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CAM THERAPIES IN THE USA IN TURMOIL FOLLOWING RELEASE OF FDA DRAFT GUIDANCE DOCUMENT

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By the Alliance for Natural Health (ANH)

What's all the fuss about?

In December 2006 the FDA finalised a draft guidance document (Docket No. 2006D-0480] entitled "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration". The document seeks to provide "industry" – practitioners and suppliers of products – the FDA's current thinking on the relationship between existing laws and the practice of 'complementary and alternative medicine' (CAM).

The document has generated everything from internet hysteria, much of it triggered by a misinformed take circulated in early April by the Natural Solutions Foundation through to a non-plussed 'this guidance document changes nothing' approach, which is keeping the heads of others firmly planted in the sand.

Among all the hype, the ANH's US-based affiliates, the American Association for Health Freedom and the Health Freedom Foundation, issued a statement on the draft guidance document on April 19. Click here to read the full statement. You'll notice that the AAHF uses none of the 'it's all over tomorrow' language, yet hints at some real concerns over the FDA's guidance. Once the AAHF's lawyers have completed their full assessment of the document, we'll be hearing more from them. The AAHF should also be commended for being successful in their appeal for an extension to the submission date for comments. Another take came from the National Health Federation in the US, for which Dr Rob Verkerk from the ANH acts as a scientific advisor, particularly on Codex matters. Lee Bechtel, the NHF's lobbyist, provided a detailed account of the Guidance, stressing the fact that it has no legal sway at all. You can read Lee's views on the NHF website in his release entitled *Much Ado About Nothing* (27 April 2007).

When you spend as much time as we do in the ANH looking at legislatures around the world, and looking at trends within those legislatures, patterns become apparent. It is the pattern that is apparent within the FDA's CAM Guidance that we find to be of greatest concern. Clearly, the Guidance has no direct legal impact in itself and does not allude to any specific changes, but it certainly points towards the often-feared, full implementation of the Dietary Supplement Health & Education Act [DSHEA] – as well as more liberal use of the Public Health Service (PHS) Act.

Since 1994, a large number of American natural health suppliers, and many thousands of 'practitioners' that have relied on use of natural products for healthcare purposes, have lived in the belief that the framework DSHEA would allow them to continue using therapeutic natural products for ever and a day. This actually has never been true, as DSHEA, since its passage in 1994, has always contained language that could make this legislation a lot more onerous than it is perceived to be. The FDA's post-market oversight authority alone, together with its intentions relating to quality and purity (Good Manufacturing Practice) of products, could have been anticipated at the outset to pose significant challenges to many sectors of the natural products industry.

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Dietary supplement or drug?

One of the most worrying aspects of the FDA's Guidance is the fact that it regularly refers to the possibility of licensed drugs being prescribed by practitioners. In essence, it indicates that products used in CAM practice might be categorised as foods or drugs. It does this in the context where the vast majority of natural products used in alternative medicine are in fact dietary supplements, not drugs!

A key criterion that turns a product that might readily be taken to be a food (which includes dietary supplements as classified by DSHEA) into a drug, is its intended use. Let's remind ourselves of the definition of drug, under the Federal Food, Drug, and Cosmetic (FFDC) Act: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"

The FDA Guidance speaks in plain language. We all know just how healthy raw vegetable juices are, but we also aware that when a practitioner deals with a cancer patient, the practitioner is very likely to want them to recommend raw vegetable and fruit juices as part of the recommendations offered. This could get them into a lot of trouble, as suggested by the following quote directly from the Guidance (page 2):

"If the juice therapy is intended for use as part of a disease treatment regimen instead of for the general wellness, the vegetable juice would also be subject to regulation as a drug under the Act."

It's hard to think only of 'general wellness' when someone is dying of cancer. A good practitioner tends to be thinking much more about: how do I modulate the immune system? How do I increase serum antioxidant levels? How do I help the patient re-establish effective self-healing mechanisms in the body….

In short, although it might be easy for products in the retail sector to stick within the structure/function claim constraints of DSHEA, the most difficult thing for any CAM practitioner is the context in which he or she practices. The FDA has the legal power to say that any practitioner who is seeing patients or clients with serious diseases, and are then providing recommendations, is effectively providing products which are "intended for" the "mitigation, treatment or prevention of disease". If this were to be the interpretation, any use of dietary supplements by practitioners could be considered illegal. This is at least as worrying as some of the developments and legal and regulatory interpretations going on in Europe, with which we are very familiar.

