

NIH Needs for Evaluating Dietary Supplement Efficacy and Safety: Omega-3 Fatty Acids

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DSHEA

(Dietary Supplement Health and Education Act - 1994)

- Amended the Food, Drug & Cosmetic Act
- Defined dietary supplements
- Established regulatory framework
 - Food and Drug Administration (FDA)
 - As foods, not as drugs
- Established rules for what a label should contain
- Gave FDA authority to write Good Mfg. Practices
- *Called for creation of the Office of Dietary Supplements at the NIH*



Dietary Supplements: DSHEA Definition

- Product intended to supplement the diet
- Contains one or more of the following:
 - Vitamin
 - Mineral
 - Herb or other botanical (*not tobacco*)
 - Amino acid
 - Other dietary substance



ODS Programs & Activities

- *Evidence-Based Reviews*
- Health Effects of Bioactive Factors
- Disease Prevention and Health Promotion
- Analytical Methods and Reference Materials
- Botanical Research Centers
- Dietary Supplement Databases
- Surveys of Supplement Use
- International Nutrient Risk Assessment
- Training and Career Development
- Workshops and Conferences
- Communications and Information



Evidence-Based Review Program

- Directed by Anne Thurn, Ph.D.
- Systematic review of the literature, with meta-analysis as appropriate, on DS efficacy and safety
- In collaboration with AHRQ's Evidence-Based Practice Center Network
- Major reason for conducting these reviews is to assist NIH in the development of research agendas



Current Status

■ Completed

- *Ephedra* in weight management and athletic performance enhancement
- *Omega-3 fatty acids* in foods and supplements for a variety of health conditions

■ Ongoing

- *Antioxidants* in berries and B-vitamins for age-related neurodegenerative diseases
- Health effects of *vitamin D*
- *Multivitamins/minerals* in chronic disease prevention



Additional NIH-Sponsored Evidence Reports Relevant to Dietary Supplements

■ Completed

- *Garlic* effects on CVD and cancer (NCCAM)
- *Antioxidants (C, E, CoQ10)* and CVD and cancer (NCCAM)
- *Chromium* and type 2 diabetes mellitus (ODS, NIDDK)
- *Milk thistle* and liver disease (NCCAM)
- *Melatonin* and sleep disorders (NCCAM)

■ Ongoing

- *Soy* effects on health outcomes (NCCAM/ODS)



Congressional Language for FY 2002 NIH Appropriation

“The Committee is aware of promising research showing the significant positive health effects related to the consumption of omega-3 fatty acids through foods or supplements. Given the significant human and financial costs associated with coronary heart disease, the Committee urges the Office to begin preliminary work on a major assessment of the health benefits of omega-3 fatty acid consumption.”



Perspectives - I

- Small effects: gather strength from pooling smaller studies
 - Problems with pooling unlike studies
- Heterogeneity of interventions, study populations, endpoints/biomarkers
 - Failure to control for variation in quality of trial compounds
- Studies rarely powered to evaluate harms
 - Remember: assume safety anyway



Perspectives - II

- The hard work is done at the beginning: developing questions
 - Involve relevant NIH ICs, other agencies
- Then, walk away
- Process overseen by AHRQ with input from Technical Expert Panel (TEP)
 - Access to relevant literature
- Draft report reviewed by TEP, NIH, other experts, stakeholders



Omega-3 and CVD Research Agenda

- **NHLBI and ODS convened expert panel in 2004 to evaluate evidence and rationale for mounting clinical trial(s)**
 - Primary prevention?
 - Who?
 - Dose?
 - Duration?
 - Biomarkers/Risk factors?
 - Endpoint(s)?

- **Posted on NHLBI Web site:**

www.nhlbi.gov/meetings/workshops/omega-3/omega-3-rpt.html



Dietary Supplement Clinical Trials

Co-sponsored by ODS

Sponsor	Title of Grant
NCCAM	Comparing Effects of 3 Sources of Garlic on Serum Lipids
NIDDK	Adjuvant Therapy for Vascular Inflammation in Diabetes
NICHD	Supplemental Calcium in Overweight Out-Patients, <i>SCOOP</i>
NIAMS	Bone-Sparing by Ca Salts with and without Extra Phosphorus
NCCAM	Drug Interactions and Bioavailability of Cranberry
NIDDK	Alternative Therapies for Benign Prostatic Symptoms



NIH Funding for Dietary Supplement Research

(sources: HNRIM, CARDS)

Fiscal Yr	Total Grants	Dollars
1999	374	\$ 98 million
2000	363	\$118 million
2001	443	\$127 million
2002	569	\$171 million
2003	852	\$260 million
	TOTAL	\$774 million



OFFICE OF DIETARY SUPPLEMENTS

Visit the ODS Web site
<http://ods.od.nih.gov>

or e-mail to ods@nih.gov

