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**CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®**

**Comments Before the White House Commission  
on Complementary and Alternative Medicine Policy  
on Information Development and Dissemination**

**Meeting in Washington, DC  
March 26, 2001**

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Mr. Chairman. Members of the Panel. Good afternoon.

I am Dr. Bill Soller, Senior Vice President and Director of Science & Technology of the Consumer Healthcare Products Association (CHPA), the 120-year-old trade organization representing the manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research and advertising sectors of the self-care industry.

CHPA has commented on numerous aspects of the evolving regulatory framework for dietary supplements, including aspects relating to claims, advertising, promotion, adverse experience reporting, Good Manufacturing Practices (GMPs), analytical methods, among other areas of interest to our members.

I addressed the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP; hereafter, the Commission) at its March 16, 2001, Minnesota Town meeting, where I commented on the need for the Commission to support actively the appropriate funding of the Food and Drug Administration (FDA) to implement its long-range plan for dietary supplements.

I repeat this plea today, noting that last week at a hearing of the House Committee on Government Reform Mr. Joe Levitt, director of the FDA Center for Food Safety and Applied Nutrition (CFSAN), indicated CFSAN seeks appropriations of \$6 million per year, starting with \$3 million, scaling up in the second year to about \$4.5 million, and reaching full funding in year three.

If Complementary and Alternative Medical (CAM) practitioners are concerned with quality and labeling issues affecting dietary supplements, then fiscal support to develop

reasonable standardization that appropriately implement the statutory provisions of the Dietary Supplement Health and Education Act (DSHEA) is vital to their interests, as well as those of consumers, patients, and, indeed, the industry.

I thank you for your invitation to me to return to the Commission to address the following questions pertaining to CAM information, specifically:

- Are current regulations adequate to assure consumer access and assure consumer safety?
- What are the barriers to consumers getting the information they need?
- What is the company responsibility in providing information to the consumer?
- Is the information provided to consumers accurate, adequate and useful?
- What recommendations the Commission should consider in their report to the President and Congress?

The answers to these questions should be set against the backdrop of Congress' intent in enacting DSHEA. Specifically, Congress wanted to facilitate providing consumers with products; information and education that would help promote health, and prevent disease through maintenance of healthy aspects of the structure and function of their bodies. In fact, Congress notes in the "findings" section of the Act, that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." Clearly, adequate truthful information transfer is vital to meeting the intent of DSHEA.

In addition, while my answers to these questions are made primarily from a dietary supplement standpoint, the general points that I make are applicable across other CAM product categories.

***Are current regulations adequate to assure consumer access and assure consumer safety?***

Yes, in relation to dietary supplements, both the FDA and the Federal Trade Commission (FTC) are on record stating they have the tools and the intention to regulate such products. For example:

- On March 25, 1999, by Food and Drug Administration Commissioner Jane E. Henney, M.D. before the House Committee on Government Reform stated: "FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA."
- Similarly, Ms. Jodie Bernstein, Director of the FTC Bureau of Consumer Protection, has given the Bureau's commitment to effective regulation of dietary supplements: "... FTC must and will continue to maintain an enforcement presence here, giving

priority to cases that present serious safety considerations or prey on the very sick and especially vulnerable consumer.”<sup>1</sup>

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) work together under a long-standing agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements<sup>2</sup>: FDA has the primary responsibility for claims on the product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale; FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials.

The Food and Drug Administration<sup>3 4</sup> has the power to:

- Stop any company from selling a dietary supplement that is toxic or unsanitary [see Food Drug and Cosmetic (FDC) Act, Section 402(a)];
- Stop the sale of a dietary supplement that has false or unsubstantiated claims [see FDC Act, Section 403(r)(6)];
- Take action against dietary supplements that pose “a significant unreasonable risk of illness or injury” [see FDC Act, Section 402(f)];
- Stop any company making a claim that a product cures or treats a disease [see FDC Act, Section 201(g)];
- Stop a new dietary ingredient from being marketed if FDA does not receive enough safety data in advance (see FDC Act, Section 413);
- Require dietary supplements to meet strict manufacturing requirements (Good Manufacturing Practices), including potency, cleanliness and stability [see FDC Act, Section 402(g)].

The Federal Trade Commission<sup>4</sup> has the power to:

- Enforce laws outlawing “unfair or deceptive acts or practices”<sup>5</sup> and false advertisements to ensure consumers get accurate information about dietary supplements, so they can make informed decisions about these products [see Federal Trade Commission (FTC) Act, Sections 5 and 12];
- Challenge and stop advertising that is not adequately substantiated (see FTC’s Deception Policy Statement and Advertising Substantiation Policy Statement);
- Investigate complaints or questionable trade practices; FTC can investigate either informally or formally, where it has strong compulsory investigative authority,

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<sup>1</sup> Bernstein, J.: the FTC and Dietary Supplements. FDLI Conference on Substantiating Claims for Dietary Supplement Advertising and Labeling, Washington, D.C., November 13, 1997.

<sup>2</sup> Federal Trade Commission, Bureau of Consumer Protection: Dietary Supplements: An Advertising Guide for Industry. 1998. (see [www.ftc.gov](http://www.ftc.gov))

<sup>3</sup> Taken from comments by Scott Bass, Esq. before Representative Dan Burton, Chairman of the House of Representatives Committee on Government Oversight, Oversight Hearing on the Dietary Supplement and Health Education Act of 1994, March 25, 1999.

<sup>4</sup> Soller, R. W.: Regulation in the Herb Market: The Myth of the Unregulated Industry. *Herbalgram* Feb.-Mar., 2000.

