website database development is underway. To date, over 1500 specific programs related to childhood overweight have been registered on the website including over 100 Federal programs. There has been a tremendous interest in this project from numerous organizations, corporations, health care organizations, and Federal agencies. In April 2004, *Shaping America's Youth* will release a report summarizing the

results of the database and simultaneously launch an interactive website allowing all individuals free access to the database. To be included in the report, program information must be submitted by February 15, 2004. The website is www.shapingamericasyouth.com. Ms McMurry suggested that programs summarized for the Healthy People 2010 Nutrition and Overweight Progress Review be included in this database. Dr. Hubbard noted that the promoters of this activity could search the CRISP site to find off various government activities.

Ms. McMurry provided an update on activities relating to the *2005 Dietary Guidelines for Americans*. The Dietary Guidelines Advisory Committee (DGAC) held its second public meeting on January 28-29, 2004 at the Hotel Washington in Washington DC. The agenda and other information from the January meeting are available at

<http://www.health.gov/dietaryguidelines/dga2005/AgendaPublicJan2004Mtg.pdf>.

Over 160 individuals attended and over 30 presented oral testimony. The Committee is charged with reviewing current scientific and medical knowledge and recommending to the Secretaries of DHHS and USDA revisions to the Dietary Guidelines, if warranted, for the 2005 edition. At its first meeting in September 2003, the DGAC decided that the science had changed since the 2000 edition of *Nutrition and Your Health: Dietary Guidelines for Americans* and that further evaluation of the science was necessary. Therefore, the DGAC is proceeding to conduct a review of current scientific and medical knowledge and to provide a technical report of any recommendations to the Secretaries for the year 2005 edition. Eight subcommittees were formed to review scientific evidence related to energy balance, fatty acids, carbohydrates, nutrient adequacy, ethanol, food safety, fluids and electrolytes, and lifecycle issues. Ms. McMurry led a discussion with the members of the NCC regarding scientific resources that may be useful to the Committee in its deliberations. Ms. McMurry indicated that the DGAC would appreciate input on scientific resources, questions, and suggestions for expert presenters that may be helpful to the DGAC. Appendix C lists the draft research questions that were distributed at the January 2004 meeting. The discussion topics for the eight subcommittees of the DGAC are listed below:

- Overarching issues (healthy people vs. general population; translating nutrient research to food-based recommendations; macronutrient ratios; information quality guidelines);
- Energy Balance (weight management-prevention/loss/maintenance of weight loss; energy density; nutrient density; portion sizes; satiety; physical activity);
- Fatty Acids (use of 20-35% of energy for fat; quantitative trans fat; stearic acid/palm oil; n-3 fatty acids in fish; mono- and polyunsaturated fatty acids);
- Carbohydrates (fiber vs. fruits/vegetables/whole grains; added sugars; fructose; glycemic index/glycemic load);
- Nutrient Adequacy (vitamin E; Food Guide Pyramid dietary patterns/food groups; nuts/legumes); NCC members noted that vitamin D should also be considered under Nutrient Adequacy.

- Food Safety (listeria; mercury);
- Ethanol (caloric content of alcoholic beverages);
- Fluid/Electrolytes (caffeinated beverages; US Preventive Services Task Force recommendations on sodium); Ms. McMurry noted that the DGAC chose not to address the health effects of caffeinated beverages.
- Lifecycle. Dr. Raiten, National Institute of Child Health and Development (NICHD), raised the issue of the lack of consideration of women's nutrition in the context of pregnancy (birth outcomes), and lactation, and infant feeding and potential impact on subsequent health outcomes throughout the lifecycle. It was noted that breastfeeding was mentioned in the DGA but only in the context of alcohol consumption. It was also recognized that although the parameters of the DGA limit coverage to age two and older, there is a tremendous amount of interest and emerging data indicating the importance of nutrition to maternal health (preeclampsia/pregnancy-induced hypertension)/ birth outcomes (low birth weight, etc.) and subsequent long-term health outcomes. Ms. McMurry agreed to ask the lifecycle subcommittee whether it plans to address these areas. She noted that although the Dietary Guidelines pertain to healthy Americans over the age of 2, the DGAC is considering issues related to various stages of the lifecycle.

