



FTC Enforcement of Health Claims

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**These views are my own and not those of the FTC or any Commissioner*



FTC Jurisdiction Is Broad

- FTC Act
 - Section 5 (15 U.S.C. § 45) outlaws “unfair or deceptive acts or practices”
 - Section 12 (15 U.S.C. § 52) prohibits false advertisements for foods, drugs, devices, or cosmetics
- We do not regulate the practice of medicine with individual patients



Actions Against Licensed Medical Professionals

Marketers of Joint Pain Supplement Agree to Settle FTC Charges of Deceptive Advertising, Endorsements

October 5, 2016



Defendants targeted seniors and retirement communities with misleading health claims about stem cell therapy and charged up to \$5,000 per joint injection

August 17, 2021





Same Legal Standards Apply to All Products, All Industries

- FDA regulatory status does not affect legal obligations under the FTC Act (and using the DSHEA disclaimer is not a safe harbor)
- All channels of advertising are covered, including traditional media (print, radio, television), online ads, websites, social media, email, product labeling, and point-of-sale displays



Enforcement Options

- Informal (*e.g.*, closing letter)
- More formal, but short of court filing (*e.g.*, warning letter)
- Formal enforcement action
 - Federal Court (since 1973)
 - Administrative Proceeding (since 1914)



Remedies

- Injunctions
- Redress/Disgorgement*
- In certain circumstances, civil penalties may be available (currently up to \$51,744 per violation; increased each year for inflation)



What Claim Is Being Made?

- Advertiser is responsible for both express and implied claims – what is important is the “net impression” of the ad from the viewpoint of the intended audience
- Advertiser is responsible for claims made through endorsements and testimonials
- If an ad is subject to more than one reasonable interpretation, advertiser is responsible for each one



What Scientific Proof Do You Need for Health Claims?

- All health claims require competent and reliable scientific evidence
- Disease treatment or cure claims require human clinical studies (randomized, placebo-controlled, double-blind, measuring relevant endpoints or validated surrogate markers, with statistically significant results)



What About Claims of Clinical Proof?

- An advertiser must have at least the level of proof claimed (*e.g.*, reference to a clinical study or scientific research)
- Claims that a product is “clinically proven” or “scientifically proven” to work require evidence sufficient to satisfy the relevant scientific community of the claim’s truth



Health Products Compliance Guidance



- Updated in December 2022 – drawn from experience in FTC enforcement cases
- Staff interpretation of substantiation requirements
- Does not have the force of law



FTC Coordination with FDA

- Memorandum of Understanding
 - FTC has primary responsibility for *advertising* of foods, OTC drugs, devices, and cosmetics
 - FDA has primary responsibility for *labeling* of foods, drugs, devices, cosmetics; and Rx drug advertising
- Continuing communication, coordination, and information sharing
- Many joint enforcement initiatives



In re A&O Enterprises dba iV Bars and Aaron K. Roberts

- Respondents operated a chain of IV clinics in Texas and Colorado
- FTC challenged false or unsubstantiated claims that the IV cocktails were:
 - Effective treatments for cancer, cardiovascular disease, MS, diabetes, fibromyalgia, etc.
 - Clinically proven to treat various diseases
 - Safe for all ages
 - Free of side effects



Advertising in iV Bars Case

Benefits

100% absorption
High doses not tolerated orally
Safe & painless
Fast, lasting results
No side effects or down time
No preservatives or additives
Safe for all ages
Most take only 30-45 min
Medically-supervised facility
Allowed by all major athletic associations

Adrenal fatigue
Cancer
Asthma
Colds & flu
Celiac disease
Gluten sensitivity
Chronic fatigue syndrome
Chronic pain
Congestive heart failure
Dehydration
Depression & anxiety

Conditions

Diabetes
Effects of Aging
Infertility & pregnancy
Fibromyalgia
Gastrointestinal conditions
General wellness
Hangovers
Heavy metal toxicity
High blood pressure
Immune health
Aids in Weight Loss

Injuries
Low energy
Poor memory
Migraine & tension headaches
Neurodegenerative disorders
Nutrient deficiencies
Post surgical healing
Preventative care
Skin conditions
Stress
Revitalize hair & nails



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Advertising in iV Bars Case

Case #3: Multiple Sclerosis

A 65 year-old male with progressive multiple sclerosis presents to the clinic wheel chair bound. The patient has tried medications, physical therapy and speech therapy. However, there have been little noticeable benefits with regards to his leg strength and neurological function. The patient reported no problems with bowel or bladder control. The patient received an intravenous infusion of glutathione. After the first infusion, he reported increased strength in his legs. His physical therapist and caretaker also reported noticing an improvement in his leg strength and ability to walk. After the second glutathione infusion, the patient reported that the feeling in his hands has returned. The patient's increase in leg strength and hand sensation has continued without any reported decline. There were also no reported adverse reactions.



Advertising in iV Bars Case

Case#4: Diabetic peripheral neuropathy/Restless leg syndrome

A 65 year-old male presents to the clinic with a ten plus year history of rheumatoid arthritis, diabetes, high blood pressure, neuropathy and restless leg syndrome. The patient is taking blood pressure and anti-hypertensive medications. His blood sugar and blood pressure is well maintained with his current medication regimen. However, he continues to have joint pain and leg pain. The leg pain is worst at night and occasionally wakes him up. The patient was started on intravenous vitamin C and glutathione therapy. After the fourth treatment, the patient's restless symptoms and joint pain was completely resolved. The patient took a two-month break from therapy and some of his leg symptoms returned. Although the symptoms have returned, they were not of the same intensity. He was re-started on vitamin C and glutathione therapy. His symptoms started to improve after the first IV. He is currently on a maintenance protocol.



Advertising in iV Bars Case

HOW IT WORKS

iV Bars "Myer's Cocktail" is an Intro Venous Vitamin Infusion which will enhance your Immune System, Release Fatigue, help with Allergies, reduce symptoms of Fibromyalgia and Asthma.

TREATMENT

An alternative treatment for a broad range of conditions including asthma, fibromyalgia, chronic fatigue syndrome and even some of those hangover cases.



iV Bars Consent Order

- Requires human clinical testing for disease claims
- Requires competent and reliable scientific evidence for other health claims
- iV Bars also agreed to send an email notice to consumers who had purchased the Myers Cocktail, informing them that scientific evidence has not shown the cocktail to be an effective treatment for any disease



COVID-19 Warning Letters

- The FTC issued more than 450 warning letters to marketers promoting products and services to prevent, treat, or cure COVID-19
- About one-third of the letters were issued jointly with the FDA
- More than 70 letters challenged various IV therapies (*e.g.*, Vitamins C and D, glutathione, Myers Cocktail)
- Many clinics offer IV therapies along with other alternative or compounded treatments (*e.g.*, vitamin injections, ozone, HBOT, stem cells, peptides)



Questions?

- www.ftc.gov
- www.ftc.gov/tips-advice/business-center

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