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Let CAM Continue to Develop Freely

To: **Food and Drug Administration**
From: Natural Solutions Foundation
Re: FDA Docket No. 2006D-0480

These comments are submitted by Major General Albert N. Stubblebine, Rima Laibow, MD and Ralph Fucetola, JD on behalf of **Natural Solutions Foundation** with regard to the Food and Drug Administration's draft "*Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.*" They are submitted with reference to the request of FDA for comments on the proposed Guidance stated at: http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-3259.htm .

The Natural Solutions Foundation is a tax exempt, recognized nongovernmental organization active in the United States and internationally, communicating Natural Solutions to the many health problems caused by government intervention, with emphasis on FDA and *Codex Alimentarius* over-regulation of natural foods and supplements.

Complementary and Alternative Modalities (CAM), including traditional remedies and nutrition to achieve and maintain a healthy status, are preferred by many Americans to so-called "standard" allopathic medical treatment, primarily due to the well-documented iatrogenic death and disabilities, the dangerous side effects and persistent failures of the so-called "standard" model. The Dietary Supplement and Natural Remedies market has grown to over $28 billion dollars annually as Americans consistently vote with their dollars choosing CAM products out of un-reimbursed funds.

The Foundation urges the FDA to take into account an important legal distinction that FDA appears to ignore totally in the draft Guidance. That distinction is between "treatment of disease" and "therapies that may benefit." In keeping with that distinction, explained below, it is suggested that the Guidance be titled, "Guidance for Industry on Complementary and Alternative *Modality* Products and Their Regulation by the Food and Drug Administration." CAM is not "medicine", does not rest in medical models and allopathic methods and does not seek to be considered "medicine." In fact, CAM seeks to shed the appearance of "medicine" which is not in keeping with CAM traditions and activities.

We request the FDA take the following steps: (1) hold public hearings on the proposed Guidance; (2) formally revise the Guidance title to replace the word "Medicine" with "Modality" and (3) use of the terms "therapy" and "therapeutic" with reference to Complementary and Alternative Modality health practices, instead of the words "treat" and "treatment of disease" which are used exclusively in the draft Guidance. The terms "treat" and "treatment of disease" are, in fact, antithetical to CAM therapies.

CAM health practices can be generally defined as traditional or other practices that are used by individuals, often for self-help, to achieve and maintain a healthy status, either on their own or complementary to standard medical care. These practices do not include the potentially dangerous use of invasive techniques and toxic drugs that are the sole province of licensed medicine. They do, however, include developing therapies and nonstandard approaches that are outside the scope of licensed medicine. Such approaches as Nutrition, Homeopathy, Hands-on-

Healing, Magnetics, Sound Health, Energy Therapies, Biofeedback, Meditation, Breath Work, Reiki, Chi Gong, Tai Chi and Herbology are examples of complementary and alternative therapeutic practices. Traditional Chinese, Ayurvedic medicine or folk remedies and "Dr. Mom" home remedies are also examples of CAM practices. These practices aim, in the words of the late Philip J. Hodes, PhD., at "more efficient physiological integration and function of the human organism, leading to optimal wellness." This definition is the polar opposite of non CAM practices which seek to suppress or ameliorate symptoms without an approach to optimal wellness.

The terms “therapy” and “therapeutic” do not occur, for example, in the context of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Rather, that statute, passed by unanimous Congressional Consent, tells us that Dietary Supplements may not “diagnose, treat, cure or prevent” any disease. It does not specifically forbid the use of the word “therapy” (or “therapeutic”). Under the Supreme Court’s rule in the Thompson v Western Medical case, we should expect that these words would not be forbidden by the Courts and should not therefore be overtaken by the regulators.

Further, the Code of Medical Ethics of the American Medical Association also acknowledges an independent use of the term “therapy.” The original Hippocratic Oath, with its injunction to "Do no harm." has been replaced by a complex Code detailing the relationship between physician and patient and alternative practitioner. Changes made during the early 1990's were inspired by anti-trust lawsuits brought (and won) during the 1980's by chiropractors and other non medical practitioners. These changes are just now becoming recognized by regulators and courts.

While "treatment which has no scientific basis" remains condemned (Opinion 3.01), under Opinion 3.04, physicians are free to "refer" a patient "for therapeutic or diagnostic services to another physician, limited practitioner or any other provider of health care services permitted by law to furnish such services, whenever he or she believes that this may benefit the patient." Thus, unscientific "treatment" is distinguished from "health care services permitted by law." "Treatment" -- which means the use of standard medicine and surgery to "cure" disease -- is distinguished from other health care services (therapies) which need only meet the lesser "may benefit" standard. While physicians "prescribe" treatments for disease, therapies that may benefit may be subject to "referral" thereby further indicating the distinction. Thus, for example, Dietary Supplements that support normal structure and function to support therapeutic outcomes can be seen to complement licensed medicine, but not to be held to its strictures, nor limited in its practice to licensed physicians. Since such therapies are not prescription services, members of the public may choose such services without the permission of their physician. Purveyors may restrict sale of therapeutic products to physicians, complementary practitioners, exercise and health care professionals, although they should not be required to do so.

