



# Guidance Regarding the Recommendation and Sale of Dietary Supplements

Tony Peregrin; in collaboration with the 2019-2020 Ethics Committee

**T**HIS ARTICLE UPDATES AND replaces the “Guidelines Regarding the Recommendation and Sale of Dietary Supplements,” which had been in effect since May 2002.<sup>1</sup>

The purpose of this update is to provide current guidance to nutrition and dietetic practitioners when making the decision to recommend or sell dietary supplements. Individual practitioners are advised to consult experts in their location of practice regarding these topics and to review the code of ethics (COE) for the nutrition and dietetics profession, which was updated in 2018 by the Academy of Nutrition and Dietetics (Academy) and its credentialing agency, the Commission on Dietetic Registration (CDR)<sup>2</sup> (see [Figure 1](#)). The Academy–CDR COE is responsive to topic areas relevant to contemporary nutrition and dietetics practice, including the ethical and legal

considerations for recommending and selling dietary supplements.

The guidance in this report should be considered as the basis for recommendations relative to best practices and is not enforceable except in regard to the COE.

This document also links principles and standards of the Academy–CDR COE to specific topic areas wherever possible and identifies how these guidance statements relate to specific areas of practice such as assessment of nutritional status related to dietary supplement use, recommendation for dietary supplements, monitoring and evaluating the benefits and efficacy of dietary supplements, and appropriate documentation. There is also guidance that identifies professional competency and the legal responsibilities of the practitioner when recommending or selling dietary supplements.

The Dietary Supplement Health and Education Act of 1994 established the definition of dietary supplements as products (other than tobacco) intended to supplement the diet and meet at least 1 of the following criteria<sup>3,4</sup>:

- Contains 1 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, soft gel, gel cap, 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 or has been authorized for investigation as a drug, antibiotic, or biologic.

More than one-half of adult Americans use dietary supplements, according to data provided by the National Health and Nutrition Examination Survey 2011-2014, and a study published in the *Journal of the Academy of Nutrition and Dietetics* revealed that adults were “two and a half times more likely” to use dietary supplements while taking prescription medication compared with adults without a medical condition.<sup>5,6</sup> The burgeoning number of consumers using dietary supplements, which are estimated to include more than 50,000 products in various forms, has given rise to a more than \$40 billion industry.<sup>7</sup>

According to the Academy’s Position Paper, “Micronutrient Supplementation,” the most common dietary supplements used by Americans contain micronutrients. Although there is a lack of evidence at this time in support of micronutrient supplementation for chronic disease prevention, micronutrient supplements may be warranted when nutrient intake is lacking from dietary sources or for certain health conditions.<sup>8</sup> With this caveat in mind, the expertise of the nutrition and dietetics practitioner is needed to educate consumers on the appropriate selection and safe use of micronutrient supplements. This includes staying abreast of the issues that affect dietary supplements overall, including their safety, efficacy, and regulations that govern them.

## GUIDANCE FOR THE USE OF SUPPLEMENTS

### Recommending Supplements

1. All patients or clients should receive a complete assessment of nutrient intake from food and beverage sources, as well as dietary supplements, as a routine component of their

2212-2672/Copyright © 2020 by the Academy of Nutrition and Dietetics.  
<https://doi.org/10.1016/j.jand.2020.05.009>

The [Continuing Professional Education \(CPE\) quiz](#) for this article is available for free to Academy members through the MyCDRGo app (available for iOS and Android devices) and through [www.jandonline.org](http://www.jandonline.org) (click on “CPE” in the menu and then “Academy Journal CPE Articles”). Log in with your Academy of Nutrition and Dietetics or Commission on Dietetic Registration username and password, click “Journal Article Quiz” on the next page, then click the “Additional Journal CPE quizzes” button to view a list of available quizzes. Nonmembers may take CPE quizzes by sending a request to [journal@eatright.org](mailto:journal@eatright.org). There is a fee of \$45 per quiz (includes quiz and copy of article) for non-member Journal CPE. CPE quizzes are valid for 1 year after the issue date in which the articles are published.

