Nutraceuticals and Social Media: FDA and FTC Like and Subscribe to the Next Big Trend in Litigation

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ABSTRACT

The Article discusses growth of the nutraceutical industry and social media as well as the risks and rewards when using influencers on Instagram, TikTok, YouTube, and other social media sites to promote nutraceutical products. The Article discusses the U.S. Food and Drug Administration's (FDA's) and the Federal Trade Commission's (FTC's) enforcement priorities on mental health claims in dietary supplements; recent actions against companies for deceptive influencer endorsements and testimonials regarding nutraceuticals; as well as state-level consumer protection claims, including an example from a recent case in Texas.

I. INTRODUCTION

If you have been on Instagram or Facebook in the past decade, you have likely seen nutraceuticals marketed in the form of teas, protein powder, or a hair-growth gummy. Even if you have managed to avoid social media, you may have purchased and consumed a nutraceutical product, such as fiber supplements, fish oil, and probiotics. So, what are nutraceuticals? The term "nutraceutical" was coined from "nutrition" and "pharmaceutical" in 1989 by Stephen DeFelice, MD, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ. According to DeFelice, "a nutraceutical is any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease." Such products may range from isolated nutrients, dietary supplements, and specific diets, to genetically engineered designer foods, herbal products, and processed foods such as cereals, soups, and beverages. Health Canada defines nutraceutical as an isolated product or purified form of food that is generally sold in medicinal forms not usually associated with food—like tablets and capsules with a demonstrated physiological benefit. Merriam Webster defines nutraceutical as "a foodstuff (such as a fortified food

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¹ Maruthi Prasad Palthur, Sree S. S. Palthur & Suresh Kumar Chitta, *Emerging Product Categories in India: A Regulatory View*, 64 FOOD & DRUG L.J. 677, 678 (2009) (quoting Am. Nutraceutical Ass'n, Nutraceutical information page) (last visited Sept. 8, 2009).

or a dietary supplement) that provides health benefits in addition to its basic nutritional value." Importantly, the term "nutraceutical" as commonly used in marketing has no regulatory definition under the U.S. Food and Drug Administration (FDA) or the Federal Trade Commission (FTC).

If you have purchased a nutraceutical under any of the above definitions, you are in good company. According to a 2017 report, nearly two-thirds of Americans are taking some type of nutraceutical product, and the U.S. nutraceutical market is expected to reach \$599.71 billion by 2030.³ Moreover, social media has played an integral role in the growth of the nutraceutical market, with Instagram leading the charge. Nutraceutical companies were one of the first industries to capitalize on social media influencers hoping for high-quality, authentic content and consumer audience engagement. However, as the nutraceutical and social media markets expand, so do the associated risks.

To illustrate some of these risks, imagine owning a nutraceutical company that makes protein powder supplements for men and is looking to diversify its product line. While perusing the *Journal of Medicinal Food*, you run across the following study: "Dietary Supplementation with Specific Collagen Peptides Has a Body Mass Index-Dependent Beneficial Effect on Cellulite Morphology." The double-blind, placebo-controlled study concludes that "oral supplementation with specific bioactive collagen peptides over a period of six months led to a clear improvement of the skin appearance in women suffering from moderate cellulite." Intrigued, you do another search and find a second double-blind, placebo-controlled study in the peer reviewed journal of *Skin Pharmacology and Physiology*, "Oral Intake of Specific Bioactive Collagen Peptides Reduces Skin Wrinkles and Increases Dermal Matrix Synthesis." This study finds that "oral intake of specific bioactive collagen peptides... reduced skin wrinkles."

Realizing the potential, you now locate a supplier for the bioactive collagen peptides, add the collagen peptide to your product list, put it in new packaging marketed towards women, and make the product available directly from your website. You then carefully label your new cellulite- and wrinkle-improving protein powder supplement to avoid running afoul of FDA regulations. You ensure that the label is not misleading; that it includes a disclaimer that the statement has not been evaluated by FDA; and that the product is not intended to diagnose, treat, cure, or prevent any

² Nutraceutical, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/nutraceutical (last visited Apr. 20, 2023).

