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FOOD LABELING

FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims

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Highlights

Highlights of GAO-11-102, a report to congressional committees

Why GAO Did This Study

The Food and Drug Administration (FDA) oversees federal requirements to prohibit false or misleading food labels; the Federal Trade Commission enforces the prohibition against false or misleading advertising. By statute, health claims on food labels must have significant scientific agreement, but in 2002, in response to a court decision, FDA decided to allow qualified health claims with less scientific support. Structure/function claims refer to a food's effect on body structure or function and are also used on food. Congress directed GAO to study FDA's implementation of qualified health claims for food. GAO examined (1) the results of FDA's efforts to allow the use of qualified health claims and oversight of these claims and (2) consumers' understanding of the claims. GAO also examined FDA's oversight of structure/function claims. GAO reviewed FDA documents and consumer studies and interviewed stakeholders from health, medical, industry, and consumer groups.

What GAO Recommends

GAO recommends FDA identify and request from Congress authorities to access companies' evidence for potentially false or misleading structure/function claims on food to establish scientific support, provide guidance to industry on the evidence it needs to support such claims, and provide direction to FDA inspectors to help identify claims for further review. FDA generally agreed with the first two recommendations but found the third to be impractical; GAO clarified that recommendation.

View GAO-11-102 or key components.
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What GAO Found

FDA's efforts to protect consumers from false or misleading claims are conducted in a complex and challenging legal and regulatory environment. From 2002, when FDA announced its decision to allow qualified health claims on food labels—following a court decision involving its authority to regulate dietary supplements—through September 2010, FDA received 16 petitions from companies proposing 60 claims on food labels. After reviewing the scientific evidence presented in the petitions, FDA determined that there was enough credible scientific evidence for the agency to allow the use of 12 qualified health claims, by modifying language to qualify the claims and characterize in detail the strengths and limitations of the scientific support for those claims. In overseeing qualified health claims for food labels, FDA has issued two warning letters to food companies—both in 2010—for citing health benefits that were not in the allowed qualified health claims or supported by scientific evidence.

Research showed, and stakeholders indicated, that consumers find it difficult to understand the differences between health claims with significant scientific agreement and the lower level of scientific support for qualified health claims. Research also showed that consumers find it difficult to distinguish among the many different types of claims on food labels, including health claims, qualified health claims, and structure/function claims.

FDA data indicate that companies now minimally use qualified health claims on foods but more widely use structure/function claims to convey their foods' health benefits. Companies' use of structure/function claims is subject to the general statutory requirement that labeling not be false or misleading. However, FDA has not given companies guidance on the scientific support needed to prevent false or misleading information for a structure/function claim for food or given its inspectors instructions for identifying potentially false or misleading information in such claims when examining food labels as part of food facility compliance inspections. Even if FDA were to provide such guidance, structure/function claims pose a serious oversight dilemma for the agency. That is because FDA—unlike the Federal Trade Commission (FTC), which can require companies to submit any relevant evidence as part of an investigation of whether claims are substantiated—does not have the ability to compel companies to turn over their substantiation documents. GAO's work indicates that FDA's efforts to meet that burden are hampered by the lack of access to the evidence that a company relies on to make such a claim. In particular, while FDA may ask a company to provide its scientific support for a claim, FDA does not have express legal authority to compel the company to provide such information. FTC, on the other hand, which is responsible for protecting consumers from false advertising generally, has the authority to compel companies to provide the support. FTC officials said that the Commission would have difficulty taking enforcement actions against companies for alleged false structure/function claims on food labels and in advertisements without access to companies' proprietary market and scientific research.