The following list of resources may be helpful in expanding knowledge of dietary supplements and was adapted from the Academy of Nutrition and Dietetics' 2018 Position Paper: "Micronutrient Supplementation" by Melissa Ventura Marra, PhD, RDN, and Regan L. Bailey, PhD, MPH, RD.<sup>8</sup>

- Academy of Nutrition and Dietetics
  - Evidence Analysis Library
  - *Journal of the Academy of Nutrition and Dietetics*
    - Scope and Standards for the RDNs and NDTRs Collection
    - Quality Certification Programs for Dietary Supplements
    - A Free New Dietary Supplement Label Database for Registered Dietitian Nutritionists
  - Position Papers
    - Position of the Academy of Nutrition and Dietetics: Micronutrient Supplementation
      - Includes a figure with select evidence-based resources for information related to dietary supplements
  - Sports Nutrition Care Manual (subscription required)
    - Dietary Supplement Evaluation
- Agency for Healthcare Research and Quality (AHRQ)
- The Department of Defense Dietary Supplement Resource: Operation Supplement Safety
- Federal Trade Commission
  - Dietary Supplements: An Advertising Guide for Industry
- Micronutrient Information Center, Linus Pauling Institute, Oregon State University
- National Academies of Sciences, Engineering, and Medicine
- National Institutes of Health
  - Dietary Supplement Label Database
  - Office of Dietary Supplements
  - US National Library of Medicine
    - MedlinePlus
    - PubMed
- National Sanitation Foundation International
- The US Anti-Doping Agency: Supplement 411
- Therapeutic Research Center, Natural Medicines Comprehensive Database (subscription required)
- US Department of Agriculture, Nutrition.gov: Dietary Supplements
- US Food and Drug Administration
  - Dietary Supplement Ingredient Advisory List
  - Dietary Supplements
  - How to Report a Problem with Dietary Supplements
    - MedWatch
    - Questions and Answers on Dietary Supplements
- United States Pharmacopoeia (USP)

Note: This list is not inclusive. The Academy of Nutrition and Dietetics has not participated in the development of the sites listed, does not exert any editorial or other control over the sites, content, and does not endorse any product or services.

**Figure 1.** Resources for expanding knowledge of dietary supplements.

nutritional status assessment. Assessment, as it relates to dietary supplements, should include:

- List of supplements
  - Dose and frequency
  - Brand and chemical form
  - Rationale for use (patient or client perspective)
  - Evaluation of nutrient intake and supplement adequacy
2. Recommendations for dietary supplements should be based on a thorough review of the currently available scientific evidence with consideration for:
    - Level and strength of currently available scientific evidence
    - Demographic characteristics (age, gender, ethnicity, economic status, etc)
    - Disease states
  3. Dietary supplementation should be complementary to nutrient intake from foods (for example, efforts to improve dietary sources to meet nutrient needs should be made prior to,
    - Clinical parameters (blood pressure, weight, biochemistries, etc)
    - Medications (prescription and over-the-counter)
    - Risks and potential benefits

- Commission on Dietetic Registration
  - CPE Database
- eatrightSTORE, CPE opportunities
  - Certificates of training
    - Integrative and Functional Nutrition—Module 5: Dietary Supplements: A Risk Management Framework for Practitioner and Client Decision Making
  - FNCE<sup>a</sup> sessions
  - Online courses

<sup>a</sup>FNCE = Food & Nutrition Conference & Expo.

**Figure 2.** Continuing professional education (CPE) resources.

or in conjunction with, dietary supplementation).

4. All recommendations should be made in the patient's or client's best interest and should be safe to use as well as not cause harm with respect to ongoing disease states based on the best information available to the nutrition and dietetics practitioner.

