

Office of Dietary Supplements Update

National Institutes of Health
U.S. Department of Health and Human Services

ODS-Sponsored Conference on Vitamin D to be Held September 5-6 at NIH

Inside this issue

ODS vitamin D conference Sept 5-6	1
ODS practicum on supplements	1
News for researchers	2
New supplement assessment tool	2
Past and upcoming events	3
In Memoriam: Stephen Straus MD	4
New ODS staff: Bientou Seck, PhD	6
NIDDK's Mark Levine awarded prize	7
Publications by ODS staff	8

Vitamin D is an essential nutrient whose roles in bone building and calcium metabolism for bone growth and maintenance throughout life are well known. Other potential roles in human health include immune function, reduction of inflammation, and effects on cell division, differentiation, and longevity. Vitamin D is a unique nutrient in that needs can be met in three distinct ways: exposure to sunlight which enables the body to produce the vitamin, by eating foods that naturally contain it or to which the nutrient has been added, and by taking vitamin D-containing dietary supplements. Questions as to the vitamin D status of the U.S. population follow reports of rickets (the classic vitamin D deficiency disease) and potentially low

blood levels of the vitamin among various subgroups.

The first NIH conference on *Vitamin D and Health in the 21st Century*, held in 2003, considered knowledge regarding the measurement and maintenance of vitamin D status and the development of effective programs to reduce the prevalence of insufficiency. It also identified research needs, including:

- Dose-response relationships between sunlight exposure with specific health outcomes in various racial and ethnic groups;
- How genetic polymorphisms might inform the tissue-specific roles of vitamin D;

(continued, page 4)

ODS Conducts First Practicum on Dietary Supplements to Enthusiastic Professional Audience

Approximately 50 professors and graduate/doctoral students from academic departments of nutrition and food science across the country spent May 21-25 at the NIH to attend an ODS practicum titled *Current Issues and Recent Developments in Dietary Supplement Research*. A faculty drawn from ODS, NIH, other federal agencies, and academia, with additional presentations by stakeholders representing the dietary supplement industry, professional associations, and consumer groups gave attendees a thorough grounding in a wide range

of topics on dietary supplement science and beyond. The practicum was organized by Dr. Mary Frances Picciano, ODS Senior Nutrition Research Scientist, and Dr. Paul Thomas, ODS Scientific Consultant. It was held at the Natcher Building on the NIH campus.

Among the goals of the practicum were to provide a comprehensive overview of issues, concepts, controversies, and

(continued, page 2)



Office of Dietary Supplements
National Institutes of Health
6100 Executive Blvd.
Rm. 3B01, MSC 7517
Bethesda, MD 20892

Phone: 301-435-2920
Fax: 301-480-1845

WE'RE ON THE WEB!
[HTTP://ODS.OD.NIH.GOV](http://ods.od.nih.gov)

News for Researchers

ODS collaborates on funding initiatives across NIH and with other agencies through mechanisms such as Requests for Applications (RFAs) and Program Announcements (PAs). Several are highlighted below. For further information on these and other ODS-funded opportunities, visit http://dietary-supplements.info.nih.gov/Funding/PAs_and_RFAs.aspx.

Nutrition and Alcohol-Related Health Outcomes (PA-07-403 and -404 and -405)

Applications for R01, R03, and R21 grants are encouraged to examine associations between nutrition and alcohol-related health outcomes in humans and animal models. Study designs may include biomedical research, epidemiologic approaches, and intervention studies. Specific areas of research include fetal alcohol syndrome disorders, chronic disease, and cognitive impairment and decline.

Advancing Novel Science in Women's Health Research (PAS-07-381 and -382)

Applications for R21 and R03 grants are being solicited that promote innovative, interdisciplinary research to advance new concepts in women's health research and the study of sex/gender dif-

(continued, page 3)

Survey of Supplement Education (continued from page 1)

unknowns about dietary supplements and their ingredients; show the importance of scientific investigations to evaluate the efficacy and safety of these products; and supply information and resources that would enable attendees to provide more instruction about dietary supplements at their academic institutions. These goals were well met according to evaluations the attendees completed. "As for the practicum goal to instill interest among students and investigators in undertaking research on dietary supplements, only time will tell," notes Dr. Picciano.

