Attack on Multiple Fronts in Nutraceutical Marketing: The threat of FTC, FDA and Consumer Class Actions

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Nutraceutical products recently have been the subject of a multitude of class-action lawsuits questioning their marketing, efficacy, and safety. The often hyperbolic health and nutritional claims touted in labeling and advertising for food and dietary supplements provide fertile ground for "consumer fraud" claims, particularly in states like California that have plaintiff-friendly laws. As a defense to these actions, nutraceutical companies may assert federal preemption – arguing that the federal government controls nutraceutical marketing and preempts states from imposing different requirements through civil litigation. On the other hand, civil plaintiffs often attempt to bolster their claims for

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damages by arguing that marketing violates federal law.

The regulatory scheme controlling the marketing of nutraceutical products is far from clear. Authority is shared between the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), but the explosion of social media and e-commerce into the marketplace has created many unanswered questions about the respective scope of their authority. The lack of clear guidance not only leaves companies vulnerable to enforcement action by both FDA and FTC, but the lack of bright-line federal standards may embolden an aggressive plaintiffs' bar to file class-actions, complicate potential preemption defenses and make it easier for plaintiffs to argue a violation of federal law.

A. Regulatory Authority of FDA vs. FTC – Dangers of Overlap and Falling Through the Cracks

FDA and FTC operate under a liaison agreement under which FTC possesses primary enforcement responsibility for advertising, while FDA has primary enforcement responsibility over labeling and packaging. However, the line between the two, however, is often blurred. For example, FDA has stated that in certain circumstances information about FDA-regulated products disseminated over the internet can be considered labeling, particularly when consumers can purchase the product directly from the website. Additionally, some courts have interpreted "labeling" to include any visual, audio, or other material that bears a strong contextual relationship to the product and is distributed at the point of sale.

While the agencies have published guidance regarding the intersection of authority between FDA and FTC, it not only fails to address all of the areas of uncertainty, but has quickly become outdated by rapidly changing trends in health food development, promotion and methods of communication. In recent years, methods of purchasing nutraceuticals have grown to include infomercials, websites, and even cell phone apps. There are new vehicles for marketing, such as blogs and social media (*e.g.*, Twitter and Facebook.). This social media and internet boom has amplified the confusion over what is labeling and what is advertising.

One example of the blurred line involves Phusion Products LLC, makers of Four Loko, a caffeinated alcoholic beverage allegedly linked to injuries and deaths. Both FDA and FTC sent warning letters to Phusion Products on Nov. 17, 2010 stemming from the same alleged acts. Moreover, in 2011, FTC required packaging and label changes for Four Loko drinks regarding the per-can alcohol volume, even though FDA has primary enforcement over labeling and packaging. There are multiple similar instances of FDA sending warning letters to dietary supplement companies concerning claims made on websites, which most would consider advertising within the purview of FTC.

The recent case of *Wilson v. Frito-Lay North America Inc.,* involved claims that Frito-Lay's statements about its snack products – including the description "all-natural" -- violated the Food Drug and Cosmetic Act and were civilly actionable under California law. In this context, the court considered whether company websites identified on product labeling themselves constitute "labeling." Specifically, the court addressed whether the statement "Visit our website @ fritolay.com" printed on a bag of chips transformed every statement on that Frito Lay website into labeling. Without discussing FTC's authority in the area, the Court concluded it did not because none of the website language explained or supplemented the product, and because consumers were not told the website would inform them of the details of the products' nutritional facts. But the very fact that the court entertained the argument that referring consumers to a website could turn statements on that website into labeling highlights the confusion in this area, and should raise concerns among nutraceutical manufacturers.

B. Missing in Action – Regulatory Guidance for Marketing by Social Media

Both FTC and FDA have treated social media as advertising, and FTC has touched on the issue in its guidance. Despite requests, FDA has yet to release guidance about marketing via social media, opting instead to address the issue on a case-by-case basis.

It has long been a matter of speculation whether a company "liking" statements about its product on Facebook or "re-tweeting" those statements on Twitter might be construed as an endorsement of the content subject to federal regulation. FDA apparently thinks the answer is "yes," although in the context of a product FDA considered to be a drug rather than a nutraceutical. FDA issued a warning letter to AMARC, a dietary supplement company, for "liking" an unapproved claim regarding its product, PolyMVA, on Facebook. The

post, by a third party, stated: "PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation…Thank you AMARC[.]" FDA's warning letter suggests that it interprets a Facebook "like" as an endorsement of the statement. Whether FDA or FTC will take the same position with respect to nutraceuticals as opposed to drugs (which are within FDA's exclusive purview), remains to be seen, but the AMARC warning letter should give companies pause about "endorsing" statements about their products via social media.

