

False and Deceptive Health Claims: Buyers Beware

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By Aparajita Lath

When it comes to health-related consumer purchases, buyers surely need to beware.

This is because the regulatory landscape of health-related products contains loopholes that allow false or misleading claims to proliferate. This article reviews recent instances of the issue, and discusses relevant regulations.

Health claims: regulation and confusion

The Federal Trade Commission (FTC) and the U.S. Food and Drug Administration share jurisdiction over (<https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003>) labelling, marketing, and advertising of dietary supplements, foods, drugs, devices, and other health-related products.

The FDA's primary responsibility is over claims that appear on product labels (including packaging, product inserts, and promotional material at the point of sale), and the FTC regulates claims made in advertising in general.

FDA regulations prescribe different standards for different products and claims. For example, food, dietary supplements, drugs, and other products are each subject to different FDA requirements. Further, health-related claims are subject to different evidentiary standards (<https://faculty.westacademic.com/Book/Detail?id=341299>), as these claims can vary in terms of form and degree — from disease prevention claims, to structure / function claims, to drug claims. For instance, a claim on a dietary supplement for “occasional heartburn” relief



(structure/function claim) may be less strictly regulated (<https://pink.pharmaintelligence.informa.com/PS090718/FTC-Criteria-For-StructureFunction-Claim-Ad-Evaluation-Sought-By-Marketers>) than a claim for “relief of heartburn” (disease claim).

While the FTC does not distinguish between different kinds of products or claims, it aligns with the FDA's requirements of substantiation for such claims.

A recent example

Recently, the FTC settled a lawsuit against ZyCal Bioceuticals Healthcare Company (https://www.ftc.gov/system/files/ftc_gov/pdf/84_proposed_stipulated_order_submitted_to_court.pdf), which was charged with making bogus health claims.

For several years (https://www.ftc.gov/system/files/documents/cases/zycal_complaint.pdf), ZyCal advertised and marketed pills containing Cyplexinol under the brand name Ostinol. This product was promoted as a bone and cartilage growth stimulant that could also relieve joint pain and conditions such as osteoporosis and osteoarthritis.

Product information and promotional material contained statements such as (https://www.ftc.gov/system/files/documents/cases/zycal_complaint.pdf): the product *“stimulate[s] cells to grow bone tissue,”* and *“contains a biologically active protein complex proven for 40 years and used clinically for 20 years to grow bone.”* Claims that these health benefits were clinically or scientifically proven were also made.

This product was sold directly to consumers and to healthcare professionals. As the FTC complaint reveals (https://www.ftc.gov/system/files/documents/cases/zycal_complaint.pdf), from 2014 to 2017, ZyCal generated gross sales minus returns of more than \$3.1 million to health professionals and more than \$1.5 million to consumers.

As it turns out, these health claims were deceptive, false and unsubstantiated (<https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-order-bar-zycal->



bioceuticals-deceptive-health-marketing). The truth was that ZyCal had no competent or reliable scientific evidence to substantiate any of these health claims nor were the statements clinically proven.

In 2023, the FTC barred ZyCal from making any of these false and misleading representations, unless backed by evidence.

Cautionary tales from the past

The ZyCal case is just one in around 200 cases (<https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance>) that the FTC has settled or adjudicated in the past.

The list below provides a flavor of the kind of false and misleading health claims that are being made and those the FTC cracked-down on between 2020 and 2022:

S.No.	False and Deceptive Health Claims
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| 1. | Six sellers of cannabidiol (CBD) products made wide ranging unsupported claims about their products ability to treat serious health conditions (https://www.ftc.gov/legal-library/browse/cases-proceedings/202-3094-epichouse-llc-first-class-herbalist-cbd-matter), including cancer, heart disease, hypertension, Alzheimer's disease, and others. |
|----|---|



2. A St. Louis-based chiropractor deceptively marketed products containing vitamin D and zinc as being scientifically proven to treat or prevent COVID-19 (<https://www.ftc.gov/legal-library/browse/cases-proceedings/202-3188-quickwork-llc-eric-nepute>).

Similarly, action has been initiated against another company that falsely pitched its saline nasal sprays as an effective way to prevent and treat COVID-19 (<https://www.ftc.gov/legal-library/browse/cases-proceedings/2123045-xlear-inc>).

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3. A stem cell company made bogus claims that its stem cell therapy was effective in treating arthritis (<https://www.ftc.gov/legal-library/browse/cases-proceedings/182-3125-stem-cell-institute-america-llc>), joint pain, and a range of other orthopaedic ailments.

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4. The marketers of three supplements charged for false claims regarding pain-relief and treatment of age-related ailments. They deceptively marketed products to older people. (<https://www.ftc.gov/legal-library/browse/cases-proceedings/172-3132-172-3143-nordic-clinical-inc-encore-plus-solutions-inc>)

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5. Certain fish oil supplements were falsely marketed as clinically proven to treat non-alcoholic fatty liver disease (<https://www.ftc.gov/legal-library/browse/cases-proceedings/192-3088-basf-se-matter>).

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6. Well-known social media influencers marketed products that falsely and deceptively claimed to (<https://www.ftc.gov/legal-library/browse/cases-proceedings/182-3174-teami-llc>) fight cancer, clear clogged arteries, decrease migraines, treat and prevent flu, treat colds and serve as weight-loss aids.



7. Robocalls were used to deceptively market dissolvable oral film (<https://www.ftc.gov/legal-library/browse/cases-proceedings/172-3117-x190001-jason-cardiff-redwood-scientific-technologies-inc>) strips as effective smoking cessation, weight-loss, and sexual-performance aids.

Buyer beware

The claims identified above explicitly state that the products prevent or treat specific diseases. Such claims are required to meet the FDA standards of substantiation, which require 'significant scientific agreement' for such claims (<https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance>). Such claims also generally need to be supported by human clinical testing.

In most cases (<https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance>), testing is required to be (a) randomized, double-blind, and placebo-controlled; and (b) conducted by researchers qualified by training and experience to conduct such testing. In the absence of these requirements, the claims are inaccurate, false and misleading. This is patently dangerous for consumers.

Moreover, even when products make more limited health claims, a host of concerns remain. For example, consumers may not be aware of subtle differences in wording that allow manufacturers to legally market a health-related product without rigorous evidence supporting its use. This adds to the confusion and makes health-related purchasing decisions burdensome, tiring, and potentially hazardous for consumers.

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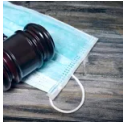
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