The next two meetings for the DGAC will be scheduled for March and May 2004, and the final report is due in June 2004. The report will be reviewed by DHHS and USDA during July and August 2004 and public comments will be accepted. Public release is scheduled for January 2005.

UPDATE OF THE NIH OFFICE OF DIETARY SUPPLEMENTS (ODS)

Dr. Kenneth Fisher, ODS, reviewed the recently released ODS Strategic Plan for 2004-2009 and provided a handout (Appendix D) and web access to the document (<http://ods.od.nih.gov/strategicplan2004>). Key features of the plan include an increased emphasis on research related to evaluating the role of dietary supplements in disease prevention, as well as an expanded outreach and education component.

Dr. Paul Coates, Director ODS, provided the following updates:

- Drs. Johanna Dwyer and Anne Thurn, both of ODS, are working with the Office of Medical Applications of Research (OMAR) to develop a *State-of-the-Science Conference on Multivitamins/Minerals and Chronic Disease Prevention*, which will be jointly sponsored by ODS and several NIH Institutes and Centers. As is customary, OMAR will call for an evidence report by one of AHRQ's Evidence-Based Practice Centers in advance of the Conference. The report will be released at that time, and testimony will be heard from interested parties. The main goal is to determine the next steps in an NIH research agenda on this topic.
- ODS is a co-sponsor, along with the National Institute for Child Health and Development, National Institute of Mental Health, and National Center for Complementary and Alternative Medicine of a conference entitled *Carnitine: The Science Behind a Conditionally Essential Nutrient* at Lister Hill Auditorium on

March 25-26, 2004. For further information, visit the website at www.scgcorp.com/carnitine2004/.

- Each year, ODS announces its interest in co-sponsoring conferences with NIH Institutes and Centers. This year, ODS has provided support for nine conferences (details in Appendix E). ODS encourages Institutes and Centers to discuss their plans for upcoming conferences with Dr. Rebecca Costello, ODS.
- Dr. Nancy Potischman, NCI, and Dr. Mary Frances Picciano, ODS, have commissioned a comprehensive review of the literature to assist the leadership in planning for *The National Children's Study (NCS): Review of Diet and Dietary Supplement Intake Assessment Methodology*. Additional information is available in Appendix F.
- Dr. Barbara Bowman, CDC, will be spending several months on the NIH Campus and part of that time with ODS. Dr. Elizabeth Yetley, a longtime colleague in FDA's Center for Food Safety and Applied Nutrition, will join the senior staff of ODS in February 2004. Dr. Christine Taylor, FDA, is currently assigned to the FDA Commissioner's Office and will begin a detail with the World Health Organization in April 2004.

HEALTHY PEOPLE (HP) 2010 NUTRITION AND OVERWEIGHT PROGRESS REVIEW

Dr. Crystal McDade-Ngutter, Emerging Leaders Program assigned to DNRC, noted that the HP 2010 Progress Review on Nutrition and Overweight was held on January 21, 2004 in the Hubert H Humphrey Building, Washington DC. Dr. Larry Fields, Senior Advisor to the Assistant Secretary, chaired the Progress Review, and NIH and FDA were co-leads. Surgeon General, Dr. Richard Carmona, DHHS staff, and representatives from the Department of Education and USDA were in attendance. Dr. Ed Sondik presented data trends for the six objectives that were highlighted at the Review. These six objectives included those for promoting healthy weight and healthy dietary choices. Data for the three weight objectives reflected a negative trend, showing an increase in obesity among children, adults, and specific ethnic groups. The objectives for fruit, vegetable, and grain consumption showed little or no progress. After Dr. Sondik's presentation, representatives of the the co-lead agencies (Dr. Murray Lumpkins from FDA and Dr. Allen Spiegel and Dr. Barbara Alving from NIH) discussed major strategies and barriers to promoting healthy weight and dietary patterns. The full text of the Nutrition and Overweight focus area of HP 2010 is available at www.heathypeople.gov/document/html/volume2/19/nutrition.htm.