³ Nutraceuticals Market Size Worth \$599.71 Billion By 2030, GRAND VIEW RSCH., INC. (Apr. 2023), https://www.grandviewresearch.com/press-release/global-nutraceuticals-market (last visited Jul. 26, 2023).

⁴ Michael Schunck, Vivian Zague, Steffen Oesser & Ehrhardt Proksch, *Dietary Supplementation with Specific Collagen Peptides Has a Body Mass Index-Dependent Beneficial Effect on Cellulite Morphology*, 18 J. MEDICINAL FOOD 1340 (2015), https://doi.org/10.1089/jmf.2015.0022.

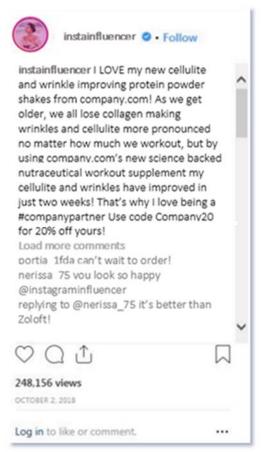
⁵ Id.

⁶ Ehrhardt Proksch, Michael Schunck, Vivian Zague, Dörte Segger, Joachim Degwert & Steffen Oesser, Oral Intake of Specific Bioactive Collagen Peptides Reduces Skin Wrinkles and Increases Dermal Matrix Synthesis, 27 SKIN PHARMACOLOGY & PHYSIOLOGY 113 (Dec. 24, 2013), https://pubmed.ncbi.nlm.nih.gov/24401291/.

⁷ *Id*.

disease. The label also references your website, which contains a link to the studies. You decide to outsource the marketing and take advantage of the explosion of social media since your last product release.

Your new marketing team contracts with an enormously popular social media influencer to promote the product to her millions of followers. The influencer posts before and after pictures and says that your nutraceutical improved her crow's feet and cellulite in just two weeks. In response to a few comments and questions from followers on the post, the influencer replies that the supplement was "better than Zoloft," got her out of a workout slump, and is a "natural antidepressant." Thrilled with the engagement on the original post, your marketing team links the influencer's post to your website. Your marketing team then builds on the momentum of the post by contracting with an army of



affiliate advertisers, who receive a small commission when a customer clicks on a special link to purchase the nutraceutical from your website. Some of the affiliate marketers include a popular fitness TikToker who repeats the mental health claims made by the influencer and directs viewers to the affiliate link in her bio. The TikTok gets millions of views and within forty-eight hours of the original post, hundreds of TikTok accounts stitch the fitness influencer's video with their own videos, and the original TikTok gets reposted to Reddit, Instagram, and Facebook. Sales of your new wrinkle- and cellulite-erasing nutraceutical skyrocket, and your product becomes one of the best-selling nutraceuticals on the market.

Everything seems great until you get a warning letter from FDA.

This is to advise you that the Food and Drug Administration (FDA) reviewed your website in March 2022 and has determined that you take orders there for your protein powder collagen supplement. The claims on your website establish that your product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because it is intended for use in the cure, mitigation, treatment, or prevention of disease

^{8 21} C.F.R. § 101.93.

The FDA warning letter references the page on your website that has a link to the influencer's post, cites to the influencer's "natural antidepressant" and "better than Zoloft" comments, and mentions the web addresses for multiple affiliate marketers who repeated the "natural antidepressant" claims. You have not even finished reading the FDA warning letter when your assistant rushes in and hands you a notice from FTC claiming your company is engaging in "unlawful practices relating to the use of endorsements and testimonials" and putting you on notice of "civil penalties of up to \$43,792 per violation." At this point, you think it cannot get any worse, when a Google alert pings your email. The national headlines report that the social media influencer is a co-defendant in a consumer protection lawsuit filed against your company. Shocked and confused, you try not to panic at the nightmare trifecta of FTC enforcement, FDA enforcement, and a consumer protection lawsuit.

