

LE Magazine May 2001

COVER STORY

What's Wrong With The

FDA

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"That whenever any form of government becomes destructive of these ends, it is the right of the people to alter or abolish it."
Thomas Jefferson, Declaration of Independence
July 4, 1776

Congressional committees and investigative journalists have exposed massive incompetence, neglect and fraud at the FDA. In the Courts, the agency continues to lose critical cases as Federal Judges rule that FDA policies are blatantly unconstitutional.

In the article that begins on the next page, we reveal the most recent defeats the FDA has suffered in the Federal Courts. We then follow with a report that deals with FDA problems uncovered by Congressional committees and investigative journalists.

For the past 21 years, The Life Extension Foundation has compiled evidence indicating that the FDA is the number one cause of death in the United States. The FDA causes Americans to die by:

- Delaying the introduction of life-saving therapies
- Suppressing safe methods of preventing disease
- Causing the price of drugs to be so high that some Americans do without
- Denying Americans access to effective drugs approved in other countries
- Intimidating those who develop innovative methods to treat disease
- Approving lethal prescription drugs that kill
- Censoring medical information that would let consumers protect their health
- Censoring medical information that would better educate doctors
- Failing to protect the safety of our food
- Misleading the public about scientific methods to increase longevity

The greatest threat the FDA poses to our health is the fact that the agency functions as a roadblock to the development of breakthrough medical therapies. Innovation in medicine is stifled by FDA red tape, which is why Americans continue to die from diseases that long ago might have been cured if a free marketplace in drug development existed.

The Life Extension Foundation is the only organization that chronicles the multiple abuses committed against the American public by the U.S. Food and Drug Administration (FDA). At the end of the last article in this section, we make proposals for reforming the FDA.

FDA Suffers Second Massive Legal Defeat in "Pearson vs. Shalala II"

Court to FDA? The First Amendment Must Be Followed

by William Faloon

In the July 1999 issue of Life Extension magazine, we announced an unprecedented legal victory against the FDA in a landmark Federal Appellate Court ruling. The title of the 1999 case was "Pearson versus Shalala." For the purposes of this article, we will refer to the 1999 case as "Pearson I." When discussing the most recent triumph over FDA tyranny, this case will be called "Pearson II."

The historical significance of Pearson I cannot be overstated. By an 11-0 margin, an appellate court mandated that the FDA abide by the First Amendment (free speech) provisions of the United States Constitution. Prior to this ruling, the FDA behaved as if the First Amendment did not apply to them.

Still reeling from the devastating loss in Pearson I, the FDA on February 2, 2001, suffered yet another massive legal defeat in the Pearson II case. Pearson I and II are significant victories for freedom of informed choice in the health care marketplace. They make it clear that the First Amendment to the United States Constitution disarms FDA of any power to ban nutrient-disease claims (so-called "health claims") unless FDA has solid evidence that the claims actually mislead. The Courts have ordered FDA to stop censoring science on dietary supplement labels and to let that science reach consumers. The Courts ruled that the only constitutional right the FDA has on the issue of health claims is to insist on reasonably worded disclaimers such as, "These statements have not been evaluated by the Food and Drug Administration."



What the FDA wanted to censor

In Pearson II, Durk Pearson, Sandy Shaw, the American Preventive Medical Association, Dr. Julian M. Whitaker and Pure Encapsulations, Inc. appealed an FDA ruling that would have prevented the public from learning that synthetic folic acid is more effective than food folate in reducing neural tube defects. The specific claim the FDA wanted to ban was:

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

In the Pearson I decision, the Federal Appellate Court ruled that the FDA had unconstitutionally suppressed this health claim. Over two years later, FDA still suppressed the claim in disobedient disregard of the Pearson I ruling. The FDA's decision to suppress this health claim not only violated the First Amendment rights of the Pearson plaintiffs, it also deprived the public of health information vital to every fertile American woman.

The FDA ignores the Court's ruling

The fact that synthetic folic acid in amounts ranging from 400 mcg to 800 mcg is more effective than food folate in reducing neural tube defects is well-established in the scientific literature. The Institutes of Medicine of the National Academy of Sciences has determined that synthetic folic acid is twice as bioavailable as food folate and, thus, is more effective in reducing neural tube defect risk. Despite the ruling in Pearson I, and despite the overwhelming scientific evidence in favor of the claim, the FDA held for a second time that the claim would not be allowed. In the process, it once again denied American women information they need to save them and their future children from the horrible affliction of neural tube defects. It also proved that this agency continues to be willing to harm the public health to keep in place its regime of censorship over health claims.

Pearson II is an outgrowth of Pearson I. A landmark First Amendment decision, Pearson I struck down as unconstitutional four FDA rules that suppressed the health claims that Durk Pearson, Sandy Shaw, the American Preventive Medical Association and Citizens for Health wanted to make. The four claims were:

- 1 Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.