WORLD HEALTH ORGANIZATION (WHO) ACTIVITY UPDATE

Dr. Hubbard noted that there had been several conference calls (the most recent one on 4 February 2004) concerning the US response to the *Report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Disease* (released April 2003) and the subsequent strategy for implementation of the recommendations from this report. This effort has been lead by Ms. Mary Lou Valdez in the DHHS Office of Global Health Affairs. The US response expresses concern that the Report does not follow an evidence-based approach,

although the US agrees with the general intent of the Report. The additional US response will be submitted to the WHO by the end of February 2004 and final action is anticipated at the World Health Assembly in May 2004.

UPDATE OF DNRC ACTIVITIES

Nutrition Education Subcommittee. Dr. Jean Pennington, DNRC, provided an update of the activities of the NIH Nutrition Education Subcommittee (NES). During the calendar year 2003, the NES received and reviewed 30 documents (15 from within NIH and 15 from other DHHS or USDA agencies). Since the beginning of 2004, the NES has received four documents for review (three from NIH and one from USDA). Documents reviewed or under review since the last NCC meeting include:

- Calcium Fact Sheet (ODS, NIH)
- How Much Food for a Day? (Food and Nutrition Service, USDA)
- NIH National Nutrition Month Desk-to-Desk Flyer (DNRC, NIH)
- Sisters Together: Energize Yourself and Your Family (Weight-control Information Network (WIN), NIDDK, NIH)
- Sisters Together: Celebrate the Beauty of Youth! (WIN, NIDDK, NIH)
- Sisters Together: Fit and Fabulous as You Mature (WIN, NIDDK, NIH)
- FoodPlay (Agriculture Marketing Service, USDA)

The NIH National Nutrition Month desk-to-desk flyer for 2004 encourages physical activity and good eating patterns. It will be distributed to NIH employees during the first week of March 2004.

Intra- and Inter-Agency Efforts on Obesity. Dr. Hubbard noted the following obesity-related activities:

- The HP2010 Progress Review (noted above).
- The US response to the WHO/FAO Report (noted above).
- The strategic plan of the NIH Task Force on Obesity, which is expected to be available on the web (<http://obesityresearch.nih.gov/>) in mid-February 2004.
- The FDA Obesity Working Group, which is also expected to produce a mid-February 2004 report.
- Secretary Tommy Thompson's Prevention Steering Committee has an Obesity Working Group, which is also working on a report. His office has requested that a draft report be completed by February 9, 2004 with plans for subsequent release after a chance for comment by various agencies.
- The NIH NHANES Interest Group met on 5 February 2004. NHLBI is interested in finding support to work on weight loss and maintenance questions for NHANES.
- FDA put out a Request for Comments on their *Draft Guidance on the Clinical Evaluation of Weight-control Drugs*. The draft guidance provides recommendations for the design and conduct of phase 1-3 clinical studies aimed at demonstrating the efficacy and safety of weight-loss medications. Comments are due by April 26, 2004. Information is available at <http://www.fds.gov/OHRMS/DOCKETS/98fr/04-1496.htm>.

Dr. Darla Danford, NHLBI, noted that NHLBI is convening a *Healthy Weight Community Outreach Initiative Strategy Development Workshop* scheduled for February 17-18, 2004 in Bethesda, Maryland. This workshop will bring together scientific experts, professional organization, and community stakeholders and constituency groups to share their insights and experiences. The objectives of the workshop include:

- to examine community-based obesity-related “best practices”;
- to help determine the unique niche for the new NHLBI Healthy Weight Community Outreach Initiative;
- to recommend appropriate and effective program strategies and interventions (e.g., message concepts, channels, materials, community-based activities); and
- to identify potential program partners and partnership opportunities.

A summary of the workshop will be prepared.

Dr. Danford also noted that the Executive Summary of the *Think Tank on Enhancing Obesity Research* at the NHLBI held last spring is available at http://www.nhlbi.nih.gov/health/prof/heart/obesity/ob_res_exsum/index.htm. The summary report will be available in February 2004.