There is however a more hopeful interpretation given on page 12 of the Guidance, where the example of cranberry for urinary tract infections is explored. Fortunately the Guidance implies that the context of the practitioner-patient is probably not sufficient to constitute "intention for disease treatment", which would otherwise make cranberry products drugs. The Guidance proffers that it is the label claim that is the deciding factor. If you stick within the area of structure/function claims and state on the label "maintains the health of the urinary tract" your product will still remain a dietary supplement. However, should your product carry a claim like "prevent urinary tract infections" you will then have ventured into drug territory.

However, this interpretation in the Guidance could perhaps be seen as nothing more than a temporary fix. Wait until Codex has followed the European Union on its path towards limited health claims based on "generally accepted evidence" – and the range of claims that might be allowed could reduce dramatically. How can this system ever allow for claims for emerging science? How can you ever have an innovative product that is then not forced into a drugs regime? Some might refer to this as a key part of the game plan for a regulatory 'stitch up' for natural products.

FDA Guidance pushes CAM towards 'drug' classification

Although there's nothing new in the Guidance in terms of legislation, it is worth remembering that DSHEA has never been fully implemented. It's also worth reminding ourselves that DSHEA always set out to give the FDA powers to jump on any product that they deem to pose an "unreasonable or significant risk of illness or injury." None of us have any problem with this in principle – we only have a problem if they use flawed science or evidence to construct a case which incorrectly classifies a product or treatment as unsafe.

Now this is where you really need to take stock – and see what's going on outside the US, with full support from the FDA officials that populate the US delegation in the Codex Committee on Nutrition and Special Dietary Uses. This Committee is presently engaged in 'copy-catting' a flawed system of risk assessment being developed by the EU that says that the safe maximum (supplement) level of vitamin C might be just 1000 mg, or 10 mg of vitamin B6. It's no better for other vitamins – the overall approach is flawed – and this is something the ANH has been working at exposing for several years.

But these 'upper levels' – once rubber stamped by Codex, and the FDA delegation that is party to it, will act as the internationally agreed borderline as to what is considered safe as a food – or a dietary supplement. These 'upper safe levels', we are told, have been agreed by international, qualified experts, most of which have strong ties, it seems, with the drugs companies. It's therefore not at all difficult for a regulator to make the case that dietary supplements marketed at doses above this internationally agreed borderline are unsafe!

With this knowledge, read the following paragraph in the FDA's latest Guidance (page 7; taken from Section 201 of the FFDC Act, of which DSHEA is part) which defines the category of "new drug" and see what you think:

"Any drug…the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof…"

It's always a particular worry when you are reliant on those that are "experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs." These so-called experts have traditionally been some of the biggest enemies of natural healthcare! They tend not to be keen on seeing people getting better through the use of unpatented natural products. It goes without saying that the biggest problem with a drug or new drug classification is the costs involved to meet the very substantial clinical investigations required to prove safety and efficacy. This is simply prohibitive to any but the very largest companies. It's obviously core business for the drug companies.

DSHEA *vs* the Public Health Service Act

While all eyes have been focused on DSHEA and the FFDC Act, the Guidance reminds us of the importance of the Public Health Service (PHS) Act. It emphasises that Section 351(a)(1) of the PHS Act firmly includes "biological products" under its remit, and this classification might easily sweep up a diverse range of products including probiotics, hormonal/glandular products and animal-based Ayurvedic and other traditional medicinal products. Again, we must recognise that the FDA has the legal firepower to make such classifications, and the Guidance even states that probiotics could "conceivably" be classified as "biological products" under the PHS Act. Should this happen – all such products would require licensing – more money, more studies, more

red tape, more prohibition for the majority of suppliers. The FDA reminds us of its powers when it tells us: “the PHS Act gives us the authority to establish requirements for the approval, suspension, and revocation of biological product licenses.” [See pages 1 and 13 from the Guidance, in particular].

Totality of US legislative powers

There is no doubt that the Guidance provides further evidence that the FDA is intent on tightening the regulatory burden for companies, by bringing in fuller implementation of existing laws, through the FFDC and PHS Acts. There is support for this in Congress, with Kennedy’s Food & Drug Administration Revitalization Act (S1082) being the latest example.