- 2 Consumption of fiber may reduce the risk of colorectal 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 foods in common form.

The Court also held FDA's interpretation of its health claims review standard unconstitutional. It ordered FDA to allow the four claims even if they failed to satisfy that review standard.

The Court ruled the FDA's health claim standard to be arbitrary and capricious because it was so subjective that no one could determine precisely what level of scientific evidence FDA expected in order to approve a claim. It ordered FDA to define a new standard comprehensibly—something that FDA has still not done. It told FDA that even in the presence of a defined standard the agency would be expected to allow health claims except in the narrowest of circumstances: when it proved with empirical evidence that a health claim was not only misleading to consumers but also that it could not be rendered nonmisleading through the addition of a disclaimer. Pearson I made disclosure over suppression the order of the day. FDA was supposed to implement the decision immediately, fully and faithfully. FDA did not. In fact, FDA still has not done so.

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Supporting Anti-FDA Litigation

Only a handful of people are paying the legal costs of battling the FDA's attempt to deny the public access to truthful, non-misleading scientific information. The First Amendment victories over the FDA to date have been remarkable, but the FDA continues to squander tax dollars in an effort to protect the drug companies against low-cost dietary supplements. You can help support litigation being spearheaded by Durk Pearson, Sandy Shaw, Julian Whitaker and others by sending a donation to:

Pearson and Shaw
Litigation Fund
Emord and Associates
5282 Lyngate Court
Burke, VA 22015

All of the legal briefs filed for Durk and Sandy by Jonathan Emord and Associates can be found at www.emord.com.

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FDA dragged into Court again

In Pearson II, Durk Pearson, Sandy Shaw and the other Pearson plaintiffs returned to federal court to force FDA to comply with Pearson I by allowing the plaintiffs' folic acid claim to enter the marketplace immediately. The Court granted the plaintiffs request for a preliminary injunction to the extent that it declared FDA's action unconstitutional. The Court held that "FDA acted unconstitutionally, and particularly in violation of the Court of Appeals decision in [Pearson I], in suppressing Plaintiffs' claim rather than proposing a clarifying disclaimer to accompany the Claim." FDA has sixty days to implement the decision but, rather than do that, it has asked the Court to reconsider its ruling, another delaying tactic.

Pearson II is a particularly bitter defeat for FDA because it comes at the hands of the very judge who ruled in favor of FDA in the case reversed by Pearson I: Judge Gladys Kessler of the U.S. District Court for the District of Columbia. At oral argument before she ruled in Pearson II, Judge Kessler explained that she had been persuaded that her earlier decision had been incorrect. She said that she believed that the Court of Appeals' decision in Pearson I was the proper resolution of the matter. She then issued a very well-reasoned decision that constitutional law experts who have studied the case believe will be very hard, if not impossible, for FDA to appeal successfully.

If FDA does file an appeal, it will face the same Court that denied FDA's request for rehearing of Pearson I by 11 to 0.

In Pearson II, Judge Kessler rejected FDA's arguments one by one. She found FDA's failure to comply with the Pearson I order inexcusable, writing, "there is no question that the agency has acted with less than reasonable speed in this case; for example, it waited for more than 18 months before revoking rules declared unconstitutional by the Court of Appeals." She found it "clear that the FDA simply failed to comply with the constitutional guidelines outlined in Pearson." She stated that "the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion." She found that "FDA has continually refused to authorize the disclaimers suggested by the Court of Appeals—or any disclaimer, for that matter" and "has simply failed to adequately consider the teachings of Pearson: that the agency must shoulder a very heavy burden if it seeks to totally ban a particular health claim."

In granting the injunction against FDA's decision to prohibit the folic acid claim, Judge Kessler found, "FDA's decision... was arbitrary, capricious and an abuse of discretion." She thought it "very clear that Plaintiffs are harmed by the FDA's suppression of the Folic Acid Claim," explaining that the continued violation of their First Amendment rights constituted "irreparable harm."

Judge says FDA's position "Harmed the public interest"

Indeed, Judge Kessler found the FDA's suppression of the claim



FDA loses case against compounding pharmacies on First Amendment grounds

Most Americans don't know that they can legally obtain certain drugs that are not FDA-approved at compounding pharmacies. The cost of these "compounded" drugs is often lower than what it costs to buy finished drugs made by pharmaceutical companies. The reason most Americans don't know about drugs available at compounding pharmacies is that up till now, the FDA said it was "illegal" for compounding pharmacies to promote the drugs they offered.