The five-day practicum included sessions on supplement use and reasons for use; regulations; contrasts between bringing foods, drugs, and supplements to market; ingredient characterization and quality control; examination of supplement-relevant databases; assessing the health effects of supplements; and the use of science to develop advice and public policies about these products. Attendees met with representatives of the dietary supplement industry, professional associations, and consumer groups that study, advocate, and educate about supplements for a day near the Washington Mall, in sight of the Washington Monument and Capitol (see the practicum agenda on page 5). "The entire practicum was designed to encourage questions and discussion, and attendees took every opportunity to speak up," remembers Dr. Thomas. "They all received a large notebook with practicum materials, readings, and resources."

ODS plans to conduct this dietary supplements practicum on an annual basis. Dates for the 2008 practicum have already been set for June 9-13 at the NIH and will be open to faculty and graduate students in all health-related disciplines such as nutrition, food science, pharmacology and pharmacogenosy, exercise/kinetics,

medicine, dentistry, nursing, and complementary and alternative medicine (CAM). A notification to apply for the 75 available slots and application procedures will be posted on the ODS Web site in early 2008 and noted in this newsletter. Similar to the 2007 practicum, there is no charge to attend, but participants will be responsible for their travel, accommodations, and meals.



New Tool Developed to Assess Dietary Supplement Use

Determining an individual's total nutrient intake requires that both food intake and dietary supplement use be assessed. The University of Minnesota Nutrition Coordinating Center has developed a tool for assessing supplement use that may be used in combination with the collection of a 24-hour dietary recall. This new tool, developed with funding from ODS, is now available as part of the 2007 release of the Nutrition Data Systems for Research (NDSR). NDSR is a software application designed for direct data entry and fully automated coding of interviewer-administered dietary recalls. The new tool added to the software allows dietary supplement use to be assessed.

Further information about the NDSR is available at <http://www.ncc.umn.edu> or by contacting Priscilla Goldstein at goldstein@epi.umn.edu.

Events: Past and Upcoming

June 28

Black Cohosh Safety Workshop

Gaithersburg, MD

Dr. Joseph Betz developed and moderated this workshop which included an international group of speakers and discussants. A meeting summary is being developed for publication.

July 18-20

2007 Botanical Research Centers Directors' Meeting

Bethesda, MD

Annual meeting for the Directors and staff of the six Dietary Supplement Research Centers focused on botanicals, which are co-funded by ODS and the National Center for Complementary and Alternative Medicine (NCCAM).

July 28 to August 1

Institute of Food Technologists Annual Meeting & Food Expo

Chicago, IL

<http://www.am-fe.ift.org/cms>

Drs. Johanna Dwyer, Joseph Betz, and Leila Saldanha presented at this expo. ODS also exhibited here.

September 5-6

Vitamin D and Health in the 21st Century: An Update

Bethesda, MD

<http://vitamindandhealth.od.nih.gov>

Conference sponsored by ODS; co-sponsors are the National Cancer Institute (NCI), National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the American Society for Nutrition (ASN). There is no charge for the meeting but attendees must register. Go to Web site for information and to register.

September 10

Analytical Methods and Reference Materials (AMRM) Program Stakeholders' Meeting

Bethesda, MD

http://dietary-supplements.info.nih.gov/News/amrm_stakeholders_mtg.aspx

This meeting will present the progress that has been made by the AMRM program since its inception five years ago and receive comments on the future directions for the next five years. Go to Web site for information and to register.

September 16-20

121st AOAC Annual Meeting & Exposition*

Anaheim, CA

http://www.aoac.org/meetings1/121st_annual_mtg/main.htm

ODS will exhibit at this expo and present a poster on its Analytical Methods and Reference Materials (AMRM) program.

