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## On The COVER

VICTORY!  
For Freedom of Speech



### Winning Our First Amendment Suit Against The FDA

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& Sandy Shaw

On January 15, 1999, in a landmark decision, a panel of 6 the US Court of Appeals for the District of Columbia Circuit ruled 3-0 in favor of plaintiffs-meaning us deciding that the Food and Drug Administration's (FDA) health claim approval process was unconstitutional under the First Amendment. Furthermore, the Court ruled that the FDA's actions were "arbitrary and capricious" under the Administrative Procedure Act. We are thrilled with the decision. This action on the part of the Court shows that Constitutional restraints on government will prevail if one has conviction, a good attorney and a lot of patience. For now, the FDA's encroachment on civil rights has been stopped. Despite little coverage in the mainstream press, the decision is going to have immense impact on the consumer's right to know.

Although we were the legal winners of the case, the real winners were you, the American public. The Court's decision preserves your access to truthful information about dietary supplements. The Court made it clear that censorship of free speech will not be tolerated. Under the guise of protecting consumers, the FDA had attempted to curtail public information about dietary supplements. According to the decision, the FDA's rules about what can and cannot be said on a vitamin bottle have to be thrown out. The agency must go back and make rules that don't conflict with the First Amendment's guarantee of free speech.

Our challenge began when the government refused to allow claims we wished to make on dietary supplements, including such things as "Antioxidant vitamins may reduce the risk of certain cancers" and "Omega-3 fatty acids may reduce the risk of cardiovascular disease". These claims are backed up by scientific evidence, yet the FDA nixed them based on something called "significant scientific agreement". There may be scientific evidence, they argued, but not everyone agrees. This so-called "significant scientific agreement" rule was purely a creation of the FDA, yet the agency could not, or would not, define it. What it boiled down to is the agency had created for itself a stone wall it could throw up at will. Drug companies could claim that their products prevented X based on scientific evidence, but supplement manufacturers could not. We wanted to knock down this wall so that people could have access to information about vitamins and other supplements. We believe that consumers are perfectly capable of judging for themselves whether they want to take a dietary supplement as long as they have truthful information. Fortunately, the Court agreed with us and the FDA's "Father Knows Best" approach was soundly rejected by the Court which apparently found some of the agency's arguments about a person's ability to make their own decision ridiculous. We got a laugh out of the Court's take on some of the FDA's arguments. In responding to the assertion that all claims lacking "significant scientific agreement" (we still don't know what that is) are misleading, the Court wrote:

"As best we understand the government, its first argument runs along the following lines: that health claims lacking 'significant scientific agreement' are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous."

Both of us got a good laugh out of that. See ADDENDUM containing excerpts from the oral arguments for even more laughs.

Fortunately, the Court also rejected the "significant scientific agreement" rule. An undefined standard is no standard at all, the Court declared. The rule was a violation of the Dietary Supplement Health and Education Act (DSHEA) which requires the FDA to establish a standard for health claims.<sup>1</sup> If the FDA continues to press for "significant scientific agreement," the Agency must define it. It cannot define it simply as whatever it says on a case-by-case basis. We predict, however, that the FDA will attempt to subvert the Court's ruling by proposing the same old rules dressed up in new verbiage. We will be filing Public Comments, and we urge you to do the same!

When the FDA had argued that people might misconstrue information on a vitamin label as something sanctioned by the government, we had suggested a "split label." This approach would make it clear that the FDA didn't approve the claim. We thought this was a good solution to the problem, but the FDA rejected the idea. The Court didn't. When it got the same argument from the Agency, the Court responded:

"The government's general concern that, given the extensiveness of government regulation of the sale of drugs, consumers might assume that a claim or a supplement's label is approved by the government, suggests an obvious answer. The agency could require the label to state that 'The FDA does not approve this claim.'"

We are lucky and surprised that the Court considered our First Amendment challenge to what the government was doing. Although we strongly believed that the foundation of our argument is found in the words "Congress shall make no law...abridging the freedom of speech, or of the press," courts do not generally address constitutional issues. They prefer to rule on technical issues, and leave the Constitution to the Supreme Court. But the Court went right to the Constitution, saying:

"Normally we would discuss the non-constitutional argument first, particularly because we believe that it [our challenge to the FDA's "significant scientific agreement" standard] has merit. We invert the normal order here to discuss first appellants' most powerful constitutional claim, that the government has violated the First Amendment by declining to employ a less draconian method- the use of disclaimers- to serve the government's interests [of protecting the public from misleading information]."