We have analyzed the word “therapy” and the similar word “therapeutic” because these words are not forbidden by DSHEA and are referenced by the AMA Ethics Code. We recommend “Therapeutic Nutritionals” for alternative practices centered on Nutrition. We recommend the use of the qualifying word, “Nutritional” in this context to make it completely clear that the practitioner is not offering “treatment of disease.”

The claims made for Therapeutic Nutritionals must, of course, be allowed Structure and Function Claims. Thus, for example, under current law as interpreted by the FDA, one cannot claim that a

nutrient lowers cholesterol levels – since there is now a "disease" of hypercholesterolemia – but can claim that a nutrient maintains normal cholesterol levels for persons with normal cholesterol. A purveyor may say that a certain combination of multivitamins was designed to maintain normal structure and function for a person with diabetes, but not that the combination "treats" diabetes or affects the blood sugar level. Similarly, any Health Claim made for any alternative practice must meet the FTC standard of "truthful and not misleading" and must be based on standard commercial substantiation criteria.

CAM products are intended to benefit normal structure and function and are not prescribed as treatment for medical or psychological conditions, nor for diagnosis, care, treatment or rehabilitation of individuals, nor to apply medical, mental health or human development principles."

As the High Court said in Thompson, "**We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.** * * * Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring … a warning..."

What is the proper level of substantiation for CAM nutrient or health claims? It is not the "significant scientific agreement" required of drug claims, but rather, the general "competent scientific evidence" standard that applies to all commercial claims. That does not imply that purveyors need to have multiple double-blind experiments (as may be required for drug approval). Substantiation merely needs to be competent and scientific. We urge this to include research studies (which is when scientists review the work of others and apply it to specific questions) and clinical trials (which may be as formal as double-blind, placebo controlled investigations but need not be, since multiple variables, like those involved in CAM practices designed to promote optimal health, are not well studied by double-blind, placebo controlled investigations) as well as traditional knowledge, clinical case studies, observational reports and clinical experience. All of these sources of information and experience have a role to play, but ultimately, such substantiation must rest on the informed professional opinion of some credentialed or appropriately experienced person who can (in the case of Dietary Supplements, for example) sign onto the Structure and Function Claims Notice to the FDA, attesting that "the notifying firm has substantiation that the Statement to which this Notice applies is truthful and not misleading." (Regulations under 21 U.S.C. 403(r) (6)).

The Natural Solutions Foundation favors a market approach to these issues and urges the FDA to reduce regulation to those minimum levels that will encourage the continued rapid development of CAM approaches. Especially when dealing with Dietary Supplements and Traditional Remedies, we are dealing with foods **which, as foods, are presumed to be safe**. There is no need for the high level of regulation that is required for the dangerous and invasive drugs and techniques of so-called "standard" medicine. Even with this stringent level of oversight, drugs are a major cause of death in every developed country while CAM remedies are an insignificant-to-absent cause of death world-wide. Rather, this is a situation where the public is best served by a policy of Laissez-Faire: allow CAM to develop freely in the public interest.

Throughout the world today people are looking to traditional methodologies and leading-edge CAM techniques because they offer alternatives to toxic, expensive drugs with their

dangerous side effects, un-manageable and unreasonable costs and other invasive technologies of modern medicine. This search for alternatives is protected by the fundamental right of individuals to communicate and learn; to heal and be healed. This has been settled law for over a hundred years.

"The state has not restricted the cure of the body to the practice of medicine and surgery -- allopathy, as it is termed, -- nor required that, before anyone can be treated for any bodily ill, the physician must have acquired a competent knowledge of allopathy and be licensed by those skilled therein. To do that would be to limit progress by establishing allopathy as the state system of healing, and forbidding all others. This would be as foreign to our system as a state church for the cure of souls. All the state has done has been to enact that, when one wished to practice medicine or surgery, he must, as a protection to the public [not to the doctor], be examined and licensed by those skilled in surgery and medicine. To restrict all healing to that one kind -- to allopathy, excluding homeopathy, osteopathy, and all other treatments -- might be a protection to doctors in surgery and medicine; but that is not the object of the act, and might make it unconstitutional, because creating a monopoly." North Carolina's Supreme Court in State v MacKinght, 42 S.E. 580, 1902 at p 582.

Costs, safety and, most of all, liberty, require that the distinction be made and maintained by the FDA between “treatment” and “therapy” if the US Constitution and public are to be served.

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Respectfully submitted,

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