

LE Magazine July 1999

INTERVIEW

Durk Pearson
& Sandy Shaw

Durk Pearson and Sandy Shaw are two leading independent experts in anti-aging research and brain biochemistry. Since 1968, they have been pioneers in the life extension field. Among other best sellers, Durk & Sandy are the authors of *"Freedom of Informed Choice: FDA Versus Nutrient Supplements"* that discusses constitutional and scientific issues relating to the FDA's regulation of the dissemination of scientific information.

Durk & Sandy's battle began in 1992, when they started filing Public Comments in response to the FDA's proposed rules regulating what health claims they would permit for dietary supplements. On January 15th, 1999, Durk Pearson and Sandy Shaw, along with The American Preventative Medical Association and (from a separate appeal) Citizens for Health, won a long and hard-fought battle with the U.S. Food and Drug Administration. In a landmark decision upholding the First Amendment right of free speech, as opposed to government (FDA) regulation of truthful non-misleading "health claims," the U.S. Court of Appeals for the District of Columbia ruled against the FDA on all issues by a 3-0 vote. The FDA appealed to the U.S. Court of Appeals for the D.C. Circuit. On April 2, 1999, the Court turned down the FDA's request for a re-hearing 11-0.



The following excerpts were taken from an interview that Life Extension magazine conducted in November 1998, prior to Durk & Sandy's victory over the FDA. Excerpts from a second interview conducted after the court's ruling in their favor will be published in a follow-up issue.

-The Editors

Life Extension Magazine: What do you believe are the current challenges that limit your ability to extend lifespan?

Sandy Shaw: When we first became interested in life extension in 1968, the [lack of scientific information was the main obstacle preventing] the extension of lifespan. Now, the major limit on what can [be done] to extend lifespan is government regulation. It isn't enough to conduct aging research and discover what causes aging and how to intervene to prevent it. Those research and clinical findings should be able to translate into therapies that people can [utilize]. The government, especially the FDA, has long stood as the major obstacle to that translation.

. . .In trying to exercise its regulatory control over information on dietary supplement labels and ads, the FDA has really opened up a can of worms for itself. It was inevitable that it would be challenged in court, because the FDA is so far behind in terms of approving health claims. . . .Recently, the FDA lost a big case when. . . a Chinese red yeast rice, naturally containing cholesterol-lowering lovastatin and other statins, was ruled a dietary supplement and not a drug by a federal court. Remember, lovastatin is an FDA approved prescription drug, which now has no protection against its dietary supplement competitor. The pharmaceutical industry has supported the FDA. . . because the FDA has been able to provide competitive protection. That protection, at least as it relates to dietary supplements, is breaking down. . . as the FDA loses control.

LEM: So it has to do with the labeling of dietary supplements?

Durk Pearson: That's right, [it has to do with the intent to require dietary supplements to] go through the drug approval process. A new chemical entity now costs about \$500,000,000 and about ten to twelve years to get FDA approval and. . . get to market. Fortunately, declaring a compound to be a drug because of what a manufacturer says about it-i.e. providing information about a health effect-has severe problems with the First Amendment.

SS: Only companies with very large amounts of money, big. . . pharmaceutical companies have the money to get anything approved under those conditions.

LEM: What are the FDA's current health claim rules?

DP: Well, according to the FDA's rules, it is just as illegal to make a truthful statement about the health benefits of the product without FDA approval as it is to make a fraudulent statement. This really provides a perverse incentive to hype a product, since there is so little truthful information allowed out there to counteract the effect of the false information.

SS: In order to make any health claim for a dietary supplement-[whether it be for the] treatment or prevention of a disease, FDA approval [is mandatory], and that is almost impossible to obtain. There is [virtually] no level of evidence that is adequate to get their approval. In the eight years since the Nutrition Labeling and Education Act was passed, in which Congress mandated that the FDA review and approve health claims, only two such claims have been approved for dietary supplements: folic acid reduces the risk of neural tube defects; calcium supplements may reduce the risk of osteoporosis.

DP: The folic acid/neural tube defect claim [was approved] to relieve the political pressure. And that's it. The FDA has been ordered by Congress to approve health claims now since 1992. And here we are. We have two.

LEM: What about low dose aspirin, making claims that it actually prevents cardiovascular disease, by preventing blood clots?

SS: We have written extensively about the aspirin effects on platelet aggregation, which leads to blood clotting, and this has been known now for decades. The FDA has finally approved aspirin-for communication to doctors, but not to the general public-as an aid to help prevent further damage, prevent a first heart attack and promote survival in people who are having an acute heart attack. But why can't the information be communicated to the public? Under the First Amendment of the Constitution of the United States, the federal government is told that Congress can "make no law." And Congress is the law making body for the federal government. This restriction on the communication of information about aspirin is clearly unconstitutional.

