

Health Claims and Dietary Supplements: Appropriate Criteria?

Alice H. Lichtenstein, D. Sc.
Professor of Nutrition - SNSP
Senior Scientist - JM USDA HNRC on Aging
Tufts University
Boston, MA

Should health claims be allowed on dietary supplements on a basis other than significant scientific agreement?

If so, what should that basis be and what are appropriate criteria for making decisions about allowing such claims?

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- Potential criteria
- Recent examples

Potential criteria:

- How do we establish a relationship between a nutrient and health?
 - Association
 - Intervention

Association:

- Do we have sufficient discriminatory power?
 - To assess nutrient intake
 - To attribute outcome to single factor

Association:

- Nutrient intake;
 - Accurate reporting
 - No bias in reported
 - Accurate nutrient data base

- Confounding;
 - Intake nutrient X associated with intake nutrient Y
 - Specific dietary pattern associated with lifestyle behavior

Intervention;

- Supplementation with vitamin E;
 - Null or positive effect on CVD
 - Null effect on cancer
- Supplementation with β -carotene/ vitamin A;
 - Null effect on CVD
 - Potential negative effect (β -carotene) on lung cancer

Intervention;

- Supplementation with folate;
 - Increase plasma folate levels
 - Decrease plasma homocysteine levels
 - Positive effect on neural tube defects
 - ? Effect on CVD
- Supplementation with vitamin C;

Complex

Intervention;

- Supplementation with vitamin C;
 - “Vitamin C supplement intake and progression of carotid atherosclerosis; the Los Angeles” Atherosclerosis Study (AP news release; 3-9-00)
 - Vitamin C supplement use associated with progression of arterial thickening
 - “Doctors warns against big doses of vitamin C during cancer treatment” (AP news release; 3-27-00)
 - Vitamin C MIGHT inadvertently protect tumors from radiation and chemotherapy

Intervention (continued);

- Supplementation with vitamin C;
 - “Vitamin C, E may protect the aging brain” - Honolulu - Asia Aging Study (Reuters news release; 3-28-00; Neurology 2000;54:1265)
 - Vitamin E and C supplements may protect against vascular dementia and may improve cognitive function in late life. No protective effect for Alzheimer’s dementia was observed.

Limitations of Knowledge Base

- Nutrients;
 - Essential
 - “Non-essential” biologically active compounds
- Interactions;
 - Physiological levels
 - Pharmacological levels

Open Questions:

How do consumer's use health claims on dietary supplement labels?

- Intended use
- Actual use

Do health claim statements on dietary supplement labels effectively communicate the message(s)?

- Accurately
- Understandability

Open Questions:

Were supplemental information to be added to dietary supplement labels how would it be interpreted?

- Would the language become too complicated and cumbersome?
- Could enough information be included to allow consumer to make an “informed” choice?
- What would the intended message be?
 - caveat emptor (buyer beware)

Open Questions:

Would health claims on dietary supplement labels;

- alter food choices
- displace conventional treatment?

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Risk/Benefit Ratio

Primum non nocere

(First, do no harm.)