Mechanisms of Obesity Co-Morbidities Workshop. Dr. Pamela Starke-Reed, DNRC, noted that the meeting *Adipose Tissue Secretory Function and Its Role in Obesity-Associated Co-Morbidities* was held on December 11-13, 2003 at the Renaissance Hotel in Washington DC. The organization of this workshop was a trans-NIH effort including the DNRC and a number of NIH Institutes, Centers, and Offices. A summary of the meeting will soon be available on the website, (http://www.niddk.nih.gov/fund/other/obesity_web/index.htm) and may be published in a journal.

Dr. Stark-Reed noted that Ms. Karen Regan, DNRC, had recently updated the DNRC Website and that this site contains Institute and Center descriptions and highlights press releases. She encouraged NCC members to review the information.

Subcommittee on International Nutrition Research (SINR). *Subcommittee on International Nutrition Research (SINR).* Dr. Daniel Raiten, NICHD, noted that the regularly scheduled SCINR meeting that had been scheduled for December 2003 had been postponed and will likely be rescheduled for March 2004. Dr. Raiten also mentioned an effort to increase the attention to the global importance of maternal and infant nutrition. This effort has involved staff from the Fogerty International Center, NICHD, USAID, WHO, the Wellcome Trust in England and members of the academic community. The goal of the effort is to raise these issues to the level of a global strategic plan (including increased research support) analogous to the current WHO activities around diet, physical activity and health. An NIH-sponsored conference (current sponsors include NICHD, ODS, USAID) on maternal and infant nutrition and health outcomes will be held in July 2004 in an as-yet-to-be-determined site in Washington DC. Dr.

Raiten welcomed all inquiries and interest in support of this effort. A full proposal about this conference will be presented to both the NCC and SCINR.

Human Nutrition Research Information Management (HNRIM) System. Mr. Jim Krebs-Smith, DNRC, provided a status report of HNRIM-related activities. The annual HNRIM report of NIH-funded nutrition research and training (FY02) has undergone final review, and the report should be converted and posted to the public HNRIM website (<http://hnrnim.nih.gov>) within the next two weeks. Mr. Krebs-Smith issued the annual request for NIH Institutes and Centers (IC) to submit their FY 2003 data for HNRIM, and asked for IC data to be submitted no later than **Friday, March 5th**. The formal request will be sent by email within the next few days. Representatives were again encouraged to carefully review their IC's complete research portfolio - including contracts and intramural research - to identify all relevant nutrition research, based on the ICHNR Definition of Human Nutrition Research (<http://hnrnim.nih.gov/pdf/codesdefins.pdf>). He reminded members that the NIH Office of Financial Management considers the nutrition figures submitted in January to be *estimated actuals* until completion of the HNRIM process, thereby allowing for additions and changes if necessary.

REPORTS FROM NCC MEMBERS AND LIAISONS

Dr. Deborah Galuska, CDC, noted that the February 7, 2004 issue of *MMWR* will contain an article on the decreasing prevalence of inactivity.

Dr. Susan Yanovski, NIDDK, announced that the NIDDK Clinical Obesity Research Panel will be meeting on February 6, 2004 at the Natcher Building on NIH Campus from 8:30 AM to 3:00 PM. Discussions will include the NIH Obesity Research Strategic Plan and the plans for trans-NIH research initiatives; there will be two invited speakers. All are welcome to attend.

Ms. Jean Charles-Azure, Indian Health Service (IHS), announced that there will be an IHS Summit for people who work with Native American peoples in April 2005. Contact Ms. Charles-Azure if you are interested in partnering with this activity.

Ms. McMurry noted that DHHS is looking for federal space to hold the next DGAC Meeting at the end of March 2004. They need room for approximately 250 attendees.

Dr. Danford, NHLBI, provided a handout on the first National Wear Red Day (February 6, 2004). The purpose is to show support for raising awareness that heart disease is the number one killer of women in the US. More information on women and heart disease and the The Heart Truth national awareness campaign is available at <http://www.hearttruth.gov/>.