So what went wrong? Let's start with FDA.

II. FDA ENFORCEMENT

Going back to our hypothetical, the label on the packaging makes no claims about curing a disease, and the verbiage on the website written by the company is similarly careful. Moreover, there was no intent to market the product as a "cure" for depression. So how did a cellulite- and wrinkle-improving protein powder supplement turn into a depression drug?

The problem started when our hypothetical company failed to include provisions in the influencer's contract setting out protocols for communication about the product, and a requirement for the influencer to acknowledge and agree to the company's rules for how to respond to questions and comments. Our hypothetical company also failed to ensure that its marketing team was properly trained and updated on FDA's guidelines and that it had a monitoring plan in place for social media posts. In our scenario, the marketing team exponentially compounded the problem when it linked and reposted the social media influencer's post to the company's own website. FDA clearly notes that:

if the label for a product contain[s] a statement that refer[s] the consumer to a specific website for additional information about a claim for the product, the website is likely to be "labeling." The websites, in these cases, are considered written, printed, or graphic matter that supplements or explains the product and is designed for use in the distribution and sale of the product.⁹

By failing to monitor the comments or "engagement" on the influencer's post, and linking to the posts from the product website, the company inadvertently put itself directly in the crosshairs of FDA's recent enforcement priorities on mental health claims in dietary supplements.¹⁰

⁹ Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling, U.S. FOOD & DRUG ADMIN. (Jan. 2007), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-dear-manufacturer-letter-regarding-food-labeling.

Press Release, U.S. Food & Drug Admin., FDA Warns 10 Companies for Illegally Selling Dietary Supplements Claiming to Treat Depression and Other Mental Health Disorders (Feb. 19, 2021), https://www.fda.gov/news-events/press-announcements/fda-warns-10-companies-illegally-selling-dietary-supplements-claiming-treat-depression-and-other.

In 2022, our hypothetical became a reality for multiple nutraceutical companies when FDA issued more than fifty warning letters referencing the use of social media accounts in marketing. At least ten of those warning letters specifically cite to Instagram posts mentioning depression or anxiety. For example, on June 10, 2022, FDA sent a warning letter to an essential oil company for promoting CBD products for a myriad of claims including PTSD, depression, and anxiety. The FDA warning letter specifically cited and linked to six affiliate marketer social media accounts "that provide evidence of the intended uses of your products (as defined by 21 CFR § 201.128) as drugs "12"

III. FTC ENFORCEMENT

Now, moving on to FTC: The trouble in our hypothetical started with the influencer's endorsement of your product without proper disclosure language. First, the disclosure on her post was neither clear nor conspicuous. Rather, she relied on Instagram's built-in disclosure tool for the post, which caused the disclosure language to appear in small white text set against a light background image. Second, none of the scientific literature provided support for a reduction of wrinkles and cellulite in two weeks. The cellulite study concluded that "regular ingestion of [bioactive collagen peptides] over a period of 6 months led to a clear improvement of the skin appearance in women suffering from moderate cellulite." The skin wrinkle study found that "[t]he ingestion of the specific [bioactive collagen peptides] used in this study promoted a statistically significant reduction of eye wrinkle volume (p < 0.05) in comparison to the placebo group after 4 and 8 weeks (20%) of intake." Third, the before and after pictures posted by the influencer were edited via an Instagram filter.

As a result, the potential allegations against our hypothetical company are: 1) failure to provide a clear and conspicuous disclosure, 2) deceptive performance, and 3) misrepresentation of a consumer's typical or ordinary experience. This all could have been easily avoided by requiring social media marketers to agree to written guidelines and the company requiring review and pre-approval before content is posted.

