

PRESS RELEASE

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Court Finds FDA's Position against Vitamin Health Claims Unconstitutional

Court orders FDA to revise position on vitamin-cancer risk reduction claims

Washington, DC—Yesterday, the United States District Court for the District of Columbia held that FDA's position denying two antioxidant vitamin-cancer risk reduction claims was unconstitutional under the First Amendment. In June 2009, the FDA denied multiple claims about the effectiveness of selenium and vitamins C and E in reducing cancer risk, and weakened and complicated other claims to the vanishing point. ANH-USA and Durk Pearson and Sandy Shaw, represented by Emord & Associates, sued the FDA for censoring antioxidant vitamin-cancer risk reduction claims.

Qualified health claims characterize the relationship between a substance and its ability to reduce the risk of a disease or health-related condition and under the Pearson v. Shalala case are permitted in relation to foods and supplements. However, the FDA routinely rejects qualified health claims.

The FDA notes on their website site that "consumers benefit from more information on food labels concerning diet and health." But according to ANH-USA, FDA actively restricts information availability. "Unfortunately, the FDA has consistently limited the information available to consumers about the real health benefits of food and supplements", said Gretchen DuBeau the organization's executive and legal director.

Although the court upheld FDA censorship of six other claims, the court ruled the FDA violated the First Amendment when it prohibited two vitamin health claims and stated that it would only allow them in a form reworded by the agency.

The two claims held unconstitutionally qualified by FDA are:

Vitamin C / gastric cancer claim: "Vitamin C may reduce the risk of gastric cancer."

- FDA had prohibited the claim, stating that it would only allow the following language to be used: "One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer."

Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer.”

Vitamin E / bladder cancer claim: “Vitamin E may reduce the risk of bladder cancer.”

- FDA had prohibited the claim, stating that it would only allow the following language to be used: “One small study suggests that vitamin E supplements may reduce the risk of bladder cancer. However, two small studies showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer.”

The court held FDA’s rewording of the two claims unconstitutional under the First Amendment. FDA “has replaced plaintiffs’ claims entirely,” explained the court, and the claim “‘qualification’ effectively negates any relationship between cancer risk and vitamin intake. The FDA’s rewording . . . makes it difficult to tell what the original health claims are and appears to disavow the FDA’s own conclusions that those claims are supported by credible evidence.”

The court reaffirmed the landmark decision of *Pearson v. Shalala* against the FDA’s objections, holding that “[w]here the evidence supporting a claim is inconclusive, the First Amendment permits the claim to be made; the FDA cannot require a disclaimer that simply swallows the claim.”

The FDA has been ordered to revise its claim qualifications consistent with the Court’s decision.

“The decision was a partial win for our side, but we’ll keep fighting for consumer access to health-related information,” added DuBeau.

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About the Alliance for Natural Health USA (ANH-USA): www.anh-usa.org The Alliance for Natural Health USA is part of an international organization dedicated to promoting natural, sustainable healthcare through good science and good law. We protect the right of natural health practitioners to practice, and the right of consumers to choose the healthcare options and treatment modalities they prefer, including complementary and alternative medicine. As a membership-based organization, we unite consumers, practitioners, and industry to speak with a common voice and have worked since 1992 to shift the medical paradigm from an exclusive focus on surgery, drugs and other conventional techniques to an “integrative” approach incorporating food, dietary supplements and lifestyle changes.