ADJOURNMENT

The meeting was adjourned at 4:00 PM.

NEXT NCC MEETING

The next NCC Meeting is tentatively scheduled for March 4, 2004.

LIST OF APPENDICES

Appendix A - NIH NCC Meeting Agenda for February 5, 2004

Appendix B - NCC Meeting Attendees for February 5, 2004

Appendix C – Draft List of DGAC Research Questions (distributed at the January 2004 DGAC Meeting)

Appendix D – ODS Strategic Plan for 2004-2009

Appendix E - Office of Dietary Supplements FY2004: ODS Co-Funded Workshops/Conferences Overview

Appendix F – The National Children’s Study

APPENDIX A. NIH NCC MEETING AGENDA FOR FEBRUARY 5, 2004

2:00-4:00 PM, Rockledge 2, Conference Room 9100, Bethesda MD

1. **Welcome**..... Van Hubbard
2. **Approval of November 6, 2003 NCC Meeting Minutes**.....Van Hubbard
3. **Community Health and Nutrition Examination Survey**....Sue Krebs-Smith
and Vicki Burt
4. **ODPHP Update**.....Kathryn McMurry
2005 Dietary Guidelines for Americans
5. **Office of Dietary Supplements Update**.....Paul Coates
6. **Healthy People 2010 Nutrition and Overweight Progress Review**.....
Van Hubbard
7. **World Health Organization Activity Update**.....Van Hubbard
8. **DNRC Activities Update**
Nutrition Education Subcommittee.....Jean Pennington
Intra- and Inter-Agency Efforts on Obesity.....Van Hubbard
Mechanisms of Obesity CoMorbidity Workshop.....Pamela Starke-Reed
Subcommittee on International Nutrition Research.....Daniel Raiten
HNRIM Update.....James Krebs-Smith
9. **Reports from NCC Members and Liaisons**.....NCC Members
10. **Next Meeting:** tentatively March 4, 2004
11. **Other Business**

APPENDIX B. NCC MEETING ATTENDEES FOR FEBRUARY 5, 2004

| | Members Present | Members Absent | Alternates Present |
|--|------------------------|-----------------------|---------------------------|
|--|------------------------|-----------------------|---------------------------|

Chairperson: V Hubbard

NIH Members:

| | | | |
|-------|---------------|------------------|----------|
| NCI | | J Milner | |
| NHLBI | D Danford | | |
| NIDCR | | R Nowjack-Rayner | |
| NIDDK | S Yanovski | | |
| NINDS | | M Mitler | |
| NIAID | M Plaut | | |
| NIGMS | | S Somers | |
| NICHD | | G Grave | D Raiten |
| NEI | | N Kurinij | |
| NIEHS | | E Maull | |
| NIA | J Finkelstein | | |
| NIAMS | | J McGowan | |
| NIDCD | | B Wong | |
| NIMH | | P Muehrer | |
| NIDA | | G Lin | |
| NIAAA | V Purohit | | |
| NINR | | K Helmers | |
| NCCAM | M Klein | | |
| NCCR | | F Taylor | |
| FIC | | N Tomitch | |
| NCHGR | | K Hudson | |

NIH Liaison Members:

| | | | |
|--------|----------|----------------|--|
| OD/ODP | | B Portnoy | |
| CC | | N Sebring | |
| CIT | | J Mahaffey | |
| CSR | S Kim | | |
| OLPA | | | |
| NLM | | S Phillips | |
| OC | | M Stern | |
| ODS | P Coates | | |
| PRCC | | M Vogel-Taylor | |
| OBSSR | | D Olster | |

Agency Liaison Representatives:

| | | | |
|-------------|-----------|------------|-----------|
| FDA | | E Yetley | |
| CDC/NCHS | | M McDowell | |
| CDC/NCCDPHP | | S Kuester | D Galuska |
| HRSA | | M Lawler | |
| IHS | | T Brown | |
| ODPHP | K McMurry | | |
| USDA | | T Kramer | |
| DOD | | K Friedl | |

DNRC: S Frazier, W Johnson-Taylor, J Krebs-Smith, C McDade-Ngutter, J Pennington, K Regan, P Starke-Reed

