

The FDA Email Alert Controversy

By Richard Mandelbaum, RH (AHG)

Earlier this year an email began circulating around the internet, including the NEHA list-serve, alerting the public that the FDA was on the verge of outlawing all herbs as "untested drugs" as well as forbidding the use of herbs and other complementary modalities to all but licensed MDs.

Here is the original email alert:

There is a crisis in health freedom. On April 30, 2007, the FDA will close the public comment period on a "Guidance" which will classify every alternative practice as medicine so that only licensed physicians can carry out the procedure AND vitamins, minerals, herbs, etc., will suddenly become "untested drugs" which will be forbidden.

Bad? Real Bad! But public outcry can stop this assault on your health and your freedom.

Spread the word! Tell everyone in your Circle of Influence, professionals, alternative practitioners, nutrient and herb companies, everyone! Let them know how important their participation is to make sure the FDA backs off from this repressive course.

*Please share this link with them and urge them to take action:
<http://tinyurl.com/2u7ghc>*

Yours in health and freedom,

*Rima E. Laibow, MD
Medical Director
Natural Solutions Foundation
www.HealthFreedomUSA.org*

*Take action now at
http://www.democracyinaction.org/healthfreedomusa/campaign.jsp?campaign_KEY=7185&t=*

There is a profound need for all of us working with herbs and other holistic approaches to be skeptical, vigilant, and proactive in making sure that government agencies and, even more so, Congress, make no moves to limit our rights to purchase and use herbs,

and to work as herbalists. However, the truth is that a basic understanding of the regulatory status of herbs in the U.S. would have been enough for anyone to be able to dismiss this email as both alarmist and inaccurate. That basic understanding would also have been enough for anyone to read through the FDA draft guidance and, despite some possible minor concerns about it, to realize that overall it simply restated what is current law and practice.¹

As I wrote in my original post on the NEHA list-serve, a false alarm like this can do a lot of harm, and unfortunately seems to have done so in both confusing people who support holistic medicine, and in portraying herbalists and other members of the holistic community as ill-informed conspiracy theorists.

Many NEHA members no doubt followed the flurry of often contradictory emails that subsequently went back and forth across the internet. The vast majority of reactions to the FDA's draft guidance ranged from a shrug, based on the fact that the document did not represent any substantive change from the status quo, to some degree of concern about the terminology the FDA used and the confusion the publication of the draft had generated.² No one, however, including advocacy organizations quite critical of FDA and strongly in favor of free access to complementary healthcare, agreed with the alarmist nature of the original email alert.

The FDA document most likely would have received almost no attention if not for that irresponsible alert – an internet search I conducted soon after the alert began to be circulated found that almost no organization had posted any mention of it at all on its website. If something of this magnitude were truly being considered by FDA, why was there nothing being circulated on the issue from the American Botanical Council, American Herbalists Guild, American Herbal Products Association? (ABC did not circulate comments until later on.) Wouldn't retailers like GNC and Vitamin Shoppe be up in arms, since it would mean the end of their entire business? Healthy skepticism is a powerful and useful approach to all topics, and even more so to anything even remotely political. But skepticism needs to be applied evenly – to those who have an ideology we agree with and to those we don't – or it will end up leading us astray.

¹ The draft guidance 2006D-0480 itself is available online at: <http://www.fda.gov/cber/gdlns/altmed.htm>

² "ABC urged FDA to withdraw the document due to the confusion it has generated and the fact that the term 'CAM products' does not refer to a distinct regulatory category." *American Botanical Council Member Advisory: ABC Submits Comments on FDA Draft Guidelines for CAM Products, May 30, 2007*

Before addressing the substantive issues in the email alert and the FDA draft guidance, I'd like to point out that there are reasons to question the real agenda of Dr. Laibow and her colleagues. At least some in the holistic community feel they are deliberately misleading the public to keep people ill-informed and not paying attention to the real issues threatening health freedom. I have no idea if that is true or not, but do not find it hard to believe after looking at their website - www.healthfreedomusa.org. But everyone should be their own judge of that.

As for the more substantive issues in the email and FDA document, here is a reference to some of the broader issues with a list of references at the end for those who would like to learn more.

For one, it is important to keep in mind that the FDA draft is a guidance, and as such does not represent a new regulation per se. Of course an agency's interpretation of regulations can be in some cases more significant than the letter of the law, but the possible scenarios described in the email alert could not be enacted through a guidance alone. In fact, in order for any regulatory changes of this magnitude to occur, Congress would have to enact new legislation. Thankfully this is not a possibility in the short-term as there is too much support *currently* for the free use of supplements within both major political parties.

The inaccuracy of the email is most apparent when discussing the supposed clamping down on the practice of complementary medicine, since FDA does not even regulate the practice of medicine. As for the supposed classification of herbs and other supplements as "untested drugs," current law is in fact quite clear about what FDA can or cannot do in this regard. This does not mean that some within FDA wouldn't like to have more authority, and again, it doesn't mean that we shouldn't be vigilant - but a wholesale shutting down of supplements would simply be impossible.

