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## AS WE SEE IT

### The White House Urges Greater Omega-3 Consumption

There once was a time when the U.S. Government stated that there was no relationship between dietary fat intake and artery disease. Not only did the government publish their proclamation, but enforced it at gunpoint.

The basis for censoring this dietary information was an edict by the FDA that made it illegal to even imply that fats and oils had a relationship to diseases of the heart and arteries. According to the FDA, to make any statement about fat consumption and heart attack risk constituted "misbranding," a serious criminal offense. An excerpt of the FDA's misguided prohibition statement appears on the next page.



How times have changed! On May 27, 2003, The White House urged health agencies of government to encourage Americans to increase their consumption of foods rich in omega-3 fatty acids and decrease their intake of trans fatty acids. The release issued by the Executive Office of The President stated:

"Health researchers have found that Americans can significantly reduce the risk of heart disease with a modest change in their diets. The government should make this life-saving information as widely available as possible."

A basis for The White House's initiative are new guidelines by the American Heart Association that recommends consuming cold-water fish at least twice a week and other oils and food sources high in omega-3 fatty acids. The Office of The President also cited the "growing body of scientific evidence, both experimental and epidemiological, that suggests that consumption of trans fatty acids increases the risk of coronary heart disease."



William Faloon

### The political battle over what Americans eat

Junk food is big business in the United States. Historically, processed food companies used their political clout to persuade the Federal government to defend the safety of dangerous food products. The medical costs of treating diseases caused by poor diet have become so staggering, however, that even The White House 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 healthy diet as a way of preventing heart disease. Heart attack rates were three times higher in the 1950's than in the 1990's. The FDA's censorship of healthy dietary information caused millions of Americans to unnecessarily succumb to cardiovascular and other diseases.

For instance, it was long ago established that consumption of cold-water fish reduced the risk of heart attack.<sup>1</sup> 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.<sup>2-9</sup>

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.<sup>10</sup>

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 the following health claim:

### The FDA's Previous Ban On Dietary Fat and Heart Disease Claims

"The advisability of making extensive changes in the nature of the dietary fat intake of the people of this country has not been demonstrated. It is therefore the opinion of the Food and Drug Administration that any claim, direct or implied, in the labeling of fats and oils or other fatty substances offered to the general public that they will prevent, mitigate or cure diseases of the heart or arteries is false or misleading, and constitutes misbranding within the meaning of the Federal Food, Drug and Cosmetic Act."<sup>\*</sup>

<sup>\*</sup>Federal Register: December 12,

*"Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."*

1959. Reaffirmed by the FDA in the Federal Register: May 18, 1965.

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 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."

### **The White House's new position on heart disease**

The Office of The President states in its official position paper, "Since coronary heart disease kills over 500,000 Americans each year, even a small improvement in dietary habits could save thousands of lives."

The Life Extension Foundation believes The White House is understating the number of lives that could be saved. According to an article published in The Lancet,<sup>3</sup> men who consume the most trans fatty acids have twice the risk of developing heart disease compared to their counterparts who consumed the least. The American Heart Association recently published a study of 11,323 heart attack patients showing that those who took a 1000 mg fish oil supplement every day were 45% less likely to be dead at the end of 3.5 years.

The White House is not emphasizing the enormity of human suffering that would be eliminated if Americans were better educated about what foods they should eat. While it is true that 500,000 Americans die from heart disease annually, there are about one million people who suffer heart attacks each year. The economic costs of open-heart surgeries, cardiac rehabilitation, cardiac drugs and emergency room visits is bankrupting the health care system of this nation. Aggressive government action to better educate consumers about healthier diets could dramatically postpone the date when Medicare becomes insolvent.

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.<sup>11</sup>

If all Americans regularly took fish oil supplements or ate about two cold-water fishmeals a week, it could prevent about 150,000 sudden death heart attacks a year. During the seven years it took to litigate the fish oil health claim against the FDA, over one million preventable sudden death heart attacks were suffered by American citizens.