Guests: R Ballard-Barbash (NCI), V Burt (NCHS, CDC), J Charles-Azure (IHS), L DiSogra (NCI), N Emenaker (CSR), K Fisher (ODS), V Green (NCI), J Hyman (NIDCR), A Jerkins (CSR), S Kayar (NCCR), Y Kim (NCI), S Krebs-Smith (NCI), R Kuczmarski (NIDDK), J Reedy (NCI), E Rodas (NIDCD), K Stitzel (ODPHP), C Taylor (FDA), R Troiano (NCI), J Webber (ODPHP)

APPENDIX C. DRAFT LIST OF DGAC RESEARCH QUESTIONS (distributed at the January 2004 DGAC Meeting)

| Carbohydrates |
|--|
| What effect does lowering carbohydrate intake have on meeting the AI for fiber. Is there a level of carbohydrate intake at which it is unlikely that the AI for total fiber will be met? |
| What is the relationship between added sugar intake and BMI? |
| What is the relationship between glycemic load and BMI? |
| What is the relationship between fiber intake and BMI? |
| What is the relationship between added sugar intake and total fiber? |

| Fatty Acids |
|---|
| No C Questions identified at this time. |

| Energy Balance and Weight Management |
|---|
| |

What are the most commonly reported leisure-time physical activity modes for those who report <150 minutes/wk, 150-300 minutes/wk or >300 minutes/wk of leisure-time physical activity? What is the typical physical activity pattern for individuals in these 3 categories?

| Lifecycle |
|----------------------------|
| No C Questions Identified. |



OFFICE OF
DIETARY
SUPPLEMENTS

APPENDIX D. ODS STRATEGIC PLAN FOR 2004-2009

PROMOTING QUALITY SCIENCE IN DIETARY SUPPLEMENT RESEARCH, EDUCATION, AND COMMUNICATION

A Strategic Plan for the Office of Dietary Supplements: 2004-2009

**The Office of Dietary Supplements,
Office of the Director,
National Institutes of Health**

January 28, 2004



National Institutes of Health



Department of Health and
Human Services

EXECUTIVE SUMMARY

The review of ODS activities and programs developed under the five original goals led to two general conclusions. First, these goals provided a sound framework to guide ODS programs from 1998 to 2003. Second, each goal addressed an essential part of the framework but the goals were interdependent. Thus, the original goals essentially have been retained as the focus of ODS programs in 2004-2009. The goals and initiatives presented in this plan for 2004-2009, just as those developed in the first plan in 1998, emphasize the important role of ODS in research, education, and communication.

- Goal 1: Expand the evaluation of the role of dietary supplements in disease prevention and in reduction of risk factors associated with disease.
- Goal 2: Foster research that evaluates the role of dietary supplements in maintaining and improving optimal physical and mental health and performance.
- Goal 3: Stimulate and support research to further understanding of the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.
- Goal 4: Promote and support the development and improvement of methodologies appropriate to the scientific study of dietary supplement ingredients.
- Goal 5: Expand and conduct outreach activities that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements.

ODS will promote quality science in dietary supplement research, education, and communication by placing greater emphasis on the use of emerging technologies and greater emphasis on cross-disciplinary studies, expanding the infrastructure of human resources, fostering translation of research results, and establishing a process for regular evaluation of ODS programs and activities. The ODS strategic plan for 2004-2009 provides a roadmap for ODS to address both current and future research, education, and communication needs and opportunities related to dietary supplements.

The ODS Strategic Plan for 2004-2009 is available on the ODS Web site

at:

<http://ods.od.nih.gov/strategicplan2004>

Copies of the printed document will be available in the early spring.

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PROGRAMS AND PROGRESS:1998-2003

Increasing financial support accelerated implementation of the goals in the original strategic plan. Each program that was initiated is consistent with the mandates of DSHEA and with the five broad goals that formed the basis of the strategic plan.

