

Consumers Health Freedom Coalition

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March 25, 2000

Dockets Management Branch(HFA-305)
Food & Drug Administration
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Gentlepersons:

The Agency is at this late date now considering methods of implementing compliance with the appellate court decision in the Pearson case that was handed down over a year ago. The decision clearly affirms the priority of the free speech rights of the supplement manufacturers and the rights of their consumers to hear about scientifically supported claims for dietary supplements. Those who have reservations about the certainty of these claims are looking for some unobtainable or moving standard in the real world.

The FDA does not have the right to favor one of its favored industries, the large pharmaceutical manufacturers just because it is more comfortable with these firms. The large drug companies are potentially harmed financially if a competing product takes away potential customers who use dietary supplements. Therefore they and their researchers will of course not agree with the overwhelming scientific evidence supporting the claims for the effectiveness of these usually cheaper supplements. Since the Supplements are usually cheaper and have fewer or less debilitating side effects, consumers if given a free choice will very likely choose these as a treatment for their conditions.

The FDA tries to oppose the use of dietary supplements to treat disease conditions. I find this to be a false distinction that has frightening implications to patients such as me. I had epilepsy and was taking anticonvulsant medication for 25 years. In 1978 I started to take a Mega dose of the B Complex vitamins. A leading dermatologist diagnosed my condition as tuberous sclerosis and the epilepsy and the bad skin on my face and back were part of this disease. When I started the B Complex the skin condition cleared up the athlete's foot type marker between my third and fourth toe on my left foot, the marker for tuberous sclerosis, a so called "rare hereditary disease" disappeared. I stopped taking anticonvulsant medication and the seizures occurred only when I did strenuous running. This was controlled with biofeedback techniques and I have not had a seizure in over 14 years. If supplement manufacturers cannot claim that B vitamins are useful to control seizures, the many people who also have epilepsy because of a B vitamin deficiency will not be encouraged to try this alternative. The long term effects on liver function and gum disease are unnecessarily inflicted upon these patients when a safe alternative exists. Medical literature does indicate that a B6 deficiency is a possible cause of epilepsy. Since no individual member of the B Complex works in isolation the whole complex should be

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taken. In my case B6 alone did not work when I tried it but the whole B Complex did work. But I will grant that there has not been as much study of the B complex for epilepsy as some other supplements for disease conditions that I have not had personal experience with.

There have been many studies confirming the benefits if St.John's wort for depression. The *British Medical Journal*, Aug. 6 1996:313(7052):253-8 reports on a meta analysis of 23 randomized studies finding St.John's Wort effective in patients with moderate to mildly severe depression. The *Journal of Geriatr Psychiatry Neurol*, 1994: 7(Suppl 1), October:S9-11 reported significant improvement in depression, In Germany it is the treatment of choice. Does FDA want us to believe the German government doesn't know how to properly regulate drugs? Or does it have something to do with the fact that a doctor's prescription is needed for St.John's wort in Germany. You can't have it both ways. Something other than "significant scientific agreement" is standing in the way of medical claims for St.Johns Wort.

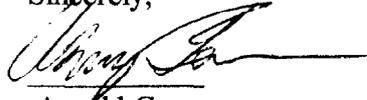
Many studies have found Coenzyme Q10 effective in treating Angina pectoris, *American Journal of Cardiology*, 1985:56(4):247-51, Heart Failure, *Biochem Biophys Res Commun*, 1992:182(1):247-53 and *Drugs Exp Clin Res*, 1985; 11(8):581-93 and 577-579 and Cardiomyopathy, *International Journal of Tissue React*, 12(3), 1990:169-71.

If the FDA wants to regain the confidence of the public it must start looking for ways to demonstrate that it is not constantly looking for reasons to deny consumers the right to information about and access to more natural, more effective, less toxic and usually cheaper dietary supplements.

What the FDA is contending is that since these supplements are actually being used by some consumers to "treat a disease" they fall within the category of a Drug and should be regulated as such. This is a completely discredited position trotted out by the pharmaceutical industry and their protectors in the FDA. It is repeated by reporters in the media who are either supporters of the drug companies or don't know the issue well enough, and therefore rely upon the so called experts in the agency that they presume has the clearest knowledge base of this "technical" field. In reality the so called technical scientific base is being used as an excuse to justify an economic premium price for the latest pharmaceutical drugs. An economic analysis of the regulatory process would find that it adds a premium price in order to obtain a degree of quality control and consistency in the product. On the other hand the consumer of dietary supplements must shop around and rely on reputation for integrity and quality of the manufacturer. The lack of troublesome side effects and usually lower price makes this a good option that FDA should encourage not obstruct. If FDA encouraged more competition from supplement manufacturers as a substitute for prescription drugs by allowing more medical claims, the high price of prescription drugs, which has become a national issue in this election year would resolve itself without major legislation.

It is time to comply with the appellate court order and the previous outpouring of mail to Congress supporting the Dietary Supplement Health Education Act (DSHEA) which was opposed by the Agency and the pharmaceutical industry. FDA must stop fighting lost causes which puts them in opposition to patients and consumers.

Sincerely,



Arpold Gore

cc: Rep. Charles B. Rangel
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