

## FDA AND FTC CENSORSHIP OF HEALTH INFORMATION MUST END

James Madison introduced the First Amendment to the United States Constitution in 1789. It was ratified by the states and became a part of the Bill of Rights in 1791. Its primary purpose was to disarm the federal government of power to censor truthful speech. Our federal courts have long recognized the indispensable role of free expression to the search for scientific truth, to innovation, and to self-improvement.

One of the signers of the Declaration of Independence, and this nation's first Surgeon General, Dr. Benjamin Rush, spoke prophetically of the risks to liberty if our Republic were ever to abandon its commitment to health freedom:

The Constitution of this Republic should make special provisions for Medical Freedom as well as Religious Freedom. To restrict the art of healing to one class of men and deny equal privileges to others will constitute the bastilles of medical science. All such laws are unAmerican and despotic.

Two hundred and fourteen years after the First Amendment became a part of the Bill of Rights, the federal Food and Drug Administration and the Federal Trade Commission now regularly violate the First Amendment and sacrifice our health freedom. From 1990 to 1995, the FDA censored the claim that folic acid (a B vitamin) reduces the risk of neural tube defect births. FDA continued to censor the claim in the market despite the federal Public Health Service's statement to all physicians that women of childbearing age should consume 400 mcg of folic acid per day before they become pregnant to reduce the risk of neural tube defects by 40 percent or more. An estimated 2400 neural tube defect births (and more neural tube defect abortions) could have been averted if FDA allowed the claim into the market. Only after congressional pressure and litigation from my firm did FDA finally allow the claim. The number of neural tube defect births since the court ordered the claim be allowed has dropped from 2400 per year to approximately 1700 per year. That's about 700 babies who are healthy each year who would otherwise have survived in a horrible state of affliction or been aborted.

FDA bans every claim of a nutrient's treatment effect on disease, regardless of its truthfulness. For example, FDA prohibits the scientifically supported claim that fish oils (omega-3 fatty acids) reduce the risk of sudden death heart attack. There are approximately 300,000 sudden death heart attacks each year. Approximately 110,000 of those deaths would not occur if all adults consumed fish oil. FDA's speech ban thus contributes to 110,000 sudden death heart attacks every year. FDA prohibits the scientifically supported claim that calcium reduces the risk of bone fractures. Thousands of Americans, particularly the elderly, suffer from bone fractures due to lack of adequate bone density. FDA's speech ban thus contributes to the pain, suffering, and occasional consequential deaths of many elderly Americans each year. FDA prohibits the scientifically supported claim that glucosamine and chondroitin sulfate treats osteoarthritis. Twenty million Americans suffer from pain and joint stiffness due to osteoarthritis. FDA's speech ban thus contributes to unnecessary pain and suffering in

millions of Americans. FDA prohibits the scientifically supported claim that saw palmetto treats benign enlarged prostates. Fifty percent of all men aged 50 and older suffer from an enlarged prostate. FDA's speech ban thus contributes to unnecessary pain and debilitation in millions of American men.

FDA censorship has not fared well when constitutionally challenged. I have had the privilege of defeating the FDA in five First Amendment cases. In *Whitaker v. Thompson I*, the antioxidant vitamin/cancer risk reduction claim case, the court held FDA censorship unconstitutional for the fourth time. It prohibited FDA from banning a claim unless it could prove (1) that no scientific evidence supported the claim and (2) that no disclaimer or qualification existed that could render the claim non-misleading. In short, the court agreed that FDA had no constitutional power to censor health information unless it could prove the information false. If it could not, then it had to let the public have the information, adequately qualified to avoid a misleading connotation. Despite the rulings against it, FDA has never implemented the *Whitaker v. Thompson I* standard. H.R. 4282 makes the court's standard the law.

Despite federal court rulings and statutory provisions to the contrary, FDA has taken the extraordinary step of censoring from the market all peer-reviewed scientific publications on nutrient-disease associations. It also censors from the market the government's own scientific publications linking nutrients to disease.

FDA's censorship of health information that could save lives and reduce pain and suffering led Congressman Ron Paul of Texas to ask me to draft a bill to end the First Amendment violations and to cause the truthful claims censored by FDA to enter the market. That bill is H.R. 4282, sponsored by 14 members of Congress, conservatives and liberals alike.

Our inquiry into the reasons for this censorship has led to two very definite conclusions. FDA's censorship is designed to protect FDA-approved drugs from competition and FDA depends upon apologists for the censorship among the ranks of dietary supplement companies and their associations to advance its speech suppression agenda. But FDA is not alone in pursuing a speech suppressive agenda.

