

COVER STORY

A New Day at FDA? After years of battling in the courts, the FDA may finally be forced to comply with the law... AGAIN

Over five hundred years before the drafting of the United States Constitution, medieval barons in England fed up with regal abuse created their own set of laws known as the Magna Carta. Latin for "Great Charter," the Magna Carta was a series of written promises designed to force any king-in this case John-to govern the land according to the customs of law and not by whim.

Although originally unwilling to yield any of his royal power, after months of violent battle-and being literally at the point of a sword-the reluctant King John finally agreed to the demands of his barons and signed the document.

Centuries later, the FDA-this time at the point of a legal sword-finally acquiesced to judicial pressure and protests by health activists and created the "Better Health Information for Consumers" initiative, a policy that allows for greater latitude when disseminating information about health foods and nutritional supplements.

In this article, we examine the latest First Amendment victory won in the courts and the FDA's recent capitulation on the issue of dietary supplement health claims.



The Food and Drug Administration (FDA) has consistently fought the use of any statement describing how a nutritional supplement can promote health. Over the past several years, a series of historic court cases has systematically required the FDA to revamp its restrictive policies and allow manufacturers to make health benefit claims for nutritional supplements and foods. The FDA, however, has not always chosen to comply fully with the rulings of the court.



Each of these court cases focused on just a few simple sentences of information that the FDA deemed dangerous and illegal. The result of this litigation and the FDA's partial compliance are finally becoming visible in the marketplace as supplement labels and foods begin to carry expanded information concerning their potential health benefits. For example, bottles of vitamin E may now claim that the supplement helps boost the immune system as well as maintain red blood cells and cardiac muscles. Prior to these court cases, the FDA prohibited such statements. While these rulings support the health industry, the clear winner is the American public, who can now make more informed choices concerning the maintenance of its own health.

Winning out over censorship

Recently, there have been two new significant developments in the quest to limit the FDA's censorship of health claims. The first was the announcement by the FDA on December 18, 2002 of a broad new initiative, "Better Health Information for Consumers," aimed at making available more information about the health benefits of dietary supplements and foods for the prevention of disease. This new policy represents a one-hundred-and-eighty-degree turn from the traditional FDA stance that no nutrient-disease claims should be allowed for foods or supplements unless they are proven to a "near conclusive degree."

Remembering Those Who Perished Needlessly

A great philosopher once stated,

The second development occurred on December 23, 2002 when the FDA lost yet another court case (*Whitaker vs. Thompson*) concerning its continued suppression of a health claim. What the FDA objected to was the simple statement, "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers." This legal action was brought by Dr. Julian M. Whitaker, along with Durk Pearson, Sandy Shaw and Pure Encapsulations,

"Those who forget the past are condemned to relive it." The Life Extension Foundation is dedicated to reminding the public about the past atrocities committed against the health of the American public by the FDA. We must never forget the tens of millions of innocent Americans who perished while the FDA did everything in its power to suppress information about the importance of disease prevention. These pointless deaths continue as potentially life-saving medications remain bogged down in the FDA's bureaucratic approval quagmire.



Inc., among others.

Judge Gladys Kessler of the United States District Court for the District of Columbia ruled that these censoring actions by the FDA were a violation of the Constitution's free speech clause. This is the second time that the FDA was brought into court over this exact statement of antioxidant benefit. The first time was in the 1999 case of Pearson vs. Shalala (commonly referred to as Pearson I) in which the judge ordered the FDA to allow the antioxidant claim with the disclaimer, "These statements have not been evaluated by the Food and Drug Administration." Despite the court's decision, the FDA refused to comply. According to Jonathan W. Emord, the attorney for the plaintiffs in all of these cases, "these victories have resulted in a First Amendment revolution at the FDA. The agency must now expand health information that will enable the public to reduce the risk of disease and live longer."

Judging by the December 18 announcement, the FDA seems to have finally gotten the message. In the past, whenever the court ruled against FDA censorship, the agency strategically took one-step forward and two steps back. The result was that the FDA only partially complied with the Judge's order and additional legal motions had to be filed to bring the FDA in line.

