

LEF Magazine August 1998

On The COVER

FIRST AMENDMENT & CODEX ALERT
 FDA COMMENTS PERIOD EXTENDED BUT....
 CSPI ASKS FDA TO BACK GERMAN CODEX PROPOSAL
 FLOOD FDA WITH COMMENTS & PROTESTS
 PRIOR TO CODEX MEETING

Citizens Petition I

Form Letter

First Amendment Alert
 By William Faloon

The picture below may be nearer to reality than you think. FDA proposed rules would severely restrict what you can learn about dietary supplements, and represents a new incursion into your health freedom. Consumer action is required.....Now!



This is about the United States of America...not China, Iraq, Cuba or the other countries where free speech is unheard of. Citizens will be outraged when they learn about the FDA's new Orwellian endeavor to suppress the dissemination of truthful medical information.

Vitamin consumers won a major victory in 1994 when Congress passed a bill that took away the FDA's power to regulate dietary supplements as drugs. The FDA has now proposed new rules to prohibit Americans from learning about certain types of medical information.

The FDA's proposed rules say that consumers can be told about how a vitamin affects the "structure or function" of the body, but that any reference to how the vitamin affects diseases will be classified as illegal speech. If the FDA's proposed rules become law, most consumers will not be able to find out about the nutrients they need to prevent, mitigate or treat any disease.

Examples of what the FDA has proclaimed to be illegal speech include such descriptions of benefits as "reduces nausea associated with chemotherapy," "protects against cancer," and "treats hot flashes." Let's look at the effects the FDA's proposed new rules will have on the consumer.

FDA-Mandated Suffering For Cancer Patients

A study in *Environmental Toxicology and Pharmacology* (Netherlands) 1996 1/3 (179-184) showed that a combination of vitamin C, glutathione and vitamin E significantly reduced chemotherapy-induced vomiting in dogs. Other studies have shown that nutrients can reduce the side effects of toxic drugs in humans. However, the FDA's proposed rules say it is illegal to suggest that chemotherapy patients who suffer from nausea and vomiting take these nutrients to reduce their suffering. While it's OK to state that the nutrients "inhibit chemotherapy-induced free radical activity in the gut," it's illegal to cite the published study showing that these nutrients inhibit chemotherapy-induced vomiting.

Since the FDA contends it's illegal to suggest anything but drugs to reduce nausea associated with chemotherapy, it would also be illegal to recommend coenzyme Q10 and vitamin E to reduce chemotherapy-induced heart muscle damage, melatonin to reduce chemotherapy-induced immune system damage, and n-acetyl-cysteine to reduce chemotherapy-induced liver damage.

The FDA is proposing that cancer patients be denied information about how to protect their heart, liver, gut and immune system against the lethal effects of FDA-approved chemotherapy drugs. These new proposed rules mandate suffering for cancer patients. They are not only immoral, they are blatantly unconstitutional.

Suppressing Evidence About Protection Against Killer Diseases

Despite the many new human studies (and thousands of animal and laboratory studies) showing that nutrients protect against cancer, the FDA says it is illegal to inform the American public about these findings. Under the FDA's proposed rules, it would be permissible to say that selenium "increases serum glutathione peroxidase levels and reduces DNA damage," but it would be illegal to inform Americans about a placebo-controlled study in *The Journal of the American Medical Association* (JAMA) on Dec. 25, 1996, showing that 200 micrograms of supplemental selenium reduced cancer mortality in humans by 50 percent.

We are calling on all Americans to protest the FDA's most recent attempts to gain dictatorial power over our cherished right to free speech. Protest the FDA's usurpation of health choices.

And since it is illegal (according to the FDA) to say that nutrients "protect against cancer," it is also illegal to say that they "protect against heart attacks." That means that folic acid can be promoted to "lower serum homocysteine levels," but not to protect against heart attacks—even though *The New England Journal of Medicine* (April 9, 1998) recommends the use of folic acid to lower heart attack risk.

The FDA would ban statements such as "treats hot flashes," but there are a wide variety of plant extracts that can be used to treat hot flashes in place of FDA-approved estrogen drugs that have been proven to cause breast, ovarian and uterine cancer. Under the FDA proposed new rules, American women won't get to hear about natural alternatives to estrogen drugs because the FDA has made it illegal to utter the phrase "treats hot flashes" for anyone who sells the plant extracts that are effective against hot flashes.

