

LE Magazine April 2002

## REPORT

A Celebration of First Amendment  
Victories Against the FDA

On May 26, 2001, a special event occurred to celebrate a string of legal defeats suffered by the FDA in the Federal Courts. Attending were some of the world's most prominent physicians, scientists and health freedom advocates.

By Michele G. Morrow, D.O.

The purpose of this event was to honor those responsible for past legal victories against FDA censorship. At the time this event took place, the latest Court ruling forced the FDA to allow a claim on folic acid labels stating that folic acid reduces the risk of certain birth defects. The FDA had previously prohibited this health claim, thus denying women access to knowledge that could help prevent horrendous birth defects in their unborn children. According to a recent survey, only 30% of women of childbearing age know that folic acid reduces birth defects. By censoring this information about folic acid, the FDA condemned tens of thousands of babies to crippling and irreversible birth defects.

The decision by the Federal Courts to allow this health claim was finalized only after a multi-year battle spearheaded by Durk Pearson and Sandy Shaw and The Preventive Medical Association (who were later joined by Dr. Julian Whitaker, Pure Encapsulations Inc. and others). The contention of those who sued the FDA was that the agency was violating the First Amendment, the Fifth Amendment, the Supremacy Clause of The United States Constitution as well as the Food, Drug and Cosmetic Act and the Administrative Procedure Act. The specific health claim sought by those who sued the FDA was:

"800 mcg of folic acid is more effective in reducing the risk of neural tube defects than a lower amount in common food form"

In 1999, the Federal Appellate Court ruled that the FDA had unconstitutionally suppressed this health claim. Subsequently, the FDA ignored the ruling and would not authorize the claim. The FDA was sued again based on their continued disallowance of this health claim. Those who sued the FDA even sought to have the FDA held in contempt of court for refusing to follow the Court's initial ruling. These cases were described in detail in the July 1999 and May 2001 issues of *Life Extension* magazine.

Paying respect to those who defended our rights



The theme of this awards ceremony was solemn, triumphant and patriotic. A banner of the American Flag proudly hung behind the podium where accomplished dignitaries spoke about the significance of this victory and honored those who fought to make it happen. The event opened with the national anthem sung passionately by gospel singer Elma Randolph. Her powerful performance evoked emotions in just about everyone who attended the ceremony. Little did anyone know then how patriotic we all would become after the September 11th event in New York and Washington D.C. Many of the "Who's Who" in the alternative medicine arena were present, including accomplished political activists of freedom of speech, prestigious government officials who support First Amendment rights as it applies to dietary supplements, respected scientists and alternative medicine physicians.



Dr. Michele Morrow interviews  
Durk Pearson

The honorable former Iowa  
Congressman Berkley Bedell served as  
Master of Ceremonies. Mr. Bedell is  
currently the Founder and President of

The National Foundation for Alternative Medicine and a member of the Board of Directors of the American Preventive Medical Association. He has worked diligently with Senator Tom Harkin to establish the Office of Alternative Medicine at the National Institutes of Health with a "mandate to investigate and validate" alternative treatments for disease. He also worked with Senator Tom Daschle to assist in writing and advocating for the Access to Medical Treatment Act, which would make it possible for patients to gain access to alternative treatments not approved by the Food and Drug Administration.

Brad Clanton, who serves as the chief counsel to the house judiciary sub-committee on the Constitution, gave the keynote address outlining the legal events that led to the First Amendment victory.

In his keynote speech, Mr. Clanton provided a historical overview of this multi-year case that resulted in the FDA's humiliating defeat. Mr. Clanton began by stating that the case was initiated when Durk Pearson and Sandy Shaw sought FDA authorization of four separate health claims that could be put on the labels of their dietary supplements. The four health claims were:

1. Consumption of antioxidant vitamins may reduce the risk of certain cancers.
2. Consumption of fiber may reduce the risk of colon cancer.
3. Consumption of omega 3 fatty acids may reduce the risk of coronary heart disease.
4. 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 common food form.