Much like our FDA example, the FTC hypothetical has already become a reality. FTC has not been shy about its position on social media, with a clear ramp up in enforcement efforts over the past two years. In 2020, a detox tea brand company, known as Teami, LLC, agreed to pay \$1 million after being served with a complaint that Teami took in "more than \$15 million by deceptively claiming their array of teas could cause rapid and substantial weight loss, 'fight against cancerous cells,' decrease migraines, unclog arteries, and prevent colds and flu." FTC alleged that Instagram posts by well-known influencers failed to adequately disclose their paid endorsements and included among the exhibits screenshots from two Instagram and reality television

Warning Letter: Young Living Essential Oils Corporate, U.S. FOOD & DRUG ADMIN. (June 10, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/young-living-essential-oils-corporate-615777-06102022.

¹² **I**d

¹³ Schunck et al., supra note 4.

¹⁴ Proksch et al., supra note 6.

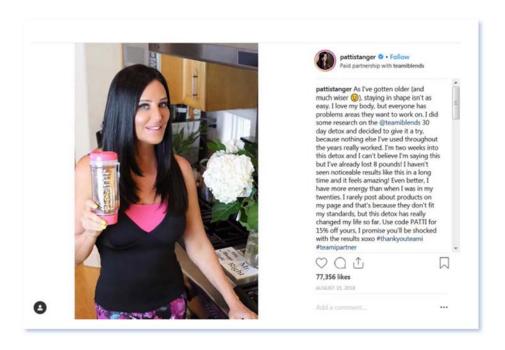
¹⁵ Lesley Fair, FTC's Teami Case: Spilling the Tea About Influencers and Advertisers, FED. TRADE COMM'N: BUSINESS BLOG (Mar. 6, 2020), https://www.ftc.gov/business-guidance/blog/2020/03/ftcs-teamicase-spilling-tea-about-influencers-and-advertisers.

celebrities, Lisa Rinna of The Real Housewife of Beverly Hills (Exhibit 15) and Patti Stanger of Millionaire Matchmaker (Exhibit 11), reproduced below. The Patti Stanger Instagram post even noted the paid partnership at the top and in a hashtag at the bottom, but FTC did not deem the language sufficient.



FTC EXHIBIT 15

¹⁶ FED. TRADE COMM'N, TEAMI, LLC: COMPLAINT EXHIBITS 1–26 (Mar. 6, 2020), https://www.ftc.gov/system/files/documents/cases/1823174teamicomplaint_exhibits1-26.pdf (last visited Aug. 4, 2023).



FTC EXHIBIT 11

Less than a year later, an October 2021 FTC press release specifically called out social media, stating that "[t]he rise of social media has blurred the line between authentic content and advertising, leading to an explosion in deceptive endorsements across the marketplace."17 FTC sent a letter to over 700 companies enclosing the FTC's Notice of Penalty Offenses concerning deceptive or unfair conduct around endorsements and testimonials.¹⁸ The press release sent a "clear message" warning advertisers that if "they use endorsements to deceive consumers, the FTC will be ready to hold them responsible with every tool at its disposal."¹⁹

FTC provides the following guidance for avoiding enforcement actions:

In order to limit its potential liability, the advertiser should provide guidance to its influencers concerning the need to ensure that statements they make are truthful and substantiated and the need to disclose

¹⁷ Press Release, Fed. Trade Comm'n, FTC Puts Hundreds of Businesses on Notice about Fake Reviews and Other Misleading Endorsements, Fed. Trade Comm'n (Oct. 13, 2021), https://www.ftc.gov/ news-events/news/press-releases/2021/10/ftc-puts-hundreds-businesses-notice-about-fake-reviews-other-puts-hundreds-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-businesses-notice-about-fake-reviews-busmisleading-endorsements [hereinafter FTC Press Release].

¹⁸ Fed. Trade Comm'n, Sample Letter for Notice of Penalty Offenses Concerning DECEPTIVE OR UNFAIR CONDUCT AROUND ENDORSEMENTS AND TESTIMONIALS, https://www.ftc.gov/ $system/files/attachments/penalty-offenses-concerning-endorsements/npo_endorsement_template_letter.$ pdf (last visited Aug. 4, 2023).

