

Guidelines regarding the recommendation and sale of dietary supplements

CYNTHIA THOMSON, PhD, RD, FADA; CONNIE DIEKMAN, MEd, RD, FADA; ALLISON SARUBIN FRAGAKIS, MS, RD; CAROL MEERSCHAERT, RD; HAROLD HOLLER, RD; CATHY DEVLIN, RD

Dietary supplement sales have increased in the United States over the past decade. This trend has influenced the practice of dietetics in that dietetics professionals are increasingly called upon to provide recommendations to patients/clients regarding the use of specific supplements. Given our education and training in diet and nutrition, our profession is uniquely positioned to meet this need. However, for many dietetics professionals this is a new area of practice that requires continuing education, awareness of legal and regulatory issues, and an understanding of professional ethics. The sale of dietary supplements by dietetics professional presents a potential financial conflict of interest (both real and

perceived) and could undermine the trust between patient/client and the dietetics professional. Therefore, the decision to sell dietary supplements should be cautiously evaluated.

In the Fall 2001, the House of Delegates of the American Dietetic Association requested the development of professional guidelines for dietetics professionals related to recommending and selling of dietary supplements in their practice. The Sale of Dietary Supplements Task Force was formed to respond to this charge.

This Task Force developed the following guidelines, which are meant to provide direction to dietetics professionals. Individual practitioners are advised to review the ADA/CDR Code of Ethics by the Profession of Dietetics (www.eatright.org/adacode.html) as well as consult experts in their area regarding the legal and regulatory issues specific to their location of practice. These guidelines should be considered as recommendations for best practice and are not enforceable except in regards to the ADA/CDR Code of Ethics. The Task Force has attempted to provide specific guidelines, which are relevant and practical for all dietetic professionals. In addition, the guidelines have been augmented with specific resources for both professional reference and continuing education as well as a business practice checklist for practitioners to ensure all pertinent issues have been addressed prior to expanding into this area of practice.

These guidelines and appendix were submitted to the House of Delegates for review. During the Spring HOD meeting, modifications were made to the guidelines based on member input. The following motion was adopted on May 5, 2002: "Therefore, be it resolved that the House of Delegates adopt the guidelines entitled, "Guidelines for Recommendations and

Cynthia Thomson, PhD, RD, FADA is an assistant professor, Nutritional Sciences, University of Arizona, Tucson, AZ, and a Member of Nutrition in Complementary Care, Research, and Nutrition Educator of Health Professionals Dietetic Practice Groups; Connie Diekman, MEd, RD, FADA Washington University in St. Louis, St. Louis, MO, Representing the House of Delegates (Professional Issues Delegate); Allison Sarubin Fragakis, MS, RD, Greenbrae, CA, author of ADA's The Health Professional's Guide to Popular Dietary Supplements, Member of Nutrition in Complementary Care and Sports, Cardiovascular and Wellness Nutritionists Dietetic Practice Groups; Carol Meerschaert, RD, Falmouth, ME, Member of Nutrition Entrepreneurs Dietetic Practice Group; Harold Holler, RD, director, HOD Governance, American Dietetic Association; Cathy Devlin, RD, manager, HOD Governance, American Dietetic Association

Sale of Dietary Supplements by Dietetics Professionals,” developed by the Sale of Dietary Supplements Task Force.”

GUIDELINES REGARDING THE RECOMMENDATION AND SALE OF DIETARY SUPPLEMENTS

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines dietary supplements as products (other than tobacco) intended to supplement the diet and meet at least one of the following criteria:

- Contains one or more of the following: vitamin; mineral; herb or other botanical; amino acid; dietary substance to supplement the diet by increasing the total dietary intake; concentrate, metabolite, constituent, extract; or combination of any of the previously described ingredients
- Intended for ingestion in a tablet, capsule, powder, softgel, gelcap, or liquid form
- Labeled as a dietary supplement
- Cannot be represented for use as a conventional food or as a sole item of a meal or diet
- Cannot include an article that is approved as a drug or biologic

All dietetics professional should consider the following guidelines when making the decision to recommend or sell dietary supplements. The guidelines are intended to address the scientific, legal, ethical and business aspects of recommending or selling dietary supplements:

1. All patients/clients should receive a complete assessment of diet and dietary supplement use as a routine component of their nutritional status assessment. Assessment should include:

- List of supplements
- Dose /frequency
- Brand /chemical form
- Rationale for use (patient/client perspective)
- Evaluation of diet and supplement adequacy

(A sample assessment form can be found on the ADA member— only Web site: www.eatright.com/members/career/supplguide.html).