A Federal appellate court has just ruled that the FDA cannot restrict advertising by pharmacists who sell compounded drugs. The decision pitted the free speech rights of pharmacists against a Federal law aimed at restricting advertising of compounds that require a doctor's prescription, but aren't subject to the FDA's approval process.

In citing previous cases, the U.S. Court of Appeals for the Ninth Circuit Court (San Francisco) stated that "government prohibitions of truthful commercial messages are 'particularly dangerous' and deserve 'rigorous review.'"

In this case, the FDA contended that restrictions on ads for compounds were an attempt to balance the needs of individual patients with the protection of the broader public

inexcusable not only because it deprived the Plaintiffs of their “rights to effectively communicate. . . health message[s] to consumers” but also because it harmed the public interest. FDA’s existing, allowed folic acid claims convey the false and misleading impression that folate in unfortified foods is effective in reducing neural tube defects when, in fact, it has never been proven effective. The only source of folic acid proven effective is synthetic, i.e. the kind of folic acid found in supplements. The only amounts shown to reduce neural tube defects consistently and reliably are above 400 mcg, with 800 mcg regarded as an ideal dose by many leading scientists. The only large-scale placebo controlled clinical trial corroborating a 100% reduction in neural tube defects in women with no prior history of neural tube defect births involved use of dietary supplements containing 800 mcg a day of folic acid (“Prevention of the first occurrence of neural-tube defects by periconceptional vitamin supplementation,” *New England Journal of Medicine* 1992 Dec 24; 327(26):1832-5). The FDA rejected this study, but Judge Kessler did not. She ruled FDA’s rejection of the study an abuse of discretion, finding the need for the information substantial. Here is what the Judge said:

“The public health risk from neural tube defects (NTD) is undeniably substantial. NTDs occur in approximately 1 of every 1,000 live births in the United States. Approximately 2,500 babies are born every year with an NTD. Of the children born with NTDs, most do not survive into adulthood, and those who do experience severe handicaps. The lifetime health costs associated with spina bifida, the most common NTD, exceed \$500,000, and the yearly costs in Social Security payments exceed \$82 million.

“Given that 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 folic acid/NTD connection to reach as wide a public audience as possible. Plaintiffs’ *Folic Acid Claim*... communicates this vitally important message.”

Is the FDA now in contempt of court?

Pearson II and Pearson I have profound implications for FDA’s regulation of health information. These decisions establish beyond any legal doubt that the FDA must comply with the First Amendment. Those decisions make it clear that FDA cannot suppress health information on the basis that the agency disagrees with the message communicated. Instead, FDA must be in the business of fostering the dissemination of health information to the public, not censoring it.

Although the Pearson I and II decisions concern dietary supplements, they rest on broad First Amendment doctrines that are the supreme law of the land and have greater authority than any FDA regulation. As a consequence, the Pearson decisions are likely to cause the toppling of FDA’s censorship of food and drug claims over time. If applied to their full extent, the First Amendment principles of Pearson mean that FDA has no constitutional power to prevent the public from receiving any truthful and nonmisleading health information about any product that agency regulates.

Those principles mean that FDA must rely on corrective disclaimers, whenever possible, as an alternative to its current practice of censorship. The days of FDA censorship are destined to come to an end. For the moment, however, the agency still (even after Pearson II) continues to censor health claims for supplements, health claims for foods and off-label claims for drugs. That would appear to be contempt of court. In one case now pending before the United States Court of Appeals involving FDA suppression of a vitamin B6, vitamin B12, folic acid and vascular disease claim, plaintiffs represented by attorney Jonathan Emord have asked the U.S. District Court to hold FDA in contempt for its noncompliance with the Pearson decision. It may well be that in due time FDA and its officers will be made to account personally for FDA’s unlawful refusal to comply with the First Amendment.

by “preventing widespread distribution of compounded drugs.”

In an opinion (that upheld a lower court ruling), Judge Cynthia Holcomb Hall wrote that “the government neither explains nor supports” its contention that wider distribution of compounded drugs would endanger the public. “In fact, most of the evidence runs to the contrary,” she wrote, noting that “compounding is not only legal under state law, but most states require their pharmacists to know how to compound.”

Judge Hall went on to say that the government offered “no evidence demonstrating that its restrictions would succeed in striking the balance it claims is a substantial interest, or even protect the public health.”

Two years ago, the FDA lost a similar case when they challenged the right of drug company representatives to promote the use of approved drugs for uses that were not approved by the FDA. In both of these cases, the FDA was trying to censor the promotion of a legal activity. Since both drug compounding and using approved drugs for unapproved uses is legal, the FDA did not have a right to ban it, so say the Courts.

The FDA expended considerable tax dollar litigating these losing cases. It is difficult to ascertain what “consumer protection” benefit the FDA expected to attain if they had prevailed in these expensive court actions.

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