



DEFEATING “PRIOR SUBSTANTIATION” ADVERTISING CLAIMS UNDER STATE CONSUMER PROTECTION LAWS

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California’s Unfair Competition Law or “UCL,” codified at Business and Professions Code sections 17200 *et seq.*, has long been a fertile source for claims in lawyer-driven false advertising class actions. But recent decisions have limited plaintiffs to those who are exposed to allegedly misleading statements and who suffer cognizable injury-in-fact, forcing plaintiffs’ lawyers to find new angles for their cases.

One of these new angles is to use Food and Drug Administration (“FDA”) or Federal Trade Commission (“FTC”) warning letters, complaints, or even press releases as a springboard for civil litigation. Plaintiffs’ counsel allege that the FDA’s or FTC’s notices contain “findings” that are sufficient to support a claim by a private plaintiff that products are mislabeled or “misbranded” because the statements they contain are not substantiated or were made without first completing adequate laboratory testing. This is sometimes referred to as a “prior substantiation” theory of liability. Alternatively, plaintiffs will allege that, in making their purchasing decisions, they supposedly relied on—surprise—the same statements the agency contends might be problematic.

Many of these cases have been filed relating to food products, such as a case filed recently against Frito-Lay in the U.S. District Court for the Northern District of California. In that case, the plaintiff alleges that defendant “misbranded” potato chip packaging because it purportedly did not include certain nutrition information required by the FDA to accompany a claim that the chips contain “0 grams Trans Fat.” In their complaint, plaintiffs reprint an “open letter” from the FDA Commissioner regarding nutrient claims on packages and cite warning letters from the FDA to various companies about possible regulatory violations. Similar cases have popped up regarding drugs, water containing particular ingredients that may help people sleep, and male enhancement products.

Companies targeted by prior substantiation claims have a number of ways to attack these cases at the outset on motions to dismiss or demurrer. Perhaps the simplest and most effective argument comes from recent state and federal decisions—including a very recent order from the Southern District of California—that have rejected prior substantiation claims outright under the UCL, holding that the FDA and FTC have exclusive jurisdiction to prosecute these claims. *See, e.g., Stanley v. Bayer Healthcare LLC*, No. 11cv862-IEG (BLM), 2012 WL 1132920, at *3 (S.D. Cal. April 3, 2012) (“Private individuals may not bring an action demanding substantiation for advertising claims. Instead, . . . only prosecuting authorities may require an advertiser to substantiate its claims.”) (citing *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Cal. App. 4th 1336, 1342 (2003)); *see also Chavez v. Nestle USA, Inc.*, 2011 WL 2150128, at **5-6 (C.D. Cal. May 19, 2011) (dismissing plaintiff’s claim for false advertising regarding “Juicy Juice Immunity and Brain Development” juice products because plaintiff’s factual allegation that defendant did not possess requisite scientific evidence for claims was insufficient to state a claim under California false advertising law; court held that “plaintiff has provided no authority for the proposition that the absence of substantiation of an advertising claim is, itself, falsity or somehow misleading. . . . In short,

the government, representing the Federal Trade Commission, can sue an advertiser for making unsubstantiated advertising claims; a private plaintiff cannot”); *Fraker v. Bayer Corp.*, 2009 WL 5865687, at ** 8-9 (C.D. Cal. Oct. 6, 2009) (dismissing plaintiff’s claim for false advertising because plaintiff alleged only that defendant had “no reasonable basis, consisting of competent and reliable scientific evidence to substantiate” its health-benefit claim related to “One-a-Day WeightSmart” multivitamins and the claim that they help users lose weight by increasing and enhancing their metabolism).

Courts in other states have rejected prior substantiation claims under their own consumer protection statutes. *See, e.g., Franulovic v. Coca Cola Co.*, No. 07-0539, 2009 WL 1025541 (D.N.J. Apr. 16, 2009), *aff’d*, 390 Fed. App’x 125 (3d Cir. 2010) (court granted summary judgment for defendant on plaintiff’s prior substantiation claim under the New Jersey Consumer Fraud Act based on allegation that company did not substantiate a claim that drinking three cans of “Enviga” green tea daily would result in weight loss); *Pelkey v. McNeil Consumer Healthcare*, No. 10-61853-CIV, 2011 WL 677424, at *4 (S.D. Fla. Feb. 16, 2011) (court granted defendant’s motion to dismiss plaintiff’s prior substantiation claim under Florida’s Deceptive and Unfair Trade Practices Act that was based on a FDA warning letter advising defendant that its advertising for its “Listerine Total Care Anticavity Mouthwash” may be misleading; plaintiff alleged that defendant’s statement that its Total Care product “does not ‘fight unsightly plaque above the gum line’” as advertised was unsubstantiated, but court held that the claim was based on an allegation that the statements violated the FDCA, which is a federal statute that does not provide a private right of action); *see also Precision IBC, Inc. v. PCM Capital, LLC*, No. 10-0682, 2011 WL 2728467 at *2 (S.D. Ala. July 12, 2011) (court rejected prior substantiation claim brought under the Lanham Act based on allegation that defendant’s statements in advertising that, among other things, competitor’s stainless steel tanks imported from China were of “lower quality” and had “serious quality issues,” holding that for plaintiff to prevail it must prove falsity, not just lack of pre-existing substantiation).

Several policy rationales exist for this rule. For example, the court in *Stanley* noted that “[t]he purpose of allowing only prosecuting authorities, and not private persons, to seek substantiation of advertising claims under [the UCL] is to ‘prevent undue harassment of advertisers’ and provide ‘the least burdensome method of obtaining substantiation for advertising claims.’” *Stanley*, 2012 WL 1132920, at *3 (citation omitted). Other courts have reasoned that false advertising claims cannot be based on a lack of substantiation because such an alleged shortcoming does not prove a statement is false. *See Precision*, 2011 WL 2728467, at *2.

It is also important for defendants to point out at the earliest possible opportunity (such as through a motion to strike) that FTC complaints and FDA warning letters are not evidence of liability and do not represent final agency action or an adjudication on the merits of anything. *See CEC Energy Co., Inc. v. Pub. Serv. Comm’n of the Virgin Islands*, 891 F.2d 1107, 1110 (3d Cir. 1989) (emphasis added) (citing *FTC v. Standard Oil Co. of California*, 449 U.S. 232, 241 (1980)); *see also Johns v. Bayer Corp.*, No. 09CV1935, 2010 WL 476688, at *3 (S.D. Cal. Feb. 9, 2010) (explaining that FTC lawsuit that resulted in a settlement and consent decree was not an “adjudication on the merits and no admission of wrongdoing or fault on the part of [defendant]”).

Finally, courts should also find that an agency complaint or letter constitutes third party hearsay, and, without independent supporting facts, is insufficient to state a claim, and strike any reference to the complaint or letter on that basis. *See Regenerative Sciences, Inc. v. FDA*, 2010 WL 1258010, at *5 (D. Colo. Mar. 26, 2010). Plaintiffs’ counsels who fail to independently investigate the underlying facts and law and rely solely on agency letters may also violate Federal Rule 11 as well as similar state-law statutes. *Garr v. U.S. Healthcare*, 22 F.3d 1274, 1279-80 (3d Cir. 1994).

There are other ways to attack these claims that are not unique to this type of action, such as moving to dismiss because plaintiff did not allege he or she was actually exposed to the advertising at issue or did not suffer any injury in fact. Those cases are beyond the scope of this article, but the recent cases discussed above should provide defense counsel with powerful ammunition for defeating this relatively new breed of UCL claim.