VENABLE® LLP

Articles

January 2013

Advertising Substantiation Standards, A Brave New World

International Research Services, Inc. Newsletter

You're back in the Old West, in a dusty frontier town at high noon. Tumble weeds blow past your boots as you tie up your horse. You notice a crowd of townsfolk gathered. They're listening to a traveling salesmen standing on the back of a wagon offering all sorts of lotions and potions to cure or mitigate life's little aches, pains, and disappointments. Just as he's about to close a sale, you see a man with a badge step out of the crowd, one hand on his holster, and declare to the traveling salesman: "Stop right there, mister! I'm with the FTC, and you'd better have two independent double blind placebo controlled clinical studies with 95% statistical significance to support those there claims or else there's gonna be trouble!" Everyone in the crowd is thinking, "Double blind what?"

How the world has changed when it comes to advertising substantiation requirements. Even in the last three years it's changed.

Over the last three years, the FTC has filed a string of Complaints and has entered into consent decrees in which the agency has articulated the level of scientific substantiation that it wants to see under various circumstances, depending on the kind of advertising claim that is being made.
By many accounts, the agency has set the bar extremely high in these recent cases, even for bona fide responsible companies that were selling legitimate well-received products to largely satisfied consumers with few complaints or returns.

So far, these cases have run the gamut from ingestibles and exercise equipment to footwear and cosmetics.

While the consent decrees only bind the companies who entered into the agreements, it is unwise for other marketers to disregard them particularly if they are making similar claims for similar kinds of products. (The agency often uses consent decrees to send a message to the larger business community about what it wants.)

Below, I discuss some of the most recent and most relevant cases. If you want more details, look online at **www.ftc.gov** where every Complaint and consent decree is posted or just email me a follow-up inquiry to . It is important to stress that in each of these cases the defendant/marketer admitted no liability in agreeing to settle with the FTC. A consent decree is just a settlement agreement; it is not necessarily an articulation of the law as a judge might articulate it following a trial in court.

2010:

In 2010, in the Iovate consent decree pertaining to dietary supplements or other food products -- if they are represented to cause weight loss -- the FTC required at least two human clinical studies. It specified that they would need to be randomized, double-blind, placebo-controlled, and conducted by different researchers, independent of each other, each qualified by their training and experience to conduct such studies. It also required that the results of these studies be sufficient to substantiate the claims "when considered in light of the entire body of relevant and reliable scientific evidence."

In the Nestle consent decree, also in 2010, pertaining to drinks containing probiotics -- if they are represented to reduce the duration of acute diarrhea in children or to reduce absences from school due to illness -- the FTC required at least two human clinical studies. It specified that they would need to be randomized and double-blind and placebo-controlled, unless the marketer could demonstrate that blinding or placebo control could not be effectively or ethically implemented. As in Iovate, the studies

AUTHORS

Gregory J. Sater

RELATED PRACTICES

Advertising and Marketing

ARCHIVES

2013 2009 2005
2012 2008 2004
2011 2007 2003
2010 2006

would need to be conducted by different researchers independent of each other.

2011:

In 2011, in the Dannon consent decree, the FTC once again required two clinical studies. This time, it was for any yogurt, dairy drink, or other food containing probiotics -- if the product were represented to relieve temporary irregularity or to help with slow intestinal transit time. (The FTC waived the requirement, though, if the advertisement for the product at issue in the Dannon case disclosed that three servings per day were required to achieve the claimed performance.)

Then in the Reebok consent decree, also issued in 2011, the FTC required at least one clinical study that would be randomized, controlled, and blinded to the maximum extent practicable, and specified that it would need to last at least 6 weeks and would need to use "an appropriate measurement tool" (which the FTC specified to be, for example, a dynamometer if it was strength which was being measured). This standard was applied to any footwear or apparel that would purport to improve or increase muscle tone, strength, or activation -- if the product were represented to be effective in strengthening muscles or to result in a quantified percentage or amount of muscle toning.

2012:

In 2012, the FTC announced another toning shoe settlement with another marketer of such shoes and, in the consent decree, applied a similar substantiation standard to the Reebok case. In the consent decree the FTC required that, for any footwear that would purport to improve or increase muscle tone, muscle strength, or muscle activation, or to result in increased calorie burn, weight loss, or loss of body fat, there would need to be at least one clinical study of at least 6 weeks duration. It would need to be randomized and controlled (including being controlled for dietary intake, if testing was conducted for weight loss or for a reduction in body fat) and blinded to the maximum extent possible. These would be the requirements, per the FTC, if the footwear product in question were to be represented to be effective in strengthening muscles. And if the product were represented to cause weight loss, then under the consent decree not one but two clinical studies would be required.

There were further such cases in the latter part of 2012, and one can expect more in the coming months as 2013 gets underway. The lesson for marketers is clear: while not all advertising claims require a clinical study, let alone two or more, more and more advertising claims do, according to the FTC, and the FTC is watching! Good legal counsel and good scientific support are essential to have.