During the past 5 years, ODS has

- organized and sponsored conferences and workshops on topics identified in the strategic plan;
- supported research using existing NIH mechanisms ranging from individual basic research projects such as grants to more complex research activities with NIH ICs (e.g. the botanical research centers);
- provided support for research of mutual interest to other federal agencies through cofunding, cooperative agreements, and contracts;
- identified and supported evidence-based reviews such as the Agency for Healthcare Research and Quality (AHRQ) report on the safety and efficacy of ephedra;
- initiated a program to enhance analytical methodology and develop standard reference preparations of dietary supplements for basic and preclinical research and clinical studies;
- participated in support of training and career development both within NIH and in academia;
- developed an ODS Web site, an ODS listserv, and, recently, an ODS newsletter;
- created publicly available databases such as International Bibliographic Information on Dietary Supplements (IBIDS) and Computer Access to Research on Dietary Supplements (CARDS);
- prepared fact sheets on vitamins, minerals, and botanicals; and
- supported and strengthened collection and dissemination of data on use and characteristics of dietary supplements.

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**NIH Office of Dietary Supplements Releases
New Five-Year Strategic Plan (2004-2009)**

The NIH Office of Dietary Supplements (ODS) has released its five-year strategic plan entitled, "*Promoting Quality Science in Dietary Supplement Research, Education and Communication: A Strategic Plan for the Office of Dietary Supplements 2004-2009.*"

"The first ODS strategic plan, developed in 1998, provided a sound basis for program development and support of ODS activities related to conduct of basic and clinical research, development of education and communication programs directed to all segments of the public and private sectors with an interest in dietary supplements. But times have changed and another leap forward is needed", said Paul Coates, Ph.D., ODS Director.

In 2003, ODS initiated a strategic planning process involving several efforts to obtain input on future needs and opportunities from the ODS constituency including the public. The goals and initiatives presented in this plan for 2004-2009, just as those developed in the original plan in 1998, emphasize the important role of ODS in research on disease prevention and health promotion, education, and communication of scientific information about dietary supplements.

The ODS Strategic Plan for 2004-2009 incorporates the vision and thrust of the recently published HHS Strategic Plan for 2004-2009 and the NIH Roadmap. ODS is committed to furthering the guiding principles and goals developed by its parent organizations. The new strategic plan includes ongoing evaluation of existing ODS programs, needs for new programs, and prioritization of resource allocation. This effort, initiated in 2004, will include annual consultative meetings with representatives of the ODS constituency and formation of an ODS Steering Group.

"I commend the NIH Office of Dietary Supplements in looking to the future and leading the way in the field of dietary supplement research," says NIH Director, Elias A. Zerhouni, M.D.

"ODS has made significant progress in advancing the recognition of the need for and the conduct of quality scientific research on dietary supplements. In addition, these efforts have increased markedly the availability of objective evidence-based information useful to the public in making decisions about efficacy and safety of dietary supplements. The ODS strategic plan for 2004-2009 provides a roadmap intended to catalyze research that will expand the scientific knowledge base to improve health of the public," said Paul Coates, Ph.D, ODS Director.

The ODS Strategic Plan for 2004-2009 is available on the ODS Web site (<http://ods.od.nih.gov/strategicplan2004>). Copies of the printed version will be available later this year. Check the Web site for information on how to receive a copy (<http://dietary-supplements.info.nih.gov/>).

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The Office of Dietary Supplements was established at NIH in November 1995 as a result of the Dietary Supplement and Health Education Act passed by Congress in 1994. The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research

results, and educating the public to foster an enhanced quality of life and health for the U.S. population. For additional information about ODS, please visit <http://dietary-supplements.info.nih.gov/>.

The Office of the Director is a component of the National Institutes of Health, U.S. Department of Health and Human Services.

