

# AS WE SEE IT

by William Faloon

## FDA Says Walnuts Are Illegal Drugs

*Life Extension* has published 57 articles that describe the health benefits of **walnuts**.

Some of this same scientific data is featured on the website of **Diamond Foods, Inc.**, a distributor of packaged walnuts.

The **FDA** has determined that walnuts sold by Diamond Foods cannot be legally marketed because the walnuts “*are not generally recognized as safe and effective*” for the medical conditions referenced on Diamond Foods’ website.

According to the FDA, these walnuts are now classified as “*drugs*” and the “*unauthorized health claims*” cause them to become “*misbranded*”, thus subjecting them to government “*seizure or injunction*”.

Let’s take a look at the science supporting the consumption of walnuts to see what the **FDA** is up to...and what you can do to stop it!

### Eating walnuts cuts heart disease risk

Ingesting nuts used to be considered unhealthy because of their high fat content. This misconception has changed over the past 17 years as human studies reveal sharply reduced incidence of heart disease in those who consume walnuts.<sup>1,2,3,4,5,6,7,8,9,10,11,12</sup>

Unlike some nuts that contain high levels of saturated fats, **walnuts** provide a unique blend of polyunsaturated fatty acids (including **omega-3s**), along with nutrients like **gamma tocopherol** that have demonstrated heart health benefits.<sup>13,14,15,16,17,18,19,20,21,22,23,24</sup>

The March 4, 1993 issue of the **New England Journal of Medicine** published the first clinical study showing significant reductions in dangerous **LDL cholesterol** and improvement in the lipoprotein profile in response to moderate consumption of walnuts.<sup>6</sup> Later studies revealed that walnuts improve **endothelial function** in ways that are independent of cholesterol reduction.<sup>1,25,26,27</sup>

One study published by the **American Heart Association** on April 6, 2004 showed a **64% improvement** in a measurement of *endothelial function* when walnuts were substituted for other fats in a Mediterranean diet.<sup>1</sup>

As most *Life Extension* members are aware, the underlying cause of atherosclerosis is progressive *endothelial dysfunction*.<sup>28</sup> Walnuts contain a variety of nutrients including arginine,<sup>29,30,31,32,33</sup> polyphenols,<sup>34,35,36</sup> and omega-3s<sup>37,38,39,40,41,42</sup> that support the inner arterial lining and guard against abnormal platelet aggregation. These favorable biological effects explain why walnut consumption confers protection against coronary artery disease.

The *U.S. National Library of Medicine* database contains 35 peer-reviewed published papers supporting a claim that ingesting walnuts improves vascular health and may reduce heart attack risk.

### **FDA ignores the science**

The federal agency responsible for protecting the health of the American public views this differently.

At the end of this editorial, we reprint the FDA's entire warning letter to Diamond Foods. Nowhere in this bureaucratic albatross is there any discussion of the science cited by Diamond Foods to support their health claims.

Instead, the FDA's language resembles that of an *out-of-control* police state where tyranny reins over rationality. To enable you to recognize the absurdity of all of this, I excerpted a few paragraphs from the FDA's warning letter to Diamond Foods as follows:

“Based on our review, we have concluded that your walnut products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations (21 CFR).”

“Based on claims made on your firm's website, we have determined that your walnut products are promoted for conditions that cause them to be drugs because these products are intended for use in the prevention, mitigation, and treatment of disease.”

“Because of these intended uses, your walnut products are drugs within the meaning of section 201 (g)(1)(B) of the Act [21 U.S.C. § 321(g)(B)]. Your walnut products are also new drugs under section 201(p) of the Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for the above referenced conditions. Therefore, under section 505(a) of the Act [21 U.S.C. § 355(a)], they may not be legally marketed with the above claims in the United States without an approved new drug application.”

“Additionally, your walnut products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your walnut products are also misbranded under section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].”

This verbiage makes it clear that the FDA does not even consider the underlying science when censoring truthful non-misleading health claims. The chilling effect on the ability of consumers to discover lifesaving medical information is a wake up call for all who recognize the ramifications of this latest act of FDA malfeasance.

