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News

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State and Federal Agencies Crack Down on Claims for Touted COVID-19 Preventatives, Treatments and Cures

The market for consumer products is likely contracting overall, but judging by empty drugstore shelves, anxious consumers remain keenly interested in purchasing over-the-counter medications, supplements and various herbs, oils, foods and beverages touted as anti-pathogens, anti-inflammatories or as providing immune support. Regardless of the possible, or even proven, health benefits of your products, if you are considering offering your product as a preventative, treatment or cure for COVID-19, the disease caused by the novel coronavirus outbreak, think twice and tread carefully. In light of heightened scrutiny by regulators and state attorneys general of deceptive advertising claims made during the COVID-19 pandemic, manufacturers of dietary supplements, CBD-derived products, and health foods and beverages should carefully review their marketing and advertising claims to ensure legal compliance.

It is important for you to remember the environment in which you are currently marketing your products. The consuming public is becoming increasingly desperate to either get in front of COVID-19 or treat it. That is the lens through which regulatory bodies, state attorneys general and consumer class action attorneys are reviewing your marketing and advertising, and it is important in this environment for your advertising not to appear predatory in any way.

On March 9, 2020, the Federal Trade Commission (FTC) and Food and Drug Administration (FDA) (together, the "Agencies") announced that they have sent warning letters to companies allegedly selling unapproved products that may violate federal law by making deceptive or scientifically unsupported claims about their ability to prevent or treat COVID-19. In these warning letters, the Agencies announced that in light of the public health emergency declared by the Secretary of Health and Human Services under Section 319 of the Public Health Service Act, 42 U.S.C. § 247d, the "FDA is taking urgent measures to protect consumers from products that claim to mitigate, prevent, treat, diagnose or cure COVID-19 in people."

The Agencies issued the warning letters to marketers of the following products: ionic, or colloidal, silver; essential oils; herbal teas; and herbal and elderberry tinctures. In each case, marketing claims were made regarding the antiviral properties of the product or the immune-boosting or preventative properties of the product. And, in each case, these properties were further touted via express or implied marketing claims as effective to prevent, treat or cure novel

coronavirus infection and COVID-19 disease. The Agencies requested responses and compliance within 48 hours and added alleged violators' names to a published list on the FDA's website of firms and websites that have received warning letters from the FDA concerning the sale or distribution of COVID-19-related products in violation of the Federal Food, Drug and Cosmetic Act ("FD&C Act").

The FDA has long made clear that it considers products making express or implied advertising claims regarding the mitigation, prevention, treatment, cure or diagnosis of disease to be unapproved new drugs sold in violation of section 505(a) of the FD&C Act, 21 U.S.C. § 355(a), or misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. Products making claims regarding COVID-19 are no exception and, in light of the Agencies' recent announcements, are receiving heightened scrutiny and enforcement.

Even if manufacturers and distributors of dietary supplements, health foods and beverages, and CBD-derived products (which are expressly prohibited from being marketed as dietary supplements pursuant to section 201(ff)(3)(B) of the FD&C Act) refrain from marketing their products as health cures or drugs in express violation of the FD&C Act, companies must remain aware that the marketing and advertising of these products remains subject to the Federal Trade Commission Act ("FTCA") and associated guidelines issued by the FTC (15 U.S.C. § 41 et seq.), the false advertising provisions set forth in Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)), and various state consumer protection, false advertising and unfair competition statutes and common law.

Under the FTCA, advertising content is considered deceptive if it contains the following elements: (a) there is a representation, omission or practice that is likely to mislead the consumer; and (b) the representation, omission, or practice is "material," meaning that it is likely to affect the consumer's decision with respect to the advertised product or service. *See* FTC Policy Statement on Deception, Oct. 14, 1983. The FTC applies a "reasonable consumer" standard, where the "reasonable consumer" will depend on the intended target audience of the advertising. *Id*. The FTC also evaluates the net impression of an advertisement, not just isolated statements or claims in it. *Id*. Omission of material information (such as disclosures or disclaimers) where such information is necessary to qualify or explain the proper meaning of a claim could also be considered deceptive. Importantly, all reasonable takeaways, both express and implied, from an advertisement considered in its totality must be substantiated by a "reasonable basis," which, in the case of health, safety or performance claims, means "competent and reliable scientific evidence." Indeed, the Agencies' recent enforcement letters sent to companies touting COVID-19 products make clear that such "competent and reliable scientific evidence" may include, where appropriate, "well-controlled human clinical studies substantiating that the claims are true at the time they are made."

Under Section 43(a) of the Lanham Act, a plaintiff with standing—almost always a competitor of the defendant—may commence and pursue a private right of action by showing the following elements: a) a statement/omission of fact about the "nature, characteristics, qualities, or geographic origin" of a product; (b) the statement/omission was false or misleading to a substantial portion of the intended audience; (c) the statement/omission was material to a consumer's decision to purchase the product; (d) the statement/omission was made in commercial advertising; (d) the advertised product was used in commerce; and (e) the statement/omission caused or is likely to cause harm to the plaintiff. See 15 U.S.C. § 1125(a).

Finally, all states have unfair and deceptive acts and practices ("UDAP") statutes or developed case law, which permit consumers (including, in some states, classes of consumers), competitors, and/or state attorneys general to take action against companies engaged in false or deceptive advertising. Related to the COVID-19 claims discussed above regarding colloidal silver, the state attorneys general of both New York and Missouri have taken action against televangelist Jim Bakker for touting colloidal silver products as a COVID-19 preventative and cure. On the Feb. 12, 2020, broadcast of *The Jim Bakker Show*, a "natural health expert" guest is alleged to have falsely implied that even though colloidal silver had never been tested against the novel coronavirus and COVID-19, it would likely be effective.

By commencing enforcement actions, it is evident that the New York and Missouri attorneys general's offices disagree that this is a truthful and substantiated claim. Additionally, the New York attorney general recently ordered Craigslist to "immediately remove posts that attempt to unlawfully and fraudulently profit off consumers' fears around the coronavirus disease 2019 (COVID-19)," including posts that have attempted to sell items that purportedly claim to provide "immunity" to the coronavirus or allow individuals to test for the disease. At this point, almost every state attorney general in the country has warned consumers of COVID-19-related scams and has vowed to take action to stop them.

In short, manufacturers of health-related products may understandably want to step up their marketing of dietary supplements, CBD-derived products, and health foods and beverages during a pandemic. Though this makes good business sense, marketing claims must be and remain truthful and supported by evidence in order to comply with applicable law. If you have questions about whether your advertising passes muster, please call us, as we are presently drafting opinion letters for clients on these very topics.

***Click here* to read more Brownstein alerts on the legal issues the coronavirus pandemic raises for businesses.**

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