

Office of Dietary Supplements Update

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

Health Benefits of Soy Appear Limited, New Review Concludes

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

Soy products come in a wide variety of forms, including foods (such as soybeans, soy flour, soy milk, tofu, miso, tempeh, natto, and okara), isolated and textured soy protein that are added to foods, and soy-derived isoflavone supplements.

Many soy products provide a nutritious mix of protein, vitamins, and minerals. However, a new evidence review by the federal government's Agency for Healthcare Research and Quality (AHRQ), which examined over 200 human studies, finds that they don't have significant effects on blood pressure, bone health, cancer, kidney disease, endocrine function, reproductive health, neurocognitive function, or glucose metabolism. Daily consumption of soy protein may lower blood levels of LDL ("bad") cholesterol (by about 3%) and triglycerides (about 6%), and soy isoflavones (at doses of 17.5 to 100 mg/day) might reduce the frequency of hot flashes in postmenopausal women. AHRQ also concluded that eating soy products is quite safe for most people; only minor gastrointestinal problems have been reported in some studies.

Overall, the report concluded, available studies were limited in number, of poor quality, or their duration was too short to reach definite conclusions. According to Office of Dietary Supplements (ODS) Director Paul M. Coates, PhD, "This report shows us that there's much more to learn about soy, and it provides suggestions for future research on soy's health effects that we and NCCAM will carefully review." In particular, studies that substitute practical amounts of soy into people's diets would better address the question of whether we should make the effort to consume it.

Effects of Soy on Health Outcomes was prepared by the Tufts-New England Medical Center's Evidence-based Practice Center in Boston under AHRQ's sponsorship. ODS co-funded this effort together with the National Center for Complementary and Alternative Medicine (NCCAM). To access both the full report and a summary, click on the link at the ODS Web site homepage or go directly to <http://www.ahrq.gov/clinic/epecsums/soysum.htm>.

ODS Deputy Director Receives Merit Award

We're pleased to note that Rebecca Bortz Costello, PhD received an NIH Award of Merit on August 18 "for her

tireless efforts in achieving the scientific and educational mission of ODS." Congratulations, Becky!

More Reviews of Omega-3 Fatty Acids Published

Reviews of the health effects of omega-3 fatty acids on mental health, eye health, and child and maternal health are now available on the ODS Web site at http://dietary-supplements.info.nih.gov/Health_Information/omega_3_fatty_acids.aspx. These reviews were prepared through the Evidence-Based Practice Center Program of the Agency for Healthcare Research and Quality (AHRQ) and were funded by ODS.

These three publications are the last in a series of AHRQ evidence-based reviews on the potential health benefits and risks of omega-3s. Previous reports have examined the role of these fatty acids in asthma, cardiovascular disease, diabetes, inflammatory bowel disease, rheumatoid arthritis, renal disease, lupus, osteoporosis, cancer, cognitive function (with aging, dementia, and neurological diseases), and organ transplantation. All reports and summaries are available on the ODS Web site.

Public Meeting Provides Feedback on ODS Strategic Plan

On May 20, ODS convened a public meeting to review its Strategic Plan in light of additional and emerging needs and potential new opportunities since publication of its document, *Promoting Quality Science in Dietary Supplement Research, Education and Communication: A Strategic Plan for the Office of Dietary Supplements 2004-2009*, in the fall of 2004.

More than 60 people attended the public meeting and others contributed their input by email. Now available on the ODS Web site are various documents from that meeting. They include a synopsis of all the recommendations received from the presenters, discussants, and commenters as well as copies of the remarks and Powerpoint presentations of speakers.

ODS staff are carefully reviewing all the constructive feedback on what we're doing right and how we might better meet the needs and interests of our diverse stakeholders—which range from academic researchers and the dietary supplement industry to healthcare providers and the public. The majority of comments addressed aspects of our current communication activities and additional opportunities that ODS should consider. We sincerely thank all of you who contributed to this process.

The ODS 2004-2009 Strategic Plan document plus all materials related to the public meeting are available at http://dietary-supplements.info.nih.gov/Strategic_Planning_2004-2009/Planning.aspx.

Workshop Evaluates Role for Diet and Supplements in Autism

ODS convened a workshop on October 6 to critically evaluate the evidence that nutritional interventions and dietary supplements might help to prevent and manage autism spectrum disorders and to identify promising research opportunities using these approaches. Collaborators included the National Institute of Mental Health, the National Institute of Child Health and Human Development, the National Institute of Environmental Health Sciences, and the National Center for Complementary and Alternative Medicine.