News for Researchers (continued from page 2)

ferences. Applications in all areas of women's health and sex/gender research are invited. The following four overarching themes are important for addressing research on women's health: Lifespan, Sex/Gender Determinants, Health Disparities/Differences and Diversity, and Interdisciplinary Research.

Exploratory Cancer Prevention Studies Involving Molecular Targets for Bioactive Food Components (PA-07-362)

This initiative seeks to promote cancer prevention research focused on the identification and characterization of molecular targets for bioactive food components. A bioactive food component is defined as a dietary constituent that has a health benefit by altering one or more cellular processes when provided in quantities over and beyond that needed for basic nutrition. Applications must relate the response in a molecular target to an early morphologic change, such as in colon formation of preneoplastic aberrant crypt foci, in breast ductal carcinoma in situ, or in prostate intraepithelial neoplasia, etc. Applications which compare tissue specificity in response to a bioactive food component are considered appropriate for this initiative as are those that examine polymorphisms in molecular targets and their influence on the physiological significance of bioactive food components.

(continued, page 7)

Vitamin D conference (continued from page 1)

- How body weight affects vitamin D status;
- Better surveillance of at-risk groups such as African Americans; and
- The need for more complete data on the vitamin D content of foods.

Progress has been made in addressing many of these research needs. Yet since the 2003 conference, new issues have been raised. For example, reports indicate concerns about the potential for vitamin D insufficiency/deficiency in the U.S. population. Some have suggested that vitamin D inadequacy occurs at blood levels previously viewed as adequate. It is time to assess current knowledge of the efficacy and safety of vitamin D to identify new research needs that will help ensure vitamin D sufficiency across the lifespan. For this reason, the NIH Office of Dietary Supplements will convene a conference on *Vitamin D and Health in the 21st Century—An Update*, September 5-6, 2007, in Bethesda, Maryland. It is co-sponsored by the National Cancer Institute (NCI), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the American Society for Nutrition (ASN).

The goals of the conference are to:

- Evaluate the need for and safety of vitamin D across the lifespan since the 2003 conference in light of recent research, updated assessment and evaluation tools, and a new evidence-based review of the vitamin;
- Present current nutrition monitoring data on vitamin D status, sources of vitamin D, and body functions affected by the vitamin;
- Identify knowledge gaps, methodological challenges, and research needs pertaining to the body's production, activation, and metabolism of vitamin D and how vitamin D status should be assessed; and

- Provide opportunities for discussion on the roles of vitamin D and health at various stages of life and strategies to ensure adequate vitamin D exposure from ultraviolet light, food, and dietary supplements.

The two-day conference will open with a review of vitamin D production (when ultraviolet light strikes the skin), bioavailability, metabolism, active forms, and metabolic turnover. Vitamin D's effects on body function across the life cycle and measurement of status will also be critically evaluated. Other topics to be addressed include the impact of dietary intakes and sun exposure on blood levels of 25-hydroxy D (the form measured to assess status), vitamin D toxicity, and adverse outcomes from excessive intakes.

At the conference, invited experts will present information pertinent to these topics and goals. A systematic literature review on vitamin D prepared under contract with the Agency for Healthcare Research and Quality (AHRQ) will be summarized. (The report will become available a week or two prior to the conference, and our Web site will contain a link to it). Each of the four sessions will include a panel of presenters addressing predetermined core questions that will lead to suggestions for future research. Attendees will have opportunities to engage in discussions with the panels. Each panel's summary presentation will become part of the conference record and be used by organizers to compile conference proceedings and to inform NIH's research agenda.

The conference is intended for scientists and health professionals with a background or interest in vitamin D. Conference sessions will be held at the Masur Auditorium at the Warren Grant Magnuson Clinical Center (Building 10), NIH, Bethesda, Maryland. The American Dietetic Association has approved 14 hours of level 2 continuing professional education credits.

In Memoriam: NCCAM Director Stephen Straus, MD

Stephen E. Straus, M.D., the first director of the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH), died of brain cancer on May 14 at his home in Potomac, Maryland. He was 60 years of age.

