

# Decision Highlights Questions Over Substantiation for Weight Loss Claims

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The Eleventh Circuit recently issued a decision in an contempt proceeding against Hi-Tech Pharmaceuticals and several individuals. The case highlights the ongoing debate over whether clinical trials are required for weight loss claims and, if so, whether the clinical trials must be on the full product formulation rather than active ingredients.

In 2008, a federal district court in Georgia held the Hi-Tech defendants liable for disseminating deceptive advertising for several products, including two weight loss products, Thermalean and Lipodrene. The court found that the defendants' advertising for Thermalean and Lipodrene conveyed that the full product formulations had been clinically tested. In the absence of such testing, the court found that the defendants lacked adequate substantiation. The injunctive order issued by the court against the defendants, however, did not require any sort of clinical testing for future weight loss claims. Rather, the order simply required the defendants to possess "competent and reliable scientific evidence," defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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 2011, the FTC initiated contempt proceedings against the Hi-Tech defendants in the same federal district court. The FTC alleged that the defendants had violated the 2008 order by disseminating unsubstantiated advertising for three new weight loss products and a reformulated version of Lipodrene. In support of their advertising, the defendants offered evidence, including an expert report. The court, however, refused to consider the evidence given that none of the materials offered were clinical trials on the full product formulations. The court held that its prior decision on product testing collaterally estopped the defendants from offering any lesser forms of evidence in the contempt proceeding. The Eleventh Circuit reversed this holding. It found that the lower court reviewing the new evidence would not create successive, identical litigations. It observed that both the products and the particular claims at issue in the contempt proceeding differed from the products and claims at issue in the original litigation. The lower court will now hear the case again on remand.

If, on remand, the FTC argues once again that full product testing is required for weight loss claims, it will have an uphill fight. Its orders issued since mid-2010 have allowed weight loss claims to be substantiated with testing on either the full product or active ingredients. Although one other district court has also held that full product testing is required, allowing active ingredient testing is consistent with the greater weight of relevant precedent, including First Amendment cases. The FTC orders since 2010 appear to acknowledge that. Whether some sort of clinical testing is nevertheless

required – either on the full product or actives – will likely involve a battle of experts. In prior litigations, the FTC has offered reports in which scientific experts have opined that some type of well-controlled clinical testing is required to substantiate weight loss claims.