## Documentation and Reporting

1. The nutrition and dietetics practitioner is responsible for reporting any adverse reactions by utilizing available documentation procedures according to the US Food and Drug Administration (FDA) and should advise patients or clients to do the same<sup>8</sup>:
  - Adverse reactions should be reported to the FDA.
  - Referring health care professionals should be notified of any adverse reactions.
2. All recommendations for dietary supplementation should be documented in the patient's or client's medical record. Documentation, at a minimum, should include:
  - Listing of current supplements
  - Dosage and frequency of use
  - Rationale for recommendation
  - Plan for outcomes monitoring
  - Purchases and dispensed volume for each supplement
  - Adverse reactions

## Professional Competence

1. The nutrition and dietetics practitioner assumes responsibility and accountability for personal competence in practice (based on Principle 1 of the COE) and therefore should participate in continuing professional education in this area (Figure 2).
2. The nutrition and dietetics practitioner may make dietary supplements available to patients or clients with respect to the unique nutrition needs of the individual (based on Standard 1e of the COE). The nutrition and dietetics practitioner shall:
  - Avoid bias to ensure patient's or client's choice in selection and use of dietary supplement (based on Standard 1c of the COE).
  - Provide appropriate educational materials to patients or clients about dietary supplements.
3. The nutrition and dietetics practitioner provides disclosure of any financial relationship regarding the recommendation or sale of dietary supplements to patients or clients (based on Principle 2 of the COE). The nutrition and dietetics practitioner must disclose any financial arrangements with specific manufacturer(s) or supplier(s) to sell dietary supplements (based on Standard 2a of the COE).
  - Disclosure should be accomplished through face-to-face communication or by posting a written or digital notification that is at an appropriate reading level and language a prominent

location that is accessible by all patients or clients.

- Nutrition and dietetics practitioners should inform clients or patients on the availability of products being recommended as well as equivalent products on the market.
4. The nutrition and dietetics practitioner provides factual information regarding the availability of dietary supplements for purchase (based on Standard 2e of the COE) and does not advertise in a false or misleading manner (based on Standard 3d of the COE).
  5. The nutrition and dietetics practitioner maintains current knowledge regarding the regulation of dietary supplements such as<sup>8</sup>:
    - Definition of Dietary Supplements (FDA)
    - Standards for identity, strength, quality, and purity (ie, US Pharmacopoeia, National Sanitation Foundation [NSF] International)
    - Labeling issues (FDA)
    - Health claims, structure and function claims, disease claims (FDA, Federal Trade Commission)

## GUIDANCE RELATED TO SELLING OF SUPPLEMENTS

### Regulatory and Legal Considerations

With regard to selling dietary supplements, the Academy position paper also urges practitioners to be “aware of the regulatory, legal, and ethical issues of recommending and selling of micronutrient supplements.”<sup>8</sup> The Academy—CDR COE also underscores

the importance of complying with “all applicable laws and regulations” as part of a commitment to maintaining “integrity in personal and organizational behaviors and practices” (based in Principle 2 of the COE).<sup>2</sup>

1. The nutrition and dietetics practitioner understands the potential legal issues<sup>8</sup> and complies with legal restrictions related to selling dietary supplements to patients or clients (based on Standard 2b of the COE). Knowledge of the following issues is critical:

- Malpractice
- Authorized scope of practice
- Institutional policies (hospital, clinic, etc)
- Business insurance (coverage for this activity)
- Federal, state, and local laws and regulations, including zoning and any ordinance issues, business licenses, scope of practice of other health care professionals, inconsistencies between states, etc

### Ethical Business Practices

Exhibiting ethical business practices particularly when selling dietary supplements also necessitates limiting sales to products with a strong evidence base and safety profile. The American Medical Association’s Code of Medical Ethics Opinion 9.6.4 (Sale of Health-Related Products) suggests physicians who choose to sell products have an ethical obligation to “offer only products whose claims of benefit are based on peer-reviewed literature or other sources of scientific review of efficacy that are unbiased, sound, systematic, and reliable. Physicians should not offer products whose claims to benefit lack scientific validity.”<sup>9</sup>