¹⁹ FTC Press Release, *supra* note 17.

unexpected material connections and take other steps to discourage or prevent non-compliance. The advertiser should also monitor its influencers' compliance and take steps necessary to remove and halt the continued publication of deceptive representations when they are discovered and to ensure the disclosure of unexpected material connections.²⁰

As with traditional advertising, social media influencer endorsements cannot make claims that would be considered deceptive. Moreover, they must be the honest opinion of the endorser.²¹

Further demonstrating FTC's priority on social media enforcement, in July 2022, FTC published its proposed changes to its *Guides Concerning the Use of Endorsements and Testimonials in Advertising*.²² In that publication, FTC: 1) warned social media platforms that some of their tools for endorsers are inadequate and may open them up to liability; 2) clarified that fake reviews are covered under the guides and added a new principle that in procuring, suppressing, boosting, organizing, or editing consumer reviews, advertisers should not distort or misrepresent what consumers think of their products;²³ 3) clarified that tags in social media posts are covered under the guides and modified the definition of "endorsers" to bring virtual influencers—that is, computer-generated fictional characters—under the guides; and 4) added an example addressing the microtargeting of a discrete group of consumers.²⁴

IV. STATE CONSUMER PROTECTION

Moving on to the third part of the nightmare legal trifecta: state-level consumer protection claims.

In our hypothetical, your company was served with a lawsuit naming you as a codefendant in a case brought by your state attorney general against the popular social media influencer hired by your marketing team to promote the product to her millions of followers.

The influencer had been promoting your product on her YouTube explaining that she overcame her depression and got rid of her cellulite in two weeks, and in the same videos offered links to her "personalized fitness and nutrition plans" along with the affiliate marketing link to your company's product. Consumers started filing complaints with their state attorney general when she failed to provide the fitness plans and when their cellulite failed to disappear in two weeks.

Guides Concerning the Use of Endorsements and Testimonials in Advertising, 87 Fed. Reg. 44,288 (proposed July 26, 2022), https://www.federalregister.gov/documents/2022/07/26/2022-12327/guides-concerning-the-use-of-endorsements-and-testimonials-in-advertising.

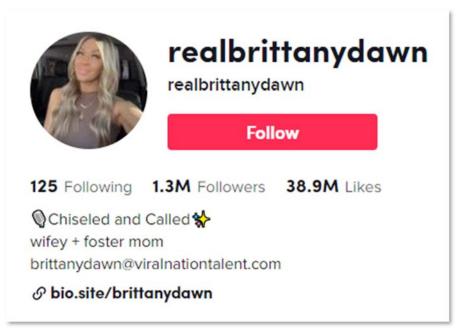
²¹ FTC's Endorsement Guides: What People Are Asking, FED. TRADE COMM'N, https://www.ftc.gov/business-guidance/resources/ftcs-endorsement-guides-what-people-are-asking (last visited Aug. 4, 2023).

²² Guides Concerning the Use of Endorsements and Testimonials in Advertising, 87 Fed. Reg.

²³ See, e.g., Press Release, Fed. Trade Comm'n, Fashion Nova will Pay \$4.2 Million as part of Settlement of FTC Allegations it Blocked Negative Reviews of Products (Jan. 25, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/01/fashion-nova-will-pay-42-million-part-settlement-ftc-allegations-it-blocked-negative-reviews.

²⁴ Guides Concerning the Use of Endorsements and Testimonials in Advertising, 87 Fed. Reg.

Just last year this hypothetical lawsuit became a reality for Texas-based influencer Brittany Dawn Davis.



On February 1, 2022, the Texas Attorney General filed a lawsuit against a fitness influencer, Brittany Dawn Davis and her company Brittany Dawn Fitness, LLC.²⁵ Presently, Davis has 1.3 million followers on TikTok and about 480,000 on Instagram, as well as 438,000 YouTube subscribers.

The lawsuit alleges the influencer "violated the Texas Deceptive Trade Practices—Consumer Protection Act, Texas Business and Commerce Code section 17.41" and seeks damages as well as civil penalties of up to \$10,000 for each violation, which could total anywhere from \$250,000 up to \$1 million if proven.²⁶ In legal pleadings, Davis denies all of the allegations.