2. Recommendations for dietary supplements should be based on a thorough review of the currently available scientific evidence with consideration for:

- Level of currently available scientific evidence (see Appendix “A”).
- Demographic characteristics (age, gender, ethnicity, economic status, etc.)

- Disease states
- Clinical parameters (blood pressure, weight, biochemistries, etc)
- Medications (prescription and over-the-counter)
- Risk and/or benefits

3. Dietary supplementation should be complementary to diet (ie, efforts to improve diet to meet nutrient needs should be made prior to, or in conjunction with, dietary supplementation).

4. All recommendations should be made in the patient/client’s best interest and should be safe to use, including reasonable assurance of freedom from product toxicity as well as not causing harm with respect to ongoing disease states.

5. The dietetics professional is responsible for reporting any adverse reactions by utilizing available Food and Drug Administration (FDA) documentation procedures:

- Adversereactions can be reported to www.fda.gov/medwatch/report/hcp.htm
- Referring health care professionals should be notified of any adverse reactions.

6. All recommendations for dietary supplementation should be documented in the patient/client’s medical record. Documentation should include:

- Listing of current supplements
- Dosage/frequency of use
- Rationale for recommendation
- Plan for outcomes monitoring
- Purchases / dispensed volume for each supplement
- Adverse reactions

7. The dietetics professional assumes responsibility and accountability for personal competence in practice (based on Principle #2 of the Code of Ethics) and therefore, should participate in continuing professional education in this area.

8. The dietetics professional may make dietary supplements available to patients/clients with respect to the unique nutrition needs of the individual (based on Principle #8 of the Code of Ethics). The dietetics professional needs to:

- Avoid bias to ensure patient/client’s choice in selection and use of dietary supplement.
- Provide appropriate educational materials to patients/clients about dietary supplements (see Appendix “A”).

9. The dietetics professional provides disclosure of any financial relationship regarding the sale of dietary supplements to patients/clients (based on Principle #12 of the Code of Ethics). The dietetics professional must disclose any financial arrangements with specific manufacturer(s) or supplier(s) to sell dietary supplements.

- Disclosure should be accomplished through face-to-face communication or by posting a written notification that is easy to comprehend in a prominent location that is accessible by all patients/clients.

Given our education and training in diet and nutrition, our profession is uniquely positioned to meet this need. However, for many dietetics professionals this is a new area of practice that requires continuing education, awareness of legal and regulatory issues, and an understanding of professional ethics.

- Dietetics professionals should inform patients on the availability of products being recommended as well as equivalent products on the market.

10. The dietetics professional provides factual information regarding the availability of dietary supplements for purchase and does not advertise in a false or misleading manner (based on Principles 13 and 14 of the Code of Ethics).

11. The dietetics professional maintains current knowledge regarding the regulation of dietary supplements such as (see Appendix: "A" and "B"):

- Labeling issues (Food and Drug Administration)
- Health claims, structure/function claims, disease claims (Federal Trade Commission, see *Dietary Supplements: An Adver-*

tising Guide for Industry at www.ftc.gov/bcp/menu-health.htm#bized)

- Standards for identity, strength, quality and purity (ie, US Pharmacopoeia, NSF International)

- Definition of Dietary Supplements (Food and Drug Administration)

12. The dietetics professional understands the potential legal issues and complies with legal restrictions related to selling dietary supplements to patients/clients. Knowledge of the following issues is critical:

- Malpractice
- Authorized scope of practice in the business locale
- Institutional policies (hospital, clinic, etc.)
- Federal/state/local laws and regulations, including zoning and any ordinance issues, business licenses, scope of practice of other health care professionals, inconsistencies between states, etc.

