

ALERTS AND UPDATES

FTC Steps Up Enforcement on Health-related Claims in Advertising

October 28, 2011

In a recent settlement with Reebok, the U.S. Federal Trade Commission (FTC) clarified that it will impose substantial penalties, including restitution to consumers, on companies that make health-related claims without an adequate basis. Moreover, in the [consent decree](#), the FTC stated exactly what type of proof it would consider adequate to support health-related claims in advertising. As the FTC increases its enforcement of health-related claims in advertising, companies should consider reviewing the FTC's consent decrees to promote compliance with the FTC's advertising rules and, in particular, may want to note what information the FTC considers adequate to substantiate health-related claims.

The FTC sued Reebok—under Section 45(a) of the Federal Trade Commission Act, which prohibits unfair and deceptive acts or practices in or affecting commerce, and under Section 52, which prohibits false advertisements for food, drugs, devices, services or cosmetics in or affecting commerce—for advertising claims Reebok made related to its EasyTone and RunTone toning shoes. In its [complaint](#), the FTC alleged that Reebok claimed the toning shoes improved muscle tone and strength in the butt, hamstrings and calves, and that laboratory results showed that the shoes "improve muscle tone and strength by 28% in the gluteus maximus, 11% in the hamstrings and 11% in the calves." The FTC contended that Reebok made these claims based on inadequate or no proof because the claims were based in part on a trial that involved only five subjects.

The FTC and Reebok then entered into a consent decree that enjoins and restrains Reebok from making any type of quantifiable health-related claim (*e.g.*, Reebok's claim that wearing its product will result in a quantifiable percentage of muscle toning) regarding its toning shoes, unless the representation is based on "competent and reliable scientific evidence" that substantiates the claim. The consent decree sets forth that "competent and reliable scientific evidence" means "at least one Adequate and Well-Controlled Human Clinical Study . . . that conforms to acceptable designs and protocols, the result of which, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true." It also defines an "Adequate and Well-Controlled Human Clinical Study" to mean a "clinical study that is randomized, controlled, blinded to the maximum extent practicable, of at least six weeks duration, uses an appropriate measurement tool or tools . . . and is conducted by persons qualified by training and experience to conduct and measure compliance with such a study."

The consent decree also requires that any representations, including through depictions of results (*i.e.*, models), about the general health or fitness benefits of a product must be based on "competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true." For purposes of health or fitness claims, "competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results."

While the consent decree applies only to Reebok, it provides key compliance guidance for other advertisers who make health-related claims because it clarifies the FTC's position on substantiating health-related claims, such as using double-blinded studies and clinical trials for a duration of at least six weeks; appropriate experts; and measurement tools to

measure health-related claims. Given the FTC's current stiff enforcement agenda related to health-related claims in advertising, advertisers may want to closely review the Reebok consent decree and its health-related advertising claims for compliance with the FTC's newly articulated evidence standards.

For Further Information

If you have any questions concerning this *Alert*, please contact [Frederick R. Ball](#), [Erin M. Duffy](#), any other [lawyer](#) in the [Pharmaceutical, Pharmacy & Food](#) industry group or the Duane Morris attorney with whom you are regularly in contact.

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