The FDA is the primary agency overseeing the supplement industry, including herbs (the FTC plays a more minor role in issues dealing with truth-in-advertising and dissemination of information to the public). The primary bodies of law that govern the FDA's oversight are:

- **Food, Drug, and Cosmetic Act of 1938**, which established legal authority of FDA over food and drug regulation. This act utilizes the three major categories of "*food*" that does not require pre-market approval, "*food additive*" that for a new substance does require pre-market approval, and "*drug*", that is used explicitly for disease prevention or treatment, and also requires pre-market approval.
- **Dietary Supplement Health and Education Act of 1994 (DSHEA)**, which created the new category of "dietary supplement" that does not require pre-market approval of herbs or supplements, and does not require that herbs or other supplements be proven "effective." Only safety related issues could potentially

result in a wholesale ban of a particular herb or vitamin, with the burden on FDA to prove its case, as happened with Ephedra.

Prior to DSHEA, dietary supplements (including vitamins and minerals) were regulated either as foods or as drugs, depending on their *intended use* – an ambiguous and subjective distinction that allowed the FDA far more latitude in arbitrarily over-reaching in its regulatory capacity. Although it should be repeated that this is just a summary and there are many more nuances to the law, in general the FDA's power to remove any dietary supplement from the market rests on one of the following:

1. Safety issues, most commonly adulteration
2. Failure to follow good manufacturing practices
3. False or misleading claims
4. Drug claims, i.e. if an herbal product or other supplement makes a claim *to diagnose, cure, mitigate, treat, or prevent disease* without having gone through the pre-market drug approval process.

It is this last category that is of most relevance here. DSHEA allows herbal medicines only to make so-called structure-function claims, those vague claims you often see on tincture or capsule bottles. An example would be "supports urinary tract function" for a dandelion leaf tea or tincture. (Personally I think that structure-function claims are so vague that we would be better off without them – they may just make people think they understand what an herb does instead of having to ask an herbalist or do research on their own.)

Understanding this distinction, it is clear that the FDA in its draft guidance is merely reiterating what is already required by DSHEA, such as in these two passages:

For example, naturopathic cranberry tablets might be labeled for use to maintain the health of the urinary tract. In this example, the cranberry tablets generally would be regulated as "dietary supplements" under section 201(ff)(1) of the Act if they were labeled for use to "maintain the health of the urinary tract" rather than "prevent urinary tract infections." The cranberry tablets would be regulated as "drugs" under section 201(g) of the Act if they were labeled for use to "treat urinary tract infections" even if they were labeled as dietary supplements.³

To illustrate how a CAM practice might involve "foods," juice therapy uses juice made from vegetables and fruits. Absent any claims that would make the juice subject

³FDA Draft Guidance: Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration; <http://www.fda.gov/cber/gdlns/altmed.htm>; IV, 5 (3)

to the drug definition, the juice would be a "food" under section 201(f) of the Act because it is an article used for food or drink for man.⁴

As this email alert was circulated, one of the possible “nightmare scenarios” laid out was that even holy water was going to be banned. But holy water like *anything* would be regulated the same way – unless a disease claim were made (such as a sign in the entrance to a church that the holy water cures depression), the FDA would have absolutely no authority to do such a thing (besides the obvious fact that this happening without the Catholic Church protesting against it is a ludicrous notion).

In summary, the relatively free use of herbal medicines in the United States is currently fairly well protected under DSHEA. Ironically our freedom is more protected than in some countries we herbalists tend to refer to positively for their integration of herbs into mainstream medical practice. More governmental oversight usually accompanies more mainstream integration, and so we in the herbal community should be exceedingly cautious about our legal goals and strategies. A “third way” may be possible in our future; Germany for example has a dual-tiered system, in which herbs can enter the market similar to our DSHEA regulations if they make no disease claim, but can go also through Commission E review if they want to make such a claim. Most importantly, this review requires “reasonable certainty” rather than “proof,” as is the case under FDA⁵, and considers historical literature and traditional knowledge and practice in the decision-making process. In my opinion, we are better off minimizing any FDA role as is the case under DSHEA, rather than seeking a balanced Germany-like approach that would also run the risk of giving more authority to an agency that has been historically hostile toward and ignorant of herbal medicine.

A hoped-for silver lining of all the confusion generated by this email alert may be that (1) more herbalists will be motivated to better inform themselves about the legal and regulatory status of herbal medicines and other supplements, and (2) the FDA will be more aware than ever that it is under scrutiny with even the more obscure documents it drafts and publishes.

⁴ FDA Draft Guidance: Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration; IV (3)

⁵ Of course plenty of dangerous and not so effective drugs slip through this FDA process, as we all know!

Herbal Medicine Regulatory and Legal Issues Web Resources

(Including some advocacy organizations that are committed to health freedom are more responsible and reliable than the group that issued this email alert)

- **FDA webpage on Dietary Supplements**
Information on DSHEA, GMPs, etc.
<http://www.cfsan.fda.gov/~dms/supplmnt.html>
- **FDA Guide to Dietary Supplements for the Consumer**
A good overview (note: last revised in 1999)
<http://vm.cfsan.fda.gov/%7Edms/fdsupp.html>
- **NIH Office of Dietary Supplements**
Focus on research not regulation per se
<http://dietary-supplements.info.nih.gov/>
- **American Botanical Council**
http://www.herbalgram.org/default.asp?c=legal_issues
A good overview can be found in: Regulation in the Herb Market: The Myth of the "Unregulated Industry" by R. William Soller, Ph.D. HerbalGram. 2000;49:64-67.
- **Herb Research Foundation**
<http://www.herbs.org/links/linksregu.htm>
- **American Herbal Products Association (AHPA)**
<http://www.ahpa.org/>
- **Citizens For Health**
<http://www.citizens.org/>
- **Organic Consumers Association**
<http://www.organicconsumers.org/>