13. Dietetics professionals choosing to sell dietary supplements need to investigate all aspects of business practice. All sales should be based on sound business practices. The following should be considered (see appendix for further information):

- Pricing and profit issues
- Liability concerns, including product liability
- Inventory
- Retail policies (products returned by customers, method of payment, etc.)
- Follow-up sessions related to use of products

These guidelines are in effect until April 1, 2006 at which time they will be reevaluated. These guidelines are meant to provide direction and recommendations for best practice. They are not enforceable except in regards to the ADA/CDR Code of Ethics.

These guidelines and appendix may also be found on ADA's Web site www.eatright.com/members/supplements.html and CDR's Web site www.cdrnet.org/.

External Review:

David M. Eisenberg, MD, Presenter of the President's Lecture "Alternative and Complementary Medicine, an International Focus," October 21, 2001, St. Louis, MO (FNCE); Director, Division for Research and Education in Complementary and Integrative Medical Therapies, Harvard Osher Institute Harvard Medical School, Boston, MA

Appendix A - RESOURCES

The following evidence-based resources may be helpful in expanding knowledge of dietary supplements. Because the research is constantly evolving, it is essential to update references by checking MEDLINE (www.ncbi.nlm.nih.gov/pubmed) and by subscribing to journals and professional newsletters. The list of resources was adapted from the American Dietetic Association's Health Professional's Guide to Popular Dietary Supplements, 2nd edition by Allison Sarubin Fragakis.

Reference books

- Sarubin Fragakis, Allison. *The Health Professional's Guide to Popular Dietary Supplements*, 2nd edition. American Dietetic Association. (Second edition will be available in Fall 2002). To order: 800/877-1600 ext. 5000.
- Written by a registered dietitian and reviewed by over 25 experts
 - Alphabetized detailed descriptions of 79 supplements (including summaries of clinical trials, dosage information, food sources, safety data, drug interactions, summary chart)
 - Includes information regarding how dietary supplements are regulated
 - Appendixes listing DRI's for all vitamins and minerals, information on ethics for RDs, and resources
- Blumenthal M, et al. *The ABC Clinical Guide to Herbs*. American Botanical Council. 2002. To order: 512/926-4900
- Self-paced course/reference book
 - Complete monographs on 30 popular herbals
 - Identifies products supported by clinical research
 - Take-home patient information sheets
- Jellin JM, Gregory P, Batz F, et al. *Pharmacist's Letter/Prescriber's Letter Natural Medicines Comprehensive Database, 3rd edition*. Stockton, CA: Therapeutic Research Faculty; 2000.
- Reference book summarizing research data for hundreds of supplements
 - Web version available, with access to abstracts
 - List of brand name products and ingredients
 - Drug/Supplement Interaction Charts

Additional titles of interest include:

- Olin BR, ed. *The Review of Natural Products* (monographs). St. Louis, Mo: Facts and Comparisons Publishing Group; 1994.
- Peirce A. *The American Pharmaceutical Association Practical Guide to Natural Medicines*. New York, NY: William Morrow & Co; 1999.
- Robbers JE, Tyler VE. *Tyler's Herbs of Choice: The Therapeutic Use of Phytomedicinals*. New York, NY; Haworth Herbal Press; 1999.
- Schulz V, Hansel R, Tyler VE. *Rational Phytotherapy: A Physician's Guide to Herbal Medicine*. 3rd ed. New York, NY: Springer; 1998.
- American Dietetic Association, 216 W. Jackson Blvd. Chicago, IL 60606-6995. Phone: 800/877-1600 www.eatright.org
 - American Botanical Council, PO Box 201660 Austin TX 78720. Phone: 800/373-7105 (to place orders) 512/926-4900 www.herbalgram.org
 - Council for Responsible Nutrition, 1875 Eye Street, NW Suite 400 Washington, DC 20006-5409. Phone: 202/872-1488 www.crnusa.org
 - International Food Information Council, 1100 Connecticut Ave NW Suite 430 Washington, DC 20036. Phone: 202/296-6540 [/ificinfo.health.org](http://ificinfo.health.org)
 - Herb Research Foundation, 1007 Pearl Street Suite 200 Boulder, CO 80302. Phone: 303/449-2265 www.herbs.org