Previous First Amendment victories

As a background to the recent victory of Whitaker vs. Thompson, it is essential to look at its two predecessors, Pearson I and Pearson II.

The complaint against the FDA in Pearson I was that the agency refused to allow the following four health claims:

- "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer." (This was again taken up in Whitaker vs. Thompson.)
- "Consumption of fiber may reduce the risk of colorectal cancer."
- "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."
- "800 mcg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form."

The plaintiffs (Durk Pearson, Sandy Shaw, Julian Whitaker, et al) fought to have the FDA's health claim ban deemed unconstitutional. The court ruled that suppression of these statements was a violation of the First Amendment and ordered the FDA to allow these four claims to enter the marketplace. In reviewing the case, the court found the standard by which the FDA measured the efficacy of a health claim to be purely subjective. It is interesting to note that the FDA was not banning actual products, but only specific claims that spoke to the application of these nutritional products.

For the next two years, the FDA failed to comply with the court's original decision in Pearson I. As a result, attorney Emord and his clients went back to court to seek enforcement of Pearson I as well as relief from the FDA's continued speech suppression.

Their new case in 2001, titled Pearson II, focused on the FDA's refusal to allow the original claim that folic acid supplements were effective in reducing neural tube defects. The court stated, "The scientific consensus, even as acknowledged by the FDA, confirms that taking folic acid substantially reduces a woman's risk of giving birth to an infant with a neural tube defect. The public interest is well served by permitting information about the ability of folic acid to reduce the risk of neural tube defects to reach as wide a public audience as possible." Again, the court ruled in Pearson et al's favor on the same folic acid statement. The FDA was again ordered to comply. In effect, the court had stripped the FDA of any power to ban health claims of nutritional supplements unless the FDA had solid evidence that the claims actually misled.

What was especially egregious about the FDA's failure to immediately respond to the court's first decision was the potential harm it was causing to unborn children. Folic acid is a safe and low-cost nutrient to prevent neural tube defects. Yet the FDA would not move from its position of refusing to allow such an important statement into the market place. This is a perfect example of how public health can be harmed by excessive regulation. Thankfully, despite the FDA's attempt at suppression of this information, the mass media picked up on the story and the public quickly learned about the benefits of folic acid supplements for pregnant women. Doctors now routinely encourage their patients during pregnancy to follow a regimen that includes folic acid in order to prevent unnecessary birth defects.

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DA responds to court losses

All of this repeated litigation finally began to have an impact on the FDA's policy makers. On December 18, 2002 FDA Commissioner Dr. Mark McClellan, in conjunction with the White House, announced the agency's "Better Health Information for Consumers." This initiative is the FDA's attempt to comply with the requirements of both Pearson I and Pearson II. According to a statement by the FDA, it "anticipates that this policy will facilitate the provision to consumers of additional, scientifically supported health information" and that "the dissemination of current scientific information concerning the health benefits of conventional foods and dietary supplements should be encouraged to enable consumers to make informed dietary choices yielding potentially significant health benefits."

Before this announcement the FDA permitted limited health claims only for certain dietary supplements but not for conventional foods-even though there is much more scientific data available to support the health benefits of foods. Now average consumers will become aware of the specific health benefits of, say, eating broccoli or salmon. According to FDA documents, the consumer health information initiative is focused on three main areas:

- Helping consumers obtain accurate, up-to-date and scientifically-based information about conventional food and dietary supplements.
- Allowing only those health claims for conventional foods and dietary supplements that have been pre-approved by FDA and meet the weight of scientific evidence.
- Enforcing against false or misleading claims about dietary supplements.

The FDA now states "consumers are more likely to respond to health messages in food labeling if the messages are specific with respect to the health benefits associated with particular substances in the food." The FDA goes on to say that consumers' incorporating "beneficial foods into their diets improves public health." Providing the public with such enhanced nutritional information will hopefully contribute to the decline of such current health epidemics as diabetes, heart disease and cancer.