Each claim was considered separately.

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What was the celebration all about?  
"It's about freedom of speech," said  
Sandy Shaw

Historical information: On November 8, 1990, Congress enacted an amendment to the Federal Food, Drug and Cosmetic Act called the Nutrition Labeling and Cosmetic Act (NLEA). The NLEA prevented dietary supplements and foods that make health claims from becoming subject to the FDA's strict drug approval and drug labeling requirements. (Prior to this amendment, dietary supplements were regulated as a food unless their intended use was as a drug.) At that time, Congress specifically directed the FDA to consider whether health claims could be authorized for a number of specified nutrient-disease relationships, including the connection between folic acid and neural tube defects. The FDA responded by publishing a proposed rule in the Federal Register on November 27, 1991, proposing not to authorize any health claim linking folic acid with a reduction in the risk of neural tube defects. On January 6, 1993, the FDA adopted a final rule prohibiting claims associating folic acid with neural tube defects. On October 14, 1993, the FDA reversed its position and proposed authorizing certain claims associating folic acid with a reduction in the risk of neural tube defects. On January 28, 1994, Plaintiffs Durk Pearson and Sandy Shaw and the American Preventive Medical Association filed comments asking the FDA to authorize the folic acid claim mentioned in this article. Plaintiffs wished to use this claim on the labels and in the labeling of their dietary supplements. This is when the Pearson versus Shalala battle began. It took nearly a decade of frustrating battles and appeals processes, which consisted of multiple stall tactics by the FDA for this valuable information to finally be allowed to be made available to the public on folic acid labels. It is this achievement that we celebrate.

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Mr. Clanton went on to state that after all these claims were rejected, the "plaintiffs" (Durk Pearson and Sandy Shaw, American Preventative Medical Association, et al.) filed a lawsuit based on the FDA's decision that prohibited a health claim on the labels of folic acid supplements. Initially, the courts said that if the evidence was inconclusive, the FDA could require a disclaimer on the label, which states, "The evidence in support of this claim is inconclusive." The case was remanded back to the FDA in April of 1999, and several letters were sent by the plaintiffs asking when the agency intended to comply with the decision. Several months later in September of 1999, rather than authorize the claim as the Court of Appeals suggested, the FDA published a notice asking for additional scientific data in support of the health claims and also contracted with an outside party to conduct a literature review of all four health claims. By March 31st of 2000, the FDA still had taken no action.

After many months, the FDA concluded that the weight of the evidence presented to them regarding the claim about folic acid preventing birth defects was "inherently misleading and could not be made non-misleading with such a disclaimer." Both the District Court and the Court of Appeals rejected the FDA's conclusion after conducting a cursory review of the medical literature on this subject. One study, which was particularly impressive, found that pregnant women who were given 800 mcg of folic acid in multivitamin supplements experienced a 100% reduction in neural tube defects compared with a 40% to 80% reduction resulting from a 400 mcg dosage. The District Court granted the preliminary injunction and remanded the case to the FDA for the agency to draft an appropriate disclaimer to accompany the claim.

The FDA then filed a motion for reconsideration arguing that the court had made a mistake. The District Court denied the motion and stated that the FDA's arguments for reconsideration demonstrated the FDA's reluctance to fully comply with the Court of Appeals decision.

Mr. Clanton concluded by stating, "Pearson vs. Shalala represents another victory for freedom of speech against an FDA that is becoming increasingly aggressive in attempting to suppress the dissemination of truthful and quite often potentially lifesaving information to consumers. Pearson vs. Shalala reminds us that good intentions, especially on behalf of the government, do not always bring about good results and in fact often have devastating and unforeseen consequences. The premise of our Bill of Rights, however; is that there are some things, even some seemingly desirable things, that the government cannot be trusted to do."

