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The FTC's "Reasonable Basis" Standard Has Evolved for Disease Efficacy Claims

The Bottom Line

- *The FTC made it clear many times in 2018 that disease efficacy claims must be supported by competent and reliable scientific evidence, including human clinical testing, and that expert opinions will help guide the kind of human clinical testing and the number of RCTs that is acceptable to the FTC.*
- *Advertisers making disease efficacy claims in 2019 must make sure that they have the appropriate support in hand, before they go public with their campaigns.*

Decades ago, in an action the Federal Trade Commission (FTC) brought against Pfizer, Inc., the FTC identified several factors to weigh in determining the appropriate level of substantiation an advertiser must have for objective advertising claims. Over the years, the standard has changed, and various proceedings brought by the FTC in 2018 suggest the steps that advertisers should take in 2019 when claiming that their products treat disease.

The Evolution

In the Pfizer matter, the FTC challenged the company's "numerous statements and representations respecting the pain relieving properties" of a product it offered for persons suffering from sunburn. The FTC declared that Pfizer's statements or representations that its product actually would anesthetize nerves in sensitive sunburned skin or that it was otherwise effective required prior support before making the claim.

Put differently, the FTC decided that a company must have a "reasonable basis" for making these kinds of claims, as determined by the following factors:

- The type of claim;
- The type of product;
- The benefits of a truthful claim;
- The ease of developing substantiation for the claim;
- The consequences of a false claim; and
- The amount of substantiation experts in the field would agree is reasonable.

The FTC indicated that the analysis to determine the level of substantiation necessary to support the claims in an ad was not a simple tallying of the number of factors that demand higher or lower levels of substantiation but, rather, was flexible, considering the interplay of the six factors.

Over the years, that standard has morphed into a requirement that a company have "competent and reliable scientific evidence" for certain claims.

In April 2001, the FTC provided guidance with respect to claims made for dietary supplements — not drugs — in which it defined "competent and reliable scientific evidence" to mean "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." In other words, the level of support must be sufficient to satisfy the relevant scientific community of the claim's truth.

The guidance made clear that "competent and reliable scientific evidence" is a "flexible" standard with "no fixed formula for the number or type of studies required." The guidance recognized that "well-controlled human clinical studies are the most reliable form of evidence," but said that they are not necessary in connection with claims for dietary supplements, and that "results obtained in animal and in vitro studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible."

The FTC has supported a more stringent standard, however, when it comes to an advertiser's disease-related claims.

Several years ago, the FTC found that disease benefit claims made by POM Wonderful LLC about its pomegranate juice products were false and misleading based on the absence of proper substantiation for the claims. Based on its review of the six Pfizer factors, the FTC concluded that the proper level of substantiation for POM's disease efficacy claims required well-designed, well-conducted, double-blind, randomized controlled clinical trials (RCTs).

The Role of "Experts"

The FTC's current thinking regarding disease efficacy claims, and the importance of expert opinions, can be seen in the settlement the FTC reached this past December with the officers of a company that marketed and sold Nobetes, a pill they claimed treats diabetes, keeps blood sugar within normal levels, and reduces or eliminates the need for medications such as insulin.

The FTC alleged, among other things, that the advertising claims for the product were false or unsubstantiated. The Nobetes settlement prohibits the company and its officers from making unsubstantiated health-related claims, including claims that the use of a product will prevent, mitigate, or cure any disease, unless the claim is not misleading and is supported by competent and reliable scientific evidence.

Under the Nobetes settlement, competent and reliable scientific evidence "shall consist of human clinical testing" of the product or of an essentially equivalent product "sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true."

Moreover, the settlement provides, such testing "must be: 1) randomized, double-blind, and placebo-controlled; and 2) conducted by researchers qualified by training and experience to conduct such testing."

Significantly, this is the same definition of competent and reliable scientific evidence relied on the by FTC in a number of other proceedings in 2018, including where the FTC alleged that the defendants made unsupported claims that intravenously injected therapy products (IV cocktails) could treat serious diseases and where other defendants allegedly lacked scientific evidence that their "amniotic stem cell therapy" could treat or cure serious diseases, including Parkinson's, macular degeneration, cerebral palsy, and autism.

Related People

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