Nutrition and dietetics practitioners choosing to sell dietary supplements need to investigate all aspects of

business practice. Any sales should be based on sound business practices. The following should be considered:

- 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

### Conflicts of Interest

Potential conflicts of interest are another key ethical consideration when selling dietary supplements. The Academy—CDR COE defines “conflicts of interest” as “a personal or financial interest or a duty to another party, which may prevent a person from acting in the best interests of the intended beneficiary, including simultaneous membership on boards with potentially conflicting interests related to the profession, members or the public.”<sup>10</sup> The American Medical Association also recommends full disclosure regarding physicians’ financial interest in “the sale of products either in person or through written notification and informing patients of the availability of the product or other equivalent products elsewhere.”<sup>9</sup>

Nutrition and dietetics practitioners who choose to sell dietary supplements are ethically bound to maintain competence in this area to educate patients and clients on the safety and efficacy of dietary supplements and the implications of dietary supplement regulations and to use the Academy—CDR COE and other resources supported by the organization to maintain conscientious and transparent business practices.

In conclusion, this guidance is intended to assist nutrition and dietetics practitioners with their commitment to uphold the Academy—CDR COE when counseling

patients or clients on the appropriate and safe use of dietary supplements.

### References

1. Thomson C, Diekman C, Fragakis AS, Meerschaert C, Holler H, Devlin C. Guidelines regarding the recommendation and sale of dietary supplements. *J Am Diet Assoc.* 2002;102(8):1158-1164.
2. Academy of Nutrition and Dietetics. Code of Ethics for the Nutrition and Dietetics Profession. <https://www.eatrightpro.org/-/media/eatrightpro-files/career/code-of-ethics/codeofethicshandout.pdf>. Published June 2018. Accessed June 10, 2020.
3. National Institutes of Health. Office of Dietary Supplements. Dietary Supplement Health and Education Act of 1994 Public Law 103-417 103rd Congress. [https://ods.od.nih.gov/About/DSHEA\\_Wording.aspx](https://ods.od.nih.gov/About/DSHEA_Wording.aspx). Accessed March 1, 2020.
4. US Food and Drug Administration. Dietary supplement products and ingredients. <https://www.fda.gov/food/dietary-supplements/dietary-supplement-products-ingredients>. Accessed March 1, 2020.
5. Cowan AE, Shinyoung J, Gahche JJ, et al. Dietary supplement use differs by socioeconomic and health-related characteristics among U.S. adults, NHANES 2011–2014. *Nutrients.* 2018;10(8):114.
6. Farina EM, Austin KG, Lieberman HR. Concomitant dietary supplement and prescription medication use is prevalent among U.S. adults with doctor-informed medical conditions. *J Acad Nutr Diet.* 2014;114(11):1784-1790.
7. US Food and Drug Administration. FDA statement. Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency’s new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA’s oversight. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>. Published February 11, 2019. Accessed March 25, 2020.
8. Marra MV, Bailey RL. Position of the Academy of Nutrition and Dietetics: Micronutrient supplementation. *J Acad Nutr Diet.* 2018;118(11):2162-2173.
9. American Medical Association. Code of Medical Ethics Opinion 9.6.4. <https://www.ama-assn.org/delivering-care/ethics/sale-health-related-products>. Accessed February 25, 2020.
10. Peregrin T. Identifying and managing conflicts of interest. *J Acad Nutr Diet.* 2020;120(3):445-447.

### AUTHOR INFORMATION

T. Peregrin is an editor and writer for a Chicago-based medical association and a freelance writer in Chicago, IL.

### STATEMENT OF POTENTIAL CONFLICT OF INTEREST

No potential conflict of interest was reported by the author.

### FUNDING/SUPPORT

There is no funding to disclose.