

FTC DECEPTIVE ADVERTISING HEALTH CLAIMS SETTLEMENT - SCIENTIFIC PROOF REQUIRED

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"Treats Chronic Pain... Clinically Proven... Smart Device... Approved by the FDA..." These are all claims the Federal Trade Commission (FTC) says defendants made advertising the Willow Curve, a low-level light therapy device (LLLT), and all of which the FTC says are false and deceptive. In a settlement announced June 25, 2020, the Willow Curve LLLT device defendants will be subject to a \$22 million judgment which includes penalties being paid by two individual physicians who led the involved company LLCs. Defendants also will be prohibited from future allegedly deceptive refund and native advertising campaigns.

"When LLLT sellers say their devices will relieve pain, they'd better have the scientific proof to back it up," said Andrew Smith, Director of the FTC's Bureau of Consumer Protection, in a June 25 press release. 'People looking for drug-free pain relief deserve truthful information about these products.'"

FTC Complaint Causes of Action. The complaint asserts the following six counts against defendants which target all aspects of the allegedly improper marketing and sales of the product.

1. False or Unsubstantiated Efficacy Claims
2. False Proof Claims
3. False Claims About FDA's Review
4. Deceptively Formatted Advertisements
5. Defendants' Provision of Means and Instrumentalities of Deception
6. False Refund and Risk-Free Claims

The complaint also contains substantial snapshots of advertising and marketing materials, including scripting of infomercials, native content "research" materials, and alleged testimonials.

All of the claims are based on alleged violations of the Federal Trade Commission (FTC) act, specifically Sections 5(a) and 12, 15 U.S.C. §§ 45(a) and 52, which prohibit deception in connection with the manufacturing, labeling, advertising, marketing, distribution, and sale of

products. Relief is sought under Section 13(b), 15 U.S.C. § 53(b), which permits the FTC to obtain permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for defendants' acts or practices in violation of the FTC Act.

Scientific Proof for Health Claims. This is the first FTC enforcement settlement involving an LLLT.

The LLLT "is an FDA registered, software controlled, handheld device for joint pain relief. It combines the documented benefits of safe laser, infrared, and LEDs in one device that produces safe medical grade pain relief at a fraction of the cost."

Among other statements, certain of the Willow Curve advertisements claim: "When applied, the Curve's diagnostic sensors gather information from your skin. Then the smart device adjusts the photonic and thermal kinetic energies, stimulating the body's natural pain-relieving and anti-inflammatory responses. It's not science fiction. It's a trusted, effective breakthrough in pain relief technology."

The product marketing also touted "dynamic multi-band alternating pulse therapy (ATP) the body tissues absorb to

- Enhance central pain management systems function,
- Spark the body's opioid receptor,
- Reduce inflammatory pain response and accelerate tissue healing
- Suppress sensory fatigue (adaptation), improving extended pain relief momentum and recovery..."

According to the FTC, none of this was borne out by scientific proof specific to the Willow Curve device. The FTC alleges no clinical studies prove any of the numerous health treatment and benefit claims asserted by Defendants' advertising. The FTC contends Defendants' representation that the product's treatment benefits are equal to that of prescribed drugs or surgery. The FTC alleges that the FDA has not approved the product or corroborated any of the purported health claims defendants have made.

Purported "Independent Journalism". Count IV challenges the formatting and appearance of certain content which appear on the webpage to be independent journalism stories about the product, but which actually were drafted by the marketing team. Moreover, the content is formatted to appear similar to other independent content on the same pages. It is not differentiated or identified as advertisement. The FTC contends that such formatting is likely to cause consumer confusion and may mislead consumers.

Refunds Delays & Charges. The complaint also alleged that defendants did not comply with their representations regarding a "risk free money back" guarantee. The FTC alleges instead that "consumers who returned the device had to pay shipping and handling costs and often did not receive a refund at all or had to wait more than a year for it." One initial flag for the FTC is that returns volumes were high, as high as one-third of purchases at a certain point in time.

Consumer Class Action & Regulatory Litigation Risk for Your Products. Whether you are the maker or retailer or influencer/spoke person, you may have risk if the marketing claims are not true. In addition to the risk from federal regulators like the FTC, state Attorneys General and consumers can assert claims for unfair and deceptive advertising and marketing practices under applicable state laws. Here, the retailers and distributors who leveraged the deceptive defendant supplied product marketing materials were not also named as targets. But in consumer civil litigation, they might have been. So too perhaps could have been influencers or spokespersons, whose reputations were used to establish consumer trust and drive product sales. While these additional targets may have a variety of defenses to assert, litigation claims are disruptive and expensive and can dilute brand and diminish reputation. Product claims should be carefully vetted. Claims regarding specific efficacy and/or physical improvement ought to be well documented through scientific proof. When challenges arise, the nature and credibility of that proof will drive the outcome.

RELATED PRACTICE AREAS

- Retail & Consumer Products

MEET THE TEAM



Merrit M. Jones

San Francisco

merrit.jones@bclplaw.com

[+1 415 675 3435](tel:+14156753435)

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