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COVER STORY

New Victory Over FDA Censorship



It was long ago established that consumption of cold-water fish reduced the risk of heart attack.[1] In fact, just two to three servings of fish a week can protect against many diseases including, arthritis, stroke, certain cancers and a host of inflammatory-related disorders.[2-9]

When scientists sought to discover what components of fish were responsible for preventing heart attacks, they found that the oil played a critical role. Cold-water fish oil is high in omega-3 fatty acids that function in multiple ways to reduce cardiovascular disease risk.[10]

Based on the published scientific evidence about fish oil, a lawsuit was filed in 1994 by Durk Pearson and Sandy Shaw against the FDA seeking to force the agency to allow a health claim as follows:

"Consumption of omega-3 fatty acids may reduce the risk of coronary heart di

The FDA rejected this one sentence claim and a multi-year litigation battle erupted.

In their lawsuit, Durk and Sandy pointed out that consumers would benefit by learning of the value of fish oil in protecting against heart disease. On a legal basis, it was argued that the FDA lacked the Constitutional authority to ban this truthful and non-misleading health claim.

The FDA contended that this health claim was not adequately backed by scientific studies and that the agency had the legal discretion to ban these kinds of health claims.

Seven years of extensive and expensive litigation ensued as the FDA asserted that it had the sole authority to dictate what Americans could read on the label of fish oil supplements. After an onslaught of irrefutable scientific evidence was presented, including articles published in the most prestigious scientific journals in the world, the FDA capitulated and said it would permit the following claim:

"Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that although there is scientific evidence supporting the claim, the evidence is not conclusive."

Saving American lives

The significance of this legal victory cannot be overstated. Every year about one million Americans suffer heart attacks; 500,000 die. Approximately 300,000 of the annual heart attack fatalities are of the "sudden death" variety. The omega-3 fatty acids (found in cold water fish oils) are particularly protective against these "sudden death" heart attacks. Studies show that as few as two fish meals a week reduce heart attack risk by half.[11]

If all Americans regularly took fish oil supplements or ate about two cold water fish meals a week, it would prevent the deaths of about 150,000 Americans a year. That is about the same number of people each year as 50 World Trade Center disasters. During the seven years it took to litigate this case against the FDA, over one-million preventable sudden death heart attacks were suffered by Americans.

We celebrate that the First Amendment guarantee of free speech (along with new discoveries about fish oil's benefits) won out over deadly FDA bureaucracy and delay.

Now that this important health information can be communicated to the general public on fish oil supplements, Durk Pearson and Sandy Shaw and their allies are filing a petition with the FDA so that this potentially lifesaving information can be communicated on labels and in ads for cold water fish and other foods containing these critically important essential fatty acids.

The FDA's letter of capitulation

In the Legal Notes section of this issue, we reprint the FDA's capitulation letter to attorney Jonathan Emord, who represented Durk Pearson, Sandy Shaw, Julian Whitaker and the other plaintiffs involved in this successful litigation against the FDA.

When you read this letter, you may be appalled when you learn how the FDA complicated this easy-to-understand issue about fish oil. The significance of this is that many promising lifesaving drugs are bogged down in the FDA's regulatory quagmire. The safety and efficacy of these drugs is far more difficult to comprehend than ascertaining whether fish oil is beneficial, yet the FDA still retains absolute authority to decide whether these drugs will be approved.

When it comes to health claims on dietary supplements, the FDA's letter of capitulation exposes the agency's bias and lack of scientific integrity. It took seven years of intensive litigation to force the FDA to recognize the value of fish oil. There are too many new compounds that may prevent and treat disease to allow a central bureaucracy with a proven track record of failure to continue making life and death decisions for the American public.

An example of the FDA's ineptitude can be found on the issue of cholesterol. As you can read in the FDA's letter of capitulation on the fish oil issue, the FDA insists that products that promote heart disease risk reduction also emphasize the importance of lowering dietary intake of saturated fat and cholesterol. Yet starting in 1959 and extending into the early 1970's, the FDA made it a crime for food labels to state, "Low in saturated fat and cholesterol." The FDA censored this claim because at that time, the agency did not believe that saturated fat and cholesterol had any relationship to artery disease.[12]

The FDA's history of being on the wrong side of scientific debate provides grounds for Congress to radically reform the arbitrary power that today's antiquated laws provide to this agency.

In a related article from this issue, "A Celebration of First Amendment Victories Against the FDA", you will read of previous First Amendment victories won by attorney Jonathan Emord, Durk Pearson and Sandy Shaw, Dr. Julian Whitaker, the American Preventative Medical Association and other health freedom activists against the FDA's lethal censorship.

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