### The Freedom Awards presentations

The First Amendment Freedom Award is in recognition of and grateful appreciation for the Pearson plaintiffs' constant and unyielding Defense of the First Amendment to the United States Constitution and of Freedom of Informed Choice in the health care marketplace. The freedom award recipients were:

- Durk Pearson and Sandy Shaw
- Dr. Julian M. Whitaker
- Pure Encapsulations, Inc.
- The American Preventive Medical Association
- XCEL Healthcare

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The first to receive "The Pearson vs. Shalala First Amendment Freedom Award" were long time pioneers in the field of aging prevention, Durk Pearson and Sandy Shaw. Referred to as the "Thomas Jefferson and James Madison of the modern era," Durk and Sandy were not only the leading plaintiffs in the Pearson vs. Shalala case, but they have been advocates for freedom of speech and lobbyists against FDA censorship of health information since as early as 1978. Durk and Sandy are the co-authors of the #1 Best-seller list book, Life Extension-A Practical, Scientific Approach. Durk Pearson and Sandy Shaw have been studying the aging process for over 30 years. They popularized Dr. Denham Harman's free radical theory of aging and age related diseases years ago. Today, this free radical theory is common knowledge among those "in the know." They are also honored for their courageous and tenacious efforts in the fight against the FDA's censorship and violation of the first amendment rights.

Sandy Shaw stated, "When we first became interested in life extension in 1968, the limit to what you could do to extend your life span was information because we didn't know very much about what caused aging. Now, today, the limit to what you can do about extending your life span is not information because we know a lot more about aging now. The limit now is regulatory barriers, particularly those barriers erected by the FDA, and one of the most important of those barriers is the limit on communication of truthful non-misleading information on labels and in advertising about supplements. Without that information, how can people benefit from research that has been done, research that in most cases has been paid for by public money?"



Dr. Julian Whitaker at the podium

Sandy alluded to the anti-federalists who advocated for a Bill of Rights when the United States Constitution was being formed. "They were afraid that the people's rights would not adequately be protected without this Bill of Rights. If not for the anti-federalists, we wouldn't have a Bill of Rights and we could not have won this case," she said. "Freedom of Speech is a very important issue to us."

Durk Pearson added, "These fights are not over. The next fight is going to be applying the First Amendment to foods. The FDA says the Pearson vs. Shalala does not apply to foods. Well, the courts are going to be telling them otherwise. In the very near future we are going to be filing a health petition so that we can put a truthful, non-misleading claim on a designer food, one which states that one or more servings will reduce your risk of a heart attack. The active ingredient in this designer food is EPA/DHA," says Durk, "but it doesn't taste like or smell like fish."

During the appeals process, the FDA had one of the lawyers say in a meeting with a judge that they didn't think the first amendment applied to the FDA, Durk said. "That is frightening. The practical consequences of the FDA's violating the first amendment of the Bill of Rights are appalling. Since we have been suing the FDA concerning folic acid and neural tube defects, the FDA is responsible for over 10,000 dead and crippled babies.

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Dr. Julian Whitaker and Dr. Matthias Rath, with Durk and Sandy

"Since we have been suing the FDA over homocysteine which is a toxic metabolic by-product which causes cardiovascular disease and heart attacks, and which can be easily lowered with folic acid, vitamins B6 and B12, the FDA is responsible for approximately 350,000 premature preventable deaths of Americans. Since we have been suing the FDA over the effects of EPA/DHA, the extra long chain fish oils that help provide protection against cardiovascular disease, the FDA has been responsible for one million preventable deaths" said Durk.

Former Congresswoman from Idaho's First Congressional District, the honorable Helen Chenoweth-Hage, presented the next award to Dr. Julian Whitaker. Mrs. Chenoweth-Hage was an influential critic of the Food and Drug Administration's failure to implement fully and faithfully the Pearson vs. Shalala decision. She repeatedly wrote the then FDA Commissioner Jane Henney urging her to explain the agency's failure to comply with the Court's order.

