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Selenium qualified health claims are usable, says attorney

By Shane Starling, 08-Oct-2010

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The legal counsel who represented Durk Pearson, Sandy Shaw and others in the recent case that forced the Food and Drug Administration (FDA) to alter three approved selenium health claims, says his clients and others will use the claims.

Jonathan Emord from the Virginia-based firm Emord & Associates, said the claims would be used in Durk Pearson and Sandy Shaw's licensed supplements, especially those sold through Life Extension Foundation.

Members of another plaintiff in the case – Alliance for Natural Health USA – had also indicated they would employ the claims.

The parties to the case, along with Emord, have been celebrating the fact the FDA had heeded a May District Court order to alter the claims, while others have wondered how usable they are given the disclaimers that the FDA does not agree with the claims themselves.

The claims relate to reduction in the risk of colon, prostate, bladder and thyroid cancers. One of them reads: *"Selenium may reduce the risk of prostate cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of prostate cancer."*

Savvy

But despite the negative FDA language Emord said at least two consumer research studies indicated, somewhat counter intuitively, actually responded positively to such FDA disclaimers because they give the claim more credence than a claim that has not even been surveyed by the FDA.

"American consumers of supplements are skeptical about FDA but even more skeptical of companies that make claims without seeking FDA approval," he said. *"This reveals consumers of supplements to be savvy."*

World of second bests

Emord said an ideal world would remove the pre-approval system, so false and misleading claims would be prosecuted after the fact, but in lieu of that, disclaimers were better than suppression of health statements not deemed to meet an arbitrary level of scientific conclusivity.

"Claim disclaimers are the constitutional resort that cannot be denied the government under existing precedent," he said. *"The qualified claims regime necessarily means that government must not suppress claims but may place qualifications on clams it does not approve."*

He noted under court actions dating back to 1999 (Pearson v Shalala) allowed the FDA two kinds of disclaimers:

- That the science backing the claim is inconclusive
- That it does not agree with the claim

"The present disclaimers are, thus, the bare minimum the law permits for FDA," he said. *"We could not deny the agency this disclaimer power because the Courts have already determined FDA has this power."*

Intention to use

Responding to allegations the claims were unusable, Emord said: *"My clients who were a part of this litigation*

approved the claim qualifications and authorized me to settle on these terms. They intend to use the qualifications on labels and in labeling of selenium-containing supplements and are confident that their consumers appreciate the nuances. The proper motto is not be careful what you wish for' but, rather, 'be mindful that inaction out of fear of consequence prevents all progress'."

He added: *"I very much loathe the view that you abandon your rights because defending them may risk losing them. Had we never begun this fight over a decade ago there would be no qualified claims regime, there would be no opportunity to express less than conclusive science in the market, and consumers would be without claims associating folic acid with neural tube defect births, omega-3 fatty acids with reduction in the risk of coronary heart disease, and antioxidant vitamins and reduction in the risk of cancer. We have come a long way, and we have a long way still to go, but progress depends on every step."*

The changes were prompted by a Washington DC district court ruled on May 27 this year that the addition of lengthy disclaimers to claims linking selenium and cancer, respiratory and immunity benefits was unconstitutional under the First Amendment and demanded that the FDA amend them.

Coverage of that action can be found here.