Thus the Court said:

"even if 'significant scientific agreement' were given a more concrete meaning, appellants' might be entitled to make health claims that do not meet that standard, with proper disclaimers."

The Court had decided on the issue of making disclaimers even though we hadn't even raised the issue! This was very encouraging, and indicated to us that the Court was not going to tolerate censorship of truthful scientific information about dietary supplements. The Court appears to be hinting that should the issue come up as to whether or not there is "scientific agreement" about the efficacy of a supplement, the Court is going to allow more information rather than less. The Court is saying through its decision that in a free society, free access to information takes precedence over whatever perceived harm may come from a lack of "scientific agreement" over what a vitamin can do. Now, for example, we will be able to qualify a claim by including what kinds of studies have actually been done- cell culture, animal studies, epidemiology, etc. This will allow the consumer to get a better picture of what kind of research actually stands behind the claim. This will strengthen his or her ability to make informed choices, rather than weaken it, as the FDA had sought.

The Court indicated in its decision that it is poised to allow disclaimers as a way of notifying consumers that not everyone in the scientific community agrees that, for example, antioxidant vitamins reduce the risk of cancer.

We're glad the Court took this commonsense approach towards the notion that consumers might confuse FDA-approved claims for drugs with those made for dietary supplements. We think the FDA's rejection of using disclaimers as a way of informing the public that the FDA doesn't endorse the claims, is a reflection of their concern that if people saw the disclaimer everywhere, they might start wondering why they need FDA approval in the first place. Considering that the FDA has approved only two health claims for dietary supplements in the eight years it was supposed to be reviewing and approving health claims for dietary supplements- as mandated by the Nutrition Labeling and Education Act- its approval seems to be nonexistent anyway.

We believe that labeling information will allow consumers to become more sophisticated, and less likely to believe lies- whether they come from manufacturers or the government. As with anything new, it will take consumers a while to separate the reliable from the not-so-reliable. But eventually the lack of credibility of certain businesses will become evident, and consumers will be better off.

While we've put out one fire, another one rages. We've filed suit in the U.S. District Court for the District of Columbia (case No. 97CV00462[WBB])<sup>2</sup> to stop the government's illegal regulation of marijuana used for medical purposes ("medical marijuana"). The idea behind this suit is similar to the one we just won: the government is exceeding its constitutional authority. The suit challenges the federal government's right, under the First, Ninth and Tenth Amendments, plus the commerce clause of the Constitution, to take action against intrastate prescription and use of medical marijuana. The case is not about whether medical marijuana is good medicine or not. It's about whether the federal government has the constitutional authority to regulate the intrastate (within the state) practice of medicine. It also challenges Congress and the presidentially- appointed "drug czar's" rights to general police powers which they gained for themselves by simply decreeing that all commerce is interstate. Law-by-decree is definitely not part of a democratic government.

Under the Constitution, the federal government has the power to regulate commerce; however, the states have all powers not specifically granted to the federal government- which means that states can enact laws without its permission. Recently, the government has attempted to override the people's desire to allow the use of medical marijuana. This desire has been expressed in legislation passed by several states. By imposing its authority to regulate interstate commerce, the federal government is attempting to destroy that legislation- a violation of states' rights under the Constitution.

This challenge of the government's power is more severe than our First Amendment suit. Governmental power has gone unchallenged for several decades, allowing it to grow to the point where an entire body of law has sprung up to justify unconstitutional grants of power to the federal government ("outcome based" jurisprudence). This is the old "ends justifies the means"-type thinking which poses enormous threats to personal liberties. It is going to be very difficult to pry some judges away from this philosophy, and steer them back to the Constitution. It will take considerable courage on the part of the courts to uphold our challenge. But if we win, it will be a victory for the rights of people to create state laws which, although some in the federal government might not like, nonetheless express the will of the people. The rights of a person to choose for him or herself what kind of medical care they will get will be protected if we win this suit. As always, it is going to be very expensive, and we will need money for the appeal that will inevitably come no matter who wins.