### **FDA Approval Sought For New Omega-3/Heart Disease Health Claim**

Based on overwhelming documentation that greater consumption of omega-3 fatty acids reduce cardiovascular disease risk, Life Extension Buyers Club and Wellness Lifestyles, Inc. filed a new health claim petition with the FDA. The petition urges the FDA to reconsider the currently permitted health claim for omega-3 fatty acids and coronary heart disease risk. The

### **FDA reform urgently needed**

The cardio-protective effects of cold-water fish have been known to scientists for over 20 years,<sup>12</sup> yet the FDA actively tried to censor this information from the public. Clearly the regulatory system in this country has to be changed, as the number of years of life lost on the fish oil issue alone is incalculable.

The effects of fish oil on cardiovascular health have been consistently unambiguous, i.e., those who eat cold-water fish have fewer heart attacks. The FDA took this easy-to-understand fact and turned it into a complex legal morass that took seven years to resolve.

FDA says the scientific evidence regarding omega-3 consumption and heart disease is “not conclusive.” The petitioners argue that there is sufficient published evidence to allow the following new claim:

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

To substantiate this position, attorney Jonathan Emord filed a massive document that enumerates the scientific studies backing the benefits of omega-3 fatty acids, argues the Constitutional right to disseminate this information and calculates how many American lives are being lost because the FDA has denied this claim. Review this enormous petition filed on June 23, 2003.

There are many promising lifesaving drugs 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 if and when these drugs will ever be approved. Meanwhile, those whose lives could be saved by these yet-to-be-approved therapies perish every day.

### **The chilling effects of censorship**

Scientific disagreement can only be resolved when sufficient evidence manifests to prove one side right (and the other wrong). In the case of dietary fat and heart attack risk, history has proven the FDA absolutely wrong. There is nothing immoral about being wrong about new scientific concepts, as no one can expect perfection in these novel areas.

What is genocidal about the FDA being wrong, however, is their police-state power to suppress opposition. Those who don't agree with the FDA are subject to criminal indictment, forfeiture and imprisonment. This kind of draconian authority has a chilling effect on the dissemination and implementation of new scientific principles. Under today's totalitarian

system, creative solutions to life-threatening diseases are stifled not only because of direct FDA actions, but also by the fear of becoming the next victim of a FDA witch-hunt.

## AS WE SEE IT

### The White House Urges Greater Omega-3 Consumption

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.

Until recently, it was a criminal offense to promote omega-3 fatty acids to reduce cardiovascular disease risk. Now the White House is encouraging the FDA and other Federal agencies to do more to enlighten consumers about the benefits of omega-3 fatty acids and the dangers of trans fatty acids. The invariable question is, will future Presidential administrations encourage Americans to follow health concepts that the FDA is suppressing today? Are scientific pioneers sitting in American prisons whose original ideas will later show to be medically correct?

#### A free market solution

The consequences of not reining in the FDA's police powers are premature death for almost everyone reading this column. An alternative we have long advocated is for the FDA to state its opinion about any food, drug, nutrient, hormone or medical device on its website ([www.fda.gov](http://www.fda.gov)), but not have the power to arbitrarily shut down and imprison those with novel concepts that have not yet been FDA approved.

Consumers who want government "protection" could insist on only using FDA-approved products, while those who want to be more aggressive could experiment with products that would specifically state on their labels: "Not Approved By The FDA."

This free choice system would release the creative energies of physician-scientists whose new ideas are presently silenced by fear of FDA persecution. We believe the result of this greater freedom would be a marvelous medical renaissance.

The FDA survives because of an apathetic American public who has grown so used to government incompetence that they feel little can be done to change it. The Life Extension Foundation, on the other hand, has proven that positive changes can occur at the Federal level if enough citizens speak up.

As a member of The Life Extension Foundation, you belong to an elite group who possess the knowledge to differentiate scientific authenticity from the political hyperbole long espoused by the FDA.

For longer life,



William Faloon.



#### Trans Fats Are Everywhere!

Trans fatty acids are found in vegetable oils that are hydrogenated or partly hydrogenated. Hydrogenation is an industrial process, which is used to convert liquid cooking oils into semi-solid fats. The process alters the characteristics of the fat such that they are more suitable for use in large-scale food manufacture. These hydrogenated oils are found in many processed foods and baked goods, making them almost impossible to avoid. Trans fatty acids act as artery-clogging saturated fats in the body.