Dr. Whitaker is the founder and president of the Whitaker Wellness Institute in Newport Beach, California and a worldwide renowned lecturer and writer on alternative medicine. His organization publishes a monthly newsletter, Health & Healing, that reaches more than 500,000 subscribers. He has published eight major books about health and wellness. Dr. Whitaker participated in the Pearson vs. Shalala and was the lead plaintiff in the Whitaker vs. Shalala First Amendment litigation against the Food and Drug Administration. The Whitaker vs. Shalala case against the FDA asked the federal courts to halt the FDA's more recent attempt to avoid compliance with the First Amendment by restricting what type of therapeutic claim can be made about patented drugs.

Dr. Whitaker is a vehement advocate of liberty and freedom of informed choice as it relates to the healthcare marketplace. In 1995, Dr. Whitaker took on a personal challenge by riding a bicycle on a 10-week trip, 5,000 mile bike hike from California to Washington, D.C. He sent FDA Commissioner David Kessler a letter ahead of time, informing the Commissioner that when his bike arrived at the steps of the nation's Capitol, he would hold a press conference during which time he intended to sell dietary supplements which made truthful but FDA unapproved health claims, a violation of FDA rules. He dared the FDA Commissioner to arrest him claiming that he would challenge the arrest in federal court under the First Amendment. The media and a crowd of people showed up and Dr. Whitaker did sell his supplements; however, no FDA enforcement authorities took the bait.

Dr. Whitaker has gone out on a limb in various situations to help persons with special needs for unapproved medical alternatives. He assisted the family of a 10-year-old cancer patient in finding an alternative to a leg amputation in the face of nearly forced surgery due to threats from the Child Protection Services Department. Several years ago, Dr. Whitaker raised over \$300,000 to help fight the federal trial that the FDA brought against Dr. Stanislaw Burzynski. Dr. Burzynski is the director of an alternative cancer center in Houston, Texas. The FDA sought to shut down the clinic because he was using an unapproved medication, which was benefitting certain kinds of otherwise fatal cancer patients who were offered no other useful treatment. Today, the clinic still exists and Dr. Burzynski continues to practice medicine. These are just two of several stories with a similar theme. Dr. Whitaker has enlisted the support of his patients and newsletter subscribers for a variety of issues that have to do with access to medical alternatives and FDA censorship of information, and he himself has boldly challenged the legal system about such issues.

During his speech, Dr. Whitaker alluded to the "arbitrary and capricious activity" of the FDA. He discussed a nine-year-old patient who had a malignant brain tumor and was told by the FDA that he could not go to the Burzynski Clinic. "When you lose your freedom, you don't really know it until you need it and it is not there," said Whitaker. He mentioned a study published in the Journal of Epidemiology that found that 1000 mg of vitamin C in a male can cut heart disease by 70% and all-cause mortality by 60%. "It caused the men to live six years longer than average," he said. "It is time for us to realize that gradual erosion of our freedom is far more dangerous than an armed attack. Tyranny installed gradually is far more difficult to cut off than tyranny installed abruptly. I think this country is worth saving. I hope you do as well," said Dr. Whitaker during a powerful and moving speech.

Norman Singleton, the legislative assistant for Congressman Paul of Texas, presented The First Amendment Freedom Award to Pure Encapsulations. Pure Encapsulations, Inc. is a dietary supplement manufacturing company, which markets their products through doctors' offices and is lead by two brothers, Ray and Peter Hamel. They joined in the Pearson vs. Shalala and Whitaker vs. Shalala battles and provided support to finance the extraordinary litigation needed to enforce the decision over the preceding two years. They believe deeply that eternal vigilance is the price of freedom, said Congressman Singleton. A representative from Pure Encapsulations said, "Durk, Sandy, Dr. Whitaker and Jonathan Emord are the combination that created the most modern force in the modern era of commercial free speech and health freedom. Pure Encapsulations salutes you."