In the meantime, lets add to this the additional powers already conferred to the FDA through the Trilateral Cooperation Charter (TCC) whereby the USA, Canada and Mexico have agreed to cooperate in order “to increase communication, collaboration, and the exchange of information among the three countries in the areas of drugs, biologics, medical devices, food safety and nutrition to protect and promote human health”.

The most worrying aspect of the TCC is the way in which the three counties have agreed to define ‘health fraud’. In essence, they have provided such a wide definition of health fraud that it potentially allows the regulators in each of the three countries to go after any company making therapeutic natural health products – even if they present no harm to consumers and contain no false or misleading information on their labels or associated marketing material. In fact the FDA claims over 730 prosecutions since the TCC’s inception in 2003 through to just October 2005.

The TCC defines health fraud as follows, but note in particular the second part of the definition we have bolded for emphasis:

“The false, deceptive, or misleading promotion, advertisement, distribution, sale, possession for sale, ***or offering for sale of products or provision of services, intended for human use, that are represented as being safe and/or effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), to rehabilitate patients or to provide a beneficial effect on health****.”*

Suddenly – any product that is both safe and gives rise to beneficial effects on health i.e. the vast majority of dietary supplements, become potential subjects of health fraud. Is the development of a new regional trading block in North America, for which the TCC provides a taster, going to be the beginning of the slippery slope towards global harmonization, led by Europe, enacted through the Codex Alimentarius Commission, and policed by the World Trade Organization? It looks like it.

Parallels with Europe

European citizens have seen over the last decade a remarkably rapid transfer of power from sovereign states to unelected officials within the European Commission. A democratically elected European Parliament exists, but has very limited powers and it is regularly overruled by the European Commission. We have seen the introduction of the EU Food Supplements Directive in 2002, the first part of a framework which aims to harmonise food supplement laws across all 27 EU Member States. The ANH has challenged the first part of this law and, nearly two years after the case was ruled on in the European Court of Justice, we are beginning to see results. This progress has occurred following the submission of test dossiers for a wide range of vitamin and mineral ingredients in February/March 2007.

But the real snake pit for dietary supplements in Europe is the Human Medicinal Products Directive. This is where all products that don't make it into the Food Supplements Directive fall. Just like the definitions of a 'drug', 'new drug' and 'health fraud' in the USA, the definition of a drug in this EU Directive is unbelievably wide. In fact it makes water a drug. On top of this, the most recent amendment of this Directive (2004) has broadened its scope to the extent where this Directive has supremacy over any other Directive, should any product meet the definitions within this Directive as well as any other. All food supplements so happen to fit the definition of both the Human Medicinal Products Directive and the Food Supplements Directive.

This type of supremacy for drug laws seems to be a central part of the international 'game plan'. The plan appears to be about limiting the scope of laws maintaining natural health products as foods, increasing the scope of drug laws – and simultaneously – giving more and more power to medicine regulators, who we know, worldwide, tend to work very closely with their friends in the pharma companies. Codex provides the framework to control a limited range of substances as foods, which will automatically exclude any foods that happen to be therapeutic in nature, while everything else falls within the scope of drug laws. Here, only the the pharmas have sufficiently deep pockets to play ball. You see, the natural health stitch-up is complete. Unless of course we all complain like we've never complained before....

Telling the FDA what you think

The FDA want to have comments on their Guidance. These will be best delivered through associations, clinics and other representative bodies, rather than by individual consumers. This is because this is Guidance for industry – so it is industry that will be listened to most.

Owing to appeals by our affiliates, the American Association for Health Freedom and Health Freedom Foundation, as well as by National Health Freedom Action and others, we had been led to believe that the the deadline for public comment had been extended from Monday, April 30 to Tuesday, May 29 2007.

*[**Urgent Update**: There is now conflicting information regarding this extension, with the FDA claiming 'employee error' and stating that Monday, April 30 stands. The American Association for Health Freedom and Health Freedom Foundation continue to lobby Congress on this issue - watch this space!]*

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Electronic comments should be submitted to: http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/dockets/ecomments.

The Guidance and comments already submitted can be viewed at: http://www.fda.gov/ohrms/dockets/dockets/06d0480/06d0480.htm