The workshop, held at the National Institutes of Health, was timely because the role of nutrition in preventing and treating the symptoms of autism has been investigated for almost 50 years. Much of the research has focused on the balance of essential nutrients, including vitamins and minerals. Yet while some studies suggest that certain dietary supplements might be helpful, investigations to date have raised more questions than answers.

A report of the workshop discussions will be available later this year.

ODS Undertakes Two Projects on Dietary Supplement Use

ODS recently initiated two projects that promise to increase available information about the use of dietary supplements in the United States and their contributions to overall nutrient intakes. The projects are based on data derived from the National Health and Nutrition Examination Surveys (NHANES) of 1999–2000 and 2001–2002.

The first will identify the prevalence of total dietary supplement use (including botanicals) and total nutrient intakes from foods and supplements among infants and children at various ages. It will also examine patterns of usage and intakes by gender, age, time (1999–2000 vs. 2001–2002), and selected health-related behaviors and demographic variables. The scientific papers that result from this project will help fill the substantial gaps in knowledge about the current use of supplements by America's children.

The second project involves the development of an accurate, easy-to-use, web-based analysis tool that will enable users to quickly obtain information on nutrient intakes by various population groups from foods and supplements and their related health biomarkers. The current pilot phase focuses on two nutrients—folate and vitamin B12—and biomarkers such as blood concentrations of folate, B12, methylmalonic acid, and homocysteine. Users will be able to choose population groups based on gender as well as several categories of age and race/ethnicity.

Senior Nutrition Research Scientist Mary Frances Picciano, PhD leads the ODS teams working on these projects with representatives from the U.S. Department of Agriculture and the National Center for Health Statistics.

Recent Additions to the ODS Web Site

- Chromium Fact Sheet (<http://dietary-supplements.info.nih.gov/factsheets/chromium.asp>)
- Bibliography of journal articles on the effects of dietary supplements on hemostasis and antithrombotic therapies—that is, interactions between supplements and medications used to reduce blood clotting (such as warfarin) or to treat bleeding disorders. This 176-page document was prepared in support of a conference on the subject held at the NIH on January 13 and 14. (http://dietary-supplements.info.nih.gov/pubs/coagulation/DS_Coag_Post_Conf_Bib_July_2005.pdf)

Spotlight: New Botanical Research Center Investigates the Metabolic Syndrome

The Pennington Biomedical Research Center in Baton Rouge, part of the Louisiana State University System, is one of the largest academically based nutrition research centers in the world. There, more than 20 scientists are investigating diverse symptoms (known collectively as the metabolic syndrome) that lead to the development of type 2 diabetes and heart disease and determining whether various plant extracts might effectively prevent or treat them. This research team constitutes a new Botanical Research Center, one of six such centers across the United States being funded by ODS in collaboration with other National Institutes of Health

partners, including the National Center for Complementary and Alternative Medicine (NCCAM). The centers are expected to advance the scientific base of knowledge about botanicals, including issues of safety, efficacy, and biological action.

The Pennington Botanical Research Center (PBRC) was established in April with an award of \$7.49 million over five years. It is directed by William Cefalu, MD, whose research and clinical interests focus on diabetes, including its management and understanding the mechanisms of insulin resistance, a feature of the disease where cells throughout the body become resistant to insulin's

action and leads to higher than normal levels of glucose in the blood. In carrying out its work, the PBRC will collaborate with the Biotechnology Center for Agriculture and the Environment at Rutgers, the State University of New Jersey, which works to discover and develop novel botanical therapies from plants. Ilya Raskin, PhD, a plant scientist there, serves as Associate Director of the PBRC.

The focus of the PBRC's work—metabolic syndrome—is timely because this cluster of symptoms is common among American adults and one of our most important public-health problems. Its major

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features include obesity, insulin resistance, high blood pressure, and high blood triglyceride and low HDL ("good") cholesterol levels, leading to the development of type 2 diabetes and accelerated cardiovascular disease. With its interdisciplinary approach, the PBRC will identify and study botanicals that might help to treat the metabolic syndrome, identify their bioactive constituents, standardize and "optimize" those botanicals as therapies, learn their mechanisms of action, and prepare this information for use in clinical studies of these potential interventions in humans.