Candace Campbell, Executive Director of the American Preventive Medical Association (APMA) and a lobbyist for preventive medicine rights (APMA) accepted the award for the APMA. "Think of this as a call to arms," she said. "If we can accomplish this in such a short time with so little money, think of what we could do if all of you threw your weight behind it as well. I think we could move mountains," said Mrs. Campbell.

XCEL Healthcare also participated in the Pearson vs. Shalala litigation. Its owners, Dr. Richard Kleinberger, Dr. Daniel Gelber and Ronald Gustilo, oppose FDA censorship of truthful health information and believe absence of such information in the market is harmful to patients. XCEL is a multifaceted corporation; the company consists of a healthcare division, a nutraceutical division, a homecare division, a pharmaceutical division and a research division. They continuously make an effort to develop cutting edge treatments to combat conditions that conventional treatments fail to cure or mitigate.

The Bulwark of Liberty Awards presentation

The Bulwark of Liberty Award recognizes those who have made extraordinary efforts to advance nutrition science, educate the public on the health benefits of nutrients and end government censorship of health information. The National Foundation for Alternative Medicine and the American Preventive Medical Association presented the Bulwark of Liberty Awards to these four highly distinguished and accomplished individuals:

- The Honorable Berkley Bedell
- Charles E. Ragus
- Dr. Mathias Rath
- Dr. Charles B. Simone

The honorable Berkley Bedell, who was previously mentioned in this article, has worked behind the scenes to advocate for First Amendment rights.

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Mr. Charles E. Ragus, Founder of Advocare International, L.L.C., a successful 150 million dollar a year direct sales company, which has over 100,000 distributors, has worked for years with leading nutritional scientists and physicians to formulate test and sell dietary supplement formulations. In 2000, Mr. Ragus was a finalist for the Ernst & Young Entrepreneur of the Year Award, recognizing that he had become one of the most successful and well-respected entrepreneurs in the United States. They are fully dedicated to the cause of healthcare freedom. "I want to encourage everyone here to be a difference maker," said Charles Ragus. "It only takes one person, one voice to be a major difference maker sometimes. Our freedom and our right to assemble here today people died for once."

Matthias Rath, M.D., is an internationally recognized and respected physician and scientist who discovered important associations between vitamin C and cardiovascular health. His publications have appeared in the American Heart Association's Arteriosclerosis and the Proceedings of the National Academy of Sciences, and others. Dr. Rath is the founder and president of an international research and development firm that studies and publishes on nutrition science. Until 1992, Dr. Rath was Director of Cardiovascular Research at the Linus Pauling Institute of California, where together he and Linus Pauling published several landmark scientific works.



Dr. Rath, a German citizen, has taken an active role in informing the public about an insidious and potentially life-threatening issue. The issue is called Codex alimentarius. Codex is an international code of food standards developed by a Commission under the United Nations through the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). This international code of food standards attempts to impose very strict rules restricting all countries including the USA from access to information on health choices and the right to obtain high-potency vitamins without a prescription. This means that we would only be able to buy over the counter vitamins and supplements that have no more than the minimal RDA amounts. Stronger formulations would be prohibitive without a prescription from a doctor and consequently, more expensive as well. This would take away our freedom of informed choice and restrict access to valuable medical tools. Most doctors don't even know much about vitamins and supplements! If this passes, doctors will be the ones prescribing. How could this happen?

The Commission that created this code consists of appointed (not elected) members from each participating country. Consequently, they do not represent consumer interests. The majority of these members are representatives from multinational pharmaceutical corporations that would benefit financially if the Codex is accepted. "Presently, the European Parliament has made a substantial effort to decrease the availability of vitamins all over Europe by forming binding legislation," said Dr. Rath. "In 1989, the British parliament created a piece of legislation called Amilex 249 criminalizing the spread of natural health information. Great Britain is the #2 export country of pharmaceutical products," he said.