FTC denies those it accuses of deceptive advertising of their Fifth Amendment due process right to a presumption of innocence. Under FTC's regulations, anyone who advertises a product's health benefits if accused of deception is presumed guilty unless he or she proves the claim true to a near conclusive degree (something all but impossible in science). Under our First and Fifth Amendments, it is the government, not the accused, who must bear the burden of proof. That protects those falsely accused of being victimized by the necessity of answering costly and intrusive FTC investigation demands. Unless the government first has proof to support its claim of deception, it should not be free to impose a burden on a speaker. Placing the burden of proof on FTC to have a sound basis for its charge of deception is the least we should expect of our government before it acts against its citizens.

Apologists for FDA and FTC censorship oppose the bill. They tend to be companies with large market shares that fear free speech will cause them to experience more competition (a public good), associations that represent such companies, drug companies that do not want competition, or government bureaucrats. They have argued that protection for constitutional rights will lead purveyors of fraud to enter the market, harm consumers, and destroy the credibility of all companies in the dietary supplement industry. They would sacrifice the First and Fifth Amendment rights of all Americans on the argument that some bad actors will abuse their freedom. This is an old argument, rejected by our Constitution's framers and by the Supreme Court. We should reject it too. It lacks credence because it could only follow logically if fraud were legalized, but H.R. 4282 will not legalize fraud. Rather, it ends censorship while keeping fraud illegal.

Consider each argument the apologists for censorship present against H.R. 4282. One myth presented by opponents is that the bill would allow companies to make false claims. That is not true. The bill leaves in place FDA's prohibition on false and misleading labeling and FTC's prohibition on deceptive advertising.

A second myth presented by opponents is that the bill forces FDA to allow all claims within 100 days of their submission to the agency. That too is not true. The bill requires FDA to act on a claim within 100 days or it is automatically allowed. FDA is free to deny any claim within 100 days. The 100 day hammer provision stops FDA's current practice of delaying action on claims for years. For example, FDA granted itself five extensions of time to act on a Lycopene petition from American Longevity, censoring the claim by failing to act on it for a period of twenty-two months. FDA only acted at that time following receipt of a letter demanding an explanation for the delays from Senators Hatch and Harkin. Without the hammer provision, FDA can be counted upon to threaten companies with claim petition denials as a basis for extorting a petitioner's agreement to extend review time indefinitely. The public deserves better from its government. The information is vital. We cannot allow FDA to delay action on information that can save lives or reduce pain and suffering. Prompt review is imperative.

A third myth presented by opponents of the bill is that it forces FTC to prove an ad false before it commences a deceptive advertising investigation. The argument misleads. Currently, FTC can investigate any company's finances, trade secrets, and other proprietary information without any proof in hand that an ad in question is false. That is an abuse of federal power. Ads are by definition public. The FTC can examine them and consult with scientists concerning the truth or falsity of their health benefit representations.

Requiring the FTC to possess evidence that ads are false before it commences an investigation of a company's finances, trade secrets, and other proprietary information is the bare minimum we should expect of that agency. Probable cause or proof in support of a search and seizure warrant are required before government searches our cars, houses, and personal effects. Companies that sell dietary supplements and their executives deserve the same rights protection.

A fourth myth presented by opponents of the bill is that it causes advertising to be totally unregulated. It does no such thing. It leaves in place the statutory prohibitions against false and misleading labeling and against deceptive advertising. It does require that our federal government prove a claim false before censoring it or imposing civil penalties on the speaker.

In the end, we as Americans are entitled to protection for our inalienable rights to freedom of speech. We are entitled to speak the truth free of government harassment or restriction. We are also entitled to a presumption of innocence. Companies in the dietary supplement industry must be secure in the knowledge that our government will not penalize them for their speech unless it can prove that speech false. The FDA and the FTC currently violate the First Amendment freedom of speech and the Fifth Amendment right to due process. Dr. Benjamin Rush had it right, "all such laws are unAmerican and despotic."

#### ABOUT JONATHAN W. EMORD

Jonathan W. Emord is a Washington, DC attorney who has defeated the federal Food and Drug Administration in federal court more times than any other lawyer in American history (five times on First Amendment grounds and one time on administrative law grounds). He was the attorney for the plaintiffs in the landmark *Pearson v. Shalala* decision holding FDA censorship of four nutrient-disease claims unconstitutional under the First Amendment. He is a constitutional and administrative law attorney.

Emord and his firm have received an AV rating from the Martindale Hubbell organization, the highest rating that an organization awards for excellence in the law and for legal ethics. He is the former vice president of the Cato Institute in Washington DC. He also formerly served as a lawyer with the prestigious Washington firm of Wiley, Rein, and Fielding. He is the author of several works on the First Amendment, including his critically acclaimed book *Freedom, Technology, and the First Amendment*. He came to Washington, DC in 1985 and worked in the Reagan Administration as an attorney for the Federal Communications Commission. He is the Chairman of the Coalition to End FDA and FTC Censorship and is the author of H.R. 4282, the Health Freedom Protection Act.

He is the Principal in the Washington DC law firm Emord & Associates, P.C. ([www.emord.com](http://www.emord.com)) and represents over 450 food and dietary supplement companies, physicians, and scientists.