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AS WE SEE IT

Inside the FDA's Brain



The FDA has released a detailed report that states, "it is highly unlikely that green tea reduces the risk of prostate cancer."¹ This report is quite enlightening and we thought it appropriate to share it with Life Extension members.

The FDA made it clear that it evaluates lots of evidence when deciding whether to allow a health claim. Most of this evidence, however, is eliminated from further review because it does not meet the agency's standards.

While there are numerous published studies on green tea and prostate cancer, the FDA determined that only two met its standards. The first study cited by the agency showed that drinking three cups of green tea a day reduced prostate cancer risk by 73%.² The second study did not provide statistically significant data, but showed that drinking two to 10 cups of green tea daily reduced prostate cancer risk by 33%.³ According to the FDA, "both studies received high methodological quality ratings."



by William Faloon

Based on these two human studies, the FDA will allow the following health claim for green tea beverages:

"One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer."¹

WHY FDA CALLS THESE "WEAK" STUDIES

The FDA's gold standard is tightly controlled studies that consist of an active component and a placebo arm. The two green tea studies chosen by the FDA evaluated the effects of historical consumption of green tea beverages on prostate cancer risk.

The studies showed that the greater the consumption of green tea, the lower the prostate cancer risk. This does not, however, impress the FDA as much as a carefully designed study where half of the men would drink three to 10 cups of green tea a day while the other half drank a placebo beverage.

While the FDA admits that the study showing a 73% reduction in prostate cancer risk is significant, the agency believes the study that showed a non-statistically significant 33% risk reduction cancelled out the better study. According to the FDA, "replication of scientific findings is important in order to substantiate results."^{4,5}



THE OMITTED STUDY

While the FDA claims to have extensively reviewed the scientific literature to find the truth about green tea and prostate cancer, one important study was overlooked.

In a tightly controlled clinical setting, men with pre-malignant prostate disease were given either 600 mg a day of green tea extract or a placebo. Compared to those who received the placebo, men with this pre-malignant condition who received the green tea extract were 90% less likely to develop prostate cancer.⁶

Unlike the FDA's two hand-selected green tea beverage studies, this study met the agency's rigid design criteria and could not be classified as a "weak" study.

While the FDA may argue that green tea supplements differ from green tea beverages, the fact is that this placebo-controlled study existed, but was omitted from the FDA's report. The FDA's report concluded:

*"Based on FDA's review of the strength of the total body of publicly available scientific evidence for a claim about green tea and reduced risk of prostate cancer, FDA ranks this evidence as the lowest level for a qualified health claim. For the reasons given above, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer."*⁴

THE FDA PRESS RELEASE

The FDA was so proud of its findings that it issued a press release to alert the world that green tea has little or no value in preventing cancer. The news media picked up on the FDA's negative findings about green tea and echoed the agency's claims that green tea does not prevent cancer.

Newspapers and television stations reported that consumers were wasting their money by drinking green tea. None of these media sources bothered to check the National Library of Medicine's database to find over 600 studies relating to green tea and cancer. Even a cursory review of these studies reveals a very different story than what was contained in the FDA's press release.

The National Library of Medicine is part of the US Department of Health and Human Services, the same parent agency as the FDA!

CONSUMERS NEED TO KNOW THE FACTS

The United States faces a worsening health care crisis as aging baby boomers financially exhaust the nation's medical systems.

The FDA is empowered to regulate almost every aspect of our health care, yet this federal agency continues to behave in a manner that promotes illness. An unbiased review of the published scientific literature reveals health properties attributed to green tea, but the FDA has restricted what Americans are allowed to read on the labels of green tea beverages.



If the data about green tea and prostate cancer risk turn out to be only partially accurate, the lives of millions of men could be saved and billions of dollars shaved off future health care expenditures. Yet the law still allows the FDA to censor truthful information about foods and dietary supplements.

WE CAN CHANGE THE LAW

On May 12, 2005, a bill was introduced in the US House of Representatives that would give consumers access to truthful, non-misleading health information. This bill—the Consumers' Access to Health Information Act (H.R. 2352)⁷—seeks to amend the Food, Drug and Cosmetic Act to ensure that:

1. Accurate health claims are not suppressed;
2. Consumers are given truthful and complete information about the curative, mitigation, treatment, and prevention effects of foods and dietary supplements on disease or health-related conditions;
3. The FDA honors the intent of the Congress not to censor accurate health claims.

This is one of the most critical pieces of legislation to ever come before Congress. Passage of the Consumers' Access to Health Information Act would enable the American public to learn how to prevent many of the degenerative diseases of aging. This bill could help avert the health care crisis that is threatening to bankrupt Medicare, corporations, and aging adults.

I urge all Life Extension supporters to take action now so that they can conveniently email their own congressional Representative.

STAMP OUT FDA CENSORSHIP!

To emphasize the urgency of H.R. 2352, I gave you a brief tour inside the FDA's brain vis-à-vis its analysis of green tea and prostate cancer risk.

Please do not settle for scientific censorship. Stand up for your First Amendment rights and tell Congress you want to see H.R. 2352 enacted into law. To find the name of your Representative, call 1-202-225-3121 or visit the Legislative Action Center.

Congress has the power to abolish the FDA's authority to censor truthful, non-misleading scientific information. Please take

action now to email the letter to your Representative.

For longer life,



William Faloon

★ take action now

References

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