



## Selenium Claim Could Spur Label Changes, Sparking Consumer Confusion

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FDA is sending a confusing message to consumers with qualified health claims that reject the agency's support for possible benefits of the dietary supplement selenium that are now permitted after a legal settlement between the agency and product manufacturers, industry and consumer advocates said. The selenium claim includes a disclaimer stating that FDA does not agree with the claim.

Nonetheless, the stakeholders predicted the newly approved claims will spur other manufacturers' desire to augment statements on their labels to improve product marketing, which could then further add to consumer confusion. But, an attorney advocating for free speech and a natural-health advocacy group lauded the case as a victory for consumers.

FDA and the Alliance for Natural Health recently settled a long-standing case to allow the shortest qualified health claims and the largest number of nutrient cancer-specific claims ever issued by the agency, free speech attorney and alliance counsel Jonathan Emord said last week (see *FDA Week*, Oct. 1). The claims included an FDA declaration that the agency has not endorsed the cancer claims made on the labeling.

This duality on labels, however, leaves consumers and practitioners questioning the effects of the dietary supplement, said Andrew Shao, senior vice president for scientific and regulatory affairs at the industry trade group Council for Responsible Nutrition. "The question they're going to ask is, 'Well does it work or not?'" he said.

He said the claim is a step in the right direction because claims can be convoluted and it is difficult to communicate science to consumer. "Even with this step, I don't know that we've accomplished the goal of helping consumers make informed choices," he said.

The short claim, which fits on a package, puts marketing concerns ahead of the consumer, he said. It could spur other company requests to pare down longer, more convoluted claims, he said.

"If this sticks, there's the possibility that companies will say, 'OK, this language is easier to live with from a marketing standpoint,'" he said.

David Schardt, senior nutritionist at the consumer advocacy group Center for Science in Public Interest, said the settlement could have similar but more widespread ramifications than claims involving phosphatidylserine, a supplement linked to addressing cognitive dysfunction and

dementia. The claim, which was settled in 2003, said limited and preliminary scientific evidence reduces the risk of cognitive dysfunction and dementia. "FDA concludes that there is little scientific evidence supporting this claim," the claim states.

**Going a step further, the claim for selenium's anticarcinogenic effects states that while the supplement may reduce the risk of certain cancers, "Based on its review, FDA does not agree that selenium may reduce the risk of these cancers."**

The wording of the phosphatidylserine claim came to the surprise of people monitoring the issue, Schardt said. "First of all, why would FDA do that and secondly why would companies agree to that?" he said.

**But, in the wake of the decision, companies made claims in advertising that the supplement was the only one approved by FDA to reduce the risk of cognitive dysfunction.** "That's what's going to happen with this selenium claim," he said. Because selenium makes claims in connection with cancer, he said he expects more widespread claims concerning the supplement.

Last year, CSPI became involved in a lawsuit with Bayer over selenium claims involving multivitamins. The company, he said, eventually pulled the claims from its website and labels, but the case is still pending. "In allowing this qualified health claim, it looks like they're opening the door again," he said.

The selenium settlement produced qualified health claims for prostate, colon, bladder and thyroid cancer. Negotiations are pending for claims related to lung and respiratory tract cancer as well as digestive tract cancer.

**Negotiations on the selenium claims followed a May ruling by the U.S. District Court for the District of Columbia** that FDA had erred in its regulation of the dietary supplement and suppressed free speech. After the ruling, FDA had the option to appeal or draft a rule for supplement companies.

"What we as an organization want is to have the information out there," said Gretchen DuBeau, executive and legal director of the alliance. The claim communicates that the science is inconclusive. Its brevity makes it easy for consumers to understand, she said.

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.

By reversing the agency's decision, DuBeau said the case could apply to other claim cases. The alliance has a similar pending case regarding antioxidants, she said.

"What we've done here is really shift things in a really significant way," she said. -- *Alaina Busch*