



Selenium Pact May Set Precedent For Short Qualified Claims

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A recent settlement with FDA over qualified health claims for the dietary supplement selenium could set the bar for other nutrient-specific claims and permit short qualification claims that fit on packaging, according to a free speech attorney who has been working on the case. The agency entered negotiations with the Alliance for Natural Health following a May court ruling that FDA had erred in rejecting selenium health claims.

"I think it creates a very favorable precedent for the agency to consider," said Jonathan Emord, who represented ANH in the case. "These are remarkable because this is the shortest qualification of a claim that FDA has issued in history," Emord said, adding that it is also the largest number of nutrient cancer-specific claims issued by the agency.

Qualified health claims are used to define the relationship between a food, food component or supplement and a disease when there is significant evidence to illustrate a connection. In 2009, FDA suppressed cancer-risk reduction claims for selenium.

In May, the U.S. District Court for the District of Columbia ruled that FDA unconstitutionally censored health claims tied to the dietary supplement. After the ruling, FDA had the option to appeal or draft a rule for supplement companies (see *FDA Week*, June 17).

The negotiations resulted in qualified health claims for prostate, colon, bladder and thyroid cancer. The two parties are still negotiating selenium claims for lung and respiratory tract cancer, as well as digestive tract cancer.

"Selenium may reduce the risk of bladder, colon, prostate, and thyroid cancers. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of these cancers," one of the claims reads.

Emord said he does not expect the result of the case to open the flood gates for challenges to other qualified health claims. It is, however, applicable to other pending cases, he said.

"I'm grateful that we were able to do this cooperatively and I think it bodes well for the future," Emord said. "It's a good result for consumers," Emord said. The settlement, he said, resulted in succinct claims that could fit on packaging.

FDA did not return a request for comment before press time. -- *Alaina Busch*