The PBRC is currently engaged in three projects:

- Investigating an alcoholic extract of tarragon (*Artemisia dracunculus* L), known as PMI-5011, that appears to increase insulin action. Human studies will be conducted with this extract to evaluate its safety and efficacy.

- Determining how an extract of shilianhua (*Sinocrassula indica* Berge) provides strong anti-obesity and anti-hyperglycemic activity in mice. The hypothesis is that this Chinese herb may stimulate energy expenditure and insulin action.
- Evaluating how supplements of anthocyanins (phenolic flavonoid compounds found in such foods as berries, onions, and tea) may increase insulin sensitivity and decrease the abnormal accumulation of fat in muscle and the liver.

The Botanical Core of the PBRC is located at Rutgers University. There, Dr. Raskin and his colleagues cultivate the botanicals; ensure the identity, strength and quality of the bioactive extracts prepared from them; and conduct the analytical and structural chemistry studies of the source materials to support all research activities.

More information about the PBRC and its work can be found on the center's Web site at <http://brc.pbrc.edu>

Look For Us

ODS will be exhibiting at the following venues through the end of the year. If you attend any of these meetings, please stop by to learn more about us, meet several of our staff, and pick up some of our materials.

October 23–25
American Dietetic Association,
Food & Nutrition Conference &
Expo
St. Louis, MO

November 9–11
SupplySide West, International
Trade Show and Conference
Las Vegas, NV

Strengthening the Science of Dietary Supplement Research

The National Institutes of Health has spent almost three-quarters of a billion dollars studying dietary supplements over the last five years. ODS contributes significantly to this effort as part of its mission to stimulate and support research on supplements.

Grants are the major mechanism at NIH for supporting research. ODS provides funding through collaboration with the various NIH institutes and centers to support basic and clinical studies. Of ODS's budget of approximately \$27 million in fiscal year (FY) 2005, the majority is used

for grants, contracts, conferences, and interagency agreements that increase scientific knowledge about supplements.

In FY 2004, for example, ODS co-funded 101 grants. The research it supported includes an evaluation of the safety and potential efficacy of oyster mushrooms for the treatment of hyperlipidemia in HIV-infected patients and the identification of the biochemical basis by which chromium enhances the action of insulin. A majority of allocated funds was devoted to research on botanicals,

such as investigations of the cardioprotective effects of American ginseng and the neuroprotective mechanisms of a standardized extract of ginkgo. Each grant co-funded by ODS in FY2004—and all the way back to FY1996—is briefly described on our Web site at <http://dietary-supplements.info.nih.gov/funding/odsgrantsandcontracts.html>. This list clearly shows that as ODS's budget has grown over the years, so have the number of grants we are able to support.

Recent Publications by ODS Staff

- *Paul M. Coates*, Marc R. Blackman, Gordon M. Cragg, Mark Levine, Joel Moss, and Jeffrey D. White (editors). *Encyclopedia of Dietary Supplements*. Marcel Dekker, New York, NY. 2005. 819pp.
- *Rebecca B. Costello* (as a Writing Committee Member). American College of Cardiology Foundation complementary expert consensus document: integrating complementary medicine into cardiovascular medicine. *Journal of the American College of Cardiology* 46(1):184–221, July 5, 2005.
- *Johanna T. Dwyer*, David B. Allison, and *Paul M. Coates*. Dietary supplements in weight reduction. *Journal of the American Dietetic Association* 105(5):S80–S86, May 2005.
- *Carol J. Haggans*, *Karen S. Regan*, Lynda M. Brown, Chunling Wang, Jim Krebs-Smith, *Paul M. Coates*, and *Christine A. Swanson*. Computer access to research on dietary supplements: a database of federally funded dietary supplement research. *Journal of Nutrition* 135(7):1796–1799, July 2005.
- Maurice E. Shils, Moshe Shike, A. Catharine Ross, Benjamin Caballero, and Robert J. Cousins (editors). *Modern Nutrition in Health and Disease*, Tenth Edition. Lippincott Williams & Wilkins, Philadelphia, PA. 2005. 2,069pp.
 - Chapter 50B: Lactation. *Mary Frances Picciano* and Sharon S. McDonald. Pages 784–796.
 - Chapter 105: Dietary guidelines: national perspectives. *Johanna T. Dwyer*. Pages 1673–1686.
 - Chapter 116: Nutrition labeling of foods and dietary supplements. *Kenneth D. Fisher*, *Elizabeth A. Yetley*, and Christine L. Taylor. Pages 1827–1838.