

LE Magazine November 2004

REPORT

FDA Permits New Fish Oil Health Claim

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

When scientists sought to discover which components of fish are responsible for preventing heart attacks, they found that the oil plays 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 against the FDA in 1994 by Durk Pearson and Sandy Shaw, seeking to force the agency to allow the following health claim on fish oil supplement labels:

“Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.”

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

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. They also argued that the FDA lacked the constitutional authority to ban this truthful health claim.

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

Seven years of extensive 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.”



Life Extension Challenges FDA On Fish Oil Health Claim

The FDA's compromise health claim that the evidence was “not conclusive” did not satisfy The Life Extension Foundation. The scientific literature provided overwhelming validation that consuming cold-water fish or fish oils dramatically lowers heart attack risk.

The Life Extension Foundation Buyers Club, Inc., and Wellness Lifestyles, Inc., filed a health claim petition against the FDA on June 23, 2003. The petition urged the FDA to reconsider its permitted health claim for omega-3 fatty acids and coronary heart disease risk, and to allow the following revised claim:

“Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.”

To substantiate this position, a massive document enumerating the scientific studies backing the benefits of omega-3 fatty acids was filed, along with legal arguments supporting the constitutional right to disseminate this truthful information.



Also included in the petition was a calculation of how many American lives were needlessly being lost because of the FDA's restriction of this simple health claim. Epidemiological data were presented showing that if all Americans regularly took fish oil supplements or ate about two cold-water fish meals a week, it would prevent about 150,000 deaths a year. Life Extension further argued that during the seven years it took to litigate this case against the FDA, Americans suffered over 1 million preventable sudden-death heart attacks.

The Political Battle Over What Americans Eat

Junk food is big business in the United States. Processed food companies have historically used their political clout to persuade the federal government to defend the safety of dangerous food products. The cost of treating diseases caused by poor diet has become so staggering, however, that the government is recommending that Americans eat healthier.

For nearly two decades, the FDA protected the economic interests of companies selling high-fat and high-cholesterol foods by making it illegal to promote a healthy diet as a way of preventing heart disease. Heart attack rates were three times higher in the 1950s than in the 1990s. The FDA's censorship of healthy dietary information caused tens of millions of Americans to unnecessarily succumb to cardiovascular and other diseases.

FDA Capitulates To Scientific Reality

On September 8, 2004, the FDA announced that it would allow an expanded health claim on products containing the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

According to Acting FDA Commissioner Dr. Lester M. Crawford, "Coronary heart disease is a significant health problem that causes 500,000 deaths annually in the United States. This new qualified health claim for omega-3 fatty acids should help consumers as they work to improve their health by identifying foods that contain these important compounds (EPA and DHA)."

The FDA now permits the following statement to be printed on the label of fish oil supplements:

"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease."



Jonathan Emord

The FDA went on to recommend that consumers not exceed more than 3 grams per day of EPA and DHA omega-3 fatty acids, with no more than 2 grams per day derived from a dietary supplement. Life Extension argues that many scientific studies show that higher amounts of EPA and DHA are often needed to obtain optimal benefits, such as reduction of triglycerides and prevention of restenosis (re-occlusion of a blocked artery).¹¹

This battle over what can be stated about fish oil began back in 1994. While the FDA's announcement of a broader health claim represents a significant legal victory, Life Extension is still not satisfied with the FDA's latest health claim on fish oil supplements. We reiterate our position that evidence from peer-reviewed scientific publications supporting the benefit of EPA and DHA supplements in reducing heart attack risk is conclusive and not merely "supportive" as the FDA contends.

Life Extension congratulates attorney Jonathan Emord for the hundreds of hours of productive work he has put into this case over the past ten years. Jonathan filed the initial lawsuit against the FDA on behalf of Durk Pearson and Sandy Shaw that resulted in a precedent-setting legal victory against FDA censorship. Jonathan then prepared the petition on behalf of Life Extension and Wellness Lifestyles that resulted in the FDA allowing this new expanded health claim to be made about the protective effect of fish oils against cardiovascular disease.

It is unfortunate that Bill Clinton, as president in 1994, did not take actions he had the authority to take. President Clinton could have ordered the FDA to allow truthful, non-misleading health claims on dietary supplements. If Bill Clinton personally followed the scientifically-based diet and supplement program that the FDA was suppressing at that time, perhaps he could have avoided his recent coronary bypass surgery.



[Click to Purchase](#)

References

1. FTC Press Release, November 29, 2000. "FTC Reaches Record Price-fixing Settlement to Settle Charges of Price-fixing in Generic Drug Market."

2. Price quoted by Hollywood Discount Pharmacy in Hollywood, Florida on Jan 15, 2002.
3. Associated Press, October 4, 2001. "Drugmaker to pay \$875 million fine."
4. Robert Pear (New York Times News Service). "Health spending jumps 6.9%—Main factors: hospitals and drug costs, managed care resistance, The Herald, Tuesday, January 8, 2002.
5. Faloon William, "Dying from Deficiency," Life Extension magazine, October 2001.
6. National Vital Statistics Reports, Vol. 48, No.11.
7. Wall Street Journal, December 24, 2001, pp- A3, "Schering Fines Could Total \$500 Million."
8. <http://www.cnn.com/HEALTH/9804/14/drug.reaction/Chicago> CNN. "Study: Drug reactions kill an estimated 100,000 a year," April 14, 1998.
9. David Willman, "The Rise and Fall of the Killer Drug Rezulin," Life Extension magazine, September 2000.
10. <http://news.ft.com/ft/gx.cgi/ftc?pagename=View&c=Article&cid=FT3HZ3AFMWC&live=true&tagid=IXLHT5GTICC&subheading=heal> By David Firm in London, "More deaths linked to Bayer's Lipobay," January 18, 2002. 19:44 | Last Updated: January 18 2002 19:48
11. Calder PC. n-3 fatty acids and cardiovascular disease: evidence explained and mechanisms explored. Clin Sci (Lond). 2004 Jul;107(1):1-11.

All Contents Copyright © 1995-2009 Life Extension Foundation All rights reserved.

LifeExtension[®]

These statements have not been evaluated by the FDA. These products are not intended to diagnose, treat, cure or prevent any disease. The information provided on this site is for informational purposes only and is not intended as a substitute for advice from your physician or other health care professional or any information contained on or in any product label or packaging. You should not use the information on this site for diagnosis or treatment of any health problem or for prescription of any medication or other treatment. You should consult with a healthcare professional before starting any diet, exercise or supplementation program, before taking any medication, or if you have or suspect you might have a health problem. You should not stop taking any medication without first consulting your physician.