Organizations and associations

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Organizations providing independent certification for dietary supplement products

- United States Pharmacopoeia 12601 Twinbrook Parkway Rockville, MD 20852 Phone: 800/822-8772 www.usp.org Label Certification Program is scheduled to start in September 2003
- National Nutritional Foods Association (NNFA) 3931 MacArthur Blvd, Suite 301 Newport, CA 92660-3013 800/966-6632 www.nnfa.org
- National Sanitation Foundation International 789 Dixboro Road Ann Arbor, MI 48105 Phone: 800/NSF-MARK www.nsf.org
- ConsumerLab.com www.consumerlab.com

Publications

- *Journal of the American Dietetic Association*, (monthly), www.eatright.org. Phone: 800/877-1600. \$150/year for individual subscription
- *Journal of the American Medical Association*, (weekly), http://jama.ama-assn.org. Phone: 312/670-7827. \$145/year individual subscription
- *Nutrition Reviews*, (monthly), www.ilsj.org/publications/reviews.html. Phone: 785/843-1235. \$97.50/year for individual subscription
- *The Scientific Review of Alternative Medicine*, (quarterly), www.hcrc.org/sram. Phone: 800/421-0351. \$60/year for individuals

ADA dietetic practice groups, such as Nutrition in Complementary Care and Sports, Cardiovascular, and Wellness Nutritionists offer newsletters. See www.eatright.com/healthorg.html and scroll to see complete listing and Web sites of ADA Dietetic Practice Groups.

- *HerbalGram*, (quarterly), www.herbalgram.org. Joint effort of the American Botanical Council and the Herb Research Foundation Phone: 800/373-7105. \$25/year
- *Journal of Herbs, Spices and Medicinal Plants*, (quarterly), www.haworthpressinc.com. Phone: 800/429-6784 \$45/year

Web Sites related to dietary supplements

- **Agricultural Research Service** Dr. James Duke's Phytochemical and Ethnobotanical Databases www.ars-grin.gov/duke/index.html
- **Centers for Disease Control and Prevention** 1600 Clifton Road, NE, Atlanta GA, 30333. 404/639-3934. www.cdc.gov
- **Federal Trade Commission (FTC)** FTC guidance document on advertising of dietary supplements www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm
- **Food and Drug Administration (FDA)** FDA Center for Food Safety and Applied Nutrition 200 C Street SW Washington, DC 20204 USA Phone: 888/INFO-FDA (888/463-6332) www.cfsan.fda.gov
- **FDA Warnings** regarding certain dietary supplements www.cfsan.fda.gov/~dms/ds-warn.html
- **FDA Consumer magazine** *Tips for the Savvy Supplement User: Making Informed Decisions* www.cfsan.fda.gov/~dms/ds-savvy.html
- **FDA Guide to Dietary Supplements** http://vm.cfsan.fda.gov/~dms/fdsupp.html
- **Food and Nutrition Board Institute of Medicine** 2101 Constitution Avenue, N.W. Washington, D.C. 20418 www4.nationalacademies.org/IOM/IOMHome.nsf/Pages/Food+and+Nutrition+Board
- **FDA, General information on dietary supplements** http://vm.cfsan.fda.gov/~dms/supplmnt.html
- **FDA, Information on dietary supplement regulations**, access to *Federal Register* www.cfsan.fda.gov/~dms/ds-ind.html
- **National Institute of Health** Office of Dietary Supplements National Institutes of Health Building 31, Room 1B25 31 Center Drive, MSC 2086 Bethesda, Maryland 20892-2086 Phone: 301/435-2920 http://dietary-supplements.info.nih.gov
- **National Institute of Health** Complementary & Alternative Medicine Databases http://nccam.nih.gov/databases.html
- **National Institute of Health MEDLINE** is the National Library of Medicine's (NLM) premier bibliographic database covering the fields of medicine, nursing, dentistry, veterinary medicine, the health care system, and the preclinical sciences. The MEDLINE file contains bibliographic citations and author abstracts from approximately 3,900 current biomedical journals published in the United States and 70 foreign countries and now contains alternative medicine information www.ncbi.nlm.nih.gov/pubmed
- **NIH, International Bibliographic Information on Dietary Supplements (IBIDS)** This database was created to assist researchers, health professionals, and the general public in locating scientific literature on dietary supplements. http://ods.od.nih.gov/databases/ibids.html
- **NIH, National Center for Complementary and Alternative Medicine** NCCAM Clearinghouse PO Box 7923 Gaithersburg, MD 20898 Phone: 888/644-6226 http://nccam.nih.gov Email: info@nccam.nih.gov
- **US Department of Agriculture** USDA National Agricultural Library, Food and Information Center www.nal.usda.gov/fnic/pubs/bibs/edu/onlinecourse.html.
- **University of Illinois** NAPALERT—Natural Products Alert Database Program for Collaborative Research/ Pharmaceutical Sciences College of Pharmacy University of Illinois Chicago, IL 60612 Phone: 312/996-2246 www.ag.uiuc.edu/~fhn/napra.htm
- Healthcare Professionals can report to: 800/FDA-1088 www.fda.gov/medwatch/report/hcp.htm
- Federal Trade Commission False Advertising Claim www.ftc.gov
- Consumers can report to: 800/FDA-4010 www.fda.gov/medwatch/report/consumer/consumer.htm

