

**REMARKS ON
“FDA’S PERSPECTIVE ON REGULATING DIETARY SUPPLEMENTS”
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It appears to me that the officials of the Food and Drug Administration do not yet comprehend that they are players on a stage much larger than their offices in the Parklawn building: the stage of constitutional history.

They do not comprehend the enormity and constancy of the First Amendment and its principle of disclosure over suppression. Indeed, they continue to regard the First Amendment not as Supreme law which must govern their every action over speech but as a nuisance that can be explained away on a case by case basis.

The latest example of the agency’s attempt to avoid accountability under the First Amendment is its effort to redefine the statutory term “health claim,” to restrict claims for foods and dietary supplements to disease prevention and exclude claims for disease treatment, mitigation, and cure. The agency takes this action – by its own admission – to protect its drug approval process from competition, a competition that arises naturally from full implementation of the NLEA health claims provision.

In time the First Amendment principle of disclosure over suppression will win out. In time, consumers will be informed at the point of sale of the *potential* of nutrients to affect disease without having to await that extremely rare moment of conclusive proof, of scientific certainty. Suppression of truthful speech in the service of a supposed benevolent FDA paternalism has no place in a free society and cannot survive the test of the First Amendment. As the Supreme Court has often told us: “There is . . . an alternative to this highly paternalistic approach. That alternative is to assume that . . . information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than close them It is precisely this kind of choice between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.”

The First Amendment remains a great bastion of liberty. It is very much alive. It is greater than any part, or any official, of this government. It will be here long after those who occupy government offices have left government service.

On the microcosmic level, in the short term, it is probable that FDA’s officials will continue to favor suppression as the rule and disclosure as the exception despite the fact that the Constitution requires precisely the opposite. They will do so against court decisions, like *Pearson*. They will also continue to regard it the health claim petitioners’ burden of proof to justify avoidance of suppression when the First Amendment dictates

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that it is the Government's burden to justify suppression. On the microcosmic level, then, the battle to make this agency conform to the requirements of the First Amendment will go on and will continue to define the law in this area for the next decade. There will be wins and there will be losses but on balance the course is set by *Pearson: Pearson* and its progeny will incontrovertibly move us toward ever greater protection for the dissemination of truthful information, including inconclusive information, so long as the information is accurately stated.

On the macrocosmic level, FDA's officials do not realize it but they are indeed on the stage of history. How they respond to their current constitutional challenges will define their place in the works that chronicle this extraordinary time. A decade from now after the First Amendment has triumphed and the rear guard protectionist days of the present are but a fading memory, those officials will be remembered, if at all, as those who tried to preserve a speech suppressive regime but lost out to the greater power of our First Amendment.

Few remember those who fought to suppress free speech; but many of us remember those who fought to support and defend that liberty. How many of us remember the names of the colonial governors who favored the speech suppressive seditious libel laws of the 18th century? But many of us remember the name of John Peter Zenger whose seditious libel trial became a rallying cry for passage of the First Amendment. How many of us remember the names of the members of Congress who voted for the speech suppressive Alien and Sedition Acts of 1798? But we all remember the names of Thomas Jefferson and James Madison who in 1798 wrote the Kentucky and Virginia Resolutions condemning those acts. How many of us would remember the name of the Montgomery, Alabama Police and Fire Commissioner who sued the New York Times for libel after it ran a political ad in support of Dr. Martin Luther King if his name did not appear as the Defendant in *New York Times v. Sullivan*? In like manner, over time, we will forget the names of those at the FDA responsible for the current speech suppressive regime.

But this need not be. They would be long remembered if they experience an epiphany now, if they undergo a paradigm shift, if they come to realize that while the politics of speech control are transitory, the First Amendment is permanent. They will be long remembered if they come to appreciate the gravity of their acts, if they come to realize that in old age, after retirement, it will be better to be remembered by one's grandchildren and by future generations for having had the courage to fight against political and economic forces arrayed against the freedom of speech than to have given into those forces in violation of that freedom.

In sum, FDA has yet to embrace the constitutional requirement of disclosure over suppression. But, as with all aspects of life, change—even for those assumed to be incorrigible—is sometimes possible. We should all hope that the agency's officials will open their minds and allow the First Amendment in. We should hope that they will permit themselves to be transformed from censors into providers of truthful information. Thank you.