

AMA Policy on Dietary Supplements

Barry D. Dickinson, PhD
Director, Science Policy
Secretary, Council on Scientific Affairs

AMA "Policy"

- Resolutions and Reports adopted by the AMA House of Delegates
- "Policy" versus "Directive"
- Elements of the Public Record
- Policy Compendium (http://www.ama-assn.org/apps/pf_online/pf_online)

H-150.954 Dietary Supplements and Herbal Remedies

Urge Congress to modify DSHEA to require that Dietary Supplements:

- Undergo FDA approval for safety and efficacy.
- Meet standards established by USP for identity, strength, quality, purity, packaging, and labeling.

H-150.954 Dietary Supplements and Herbal Remedies

- Meet FDA postmarketing requirements to report ADRs including drug interactions.
- 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.

H-150.954 Dietary Supplements and Herbal Remedies

Product Labeling Disclaimer

“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.”

H-150.954 Dietary Supplements and Herbal Remedies

Labeling: Require manufacturers 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.

Advertising: Work with the FTC to support enforcement efforts based on the FTC Act and current FTC policy on expert endorsements.

H-150.954 Dietary Supplements and Herbal Remedies

Education

- Work with FDA to educate physicians and the public about FDA's MedWatch program.
- Encourage physicians and the public to report potential adverse events associated with dietary supplements and herbal remedies.

H-150.954 Dietary Supplements and Herbal Remedies

Education (cont.)

- Support FDA's efforts to create a database of adverse event information on these forms of alternative/complementary therapy.
- Continue efforts to educate patients and physicians about the possible ramifications associated with the use of dietary supplements and herbal remedies.

Directive

Resolution 501 (A-01)

- RESOLVED, That our AMA call for a coordinated effort by government, academics, and organized medicine to address the problem of the use of anabolic/androgenic steroids by students in the following ways.....

Public Comment

Products with Ephedra Alkaloids

- Encouraged FDA to initiate proceedings to remove dietary supplements containing ephedra alkaloids from the US Market.