It was a long road to get here

Those of you who have followed our work know that we have been publicly critical of the FDA for many years. Our best-selling book, *Life Extension: A Practical Scientific Approach*, published in 1982, contained a section (Appendix E) that focused on the consequences of the FDA's regulation of health claims, and why we thought the regulations violated the First Amendment protection of free speech and press. If the FDA were allowed to prohibit health claims, the public would never know about all the scientific research that might help them prevent disease, live longer and improve performance. All the effort put into scientific research would simply languish in journals and books and would go unused. Health claims on supplements are a small, but important, part of educating the public about non-toxic, and in some cases, natural, substances that could save their lives. The FDA's refusal to allow health claims seriously undermines the public's right to information.

In 1993, we began filing Public Comments in response to the FDA's proposed rules regulating health claims<sup>3</sup>. Our reading of the First Amendment says that the government has no authority at all to regulate truthful speech. An exception to free speech had arisen during the Reagan years through several Supreme Court decisions. The "commercial speech" doctrine, as it is known, allows regulation of free speech during the course of a buy/sell transaction. We began reading the Court decisions in 1993 and discovered that Court had taken a "balancing" approach to free speech. In other words, the right of free speech was now balanced against other interests. This approach attempted to allow free speech, yet let the government control it when it came to selling a product. When we compared what the FDA was actually doing with what they were allowed to do by the Court and Congress under "commercial speech" doctrine, we felt the government was going way beyond what had been allowed. Furthermore, the whole doctrine itself was antithetical to the First Amendment right of free speech. As far as we're concerned this doctrine turned buyers and sellers into second class citizens- somehow undeserving of unregulated free speech. We were alarmed at the unprecedented control "commercial speech" doctrine gave governmental agencies such as the FDA. So in 1994, we filed suit to stop what we believed to be unconstitutional governmental control over health claims. That control was killing people!

For example, the beneficial effect of aspirin on heart disease was confirmed in the 1989 Physician's Health Study<sup>4</sup> which found that in healthy men over age 50, an aspirin every other day slashed heart attack risk by 44%. To this day, people are not being informed about the potential benefit of aspirin because of the FDA. A few months ago the agency decided to allow the information to be communicated to doctors only- ten years after the study was published. How many hundreds of thousands of people have died because of the FDA's illegal and immoral policy? (Note: the latest evidence shows the best dose to be 1/4 to 1/2 of an aspirin a day. We take 1/4).

In our 1993 book, *Freedom of Informed Choice: FDA vs. Nutrient Supplements* (Common Sense Press), we discuss the constitutional and scientific issues surrounding the FDA's regulation of health claims. We explain what a disastrous effect that policy is having on public health. (We also include several diabolically nasty cartoons aimed at the FDA). Because of the book, we

met constitutional attorney, Jonathan Emord. As soon as we read his essay "The Doctrine of Commercial speech in First Amendment Jurisprudence" (Cato Institute Policy analysis, Sept. 23, 1991), we knew he had the skill necessary to take on a potential case against the FDA. Jonathan expertly guided the case from its inception in 1994, through all the legal mazes, to our victory this year. One of the most impressive results was that the Court took the unusual step of considering our constitutional arguments first. This is highly unusual, and demonstrates the strength of our arguments.

For us and against us

The federal government is not the only one who wants to destroy your right to choose. The American Cancer Society, the American Heart Association, the Center for Science in the Public Interest, and the Public Citizen and Consumer Federation of America all filed supportive briefs on behalf of the FDA.

Supporting us (and you) with amicus briefs were People Against Cancer, the Foundation for the Advancement of Innovative Medicine and Direct MDS Alternative Information Resources, among others. We spent a lot of our own money on this case, but also got major help along the way from Julian Whitaker, M.D. and the American Preventive Medical Association. Some additional financial help came from the National Health Federation, Life Enhancement Products, Life Extension Foundation, Greg and Michelle Pryor of Life Priority, Inc., and a few others who wish to remain anonymous. We greatly appreciate all the support we have gotten. Is all the time and expense worth it? Yes, when you win.