. . . "Congress shall make no law respecting an establishment of religion or prohibiting the free exercise thereof, or abridging the freedom of speech, or of the press," so forth and so on. [Congress] is to make NO laws regarding speech and press.

DP: It does not say "some" laws or "few" laws. . . It says "No laws."

LEM: Can the government be held accountable?

DP: Well, in fact, that is exactly what we're doing. First, this Supreme Court has. . . supported free speech rights in the area of

"commercial speech"-speech that accompanies the sale of a product. In fact, in a recent legal newspaper there was an article by a very concerned liberal [stating] that the Supreme Court has gone too far in protecting the First Amendment in commercial speech. Since the early 1940's, there has been a bias against commercial speech in the courts, as if it weren't deserving of First Amendment protection. . . Now, though, the decisions have begun to support protection for all truthful speech, regardless of whether it is involved in the sale of a product or not.

SS: Exactly. That somebody might profit from his or her speech somehow means it should not be free speech. . . Well, speech is speech. Either it's true or it's not true. That is the issue involved in our FDA suit. If [a statement] is true, then the federal government has absolutely no constitutional authority to interfere with it. And the Supreme Court is beginning to agree with that. There have been a number of recent commercial speech cases where it has been decided that if speech is truthful and non-misleading, there is no justification for the federal government [to interfere].

. . . But, our point is [that] regardless of the product involved, it is absolutely clear-this has actually been stated extensively in a number of U.S. Supreme Court decisions-that the government cannot attempt to regulate people's behavior by keeping them ignorant. In other words, it is true that having access to information might affect people's behavior, but that is not a justification for keeping them from getting information.

LEM: Limiting access to information is the issue here?

DP: The FDA [would like to] control information so it [can] control behavior.

SS: So, we filed our law suit with the support of other people who were willing to help [take care of some of the] legal bills. [Most of the help] came from Dr. Julian Whitaker, and the American Preventive Medical Association. They came with us all the way. The FDA is now [concerned as to] how it is going to be able to keep its regulatory empire together, when that empire depends largely upon the control of information. This is going to have a dramatic effect on FDA regulations.

. . .One of the [obstacles] that prevents people from benefitting from. . . biomedical research is that when companies make products, they [are unable to] tell people much about these products, such as how they work, what they do, and how to use them. There is a roadblock in the flow of information. . .

DP: Or, as in the case of dietary supplements, the FDA has proposed to redefine the word "disease" to reduce the amount of "structure-function" information that can be provided about a dietary supplement. It does so despite the congressional mandate to the FDA to increase the information flow to the public. The FDA is not going to be able to control information flow by redefining the word disease to be so broad as to virtually eliminate any statements that could be made about how a product helps a person stay well.

SS: The FDA re-definition of disease was its way of trying to get around the fact that the DSHEA (the Dietary Supplement Health and Education Act) has required that the FDA review and approve health claims for dietary supplements, and that a company may provide information about the structure or function of a supplement that supports health without getting FDA approval. . .

DP: An example of a structure-function claim [that is unacceptable to the FDA] is that a supplement that lowers LDL cholesterol cannot be said to lower LDL cholesterol. The reason is that many people know that high LDL cholesterol is associated with cardiovascular disease. So the structure-function information would imply reducing the risk of a disease.

SS: The FDA doesn't want the public to infer that on their own.

DP: On the other hand, the FDA proposed rule says that it is [acceptable] to say that a supplement reduces platelet aggregation because most people do not yet know that platelet aggregation is associated with ischemic heart disease and occlusive strokes. But, of course, as time goes on, more and more people will find out about that and then the FDA [may] no longer allow the communication of such information.

SS: The people that know the most are going to be able to get around the problem of FDA regulation of information simply because they can get the information somewhere else. This hurts people who need the information the most, especially if [their means and education are limited].

DP: . . .In two recent commercial cases, the Supreme Court [stated] that the government cannot regulate speech as a means of manipulation of behavior.

SS: . . . That is why we put up a lot of our own money for this FDA suit and why we felt something had to be done about the FDA and the regulation of speech. Freedom of speech is one of our most basic rights. An awful lot of our medical research is funded by tax money. We certainly are entitled to know the results of our own tax money. . .

. . . Basically, what it comes down to is if the federal government is not bound by rules other than at the political whim of the moment, our lives and liberty can be seriously [jeopardized]. People do not [always] realize that there needs to be some basis in law that restricts what a government can do, otherwise there are no rights. . .