In "Better Health Information for Consumers," the FDA makes it clear that it is finally responding to the enormous growth of nutritional awareness by the American consumer. A recently released FDA document, the Dietary Supplement Enforcement Report, states that over 158-million consumers use dietary supplements for "ensuring good health" and "preventing various illnesses." It certainly appears the FDA has realized a vast number of Americans are taking responsibility for enhancing their own health by utilizing supplements with or without FDA approval.

Dr. McClellan sums up the initiative by stating, "Our mission at the FDA is to improve health outcomes for the nation, and some of the best opportunities for improving health involve informed choices by consumers." Hopefully, this statement signals the beginning of a new and enlightened position for the FDA.

The impact of the court decisions and the FDA's new initiative are likely to be profound and far-reaching:

- Americans will have access to much more information regarding the therapeutic benefits of supplements and various food products. This will enable them to make proactive choices in managing their health. Ideally, a better-informed public will become a healthier public focusing on prevention rather than pharmaceutical cures.
- Manufacturers will now be encouraged to research and develop targeted nutraceuticals aimed at specific conditions. In the near future we might see manufacturers making the same therapeutic claims for nutritional products as for standard pharmaceuticals-but without the side effects. The FDA's initiative will remove the barriers for innovation in the expanding nutraceutical field.
- Doctors will be more likely to suggest nutritional protocols along with traditional pharmaceuticals to their patients.





While these recent developments are encouraging, much remains to be done and the battle against the FDA and its restrictive policy toward nutrient claims continues. A Federal Court recently denied manufacturers the right to state on the label the benefits of saw palmetto in reducing the symptoms of mild benign prostatic hypertrophy. As it has repeatedly done in the past, the FDA refused to review the claim, stating in this case that it was "a treatment claim and, hence was not covered under the provisions for health claims." This decision will be appealed. According to attorney Jonathan Emord, he is "not finished with the FDA until it allows health claims for foods and dietary supplements that can be used to treat diseases, not just help prevent them." The battle continues.

Don't believe the FDA's propaganda

The FDA was forced to launch its "Better Health Information for Consumers" policy and pretends now that they are in favor of allowing consumers to learn about the benefits of dietary supplements.

The reality is that health activists, Congress and Federal Judges forced the FDA to capitulate on this critical First Amendment issue. It took decades of protests by American consumers, passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994, and countless losses in the Courts to compel the FDA to pull this public relations stunt (the "Better Health Information for Consumers" initiative) that makes it appear as if they are the good guys. The facts are that Congress passed laws denying the FDA's power to suppress truthful health information and Federal Courts have mandated that the FDA adhere to the law.

When government agencies are proven wrong, they seldom admit their errors. Remember in 1991 when Saddam Hussein lost the Gulf War, he proclaimed to Iraqi citizens, "The soldiers of faith have triumphed...and are now withdrawing from Kuwait in accordance with peace." The reality was Iraqi troops were fleeing Kuwait while being pummeled by relentless American air strikes.

The FDA is in a similar embarrassing situation; they have been cornered into a position that they cannot constitutionally get out of, i.e. Congress has grown increasingly hostile to new regulatory proposals and judges are ruling against them on First Amendment issues. Instead of admitting defeat, they created the "Better Health Information For Consumers" as a charade to make it appear that the FDA came up with the idea to uncensor health information and let consumers learn some of the proven health benefits of certain foods and supplements.

The sad fact is that tens of millions of Americans needlessly died during most of the past century, as the FDA prohibited manufacturers of dietary supplements from disseminating information about peer-reviewed published scientific studies. The FDA went further by actively discouraging Americans from using dietary supplements and conducting nationwide seizure actions against companies who dared to make health claims.

Patriotic Americans who have participated in this successful health-freedom battle should feel proud to have helped defend the United States Constitution against one its most abusive domestic enemies, the FDA.

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To read recent court transcripts of cases discussed in this article, log on to attorney Jonathon Emord's website at www.emord.com.

For further information about the FDA's initiative titled Consumer Health Information for Better Nutrition mandate, log on to www.fda.gov.



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