

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 518
(A-04)

Introduced by: California Delegation
Subject: Herbal Products and Drug Interactions
Referred to: Reference Committee E
(Stuart Gitlow, MD, Chair)

- 1 Whereas, Herbal preparations and “nutraceuticals” are widely used by patients; and
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3 Whereas, These products are biologically active, producing both known and unknown
4 interactions with prescription medications; and
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6 Whereas, Patients commonly regard these products as benign and compatible with their
7 prescription medications; and
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9 Whereas, The resulting drug interactions are serious and potentially life-threatening, including
10 interactions with antiretrovirals, anticonvulsants, antipsychotics and antidepressants,
11 antiarrhythmics including digoxin, oral contraceptives, hypoglycemic agents, and anticoagulants
12 (warfarin); therefore be it
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14 RESOLVED, That our American Medical Association urge manufacturers of herbal and
15 nutritional products to prominently label their products as having the potential to cause serious
16 adverse interactions with prescription and non-prescription medications (Directive to Take
17 Action); and be it further
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19 RESOLVED, That our AMA urge manufacturers of herbal and nutritional products to list any
20 known adverse interactions and include warning that unknown interactions may occur on
21 product labels. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than \$500 to develop communication to appropriate groups.

Received: 5/3/04

RELEVANT AMA POLICY

H-150.954 Dietary Supplements and Herbal Remedies.

(1) Our AMA will work with the FDA to educate physicians and the public about FDA's MedWatch program and to strongly encourage physicians and the public to report potential adverse events associated with dietary supplements and herbal remedies to help support FDA's efforts to create a database of adverse event information on these forms of alternative/complementary therapies.

(2) Our AMA continues to urge Congress to modify the Dietary Supplement Health and Education Act to require that (a) dietary supplements and herbal remedies including the products already in the marketplace undergo FDA approval for evidence of safety and efficacy; (b) meet standards established by the United States Pharmacopeia for identity, strength, quality, purity, packaging, and labeling; (c) meet FDA postmarketing requirements to report adverse events, including drug interactions; and (d) pursue the development and enactment of legislation that declares metabolites and precursors of anabolic steroids to be drug substances that may not be used in a dietary supplement.

(3) Our AMA work with the Federal Trade Commission (FTC) to support enforcement efforts based on the FTC Act and current FTC policy on expert endorsements.

(4) That the product labeling of dietary supplements and herbal remedies contain the following disclaimer as a minimum requirement: "This product has not been evaluated by the Food and Drug Administration and is not intended to diagnose, mitigate, treat, cure, or prevent disease." This product may have significant adverse side effects and/or interactions with medications and other dietary supplements; therefore it is important that you inform your doctor that you are using this product.

(5) That in order to protect the public, manufacturers be required to investigate and obtain data under conditions of normal use on adverse effects, contraindications, and possible drug interactions, and that such information be included on the label.

(6) Our AMA continue its efforts to educate patients and physicians about the possible ramifications associated with the use of dietary supplements and herbal remedies. (Res. 513, I-98; Reaffirmed: Res. 515, A-99; Amended: Res. 501 & Reaffirmation, I-99; Reaffirmation A-00; Reaffirmed: Sub. Res. 516, I-00; Modified: Sub. Res. 516, I-00)

H-295.902 Alternative Medicine

(1) AMA policy states that courses offered by medical schools on alternative medicine should present the scientific view of unconventional theories, treatments, and practice as well as the potential therapeutic utility, safety, and efficacy of these modalities. (2) Our AMA will work with members of the Federation to convey physicians' and patients' concerns and questions about alternative care to the NIH Office of Alternative Medicine and work with them and other appropriate bodies to address those concerns and questions. (CSA Rep. 12, A-97; Appended by Res. 525, A-98)