

Dietary Supplements;
Center for Food Safety and Applied Nutrition Strategy;
Public Meeting

Statement of the AIDS Health Fraud Task Force of California

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Provided by:

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Good day. I am Marcy Fenton, a registered dietitian and HIV Nutrition Advocate at AIDS Project Los Angeles, and past chair of the HIV/AIDS Dietetic Practice Group of The American Dietetic Association. I am here today representing the AIDS Health Fraud Task Force of California, of which I have been a member for over the last 3 years. The AIDS Health Fraud Task Force of California is a collaborative network of individuals, community-based organizations, and government representatives. It is organized to empower people affected by HIV to act on their own behalf in matters of health care and to reduce the risk of harm caused by both the lack of adequate and accurate information or by misinformation.

We appreciate the FDA for conducting this meeting and our opportunity to provide input. We agree with the need to ensure consumer access to safe dietary supplements that are truthful and not misleadingly labeled, with the emphasis on “safe,” “truthful” and “not misleadingly labeled.”

Our constituents are often confused about what is true and what is not true. We are subjected to a bombardment of marketing tactics, promotion of questionable claims, products that may or may not have the ingredients identified on the label, and ingredients that may be in there may be contrary to amounts listed on the label. There is a strong assumption that supplements on the market are safe, pure, and efficacious and are scrutinized by the FDA, just by virtue of the fact that they are allowed to be on the market. Indeed, some products have proprietary patents used in promotion that increases the confusion about its legitimate use and efficacy.

Increasingly, the boundaries between dietary supplements, foods, drugs and cosmetic products have become muddled and compromised and need to be clarified. As we define AIDS health fraud as the promotion of an AIDS related health product of treatment known to be false or unproven¹, we can see that the boundary between health fraud and the promotion of numerous dietary supplements has also become dangerously muddled and compromised.

We need a way to identify what is helpful, what is harmless, what is harmful and what is harmful when in combination with other nutrients or drugs or under certain conditions. As a group, we are challenged to find a straight forward, easy and reliable way to assess products risk and benefit that is also accessible to our constituents. We need an impartial evaluator and rating of these products and this has to be our top priority. In order to provide this, it will entail most, if not all the elements of the dietary supplement program FDA has already laid out.

It would entail a greater commitment to better soliciting, collecting, analyzing and educating about adverse effects of dietary supplements. MedWatch, the FDA Medical Products Reporting Program, includes special nutritional products, (e.g., medical foods, dietary supplements and infant formulas), as well as drugs, biologics and medical and

¹ The National AIDS Health Fraud Task Force uses the FDA definition for AIDS fraud:

"The deceptive promotion, advertisement, distribution or sale of articles, intended for human or animal use, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purpose. Such practices may be deliberate, or done without adequate knowledge or understanding of the article" (FDA, 1995).

radiation-emitting devices. However most people, healthcare providers, and even FDA employees are not aware that MedWatch is supposed to be collecting data on adverse events of dietary supplements as well as medicines. Usage of MedWatch is not encouraged, not easily accessible, nor is it user friendly. One step towards changing this would be to provide the 800 number and website address on each dietary supplement label. A way to track, compile and analyze reports with easy access is crucial.

Analysis of products would have to employ evaluation methods that are much better than what is now in place. FDA will need to outline criteria of significant scientific agreement . This concern was well addressed by The American Dietetic Association in their statement to you, June 8, 1999.

The need in the HIV community for fair, honest and complete risk-benefit analysis health and nutrient content and structure and function claims is of extreme importance. Our constituents are taking new potent lifesaving medications, some that have numerous contraindications to other medications, food components and dietary supplements. The antiretrovirals that are extending lives also do not work for everyone and we need to acknowledge and address the concern that dietary factors – components in food and dietary supplements – may be interfering factors in absorption and utilization . We need to have assurances that there are mechanisms in place to study and report interactions and the adverse effects between dietary supplements and these and other drugs. Indeed, some supplements may be a factor in promoting or

inhibiting the immune system, and we really need to know and stop being passive about the situation. We need to know which supplements are safe, at which doses, under what conditions.

The direct marketing of these products has been an ongoing serious issue that still needs attention. I can tell you that in my position, I am solicited to promote, purchase or recommend products with some frequency. Recently I received calls that "*this product* has cured AIDS in children in Guatamala," "*that product* is a cure for cancer in Indonesia." We are concerned that the marketing materials and promotion are not accurate and in accordance with the label. To decipher claims and advertising promotions requires a level of knowledge and information that most individuals do not possess, mostly because the advertising is misleading and secondly, the substantiation is so poor to start with.

One last comment, in addition to including the MedWatch 800 number and website address on each dietary label, additional information on the label should include the maximum dosage, appropriate use and contraindications. Labels should be large enough to be read without straining.

Thank you for your time today. The AIDS Health Fraud Task Force of California looks forward to working with you in this important area.