**Qualified Health Claim Rulings Leave Little Leeway for Label Language**

After 18 months of delays, the U.S. Food and Drug Administration announced in separate rulings that limited evidence supports labeling tomato products and green tea as reducing the risk of prostate cancer and prostate and breast cancers, respectively. However, the agency rejected much broader claims requested by the H.J. Heinz Company (for tomato products) and Fleminger Inc. (for green tea). It also rejected a request from American Longevity to allow the tomato extract lycopene to be labeled as a cancer risk reducer. The agency also concluded that there is “limited scientific evidence” to support the claim that calcium supplements may reduce the risk of colorectal cancer or colorectal polyps.

The rulings clear the way for tomato product makers to include a qualified statement on their packaging: “Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce once a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.”

For green tea, the agency approved even more qualified language: “Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests 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 breast cancer.” Approved wording for the green tea and calcium claims is similar.

Sing Han Lee, M.D., president of Fleminger Inc., filed a request to modify the FDA-approved language. On the basis of the two studies the FDA found most convincing, he requested labeling reading, “Drinking green tea equivalent to that consumed by Asian Americans may reduce the risk of breast cancer in women,” and “Drinking green tea equivalent to that consumed by residents living in Hangzhou, China, may reduce the risk of prostate cancer.” The request is pending.

F. Kerr Dow, Ph.D., chief technical officer for Heinz, said that the company would probably not include the FDA-approved language on any of its labels. “It’s kind of confusing for the consumer,” he said. However, he maintained that the ruling is good news for his company, which may use the ruling to tout the health benefits of tomatoes in its marketing campaigns.

After these rulings, the first of their kind, the Solae Company withdrew the petition it had filed with the FDA to label its soy products as potential cancer risk reducers. “Our basic reasoning is that the criteria by which the FDA evaluates the [qualified health claim] petitions is evolving,” said Cary Levitt, J.D., vice president and general counsel for Solae. He said his company would refile its petition after evaluating the tomato and green tea rulings. The FDA’s decisions “signal that it will accept only the strongest experimental designs,” said Levitt.

Leavitt said that a large part of his company’s decision to withdraw stems from the FDA’s statement on food surveys that appears in its tomato decision letter. “Validation of the food-frequency questionnaire method is essential … the failure to validate may lead to false associations between dietary factors and diseases or disease-related markers,” the letter reads. Leavitt said that most food survey studies conducted on soy do not meet the standard and may need to be redone. “It could take a while,” he said.

In both the tomato and green tea letters, the FDA goes on to outline its entire evaluation process for qualified health claims. The agency ranks placebo-controlled interventional human studies as strongest, followed by observational studies, noting that epidemiological studies reporting health benefits for certain foods are often overturned by interventional studies finding no such link. The agency cites dietary fiber and colon cancer risk, for which it says 38 of 48 observational studies found that a high-fiber diet was associated with a reduced risk, while three more recent clinical intervention trials did not confirm a benefit.

Meta-analyses and animal and in vitro studies rank last on the FDA’s evidence scale, as they “cannot adequately support a relationship between a substance and a disease.”

After weeding out studies it considers weak, the agency evaluates each remaining study’s methodology, focusing on data collection (e.g., whether a survey instrument has been validated), outcome measures (e.g., disease states versus surrogate endpoints), study size, and quality of statistical analysis. The agency collates all of that information and then determines the strength of any food-related benefit.

For its green tea decision, the agency reviewed 220 publications but considered only 36 observational studies. For its tomato and lycopene decision, the agency evaluated five interventional and 17 observational studies.

The FDA’s decisions on tomatoes and green tea arrive 6 years after the District of Columbia Court of Appeals ruled that the agency must allow health claims on food packaging if the quality of scientific evidence for the claim is at least equal to the scientific evidence against the claim. Before 1999, the agency allowed only nonqualified health claims, based on the stonger standard of “significant scientific agreement.” For instance, it approved labels that indicate
a diet low in fat and high in fiber reduces risk of cancer. It took the FDA 4 years, until 2003, to develop and release regulations for qualified health claims. The agency repeatedly pushed back its decision date on green tea and tomatoes. In a written statement, a spokesperson for the FDA explained the delays by stating, “FDA used its limited resources to look at the scientific evidence for the petitions submitted to the agency.”

American Longevity Inc., disappointed that the FDA denied its petition for labeling lycopene supplements as cancer risk reducers, vowed to send the issue back to the courts for another round. In a statement, the company accused the FDA of violating its First Amendment right of free speech.

—Brian Vastag

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