"Dr. Straus brought a powerful measure of rigorous science into the thinking about how to study CAM interventions," remembers ODS Director Paul M. Coates, PhD. "For him, there was one overriding standard—the scientific one. He recognized the importance of collaboration with other NIH units to achieve common goals. He worked closely with ODS, for example, as more than half of the NCCAM portfolio deals with biologic therapies, most of which are dietary supplements. Dr. Straus was a generous, joyful, and brilliant man who will be missed."

For more information about the life of Dr. Straus and his accomplishments, go to <http://nccam.nih.gov/news/2007/051507.htm>.

There is no charge to attend the conference, but advance registration is required. For further information and to register, go to <http://vitamindandhealth.od.nih.gov>. There is also a link to this URL on the ODS Web site.

**Current Issues and Recent Developments in Dietary Supplement Research: An Intensive Practicum
Presented by the NIH Office of Dietary Supplements**

**Natcher Conference Center, Building 45 (on NIH Main Campus)
Rooms E1/E2 and Balcony B
Also on location at the U.S. Department of Health and Human Services**

May 21-25, 2007

Day 1 (Monday, May 21): Setting the Stage

Session 1: Who Takes What for Why, and How Do We Know?

Presentation 1: Welcome and Overview
8:30 am to 9:15 am

Presentation 2: Who's Taking What?
9:15 am to 10:00 am

Presentation 3: Why Are They Taking Them?
10:15 am to 11:00 am

Session Wrap-Up
11:00 am to 11:15 am

Session 2: It's the Law: Rules and Regulations

Presentation 1: The Dietary Supplement Health and
Education Act (DSHEA) and Before
11:15 am to Noon

Presentation 2: What the Food and Drug Administration
(FDA) Does
1:30 pm to 2:15 pm

Presentation 3: Supplement Labels
2:15 pm to 3:00 pm

Presentation 4: Claims on Supplements and Foods
3:15 pm to 4:00 pm

Presentation 5: What the Federal Trade Commission
(FTC) Does
4:00 pm to 4:45 pm

Session Wrap-Up
4:45 pm to 5:00 pm

Day 2 (Tuesday, May 22): To Market, To Market

**Session 3: Drugs, Foods, and Supplements: On Different
Paths**

Presentation 1: Bringing a Drug to Market
8:30 am to 9:15 am

Presentation 2: Bringing a Food to Market
9:15 am to 10:00 am

Presentation 3: Bringing a Supplement to Market
10:15 am to 11:00 am

Presentation 4: Interactions Between Supplements and Drugs
11:00 am to 11:45 am

Session Wrap-Up
11:45 am to Noon

Session 4: What's in the Bottle?

Presentation 1: Identity and Quality
1:30 pm to 2:15 pm

Presentation 2: Groups Conducting 3rd Party Evaluations
of Supplements
2:15 pm to 3:00 pm

Presentation 3: FDA and Good Manufacturing Practices
(GMPs) for Supplements
3:15 pm to 4:00 pm

Presentation 4: Characterizing Supplements in Journal
Articles
4:00 pm to 4:45 pm

Session Wrap-Up
4:45 pm to 5:00 pm

Day 3 (Wednesday, May 23): Meeting the Stakeholders

Panel 1: Professional Players

8:45 am to 10:15 am

Panel 2: Face to Face with the Industry

10:15 am to Noon

Panel 3: Meet the Consumer Groups

1:00 pm to 2:30 pm

Day 4 (Thursday, May 24): Assessing the Health Effects of Foods and Supplements, Part 1

Session 5: Understanding the Principles

Presentation 1: Measuring Food and Supplement Intakes
8:30 am to 9:15 am

Presentation 2: Biomarkers of Exposure
9:15 am to 10:00 am

Presentation 3: Efficacy: The Concept and Its Measurement
10:15 am to 11:00 am

Presentation 4: Safety: The Concept, Its Measurement, and Reporting
11:00 am to 11:45 am