### **What the FDA allows you to hear**

The number of people logging on to the website of Diamond Foods is miniscule. I doubt that before the FDA took this draconian action, that hardly anyone even knew this website existed.

What the public hears loud and clear, however, are endless advertisements for artery-clogging junk foods. Fast food chains relentlessly promote their 99 cent double-cheese burger as being *bigger* than their rivals. These advertisements induce many consumers to salivate for these *toxic calories* that are a contributing cause of coronary artery disease. Yet the FDA does not utter a peep in suggesting that their advertising be curtailed.

On the contrary, FDA has issued waves of warning letters to companies making foods (pomegranate juice, green tea, and walnuts) that *protect* against atherosclerosis.<sup>43</sup> The FDA is blatantly demanding that these companies stop informing the public about the scientifically-validated health benefits these foods provide.

The FDA obviously does not want the public to discover that they can reduce their risk of age-related disease by consuming healthy foods. They prefer consumers only learn about mass marketed garbage foods that shorten lifespan by increasing degenerative disease risk.

### **FDA allows potato chips to be advertised as “heart healthy”**

**Frito-Lay®** is a subsidiary of the **Pepsi Cola** company. Frito-Lay® sells **\$12 billion** a year of products that include:

- Lays® Potato Chips
- Doritos®
- Tostitos®
- Cheetos®
- Fritos®

You might not associate these mostly-fried snack foods as being good for you, but the **FDA** has no problem allowing the **Frito-Lay®** website to state the following:

**“Frito-Lay snacks start with real farm-grown ingredients. You might be surprised at how much good stuff goes into your favorite snack. Good stuff like potatoes, which naturally contain vitamin C and essential minerals. Or corn, one**

**of the world's most popular grains, packed with Thiamin, vitamin B6, and Phosphorous – all necessary for healthy bones, teeth, nerves and muscles.**

**And it's not just the obvious ingredients. Our all-natural sunflower, corn and soybean oils contain good polyunsaturated and monounsaturated fats, which help lower total and LDL “bad” cholesterol and maintain HDL “good” cholesterol levels, which can support a healthy heart. Even salt, when eaten in moderation as part of a balanced diet, is essential for the body.”<sup>44</sup>**

Wow! Based on what Frito-Lay is allowed to state, it sounds like we should be living on these snacks. Who would want to ingest walnuts, pomegranate, or green tea (which FDA now says are illegal drugs) when these fat-calorie laden, mostly-fried carbohydrates are so widely available?

According to the Frito Lay® website, Lays® potato chips are now “heart healthy” because the level of **saturated fat** was reduced and replaced with **sunflower oil**.<sup>45</sup> Scientific studies do show that when a *polyunsaturated* fat (like sunflower oil) is substituted for *saturated* fat, favorable changes in blood cholesterol occur.<sup>46</sup>

Fatally omitted from the Frito-Lay® website is the fact that **sunflower oil** supplies lots of **omega-6** fats, but **no omega-3s**.<sup>47</sup> The American diet already contains too many omega-6 fats and woefully inadequate omega-3.

Excess omega-6 fats in the diet in the absence of adequate omega-3s produces devastating effects including the production of pro-inflammatory compounds that contribute to virtually every age-related disease including atherosclerosis.<sup>48,49,50,51,52,53</sup>

For the FDA to allow Frito-Lay® to pretend there are heart benefits to ingesting their high-calorie snack products, while censoring the ability of walnut companies to make scientifically-substantiated claims, is tantamount of **treason** against the health of the American public.

### **Don't forget the acrylamides**

When carbohydrate foods are cooked at high temperature (as occurs when potatoes are fried in sunflower oil to make potato chips), a toxic compound called **acrylamide** is formed.<sup>54</sup>

According to the **National Cancer Institute**, “acrylamide is considered to be a **mutagen** and a **probable human carcinogen**, based mainly on studies in laboratory animals.<sup>55</sup> Scientists do not yet know with any certainty whether the levels of acrylamide typically found in some foods pose a health risk for humans.”

In response to these kinds of concerns, the FDA funded a massive study to ascertain acrylamide content of various foods. FDA found that potato chips and other fried carbohydrate foods were especially high in acrylamides.