C. FTC Issues Some Guidance for use of Social Media

Earlier this year, FTC updated its guidelines regarding e-commerce disclosures, specifically instructing that companies should be mindful that consumers will be reading the content on various types of devices (i.e. computer, smart phone, and tablet) and that all disclosures need to be clear and conspicuous regardless of the device. Additionally, FTC provided a template for disclosing ads within posts on social media platforms. For instance, a social media post by a paid spokesperson, including space-constrained messages such as Tweets, should disclose that it is a paid endorsement, as well as state typical results if the statement is a testimonial. This will affect advertisers, social media participants, bloggers and startup companies, to name a few. And it stands to reason that FTC will also expect digital advertising regarding nutraceutical products to contain full disclosure of nutritional facts and any other required information, even under Twitter's 140 character limit.

One intriguing issue that remains unclear is the extent to which a company might be responsible for posts by third parties regarding product results. If the claim is made on a page belonging to the company, does the company have to follow up with a statement that results are not typical and may vary? What if a tweet is re-tweeted? Neither FDA nor FTC have officially weighed in on these issues unique to social media.

D. Litigation Trends Target Nutraceutical Marketing Claims

The recent influx of nutraceutical marketing litigation seems to center around two types of product claims: (1) health-related (healthy, nutritious, or wholesome) and (2) "natural."

- *"Healthful," "Nutritious" and "Wholesome" claims*

  Putative class-actions have targeted health-oriented claims regarding products that contain trans fat, high amounts of saturated fat, sugar or sodium, or artificial colors or flavors. Per FDA regulation, the term "healthy" or similar terms (health, healthful, healthfully, healthfulness, healthier, healthiest, healthily, and healthiness) can be used in the content labeling if the product meets the conditions for total fat, saturated fat, cholesterol, and other nutrients defined by regulation.

  Classes have been successful challenging health claims even where the advertising does not expressly call the product healthy. For instance, Nutella hazelnut spread was targeted for its advertising that make Nutella seem as though it was part of a healthy, nutritious breakfast. The class plaintiffs alleged that the advertising misled consumers about the healthfulness, implying it was part of a wholesome balanced breakfast, but omitting that the nutritional value claimed was not derived from Nutella. The class plaintiffs asserted that Nutella was more analogous to a dessert topping, with high levels of fat and sugar. The company ended up settling the suit for over $3 million in 2012.

- *"All Natural"*

  Some of the most common consumer actions involve "natural" claims regarding products containing genetically modified organisms (GMOs) or other synthetic or artificial ingredients, even though the packaging truthfully lists all the ingredients. FDA has declined to promulgate a regulation defining natural, but in non-binding informal policy, FDA has indicated it considers natural to mean that "nothing artificial or synthetic" (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected. FDA applied this meaning in a 2011 warning letter to a manufacturer, stating that a potato product was misbranded as "All Natural" because it contained a synthetic chemical preservative, disodium dihydrogen pyrophosphate. This non-binding guidance, however, does not have enough weight to preempt claims by consumers.

Accordingly, claims are frequently permitted to proceed under a patchwork of state laws.

Recent putative class-action suits have targeted "natural" claims regarding products containing ingredients such as high fructose corn syrup, alkalized cocoa, factory-made ascorbic acid, vegetable glycerin, soybean oil, canola oil, yeast extract, and beta-carotene. Many beverage and snack food products claiming to be "all natural" have been targeted with class action claims.

In July 2013, Naked Juice agreed to pay $9 million to settle a consolidated putative class action in California alleging that products' labels and advertising made claims such as "all natural" and non-genetically modified, even though the products contained unnaturally processed and synthetic ingredients, derivatives of genetically modified crops, and chemically processed vitamin substitutes. Naked Juice continues to deny the allegations that the product labels were misleading or false, but has also agreed to redesign the labels to address the representations at issue.

There is no clear answer for avoiding trouble, but being overly cautious with regard to "natural" claims may be one of the most effective solutions to help mitigate risk. Even common plant-derived additives and preservatives, as well as genetically modified corn and soybeans or their derivatives, such as corn starch, have been targeted in litigation. Notably, more than 80 percent of the U.S. corn and soybean stock are genetically modified, and these products are two of the most common ingredients in food products. Accordingly, manufacturers should closely scrutinize their ingredients and the way those ingredients are processed before making "natural" claims. And the best solution may be to find alternative marketing strategies to "all natural" claims to avoid being targeted by class-action litigation.

E. Advice for Manufacturers

Until there exists a clear distinction between FDA and FTC authority and what constitutes labeling and advertising in nutraceutical marketing, nutraceutical manufacturers would do well to closely monitor the two agencies' actions and statements, as well as litigation trends involving nutraceuticals. Companies, their marketing teams, and their legal counsel should be proactive in understanding the law and regulatory environment and should consider creating compliance programs that will help ensure marketing efforts are regularly evaluated for conformity. In the meantime, manufacturers and marketers of nutraceuticals should strive for compliance with both FDA and FTC regulations and guidelines, and should expect product websites and social media pages to continue to receive heighted scrutiny by one or both Agencies. When in doubt, the manufacturer should follow a "double dose" of precaution by anticipating overlap between the FDA and FTC.