The Texas Attorney General lawsuit claims that Davis' company, at www.bdawnfit.com, "offered personalized online fitness plans that contained a nutrition component based upon personalized macronutrients" and that "[a]ccording to Ms. Davis, the macronutrients for each consumer were customized at the very beginning of the plan based on several factors including a consumer's weight, height, goals, and activity level, and she adjusted the macronutrients throughout the plan as she determined necessary." The lawsuit alleges that Davis failed to deliver on those promises and also claims Davis mislead consumers about eating disorders:

Defendant Davis posted videos on YouTube explaining that she overcame her eating disorder through exercise and healthy eating. In the same social media posts, she then offered links to her fitness and nutrition plans.

²⁵ Plaintiff's Original Petition, State v. Davis, No. DC-22-01388 (last visited Aug. 4, 2023).

²⁶ Id.

²⁷ Id.

Consumers inferred from Defendant's videos and links to her website that she had special training to address eating disorders.²⁸

Two years before the Texas Attorney General's lawsuit, Davis went on Good Morning America to apologize after complaints were filed, saying "I jumped into an industry that had no instruction manual, I'm basically going through uncharted territory." But by 2019, FDA and FTC had published guides for compliance with social media marketing and nearly every state attorney general website has easily accessible websites explaining consumer protection laws. And according to Insider.com, "a nutrition food company" ceased working with her in 2019 and another company asked Davis to stop using its affiliate links in her social media accounts. Insider also reported in 2019 that several customers in a Facebook group titled "Brittany Dawn Fitness Complaints Group" were advocating for a class action lawsuit. 22

With only about two weeks remaining before the May 15, 2023, trial date, Brittany Dawn Davis, and Brittany Dawn Fitness, LLC, settled with the State of Texas, agreeing to pay \$400,000 in penalties and restitution. In this instance, the companies that had been working with Davis had the foresight to pull their affiliate links from her social media accounts at the first sign of trouble. But Plaintiff-friendly states with favorable consumer protection laws and lucrative fee awards will be a persistent risk facing the nutraceutical industry.

V. CONCLUSION

Without proper mitigation and compliance strategies, the risk of consumer-protection lawsuits becomes exponentially greater due to the increased regulation and enforcement by FDA and FTC. Warning letters are public information and can be shared on TikTok and Instagram, becoming viral in less than forty-eight hours. Despite this, marketing with social media is probably one of the fastest and most effective ways to get a product in front of the right audience.

With the right strategy and a well-maintained plan in place, the risks can be mitigated. Companies, their marketing teams, and their legal counsel should be proactive in understanding the law and current regulatory environment so that they can be well-positioned to create robust social media compliance and monitoring programs for their company's protection.

²⁸ *Id*.

²⁹ Fitness Influencer Apologizes After Flood of Customers Call Her Programs a Scam, ABC News, (Feb. 13, 2019), at 2:22 seconds.

³⁰ See, e.g., Guides Concerning the Use of Endorsements and Testimonials in Advertising, 87 Fed. Reg. 44,288 (proposed July 26, 2022), https://www.federalregister.gov/documents/2022/07/26/2022-12327/guides-concerning-the-use-of-endorsements-and-testimonials-in-advertising; FDA Social Media Policy, U.S. Food & Drug Admin. (last visited Aug. 4, 2023), https://www.fda.gov/about-fda/website-policies/fda-social-media-policy; Consumer Protection, Attorney General of Texas (last visited Aug. 4, 2023), https://www.texasattorneygeneral.gov/consumer-protection.

³¹ Jacob Shamsian, A Fitness Influencer Who Some Say Is a 'Scammer' Still Hasn't Issued Full Refunds for Nutrition Programs Weeks After Followers Called Her Out, INSIDER (Mar. 19, 2019), https://www.insider.com/brittany-dawn-fitness-influencer-scam-partial-refunds-2019-3.

³² Id.