

Naturopathic Medicine and the FDA Guidance on CAM

Many of the 100 million Americans who use Complementary and Alternative Medicine (CAM) on a regular basis, practitioners, students and prospective students are expressing concern over a recent FDA publication on CAM products.

Is the recent paper entitled, *Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food & Drug Administration* guidance on CAM paper a cause for concern? It is sure causing alarm among health freedom advocacy groups, interest by health professionals and consternation for those who use Complementary and Alternative Medicine on a regular basis. More than 100,000 people have responded to the FDA on this subject, so it certainly has people's attention.

Is this the opening salvo in a new battle to make supplements available by prescription only? Will nutritional supplements and botanical medicines be produced by Big Pharma and prescribed by allopathic doctors? Let's read through the FDA document and come to some informed decisions together.

First let me point out 2 important facts:

1. The 1993 DSHEA act (Dietary Supplement Health Education Act) already gives the FDA the authority to regulate dietary supplements. This includes creating and enforcing standards and good manufacturing practices. It also limits the claims manufacturers can make on their products.
2. The FDA and the Federal government, in general, do NOT regulate *any* health profession. Licensure, scope of practice and prescribing privileges are strictly determined by state statute. Even if nutritional and botanical supplements became "prescription only" Naturopathic doctors would retain the right to prescribe them in the vast majority of the states in which the profession is licensed and would certainly spur legislation in others.

The FDA's stated purpose in publishing the Guidance is to restate its oversight of CAM products in two ways. First, that "a product used in a CAM therapy or practice *may* be subject to regulation as a biological product, cosmetic, drug, device or food" if they are promoted as agents to treat or cure a specific disease or health condition. For example if a botanical extract from Cranberry (*Vaccinium Macrocarpon*) is sold with a structure/function claim, to "promote urinary tract health" it is a dietary supplement. If the claim is made that the product is to "treat urinary tract infections" it is considered a drug. The supplement must meet safety (for contaminants or adulterants) and quality (that the herb in the bottle is the same as the one on the label) standards. The drug must apply for a New Drug Application (NDA) and meet the elaborate, lengthy and expensive research criteria that follows. If a legally sold botanical or nutritional supplement is promoted, it is with the structure/function claim-- *not* a drug claim.

Second, that the Food, Drug and Cosmetic and Public Health Service Acts already do regulate the vast majority of foods and supplements. Juices are considered foods and must be free of harmful bacteria and other potential toxins. Supplement manufacturers must adhere to Good Manufacturing Practices (quarantining raw materials until tested for contaminants, ensuring that

the quantity and quality of the product matches the description and dose on the label). CAM devices must be safe, e.g., acupuncture needles must be sterile.

The FDA document points out that even though it may regulate a CAM product it does not regulate the CAM practitioner. For example, it regulates the production and sales of acupuncture needles but not the acupuncturist who uses them; the herbs that a Botanical company sells, but not the Naturopathic doctor who prescribes or recommends them.

Philip Chao, Senior Scientific Advisor to the FDA Office of Policy and Planning, and co-author of the Guidance, document was recently interviewed by John Weeks, longtime editor of “The Integrator”. In response to some of John’s pointed questions, Chao pointed out that the document specifically states that it “does not create or confer any rights for or on any person and does not operate to bind FDA or the public.” Nor does it regulate practitioners ... we do not regulate how practitioners prescribe products. The practice of medicine is a state matter. To read this excellent interview, please visit The Integrator Blog special issue on this topic (http://theintegratorblog.com/site/index.php?option=com_content&task=view&id=274&Itemid=189)

The FDA Guidance document does not break new ground. There are, however, a considerable number of people who view any new pronouncement by the Agency as cause for alarm. For the 100 million Americans who use, practice or study Complementary and Alternative Medicine, we are fortunate that the FDA is overseeing the quality of the products we use and consume, yet must remain vigilant that our right to use them is never abrogated.