First Amendment constraints on FDA’s regulation of health claims

Monday, March 19, 2018

On February 20, 2018, the Food and Drug Administration (FDA) denied a petition for a health claim for the consumption of cranberry products and the reduction in risk of recurrent urinary tract infection (UTIs) in healthy women and notified Ocean Spray that FDA will instead review the petition as a request for a qualified health claim instead under the Better Nutrition Information for Consumer Health Initiative (July 10, 2003), which is implemented by FDA guidance documents, (1) Interim Procedures for Qualified Health Claims in the Labeling of Conventional Food and Human Dietary Supplements and (2) Interim Evidence-based Ranking System for Scientific Data.

A recent article in the Washington Post, Big Cranberry Juice: We can stop UTIs. Science: Maybe., reminds us of the Constitutional balancing act that FDA must perform upon finding that a proposed health claim does not meet the Agency’s “Significant Scientific Agreement” (SSA) standard for a health claim and when the proponent remains confident in the research. The article focuses on marketing concerns as the underlying basis for the potential qualified health claim and discusses critics’ arguments that any type of health claim would be misleading. The First Amendment, however, requires FDA to permit health claims that are supported by adequate scientific evidence if the use of disclaimers would remove the possibility that the claims may otherwise be misleading.

Decisions by the Federal District Court for the District of Columbia in Pearson, et al. v. Shalala, et al. 164 F.3d 650 (D.C. Cir.1999) and Alliance for Natural Health v. Sebelius (2010 WL 2110071) make clear that commercial speech enjoys the broad protections of the First Amendment and may limit FDA’s ability to restrict the language used to qualify Ocean Spray’s health claim. The petition for a qualified health claim for the consumption of cranberry products and the reduction in risk of recurrent UTIs in healthy women is open for comment until April 23, 2018. FDA will render a final decision by October 5, 2018.

© 2019 Keller and Heckman LLP

Source URL: https://www.natlawreview.com/article/first-amendment-constraints-fda-s-regulation-health-claims