This piece of legislation did not pass due to elaborate efforts by advocates such as Dr. Rath. In June, 2000, Dr. Rath distributed a newspaper to two million households in London picturing a sailor dying from scurvy stating that if the legislation passes, such a piece of literature would

be prohibited. More than one half million people used his website to protest to each member of the Commission. "Since 1996, the European governments meet every two years in Berlin. (The most recent meeting was November, 2001). Switzerland, the #3 pharmaceutical product export country, now has a national law criminalizing the spread of natural health information related to vitamins and unpatentable natural therapies," said Dr. Rath. France and Germany already imposes restrictive vitamin rules which limit access to information and restrict the right to obtain high-potency vitamins without a prescription. Canadians have limited access to vitamins and supplements as well. "In 1992, the FDA's effort to turn vitamins prescriptive medication was defeated. Under Codex in Europe they are still trying to outlaw the use of preventive and therapeutic health statements," said Dr. Rath. "We will win because we are right. No army in the world can stop the truth once the time has come." Let's hope the time has come. This is a serious issue.

Dr. Charles B. Simone, MMS, M.D., of the Simone Protective Cancer Center in New Jersey, was the next recipient of the Bulwark of Liberty Award. Dr. Simone is one of the few people in the world who has formal training in medical oncology, radiation oncology and immunology with an expertise in nutrition, cancer detection and cancer prevention. Known for his exceptional bedside manner and tenacious efforts to leave no stone unturned, he is a pioneer in integrative medicine combining effective conventional and alternative modalities to bring his cancer patients the best of both worlds.

Dr. Simone has created a series of exceptional publications about a variety of related topics, and has helped thousands of people find treatments that could extend their lives. He also started a series of outstanding scientific investigations at the NIH, which made some significant discoveries in the field of immunology and cancer. These investigations uncovered the fundamental mechanism of how human white blood cells kill foreign cells; helped demonstrate how "complement proteins" aid in destroying foreign cells; demonstrated how adriamycin, an anti-cancer drug operates at the cellular level; and conceived and developed the idea of splicing monoclonal antibodies to killing cells that seek out cancer cells, called directed effector cell killing.

Dr. Simone stated that he and his family are committed to finding the truth of what is effective in diagnosis and treatment so that the public can make informed choices. Consequently, he has opposed government censorship of health information. Dr. Simone has helped organize the Office of Alternative Medicine of the National Institutes of Health. He has also testified on multiple occasions before the United States Senate and House of Representatives on health issues, FDA reform and alternative medicine, and has appeared on numerous national television programs including "60 Minutes," "Prime Time Live" and others. He is a compassionate, sensitive, brilliant and exceptional physician, scientist and spokesperson for health related issues.



Jonathan Emord

### Summary

Jonathan Emord, the attorney who represented the plaintiffs in the First Amendment battles said, "The FDA is a mammoth agency that controls a third or more of the Gross Domestic Product of the country. The Court of Appeals process showed this agency that it too must abide by the law. The Constitution, has input beyond. . . anyone in this country who would through government actions attempt to deprive us of our freedoms. Without much money, Durk and Sandy, Dr. Whitaker and the APMA took on this agency and brought it to its knees. I salute them."

The time and efforts required to force the FDA to recognize just one health claim relating to folic acid was enormous. Health freedom advocates continue to aggressively litigate against the FDA to force the agency to allow health claims that are thoroughly documented in the peer-reviewed scientific literature.

For more information about Jonathan Emord's numerous victories over FDA tyranny, log on to [www.emord.com](http://www.emord.com).

If you wish to make a financial contribution to help finance the battle against FDA censorship, please send your check payable to:

First Amendment Litigation Fund  
C/o Emord & Associates,  
5282 Lyngate Court Burke,  
Virginia 22015.

To order a video tape of the entire Pearson vs Shalala Awards Ceremony, including the various speeches presented, call 1-800-544-4440. The cost of the video is \$23.00. Life Extension Members pay \$17.00.

Michele G. Morrow, D.O., is a Fellow of the American Academy of Family Physicians.

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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.