Reporting adverse effects of dietary supplements

Appendix B - CONTINUING PROFESSIONAL EDUCATION UNITS (CPEU)

American Dietetic Association's Food and Nutrition Conference & Exhibition (FNCE) and other affiliate/DPG education events. FNCE: www.eatright.com/fnce/
Other ADA sponsored educational events: www.eatright.com/members/meetings/other.html

Title: American Botanical Council
12 credit hours approved. Course is available beginning June 2002. Contains comprehensive monographs for 29 herbs Clinical overview with clinical studies table Patient information sheets for photocopying and distribution www.herbalgram.org/browse.php/hcpg

Title: Alternative Therapies in Women's Health
American Health Consultants AMA recognized CMEs for MDs: 20 CME's available per year; www.ahcpub.com/online.html or call 800/688-2421

Title: Botanical Medicine in Modern Clinical Practice
Annual course sponsored by The Columbia Univ. College of Physicians and Surgeons (and others). Course co-directors: Fredi Kronenberg, PhD, and Andrew Weil, MD CME Dept: 212/305-3334 <http://cpmcnet.columbia.edu/dept/cme>

Title: Current Issues in Dietary Supplements
Format: Slide presentation, bulletin boards Target Audience: Graduate students Sponsor: University of Florida, College of Agricultural and Life Sciences, Institute of Food and Agricultural Life Sciences, Department of Food Science and Human Nutrition Course Number: HUN 5246
Course Topics: Definition of Dietary Supplements, Laws, and Regulations, Labeling and Health Claims for Dietary Supplements, Antioxidants, Herbal Products, Mental Health/Weight Loss Products, Immune-modulating Herbs, Ergogenic Aids Course Description: This course introduces federal laws and regulations covering the definitions, marketing, and labeling of dietary supplements. It discusses specific vitamins, minerals, herbs, and ergogenic aids. Course Credits/Degree: 2 graduate credits Cost: \$530.43 per credit hour (out of state) Technical Requirements: E-mail accounts, 233 MHz CPU or faster, 32 MB RAM or better, 2 MB Video RAM or better, Audio Card and Speakers, 56K/90 Modem, 4 GB or larger Hard Drive, 10X CD-Rom Drive, 1.4 Mb Floppy Drive SVGA 256 Color Monitor (800x600) Printer Prerequisites: One college-level course in introductory nutrition, or consent of instructor Contact Name: Dr. Elaine Turner Contact Address: PO Box 110370 Gainesville, FL 32611-0370 Contact Phone: 352/392-1991, ext 224 Contact Fax: n/a Contact Email: ret@gnv.ifas.ufl.edu Contact: <http://grove.ufl.edu/%7Ehun5246/> Only two programs state explicit CEU credits for dietitians.