The FDA, however, has not stopped companies selling high acrylamide-containing fried carbohydrates from promoting these foods as healthy.

### **Pharmaceutical companies benefit by FDA's misdeeds**

As the aging population develops coronary atherosclerosis, pharmaceutical companies stand to reap tens of billions of dollars each year in profits. An obstacle standing in their way is scientific evidence showing that a healthy diet can prevent heart disease from developing in many people.

It is thus in the *economic* interests of pharmaceutical giants that the FDA forcibly censor the ability of companies making heart healthy foods to inform the public of the underlying science. The fewer consumers who know the facts about walnuts, pomegranate and green tea, the greater the demand will be for expensive cardiac drugs.

Once again the FDA overtly functions to enrich Big Pharma, while the public shoulders the financial burden of today's health-care cost crisis.

In this particular case, however, **processed food** companies also stand to profit from the FDA's attacks on healthy foods.

## **Chilling Effect on Innovation**

Headquartered in Stockton, California, Diamond Foods is a processor and marketer of nuts, with distribution in over 80% of U.S. supermarkets. Most of Diamond's 1,700 walnut growers are family farmers with orchards in the heartland of California's Central Valley. Their association with Diamond guarantees a market for their crops and provides the company with high quality walnuts.

In response to independent scientific studies validating the health benefits of walnuts, Diamond Foods made financial investments to educate the public and supply them with walnuts. With one misguided letter issued by the FDA all of Diamond Foods good work may be undone.

This kind of bureaucratic tyranny sends a strong signal to the food industry not to innovate in a way that informs the public about foods that protect against disease. While consumers increasingly reach for healthier dietary choices, the federal government wants to deny food companies the ability to convey findings from scientific studies about their products.

### **FDA/FTC wants more control over what you are allowed to learn**

The FDA and FTC (Federal Trade Commission) are proposing new regulations that will stifle the ability of natural food companies to disseminate scientific research findings.

One proposal being discussed within the FTC would require that supplement companies conduct studies analogous to what the FDA requires to approve new drugs. In a perfect world, *Life Extension* would agree with some of the FTC's objectives. As far as we are concerned, the more scientific research to validate a health claim, the better.

The reality is that natural foods do not carry high prescription drug price markups, so it would be economically impossible to conduct the same kinds of voluminous clinical studies as pharmaceutical companies do. As readers of this column know, many of the clinical studies the FDA relies on to approve new drugs are *fraudulent* to begin with. So even if it were feasible to conduct more clinical research on foods and supplements, that still does not guarantee the precise accuracy the FTC is seeking.

If these agency proposals are enacted, consumers will be barred from learning about new ways to protect their health until a food or nutrient meets stringent new requirements. A look at the warning letter the FDA sent to Diamond Foods is a frightening example of how scientific information can be harshly censored by unelected bureaucrats.

If anyone still thinks that federal agencies like the FDA protect the public, this latest proclamation that healthy foods are now **illegal drugs** expose the government's sordid charade.

### **Companies that sell healthy foods try to fight back**

The combined sales of the companies attacked by the FDA is only a fraction of food giant Frito-Lay®. Yet some of them are fighting back against the FDA's absurd position that it is illegal to disseminate scientific research showing the favorable effects these foods produce in the body.

As a consumer, you should be outraged that disease-promoting foods are protected by the federal government, while nutritious foods are censored. There is no scientific rationality for the FDA to do this. To the contrary, the dangerous foods ubiquitously advertised in the media are replacing cigarettes as the leading killers in modern society.

The federal government is heavily lobbied by companies selling processed foods. As *Life Extension* revealed long ago, an insidious activity of lobbyists is to incite federal agencies and prosecutors to eliminate free competition in the marketplace.

Simple fact is that walnuts are healthy to eat, while carbohydrates fried in fat are not. FDA permits companies selling disease-promoting foods to deceive the public, while it suppresses the dissemination of peer-reviewed published scientific information.

For longer life,

William Faloon

***“When the people fear their government, there is tyranny; when the government fears the people, there is liberty.”--Thomas Jefferson***

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