<sup>5</sup> An unfair trade practice is one that: causes or is likely to cause substantial injury to consumers; is not reasonably avoidable by consumers themselves; and not outweighed by countervailing benefits to consumers or competition (see FTC’s Deception Policy Statement and Advertising Substantiation Policy Statement at [www.ftc.gov](http://www.ftc.gov)).

including the power to require a respondent to produce documents, give testimony, or answer written questions [see FTC Act, Sections 6(a and b) and 9];

- Following its own investigation, negotiate a consent order or proceed through an FTC adjudication resulting in a cease and desist order, which can be quite broad in its scope (see FTC Act, Section 5);
- Seek civil penalties for violations of cease and desist orders (see FTC Act Section 5).

Given that both FDA and FTC have the tools they need to ensure dietary supplements are safe, effective, high quality and properly labeled and promoted, it is important for the Commission to consider support of the general position that both agencies should be adequately funded to ensure that DSHEA is appropriately implemented, consistent with Congress' intent in passing the statute.

***What are the barriers to consumers getting the information they need?***

The following is a categorical listing of barriers and facilitators to CAM information transfer to consumers:

Barriers

Rogue manufacturers making unsubstantiated claims  
Lack of research incentives  
Lack of a defined label warning policy within CFSAN<sup>6</sup>  
Too many information sources; no clear/central information authority  
Educationally-unprepared consumers, patients, and conventional healthcare practitioners  
Limited base of current science  
Limited standardization of CAM practitioner guidelines

Facilitators

Legitimate manufacturers making evidence-based claims  
NIH-sponsored research  
CFSAN's grant to IOM/NAS to develop a scientific approach to DS  
Health professional groups defining their roles as information multipliers  
Evidence-based CAM providers and consumer interest in visiting CAM providers  
Evolving science base for CAM products  
WHCCAMP recommendations to the President and Congress on licensing and continuing CAM education models

***What is the company responsibility in providing information to the consumer?***

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<sup>6</sup> On several occasions, CHPA has commented to FDA's Center for Food Safety and Applied Nutrition that the Center needs to articulate a clear labeling policy on when to warn. FDA has a long standing policy that has been used for consumer products, including OTC medicines and foods, which is that warnings (or decisions about product availability) should be "scientifically documented, clinically significant, and important to the safe and effective use of the product by the consumer." The importance of such a policy openly acknowledged by the Center cannot be underestimated, as it focuses public health decisions on the first hurdle, scientific documentation, as the basis for decision making. See also: [47 *Federal Register* 1982: 54754]; [53 *Federal Register* 1988: 46213]; and Soller, R.W.: When to Warn. *Regulatory Affairs Focus* Vol 2 Issue 10 Oct 97.

By law, companies must ensure that their labeling<sup>7</sup> and advertising is both truthful and not misleading,<sup>8</sup> and we believe claims made by CAM practitioners about CAM products, especially dietary supplements, should be held to the same standard.

***Is the information provided to consumers accurate, adequate and useful?***

Given that consumer- and patient-related labeling, advertising, and promotion must be by law both truthful and not misleading, the question is better re-framed in two parts:

- Is enforcement adequate to ensure the information provided to consumers is accurate, adequate and useful?
- Since both FDA and FTC acknowledge they have the statutory tools needed to implement the labeling and promotional provisions of the Food Drug Cosmetic Act and Federal Trade Commission Act, do FDA and FTC have the fiscal resources needed for adequately fulfilling their statute-derived enforcement functions, consistent with existing law?

Furthermore, CAM practitioners may distribute CAM-related products, including dietary supplements. It is therefore important that they be cognizant of the regulations and policies promulgated by FDA and FTC. For example, FDA has issued regulations pertaining to nutritional labeling, structure/function claims and health claims, to name two areas of specific interest.

FTC has re-issued a compilation of its policies, tailored for dietary supplement manufacturers (i.e., “*Dietary Supplements: An Advertising Guide for Industry*”). FTC notes in this policy guide, for example, that supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles. The FTC has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. Therefore FTC appropriately cautions that all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.

FTC’s D/S Advertising Guide has been supported by our Association. Our members, many of whom have also marketed medicinal products under the policies set forth in the guidance, recognize the value of this guide in helping to inform companies of FTC policies. CHPA has broadly distributed copies of the Guide to its members and held workshops with FTC officials to review it and respond to questions.

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<sup>7</sup> Food, Drug Cosmetic Act; Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417).

<sup>8</sup> The FTC’s truth-in-advertising law can be boiled down to two common-sense propositions: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.<sup>5</sup> A deceptive ad is one that contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC’s substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.

Companies complying with the law implementing regulations provide consumers with accurate and useful information on dietary supplements. Enforcement by FDA and FTC is intended to create a sufficiently broad environment of truthful and non-misleading information on consumer and professional products. Consequently, the issues are whether FDA and FTC have sufficient resources to fulfill their enforcement duties in this area, and whether CAM practitioners are sufficiently aware of their responsibilities in the context of promoting, for example, dietary supplements.

***What recommendations the Commission should consider in their report to the President and Congress?***

1. The Commission should provide a strong recommendation to the Administration to support for adequate funding for CFSAN to implement its long-range plan to regulate dietary supplements, consistent with DSHEA.

Funding of reasonable, appropriately-targeted regulatory activities by CFSAN would help address a significant barrier to consumers getting accurate, adequate and useful information – i.e., address the practices of rogue manufacturers who ignore the statutory and regulatory framework of DSHEA.

2. The Commission should consider encouraging FTC to develop industry and practitioner guides in the CAM product arena as was developed for dietary supplements.

Such guides are helpful to define the standard expected of industry, allowing well-intentioned manufacturers and practitioners to optimize their understanding of the ground rules.

3. The Commission should support a consistent standard for advertising and promotion of all CAM products, as explained in part herein for dietary supplements.