Title: Healing Herbs: Safety and Effectiveness
Format: Streaming Video Target Audience: Persons interested in Herbal Supplements Sponsor: Rutgers Cooperative Extension, Family and Consumer Sciences Course Numbers: n/a Course Topics: History of Herbal Remedies, Regulations on Supplements, Most Common Herbs
Course Description: This program provides information on herbal remedies. It addresses their history, ten of the more commonly used herbs, and the current regulatory dilemma revolving around herbal remedies. The quality, safety, and effectiveness of healing herbs will be discussed as well as cautions and interactions with some prescriptive drugs. Cost: Viewing is free, curriculum will soon be available for purchase Technical Requirements: RealPlayer Prerequisites: None Contact Name: Kathleen Klotzbach-Shimomura, Family and Consumer Sciences Educator Contact Address: Rutgers Cooperative Extension of Hunterdon County, Extension Center, 4 Gauntt Place, Route 3, Flemington, NJ 08822 Contact Phone: 908-788-1342 Contact Fax: n/a Contact Email: shimomura@rce.rutgers.edu; www.rce.rutgers.edu/presentations/healingherbs/index.html

Title: A Health Care Professional's Guide to Evaluating Dietary Supplements
A joint publication by the American Dietetic Association and the American Pharmaceutical Association, 2000 Format: Booklet Target Audience: Dietetics Professionals; two continuing professional education units are approved by CDR Cost: Download is free to ADA members; the 45-page booklet is available for purchase for \$20.00 for ADA members; \$25.00 for non-members plus \$4.50 shipping and handling. Catalog # 8015 Technical Requirements: Adobe Acrobat Prerequisites: None Contact Name: ADA Member Service Center Contact Address: 216 W. Jackson Blvd, Chicago, IL 60606 Contact Phone: 312/899-4899; www.eatright.com/members/career/supplguide.html for ADA members.

University of Chicago/ODS/NCCAM Funded Botanical Center CE www.uic.edu/pharmacy/research/diet. There is a charge for the CE, but the CE is acceptable for any health professional. Click on the continuing education link.

Appendix C - Business considerations for dietetics professionals considering selling supplements**Legal counsel**

- Are there any state laws or other legal restrictions on the sale of ancillary products or services by referring professionals?
- Are there any state laws or other legal restrictions in terms of recommending ancillary products or services by referring professionals?
- Are all contracts in your best interest?
- Are there any potential problems with product liability?

Type of business

- What type of business are you in?
- Would you rather concentrate solely on MNT or branch into retail sales?
- Would you rather recommend products or sell them outright?
- Is the sale of supplements a convenience or service to your clientele?

Profit

- What will your profit be? Consider time spent ordering and maintaining inventory, making sales, investigating product lines and individual products.
- Can you return product if it does not sell well?
- Do you have an environment conducive to shoplifting?
- Do you want to sell supplements at the suggested retail price, offer clients a discount or sell at cost?
- What will your retail policies be?
- What is your return policy for your customers?
- Will you accept credit cards or checks?
- How will you handle the cash?

Follow-up sales

- Will return visits for supplements sales eat into your follow-up counseling business?
- Will clients try to use a visit for a supplement purchase as a free follow-up counseling session?
- Will these return visits red flag clients who need follow-up, so you can make an appointment for them?

Zoning, ordinances, business license

- What are applicable local zoning and other ordinances? Start by checking your state Web site's small business section. Most state Web sites are www.state. (two letter abbreviation of state).us (ie, Massachusetts is www.state.ma.us).
- Will you need a business licenses? Local (city, county) ordinances may require some type of business license as well. Contact your town hall to investigate.
- Are you familiar with collecting sales tax and that you will need a sales tax license?
- Is your office zoned for retail sales?

Inventory

- Do you have the space to hold inventory?
- Is your inventory maintained out of reach of children?
- Do you have the capitol to tie up in inventory?
- Are you familiar with inventory practices, such as: rotating stock, checking expiration dates, keeping the inventory clean and dry?

Product liability

- Will your malpractice insurance cover sales of a supplement? (You will most likely need product liability insurance.)