

ODS/CRN Conference on the Science and Policy of Performance-Enhancing Products

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Paul M. Coates, Ph.D.

Director, Office of Dietary Supplements

National Institutes of Health



Examples of Ingredients in the Dietary Supplement Category

- **Vitamins, minerals, multis**
- **Antioxidants**
- **Androstenedione, DHEA**
- **Creatine, carnitine**
- **Lutein, lycopene**
- **Soy, garlic**
- **Omega-3 fatty acids**
- **St. John's wort, echinacea, ephedra, ginseng**
- **Combinations**

The Dietary Supplement Health and Education Act (DSHEA) of 1994

- **Based on several factors (excerpts from Act)**
 - Improving health status ranks at the top of national priorities
 - Importance of nutrition and supplements in health promotion and disease prevention documented in scientific studies
 - Preventive health measures can limit the incidence of chronic diseases and reduce long-term health care expenditures
 - Consumers should be empowered to make choices about preventive health care programs based on data
 - Almost 50% of Americans regularly consume supplements: \$4 billion sales in 1994, more than \$15 billion now

DSHEA and the NIH

- **DSHEA called for creation of the Office of Dietary Supplements**
- **Placed at the National Institutes of Health in the Office of the Director**
- **Formally established in 1995**

ODS: Mandated Tasks

- ◆ *Explore the role of dietary supplements to improve health care*
- ◆ *Promote scientific study of dietary supplements in maintaining health and preventing chronic disease*
- ◆ *Conduct & coordinate research at NIH*

ODS: Mandated Tasks

- ◆ *Collect & compile* databases of scientific literature & track federally funded research on dietary supplements (IBIDS and CARDS)
- ◆ *Provide advice* to other HHS agencies related to dietary supplements

ODS Implementation

- **Research**
 - **Dietary Supplement Research Centers**
 - **Promising research recommended by NIH Institutes and Centers**
 - **Evidence-based review guides research agenda development**
- **Training and Career Development**
- **Public/Practitioner Education**
 - **Fact sheets**
 - **Databases of literature (IBIDS) and federally-funded research (CARDS)**

ODS Implementation (cont'd)

- **Conferences/Workshops**
 - **In conjunction with organizations within and outside NIH**
 - **Recent examples**
 - **Role of SAME in Alcoholic Liver Disease**
 - **Dietary Supplement Use in Children**
 - **Upcoming examples**
 - **Dietary Supplement Use in Women of Reproductive Age**
 - **EB Symposium on Herbal Dietary Supplements: Health Effects and Mechanisms of Action**
 - **Dietary Supplement Use in the Elderly**



**RESEARCH
AGENDA:
Evidence-
Based
Review
Program**

Congressional Language for FY 2001 ODS Appropriation

“The Office is encouraged, in consultation with NCCAM, AHRQ, and FDA to review the current scientific evidence on the safety and efficacy of dietary supplements now on the market, which could then form a basis for further research, education of practitioners and consumers, and whether further regulatory requirements are necessary.”

Congressional Language for FY 2001 ODS Appropriation (cont'd)

“The number of Americans taking dietary supplements containing ephedra has risen dramatically. The conferees encourage the Office of Dietary Supplements to enhance clinical research on the safety and efficacy of these products.”

First Project: Ephedra Efficacy and Safety

- **ODS and NCCAM have commissioned, through AHRQ, a systematic review of the literature, with meta-analysis as appropriate, on ephedra efficacy and safety in three general settings: weight management, athletic performance enhancement, and energy enhancement.**
- **Review will include relevant reports in all languages, both published and unpublished.**
- **The major reason for conducting this review is to assist NIH in the development of an appropriate research agenda that will address efficacy and safety.**