APPENDIX E. OFFICE OF DIETARY SUPPLEMENTS FY2004: ODS CO-FUNDED WORKSHOPS/CONFERENCES OVERVIEW

| IC & CONTACT | WORKSHOP TITLE | TYPE OF EVENT | PROPOSED DATE | LOCATION |
|--|---|--------------------------|----------------------|--------------------------------------|
| NHLBI Ahmed A.K. Hasan, MD, PhD | Dietary Supplements, Coagulation, and Anticoagulation Monitoring | Workshop | Fall-04 | Bethesda, MD, NIH campus |
| NIAAA Vishnudutt Purohit, PhD | Dietary Methylating Agents and Alcohol-Assisted Neoplasms | Symposium | October-04 | Bethesda, MD |
| NICHD | | | | |
| Catherine Spong, MD | Improving Maternal and Infant Nutrition: Development of a Research Plan | International workshop | Jun 14-15, 2004 | Bethesda, MD |
| Dan Raiten, PhD | Nutritional Considerations in the Prevention, Care, and Treatment of HIV/AIDS | International conference | Nov 15-18, 2004 | Southern Africa |
| David C. Klein, PhD | Pineal Cell Biology - Gordon Research Conference | International conference | Aug 29-Sept 03, 2004 | Queens College, Oxford England |
| NIDDK | | | | |
| Kenneth May, PhD | Vitamin E and Health (R-13) | Conference | May 22-24, 2004 | Tufts University, Boston |
| Ronald Margolis, PhD | Lipids and the Pathophysiology of Obesity | Workshop | May 10-11, 2004 | Renaissance Marriott, Washington, DC |
| Kenneth May, PhD | 2004 FASEB Summer Research Conference on Trace Element Metabolism (R-13) | FASEB Conference | Jun 26-Jul 01, 2004 | Snowmass, CO |
| Kenneth May, PhD | 2004 FASEB Summer Research Conference on Retinoids (R-13) | FASEB Conference | Jun 12-17, 2004 | Callaway Gardens, GA |

APPENDIX F. THE NATIONAL CHILDREN'S STUDY (NCS)

Title X of The Children's Health Act of 2000 authorizes the conduct of a large, prospective cohort study of children, the **National Children's Study (NCS)**, that can offer a comprehensive approach to understanding how the environment, family, and society interact with the genetic constitution of the developing fetus and child. Planning groups, comprised of federal scientists, non-federal organizations with special interest in this project, and other experts are currently defining specific study hypotheses, study design, technology applications, and ethical guidelines. The NCS will include collection of dietary and supplement intake data; and exposure, susceptibility and outcome data throughout the participants' life span, from preconception to birth and then from infancy through age 18. In addition, biological specimens will be collected from both the parents and the children.

To assist NCS Committee and Working Group members at the National Institutes of Health with the planning effort, a P.O. was issued to WESTAT (7841.01) to perform a **comprehensive review of the scientific literature from 1982 through 2003 on dietary and supplement intake assessment methodology**, as well as methods of assessing food-borne exposure to environmental contaminants in the age groups targeted by the NCS. The specific age groups in the target population include pregnant or lactating women, infants (0 to 12 months), toddlers (13 to 24 months), preschoolers (25 months to 5 years), school age children (6 to 12 years), and adolescents (13 to 18 years).

The objectives of this literature review are as follows:

1. Identify and describe validated instruments for the assessment of usual food and nutrient intake patterns, and/or vitamin-mineral or herbal supplement intake patterns in the target population;
2. Identify and describe validated instruments for the assessment of exposure to environmental contaminants from food in the target population;
3. Describe the socioeconomic and ethnic/cultural characteristics of the populations in which the instruments were validated;
4. Describe dietary and supplement assessment instruments employed in large epidemiological studies conducted on one or more of the target age groups and discuss the rationale for the instrument selection;
5. Identify methodological issues inherent in the assessment of food intake in pregnant or lactating women, infants, children, and adolescents; and
6. Identify key individuals and institutions with expertise in dietary and supplement intake assessment research in one or more of the age groups of interest.

The completed review should be available in March, 2004. A workshop will then be convened (tentatively in July in Bethesda area) to develop recommendations for best available instruments for the varied hypotheses being proposed by the NCS among the various life stages to be studied. Those with an interest in participating in the planning efforts or in attending the proposed workshop should contact either Mary Frances Picciano at piccianm@od.nih.gov or Nancy Potischman at potoschn@epndce.nci.nih.gov.