

## Recent FDA Shenanigans by John Gilbert, Ph.D.

Until recently, you could write a letter to the FDA and they actually read it. Now my sources within the FDA say all letters are piled up on tables in the FDA Reading Room where anybody can read them if they want to. Reading letters sent to the FDA is completely a voluntary act. Since government employees are overworked just like everybody else, most letters are never opened. Employees just don't have time to visit the FDA Reading Room. Writing the FDA is a futile effort unless you address it to a specific person at a specific mail station. The only way to get that information is from the person you want to write.

Until recently, you could email the FDA and they would actually read it. Now emails to the FDA are blocked unless they are directed to a specific person at a specific email address. The only way to get that information is from the person you want to email. My sources within the FDA tell me that the FDA received almost a million emails instigated by three anti-Codex Alimentarius organizations. The FDA's official reaction was that this was an illegal attempt to keep pro-Codex organizations from voicing their viewpoint. The top FDA executives refuse to believe the American people actually don't want to implement Codex Alimentarius.

The only way you can communicate your concerns about any FDA proposed regulation is to fax your comments to the attention of the Receiver of Dockets. But to do so, you must have the correct fax number and address it properly. The supervisor of the Receiver of Dockets could not tell me the correct number for faxing my comments concerning the "Evidence-based Review System for the Scientific Evaluation of Health Claims." This is Docket # 2007D-0125. You can read it at <http://www.cfsan.fda.gov/~dms/hclmqui5.html>.

There are two things I really don't like about these proposed regulations:

First, the FDA defines a process for evaluating any health claims for any foods or nutritional substances based on "significant scientific agreement" (SSA). The second is the definition of "credible scientific evidence" (CSE)

Sounds good, but the FDA has already defined SSA and CSE as being the significant agreement of the FDA investigators with independently conducted double blind studies. The fact that double blind studies are easily manipulated and pose a definite risk to participants makes them unconscionable in my opinion. The fact that FDA investigators get to decide what's significant and what isn't also gives me an unfriendly feeling. Look at the record.

Cherry farmers are banned from advertising anything about the fact cherries have been scientifically proven to assist arthritis patients. Drug companies are allowed to minimize and ignore serious side effects of their toxic arthritis medications scientifically proven to reduce liver function and compromise the immune system. The FDA allows them to say: "people with liver problems should check with their physician before trying (blank) for any medication known to adversely affect the liver." The FDA allows drug companies to recommend toxic immune-building drugs to physicians should their patients show a decrease in immune function after taking their arthritis medication.

The natural product Tryptophan was banned by the FDA after one shipment of tainted Tryptophan was discovered. Five people died in one year though people had been using the product for over fifty years.

Toxic sleeping pills kill tens of thousands of people every year as a side effect of taking synthetic Tryptophan patented by various pharmaceutical companies. Other toxic drugs designed to minimize one or more side effects of the original drug increase pharmaceutical company profits at the expense of the American people.

Something other than the cold hard truth is affecting FDA decisions.

Is it possible the Golden Rule applies? The Golden Rule says that he who controls the gold, rules. Is it possible that drug companies who finance more than forty percent (40%) of the FDA budget have any input into these decisions? Is it possible that drug companies who wine and dine top FDA officials and then offer them high-paying retirement jobs have any input into these decisions?

It may be time to email your senators and representatives and tell them the FDA is out of control and pharmaceutical companies have too much influence over FDA decisions. Ask them to take control of the FDA finances by placing all fees paid to the FDA in the general fund and paying all FDA salaries and expenses out of the general fund. Remind them that Congress has a fiduciary obligation to control the FDA for the benefit of the people. Control FDA money and you control the FDA.

Secondly, ask your representatives to co-sponsor Ron Paul's Health Freedom Protection Act, HR 2117. Send the message to Congress and the FDA that you want your health freedom protected. Ask your friends to send the same message.

Thirdly, ask your representatives to add an amendment to the Health Freedom Protection Act nullifying FDA Docket 2007D-0125 and any similar attempts to undermine the Health Freedom Protection Act.

If you can't talk to the FDA, you can go over their heads and talk to their boss - your senator and representative. You'll find a list of your senators and representatives on your state's web site at [www.\(your state\).gov](http://www.(your state).gov)

[Editor's Note: Dr. Gilbert currently serves as the President of the Natural Therapies Certification Board. He is the former executive director of the Neurotherapy and Biofeedback Certification Board. He is one of the three founders of the Biofeedback Association of North America. John has several contacts within the FDA whom he has known for several years. ]