Alternative Therapeutic Practices and the AMA Code of Ethics

This essay considers the use of the terms “therapy” and “therapeutic” with reference to alternative health practices. It compares those terms to the term-of-art, "treatment of disease." Alternative 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 province of licensed medicine. They do, however, include developing therapies and nonstandard approaches that are outside the scope of licensed medicine. These are sometimes referred to as "Complementary and Alternative Modalities" (CAM).

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 Philip J. Hodes, PhD., at "more efficient physiological integration and function of the human organism, leading to optimal wellness." [From a private conversation with Dr. Hodes, 15 March 2006.]

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 unanimously by Congress, 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.

Further, the Code of Medical Ethics of the American Medical Association has also begun to acknowledge 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 during the 1980's by chiropractors and others. 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 are not required to do so.

I 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. I can recommend “Therapeutic Nutritionals” for alternative practices centered on Nutrition. I 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, 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 claim made for any alternative practice must meet the FTC standard of "truthful and not misleading" and must be based on reasonable substantiation. Telling people what an alternative practitioner does NOT do is as important as telling what is done. It is therefore important to include the proper Disclaimers for any use of alternative practices.

Nutrient purveyors must always include the Statutory Disclaimer, “These statements have not been evaluated by the Food and Drug Administration. Not intended to diagnose, treat, cure or prevent any disease.” For all Alternative Practitioners I would also recommend a more specific additional disclaimer, “_____ is intended to benefit normal structure and function and is 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 alternative practice 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 necessarily mean that purveyors need to have multiple double-blind experiments (as may be required for drug approval). Such substantiation just needs to be competent and scientific. This means research studies (which is when scientists review the work of others and apply it to specific questions) and clinical trials (which can be as formal as double-blind, placebo controlled investigations) as well as traditional knowledge and clinical experience all have a role to play, but ultimately, such substantiation must rest on the informed professional opinion of some credentialed 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)).

Many times people seek to make claims based on Traditional Uses. This is what the FTC says,

> "Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. A number of supplements, particularly botanical products, have a long history of use as traditional medicines in the United States or in other countries to treat certain conditions or symptoms. Several European countries have a separate regulatory approach to these traditional medicines, allowing manufacturers to make certain limited claims about their traditional use for treating certain health conditions. Some countries also require accompanying disclosures about the fact that the product has not been scientifically established to be effective, as well as disclosures about potential adverse effects. At this time there is no separate regulatory process for approval of claims for these traditional

> medicine products under DSHEA and FDA labeling rules. * * * The advertiser should also make sure that it can document the extent and manner of historical use and be careful not to overstate such use. As part of this inquiry, the advertiser should make sure that the product it is marketing is consistent with the product as traditionally administered. If there are significant differences between the traditional use product and the marketed product, in the form of administration, the formulation of ingredients, or the dose, a "traditional use" claim may not be appropriate."

Here is a sample of a Traditional Use Disclaimer, "This information is based on Traditional [ex., Chinese Medicine] which often uses natural herbs and nutrients to support health. The information about these ingredients has not been evaluated or approved by the FDA and is not based on scientific evidence from US sources. This product is intended to support general well-being and not intended to treat disease. If conditions persist, please seek advice from your medical doctor."

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*.

The AMA Code of Ethics and the other authoritative sources cited in this article lead to the reasonable conclusion that Alternative Therapeutic Practices are not only *not* forbidden, but that they have achieved acceptance by the public and the legal system.