LEM: Getting back to the FDA, why specifically is it so important for people to be supporting your efforts financially?

DP: The main problem is that it costs a lot of money to take a constitutional challenge through the courts. Not many people can do that on their own. As we see it, though, if people want to live for a long time, [people should have the ability to] translate research findings into practical products and . . . communicate truthful, non-misleading information about the potential health benefits of using such products. If, for example, a supplement can lower LDL [cholesterol] and increase HDL [cholesterol], [the consumer needs] to [have that information] in order to be able to benefit from it. [A person with high cholesterol levels cannot opt to purchase] everything that says, "Helps maintain cardiovascular health" (which is what the FDA has proposed). Most people are not in a position to investigate all these claims by going to a medical library to [review] . . . scientific papers. [Most people gather] much of their information from product labels and advertisements.

People who [give us monetary donations contribute] to a litigation trust fund.

SS: And we want [to make it] clear. . . that we are not spending the money on anything [other than] litigation of constitutional issues in the courts, beginning with the completion of our current FDA suit. If the FDA appeals to the U.S. Supreme Court, we will have to challenge that appeal and that will cost more money.

DP: We also have the medical marijuana suit, which is about constitutional limits to federal authority to control intrastate practice of medicine, so donations to the Pearson & Shaw Litigation Trust Fund may be used for that, too.

SS: I would also like to mention that the two of us have prepared very extensively before these suits. We did not just decide that, well, something must be done about the FDA or something must be done about the government control of medicine within states. We have read many complete Supreme Court and lower court decisions to understand the legal issues and the positions of various Supreme Court Justices.

DP: [We have become well versed] in certain narrow specific areas, such as the First Amendment, freedom of speech.

SS: . . . Of course, we're not practicing law. We do not have law degrees, nor are either of us interested in that, but in order to fight effectively and use our money effectively we realized that we would have to know about what was the state of the law. By reading court decisions, [we became educated as to] what was the actual understanding of the First Amendment, and we prepared [properly]. We have invested about \$100,000 of our own money so far, in the FDA and medical marijuana suits. It's not just the money. Cash out-of-pocket is one thing, but the time it has taken in learning all [of the legalities], and reading all these decisions and keeping ourselves informed, has been a major expense.

DP: In the past year, in fact, our share of the litigation expenses was about half of our taxable income after taxes.

LEM: What would you have done with your time if you had not been involved in the suits?

DP: We would have spent it developing products, and having fun. But the point is we have many products, but we [are unable to inform the public on] what they do. For example, we have a certain product that is made exclusively out of nutrients that can dramatically increase the rate of wound healing, but we haven't been able to [tell the public about it]. If someone breaks their arm, especially someone who is older, that person is out of luck, although such a product may increase a 70-year old's rate of healing in a broken arm by a factor of five! There are some products that are not even worth putting out on the market because we [are unable to] tell the customer what it may do for them. Few people know about [such benefits] from their own reading, so the market at present is too limited for the costs of bringing out the product.

SS: That is one of the reasons why we're doing this. But I think that the overriding reason of why we're doing this is that the two of us want to be free. We want to have freedom to make our own choices; we want others to have freedom to make theirs.

DP: That is our number one value-[freedom to make our own choices] is the bottom line of why we do it.

SS: . . . There are people [in the FDA] who think that the most important thing is for the federal government to be in control, to be able to tell people what they can and cannot do, even if some individuals die due to FDA regulations. . . Well, we can't afford to let that go by unchallenged. That's not our value and that's not our idea of the best system. . .

LEM: What effects do you believe your suit will have?

DP: The results of opening up the doors to free information flow by upholding the First Amendment's restrictions on government censorship in our FDA suit will lead to phenomenal improvements in overall health and lower health care costs. But. . . the FDA. . . will fight back. . . There will be more battling with the FDA over this. Look at what has happened already in the last 20 years. There has been an increase in life span of the average male of around five years. At that rate, every four or five years, [a lifetime is extended by one] year. Now, that is the U.S. average. . . and includes people who smoke and don't take supplements. But [those] who are taking care of themselves by taking supplements, not smoking and [avoiding] excess fat are receiving greater improvements. Such improvements can be accelerated tremendously with [decreased government regulation].

And that is what it is all about. There can be a whole new 21st century world. It will make what is out there in terms of deliverable products for good health now look like they came out of the slow-moving 19th century.

But remember, "The price of liberty is vigilance." Please join the fight.

[Back to the Magazine Forum](#)

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.