The FDA does provide some guidance as to what is permissible to say. "Helps maintain cardiovascular health" or "supports the immune system" would be permitted health claims under the agency's new proposed rules. The problem is that a person with dilated cardiomyopathy (heart muscle degeneration) will derive little benefit from therapies designed to treat coronary atherosclerosis. But under the FDA's proposed rules that the agency says are "designed to make claims for dietary supplements more informative, reliable and uniform," a person suffering from different forms of heart disease, peripheral vascular disease, transient ischemic attacks, stroke and so forth will have no idea whatsoever if a product that "helps maintain cardiovascular health" will be of value to them.

If all we are permitted to learn is that a nutrient "supports the immune system," does this mean it protects against immune deficiency associated with cancer and viral diseases? Or does the nutrient suppress an over-active immune system (autoimmunity) associated with rheumatoid arthritis, lupus, and multiple sclerosis. The FDA's proposed rules will force the consumer to guess about such life-or-death matters.

Here is another shocking example of the FDA's twisted Orwellian logic:

According to the FDA, it is illegal to promote a product to lower cholesterol levels because everyone (purportedly) knows that high cholesterol causes heart attacks. Once knowledge of the fact that elevated homocysteine causes heart attacks becomes better known, the FDA will probably say it is no longer legal to claim that folic acid lowers homocysteine levels, and only grant approval to statements such as, "Folic acid facilitates the methylation of homocysteine into methionine and S-adenosylmethionine (SAME)." But when the public learns the benefits of increasing SAME levels, the FDA will then prohibit statements about SAME as well.

In effect, the FDA's proposed rules only permit the dissemination of obscure, difficult-to-understand descriptions about nutrients that show lifesaving potential in studies published in medical journals. The rules would prohibit clear, accurate, truthful and easy-to-understand statements about these findings, and the publication of the studies (or their abstracts) themselves in conjunction with the sale of the nutrients used in these studies.

In short, the FDA's proposed rules are a deliberate attempt to keep lifesaving information from the American people and, by so doing, contribute to the premature death of millions of Americans.

Does the FDA have the legal right to keep Americans from learning about views contrary to its own? The FDA says yes, but the Supreme Court says no. With their proposed new rules, the FDA has defied the Supreme Court decision in a case called *Daubert v. Merrill Dow*.

Daubert replaced the "General Acceptance Test" (an equivalent phrase to "significant scientific agreement") with the Federal Rules of Evidence for admitting scientific testimony at a federal trial. The new standard mandated by the Supreme Court demands that there be "significant scientific evidence" to support a claim, instead of the "significant scientific agreement" standard proposed by the FDA. The difference between the two standards is enormous. The Supreme Court standard relies on scientific evidence rather than the opinions of FDA scientists and bureaucrats, who may be unaware of the evidence in favor of a claim, or may choose to ignore this evidence.

The FDA has shown a consistent pattern of bias against dietary supplements over the past 70 years. Moreover, the agency does no research of any kind itself. It depends entirely on evidence submitted to it by companies and individuals. As a result, the FDA is often ignorant of important scientific findings that no one has told it about.

According to the Daubert decision, the FDA should have recommended that it adopt Durk Pearson and Sandy Shaw's proposal to allow a gradation of label claims, depending on the amount of evidence to support the claim. Under Pearson and Shaw's proposal, the FDA would not be the sole arbiter of truth; a consumer could see at a glance whether or not the FDA had approved any given claim, but could also see how much support the claim has, based on the number ascribed to it (level 1 being the lowest threshold of evidence, and level 5 being the highest).

Because the Supreme Court's ruling on how to evaluate scientific evidence was made on June 28, 1993, after the passage of the Nutrition Labeling and Education Act of 1990 in which the FDA first thrust their "significant scientific agreement" standard upon us, there is no excuse for the FDA's proposed new rules. The FDA has chosen to defy the Supreme Court's ruling in its ongoing bias against dietary supplements. We must call this outrageous, illegal defiance of the U.S. Supreme Court by the FDA to the attention of Congress when we flood it with letters and phone calls.

Defending Freedom of Choice in Health Care

Health activists often wonder why they have to keep battling the government to protect liberties supposedly protected under the Bill of Rights. The root of the problem is that, while citizens labor long and hard to pay their taxes, the federal government is given free reign to use taxpayer dollars to increase central government authority.

The ultimate solution is to reduce the size of, and gain control over, the government. Since no politician has the fortitude to implement such changes, it is up to us to protect our constitutionally guaranteed rights against illegal government intrusion.