Avoiding trans fats may be difficult for the average consumer because the amount of trans fat in foods is not identified on their labels. It is included however in the total fat reported. The french fries, fried chicken and doughnuts from fast food outlets all contain high levels of trans fat. Trans fat is found in vegetable shortenings, some margarines, crackers, cookies and many other foods made with or fried in partially hydrogenated fats.

Foods that can have lots of hidden trans fat:

Fast food: Most fast-food and family-style chain restaurants cook fries, chicken and other deep-fried foods in partially hydrogenated oil, which often comes in a solid block that's melted in the fryer. They also slather margarine—which is trans fat—on griddles for pancakes and grilled sandwiches. To get an idea of how much trans fat is in fast food, consider a KFC Original Recipe chicken dinner. It has 7 grams of trans fat, mostly from the chicken and biscuit. Even if the chains use some of the newer liquid, non-trans oils for frying, fries are sometimes par-fried in trans fat before they are shipped to the restaurants.

Baked goods: This is the heaviest trans fat territory. Most mass-produced convenience and commercial bakery goods like cookies and cakes have plenty of trans fat. Cakes and shortening-based frostings from supermarket bakeries are particularly trans-heavy. So are doughnuts, which can contain shortening in the dough and also be cooked in trans fat. Generally, the higher quality the baked good, the less trans fat, because more butter is used.

Chips and crackers: To keep them crisp, manufacturers pump crackers full of shortening. Even crackers labeled “reduced fat” can still have trans fat. Watch for anything fried, like potato chips and corn chips, as well as “buttery” crackers.

Spreads, sauces and mixes: Margarine can be pure trans fat. As a general rule, the softer the margarine, the less artery-clogging fat it contains. There are some trans-fat-free spreads on the market and increasingly are labeled as such. Watch out for high trans-fat levels in nondairy creamers and flavored coffees, as well as in ready-made dips, including some bean dips, whipped toppings, gravy mixes and products like Hamburger Helper. Cake, biscuit and cornmeal mixes can have several grams of trans fat per serving.

Unexpected places: Breakfast cereals, breakfast bars, some energy bars, tortillas, microwave popcorn, fish sticks or other breaded frozen foods all can contain trans fat. So can some puddings and peanut butters, where it is used to give a creamier consistency. Frozen foods like pot pies, frozen pizzas and other entrees, even if labeled as lower in fat, are often made with trans fat. Very high levels can be found in packaged instant noodles like ramen and soup cups.<sup>13</sup>

To uncover the trans fat in food, try the following steps:

Method 1: Check the ingredients list for partially hydrogenated oil of any kind. These oils contain trans fats. The closer to the top of the list, the more trans fat. Check commercial baked goods (such as crackers and cookies), frozen foods and margarine, especially stick.

Method 2: Check the Nutrition Facts label to see if the product lists total, saturated, polyunsaturated and monounsaturated fats. If it does, you can figure the grams of trans fat. Here's how:

1. Add the grams of fat listed under saturated fat, polyunsaturated fat and mono-unsaturated fat.
2. Subtract this amount from the grams of total fat.
3. The remainder, if any, is the grams of trans fat.

According to the Dutch research, trans fat in the diet can cause even more health problems than saturated fats. Using a “cross over” design in which healthy subjects ate a diet containing trans fat or saturated fat for four weeks and then switched to the opposite diet for four weeks, several cardiovascular events were affected. When the subjects ate the trans diet their blood vessels dilated 29% less efficiently, and blood levels of HDL or “good cholesterol” was lowered by 20% compared to when subjects ate the diet rich in saturated fats. Trans fat has also been shown in other studies to raise the levels of LDL or “bad cholesterol” and may also increase total serum cholesterol.<sup>14</sup>

Trans fatty acids can damage arteries as much as saturated fats or even more and is associated with a higher risk of heart disease. Studies have demonstrated that while both trans fats and saturated fats have a comparable effect on increasing low density lipoprotein (LDL) cholesterol, only trans fats lower levels of good high density lipoprotein (HDL) cholesterol, thereby making them potentially much more damaging than saturated fats.<sup>15</sup>

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