Session Wrap-Up
11:45 am to Noon

Session 6: Special Focus on Dietary Supplement Databases

1:30 pm to 5:00 pm
* MEDLINE/PubMed
* IBIDS (International Bibliographic Information on Dietary Supplements)
* CRISP (Computer Retrieval of Information on Scientific Projects)
* HNRIM (Human Nutrition Research and Information Management) System
* CARDS (Computer Access to Research on Dietary Supplements)
* NOADS (NHANES [National Health and Nutrition Examination Survey] Online Analyst for Dietary Supplements)
* Dietary Reference Intakes (DRI) Research Recommendations

Day 5 (Friday, May 25): Assessing the Health Effects of Foods and Supplements (Part 2) and The Big Picture

Session 7: Doing the Studies

Presentation 1: The Different Types and What They Tell Us
8:30 am to 9:15 am

Presentation 2: Conducting a Study with Dietary Supplements
9:15 am to 10:00 am

Session 8: Science, Policy, Action, and Advice

Presentation 1: Moving from Science to Policy
10:15 am to 11:00 am

Presentation 2: Communicating Scientific Information About Dietary Supplements
11:00 am to 11:45 am

Presentation 3: Resources of the Office of Dietary Supplements
11:45 am to Noon

Final Discussion and Q&A with ODS Staff and Speakers
Noon to 12:30 pm

New ODS Staff

Binetou C. Seck, PhD

Binetou is a part-time contractor responsible for coding government-funded research on dietary supplements and information on these products into the CARDS and IBIDS databases maintained by ODS. She recently received her PhD in International Nutrition from the University of Maryland, where she also obtained her masters degree in nutrition.

Events: Past and Upcoming
(continued from page 3)

September 18-20

Development of DRIs 1994-2004: Lessons Learned and New Challenges

<http://www.iom.edu/driworkshop2007>

Workshop co-sponsored by ODS to identify issues for enhancing approaches to developing Dietary Reference Intakes for nutrients in the future. Go to Web site for information and to register.

September 26-27

Diet, Epigenetic Events, and Cancer Prevention

Gaithersburg, MD

<http://www.scgcorp.com/diet07>

Symposium co-sponsored by ODS to discuss and evaluate evidence for the impact of diet and bioactive food components on epigenetic processes, address implications for cancer prevention, and identify research needs. Go to Web site for information and to register.

September 27-30

American College of Nutrition 48th Annual Meeting*

Orlando, FL

<http://www.amcollnutr.org>

Dr. Mary Frances Picciano will speak at a session titled *Is it Time to Raise the RDA for Vitamin D?* The poster session will include one on Clinical IBIDS. ODS will exhibit at this meeting.

September 29 to October 2

American Dietetic Association Food & Nutrition Conference & Expo*

Philadelphia, PA

http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/7539_ENU_HTML.htm

ODS will exhibit at this meeting.

November 4-7

American Heart Association Scientific Sessions 2007*

Orlando, FL

<http://www.americanheart.org/presenter.jhtml?identifier=3044219>

Dr. Rebecca Costello will moderate a session titled *Dietary Effects on Blood Coagulation and Hemostasis*. ODS will also exhibit.

NIDDK Scientist Awarded Prize for Vitamin C Research

Mark A. Levine, MD of the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK) at the NIH was awarded the Linus Pauling Institute Prize for Health Research in May for his work on vitamin C. Dr. Levine, chief of the Molecular and Clinical Nutrition Section at NIDDK, has studied this nutrient for more than 20 years, helping to elucidate its biological functions, pharmacokinetics, transport into cells, role in immune function, human requirements, and possible role in destroying cancer cells. "I have a passion for science and truth, and the adventure they are," he notes.

"We're pleased to learn that Mark, a valued colleague and good friend of ODS, has been publicly recognized with this prestigious award," says ODS Director Paul M. Coates, PhD. "His work has built the foundation for the now-common Recommended Dietary Allowances for vitamin C and he has recently begun to pursue other important roles for this molecule. His approach has always been detailed, careful, and also remarkably innovative."