We are thus calling on all Americans to protest the FDA's most recent attempts to gain dictatorial power over our cherished right to free speech. The Life Extension Foundation has an impeccable track record of defeating the FDA in the courts and in Congress, but our power rests solely on the willingness of our members and other Life Extension magazine readers to protest the FDA's actions. Please complete the petitions on the following pages. Make photocopies for others who believe that a free press is the ultimate protection against governmental malfeasance. Americans have only until September 27 to respond to the FDA's proposed new rules. These petitions should be completed by every Life Extension Foundation supporter.

What To Do

Complete the Citizens Petition and mail it directly to the FDA address printed at the top of the petition.

Then send the form letter directly to your Congressional representative in the U.S. House of Representatives. After mailing this letter, please call your representative to urge his or her co-sponsorship of HR 2868, the Consumer Health Free Speech Act. Also let them know that you oppose the FDA's proposed new censorship rules.

Your letters and phone calls to Congress will help the passage of the Consumer Health Free Speech Act, which will stop the FDA from censoring the dissemination of truthful scientific information. (To locate the names and phone numbers of your Congressional representative and two senators call 1-202-224-3121.)

Please feel free to photocopy these forms so that other Americans can participate in defending the U.S. Constitution against a domestic enemy...the FDA.

The FDA should have adopted Durk Pearson and Sandy Shaw's proposal to allow a gradation of label claims, depending on the evidence to support it.

FDA Regulation: A Troubled, Varied History

Most of the confusion and controversy over the Dietary Supplement Health and Education Act (DSHEA) is due to too much of a good thing-information. There is now a steady flow of scientific research about dietary supplements and health, and that information has gotten into the hands of consumers who want the best for their bodies. While information is everywhere, people still rely on product labels to make intelligent choices.

It wasn't always possible. Twenty years ago, the FDA regulated food, and required pre-clearance of all food ingredients. As for health claims, none were permitted of food ingredients.

In 1984, Kellogg made claims for its All-Bran cereal based on a scientific agreement that people who eat more fiber have less colon cancer. The FDA admitted that the consumer benefited from information about a healthy diet, but still rejected the fiber claim for labeling purposes.

During the 1980s, surveys indicated that Americans wanted more information about nutritional characteristics to make more of their own health choices. In 1990, the Nutrition Labeling and Education Act was passed, allowing health claims on labels if there were "significant scientific agreement" about those claims; it also confirmed the FDA's controlling power over labels.

In the early 1990s, Americans became increasingly concerned about the cost and accessibility of health care, and began using vitamins, minerals and dietary supplements more than ever. The FDA's response was to propose even stricter limits on vitamins and minerals. It proposed that amino acids be classified as unapproved food additives, and that botanicals be regulated a drugs.

This period of the late 1980s and early 1990s coincided with increased militancy against dietary supplement suppliers. The FDA raided the Life Extension Foundation, and confiscated stored products on several occasions. In response, the Foundation, along with a groundswell of public support and Congressional concern over FDA overreaching, demanded a more enlightened view of dietary supplements. That led directly to DSHEA in 1994, which expanded the universe of dietary ingredients and loosened labeling strictures.

The FDA's proposed regulatory rules, announced in April, are its recommendations on how DSHEA should be implemented. Consumers have until the end of August to comment on these proposed rules.

While DSHEA noted that dietary supplements could not make "disease claims" on labels, the FDA has advanced a number of examples of what would constitute a disease, dramatically expanding the very definition of disease itself. This proposed rule would deny to Americans a wealth of scientific evidence in support of specific disease benefits of supplements.

The FDA also proposes stepped-up monitoring of what it sees as violations of its restrictions, raising the specter of a national dietary supplement KGB. It wants to monitor "third party literature" to assess compliance with its own view of truthfulness, thus taking full aim at First Amendment rights. Other aspects of DSHEA may be covered by the FDA's monitoring outreach, including prohibiting the right of health food store clerks to discuss with customers the products on their shelves. Thus, the Life Extension Foundation could be prohibited from letting you know about scientific findings on supplements, and what effects those supplements have on specific diseases.

A troubling statement within the FDA rules proposals notes that descriptive labeling on a supplement product may be OK as long as the label doesn't suggest it treats a health condition that "is beyond the ability of the consumer to evaluate." In 1984, however, consumers were quite able to understand the role of fiber in combatting colon cancer; today, they are able to understand even more, and make their own appropriate choices.

It's that kind of arrogance-the presumption that consumers can't understand what's good for them-that people are increasingly resentful of.

-- Christopher Hosford

[Back to the Magazine Forum](#)