## References

1. It is also unconstitutional because the Constitution authorizes only one branch of the government to make laws, the Congress. See U.S. Constitution, Article I, Section 1. The federal agencies can carry out the will of Congress pursuant to Congressionally created law but cannot make rules in the absence of statutory authorization. This is a constitutional principle that is widely flouted by federal agencies. (For one thing, why limit your rule making to that authorized by Congressional statute when nobody in a regulatory agency has ever been thrown in jail or lost their job or even been disciplined by the Congress for making law that went beyond or even defied the explicit will of Congress as expressed in statute?) A time is rapidly approaching when a properly chosen regulatory agency rule or rules should be challenged on the basis of Article I, Section 1 of the Constitution; however we didn't judge that this case was the right one for such a challenge or that the courts were ready for it.
2. Our co-plaintiffs include Julian M. whitaker M.D., Jeffrey A. Singer M.D., Richard D. Fisher M.D., Henry N. Blansfield, M.D., William Regelson, M.D., American Preventive Medical Association, and Life Extension Foundation. Our thanks to these brave people!
3. The reason for filing comments during the Public Comment period after an agency has published a proposed rule in the Federal Register is not because you expect the agency to care what you have to say but because it gives you standing to sue. If you do not file comments on a proposed rule and are later injured by it, you cannot go directly to the federal courts to challenge the rule; you have to first -"exhaust your administrative remedies," which means spending a lot of money in the agency's internal Administrative court where you cannot hope to win.
4. "Final Report on the Aspirin Component of the Ongoing Physicians' Health Study," New England Journal of Medicine 321 (3):131.135 July 20, 1989).

## ADDENDUM

Oral Arguments in Pearson & Shaw et al v. Shalala et al.

You can learn a lot about a court and its judges by listening to oral arguments, in which there is usually a lively interaction between each side's attorney and the judges, who interrupt frequently to ask questions and make comments, sometimes pointed and humorous. Unfortunately, we were not able to travel to Washington, D.C. to hear oral arguments, so we did the next best thing by getting and reading the transcript of the oral arguments. The following short excerpt shows how dubious the judges were of the FDA's position that unapproved health claims are inherently misleading.

THE COURT:...Do you seriously argue that these statements are inherently misleading?

THE FDA [Christine N. Kohl, representing the FDA]: In the FDA's judgment, Your Honor, yes, they are. There is such power over the consumer in the market place at the point of sale.

THE COURT:...What if the proposed statement were exactly what your FDA's parent Agency [HHS] said, quote, "Fatty acid omega-3 is under study because of a possible association with a reduced risk of heart disease in certain people." That was the only thing they wanted to put on the label, and it was word for word what HHS put out. Is your position that that is inherently deceptive?

THE FDA: Yes, Your Honor, that's the scientific judgement of the FDA that there is not-

THE COURT: So HHS, FFDA's position is that HHS is making inherently deceptive statements.

THE FDA: . . .These regulations that are being challenged apply only to labeling on the dietary supplement.

THE COURT: But why does that matter?...Why is it inherently deceptive in the label, and not in the brochure?

THE COURT: Is this [that the statements are inherently misleading in a label] some impression the FDA has? Or maybe they have some study in the back. But, I mean, I've got to tell you, I walk to the grocery store all the time...I just don't get the impression that people are absolutely terrorized when they approach a dietary supplement.

THE COURT: It's not like approaching a lawyer.

THE COURT: Yes. Label, as opposed to reading an article in a magazine. I mean, is this something that you think it really rises to the... you have to have a qualitatively different standard when they go into the grocery store?

THE COURT (a few lines later): . . .But I find the argument that this is inherently misleading is absurd...

THE FDA: Well, Your Honor, again, it is the Agency's scientific judgment based on their-

THE COURT: Well, that's not a scientific judgment. That's a legal judgment, isn't it?

THE COURT:...In order to win your case, you have to establish that this is inherently misleading. That's basically what you are arguing, isn't it?

THE FDA:...If the Court doesn't agree with the FDA's conclusion that these claims have so much potential for abuse that they are inherently misleading-

THE COURT: Potential? Wait a minute counsel. You are switching between inherent and potential. I'm trying to take out of the case, obviously, and I think Judge Garland is too, this inherently misleading notion.

THE FDA: And my response to that is, if you

THE COURT:...You [the FDA] hate like hell to give it up, but-

THE COURT: You can't legally. They [the FDA] are in trouble if they give it up..

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