The Linus Pauling Institute at Oregon State University at Corvallis presented Dr. Levine its prize, consisting of a medal and \$50,000. The Institute, named for the Nobel Prize winning chemist Linus Pauling who developed a particular interest in vitamin C, studies micronutrients and their roles in promoting health and preventing and treating disease.

November 6-8

SupplySide West*

Las Vegas, NV

<http://www.supplysideshow.com/west>

ODS will exhibit at this meeting and hold two sessions. The first, titled *Dietary Supplement Funded Research at the National Institutes of Health*, is moderated by Dr. Leila Saldanha with Dr. Rebecca Costello as a speaker. Dr. Joseph Betz will moderate a second session titled *Method Validation, Quality, and Compliance: Tools for a QA Unit*.

*** ODS will be exhibiting at these venues. Stop by to learn more about us, meet several of our staff, and pick up some of our materials.**

Recent Publications by ODS Staff

- *Leila G. Saldanha*. Government regulation of dietary supplements. Pages 639-648 in: *The Health Professional's Guide to Popular Dietary Supplements, Third Edition* (by Allison Sarubin Fragakis with Cynthia A. Thomson). American Dietetic Association, Chicago, IL. 2006. 624pp.
 - *Leila G. Saldanha*. The dietary supplement marketplace: constantly evolving. *Nutrition Today* 42(2):52-54, March/April 2007.
 - *Mary Frances Picciano, Elizabeth A. Yetley, and Paul M. Coates*. Folate and health. *CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources*, No. 018, April 2007.
 - Eileen Kennedy and Richard Deckelbaum (editors). *The Nation's Nutrition*. ILSI Press, Washington, DC. 2007. 292pp.
 - Preventive nutrition: impact of school lunch programs on diet quality. Julie Borges and *Johanna Dwyer*. Pages 67-90.
 - The impact of dietary supplements on global health and nutrition status. *Mary Frances Picciano, Paul M. Coates, and Barbara E. Cohen*. Pages 255-274.
 - John H.K. Vogel and Mitchell W. Krucoff (editors). *Integrative Cardiology: Complementary and Alternative Medicine for the Heart*. McGraw Hill, New York, NY. 2007. 416pp.
 - Herbal and dietary supplements in cardiovascular care: efficacy and incorporation into practice. Robert Alan Bonakdar, Erminia Guarneri, and *Rebecca Costello*. Pages 133-168.
 - Obesity and weight loss: an overview of diets, drugs, and dietary supplements. *Rebecca B. Costello and Johanna T. Dwyer*. Pages 447-468.
 - *Joseph M. Betz, Kenneth D. Fisher, Leila G. Saldanha, and Paul M. Coates*. The NIH analytical methods and reference materials program for dietary supplements. *Analytical and Bioanalytical Chemistry*. Published online May 31, 2007.
 - Ethan M. Balk, Tanya A. Horsley, Sydne J. Newberry, Alice H. Lichtenstein, *Elizabeth A. Yetley*, Howard M. Schachter, David Moher, Catherine H. MacLean, and Joseph Lau. A collaborative effort to apply the evidence-based review process to the field of nutrition: challenges, benefits, and lessons learned. *American Journal of Clinical Nutrition* 85(6):1448-1456, June 2007.
 - Vishnudutt Purohit, Manal F. Abdelmalek, Shirish Barve, Norlin J. Benevenga, Charles H. Halsted, Neil Kappowitz, Kusum K. Kharbanda, Qi-Ying Liu, Shelly C. Lu, Craig J. McClain, *Christine Swanson*, and Samir Zakhari. Role of S-adenosylmethionine, folate, and betaine in the treatment of alcoholic liver disease: summary of a symposium. *American Journal of Clinical Nutrition* 86(1):14-24, July 2007.
 - *Paul M. Coates*. Evidence-based reviews in support of health policy decisions. *Journal of the National Cancer Institute* 99(14):1059, July 18, 2007.
-