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The "Prior Substantiation" Doctrine: An Important Check On the Piggyback Class Action

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THERE IS NOTHING TO PREVENT a private litigant from filing suit against a consumer product advertiser or manufacturer after a federal regulatory agency, such as the Federal Trade Commission, takes action against the same company and obtains full monetary redress for consumers. In fact, as this propensity towards follow-on or "double-litigation" has gained momentum, the number of consumer class action complaints asserting state consumer protection and/or false advertising law violations has significantly increased over the past decade.[1] Moreover, as the number of new securities fraud class action filings continues to decrease due to the overall poor state of the economy as well as heightened pleading and liability standards,[2] securities class action plaintiffs' firms may instead turn to false advertising cases.

A recent trend, however, has emerged alongside the increased number of false advertising/consumer protection class action filings—plaintiffs are filing class action complaints that are virtually identical to or rely heavily upon FTC complaints or federal Food and Drug Administration warning letters. The cornerstone of these class action complaints is the allegation that the defendants do not possess prior substantiation (i.e., lack a "reasonable basis") to support the advertising claims that the plaintiffs are challenging and, as a result, the claims are false under state law. The plaintiffs assert that FTC complaints and settlements and FDA warning letters constitute conclusive findings of legal violations even when the agencies make explicit statements to the contrary.[3] Facing the risk of high damages awards, many defendants are forced into large settlements, with most of the settlement proceeds going to class attorneys in the form of attorneys' fees and costs, rather than to the individual consumer class members.[4] On the defense side, corporate defendants frequently pass these settlement costs on to consumers.[5]

In a series of recent decisions, however, courts have dismissed (or granted summary judgment to defendants in) consumer class actions premised on an "unsubstantiated advertising" theory of liability, finding the "prior substantiation doctrine"—i.e., the requirement that a defendant substantiate a claim pursuant to certain FDA and/or FTC standards—does not apply. The courts' refusal to allow plaintiffs to import the prior substantiation doctrine into private class actions has become a strong defense in false advertising actions, especially those seeking to piggyback off of FTC actions and FDA warning letters.

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The FTC's and FDA's Roles in Advertising Substantiation

The FTC is the federal consumer protection agency charged with safeguarding consumers against "unfair and deceptive trade practices," as articulated by Section 5 of the Federal Trade Commission Act.[6] It does so through its investigative powers—either by means of compulsory process (such as the issuance of a civil investigative demand or subpoena) or an informal information request seeking voluntary cooperation (such as with the issuance of an "access letter")—and challenges advertising that it finds to be false. Since its 1972 decision in *Pfizer*,[7] the Commission also has pursued claims based on advertisements that contain claims that the agency believes are unsubstantiated. During the course of an FTC investigation, the Commission invariably will request that an advertiser provide the agency with documents and information that the advertiser relied upon to substantiate the advertising claims challenged by the agency.

As the FTC reaffirmed in its Policy Statement Regarding Advertising Substantiation, for an advertisement to be substantiated, the advertiser must have had a "reasonable basis" (often in the form of "competent and reliable scientific evidence") for its advertising claims before they are disseminated.[8] If, after the Commission concludes its investigation into the challenged advertising practices, it believes that the advertiser had a reasonable basis to make the advertising claims at issue (i.e., that the claims were substantiated by adequate scientific evidence), the FTC may administratively close the investigation.

On the other hand, if the FTC determines after an investigation that there is "reason to believe" that a violation of the FTC Act has occurred, it may issue either an administrative complaint or file a complaint in federal district court. Like

any other civil complaint, the "issuance of [an] FTC complaint averring reason to believe [that a] defendant violated [the FTC Act] is not a definitive position but a threshold determination that further inquiry is warranted, a prerequisite to a definitive position that defendant violated [the] Act."[9] In other words, FTC complaints are not talismans that transform mere allegations into findings of fact or legal conclusions; rather, they are pleadings that set forth the Commission's charges and allegations. Moreover, it bears noting that:

> Regardless of the level of substantiation required . . . [in litigation], the FTC still bears the burden of proving advertising claims are false or misleading. In other words, the FTC may administratively impose on an advertiser the burden of producing evidence to substantiate its advertising claims, but the FTC, in an action for false advertising, bears the burden of proving the advertising claim is, in fact, false or misleading.[10]

For its part, the Federal Food, Drug and Cosmetic Act (FDCA)[11]—enforced by the FDA—requires that a dietary supplement advertiser have substantiation for its claims. The FDA generally has adopted the FTC's "competent and reliable scientific evidence" substantiation standard.[12] The agency typically issues a "warning letter" if it believes the advertiser is in violation of the laws or regulations that the agency enforces. Like an FTC complaint, an FDA warning letter is not a final agency action constituting a "finding" of any violation of law.[13] Rather, it warns the recipient that it should take voluntary, "prompt corrective action" (usually within fifteen business days) to correct the perceived violations, and that the failure to do so may result in subsequent legal action. Unlike an FTC complaint, however, the FDA typically issues a warning letter before an advertiser has an opportunity to respond to the agency's assertions of falsity and to provide substantiation in support of its claims; it is very much the beginning of the FDA's review process.

Often, an advertiser simply will take steps to address the FDA's concerns about its advertisements and send a letter to the FDA documenting such corrective actions. In other instances, the advertiser will write to the agency and set forth its reasons why the challenged claims are substantiated and do not violate the FDCA. In turn, if the FDA is not satisfied with the substantiation provided, it may bring an enforcement action against the advertiser.

The Prior Substantiation Doctrine and Private Class Actions

Over the past few years, courts have held that the FTC and FDA—and not private plaintiffs—retain exclusive authority to prosecute claims of unsubstantiation. As a result, courts have dismissed, or awarded summary judgment to defendants in, consumer class actions in which plaintiffs seek to shift the burden of proof onto the defendants and/or piggyback off FTC complaints and FDA warning letters by alleging that the respective defendants did not have reasonable bases to make their claims and, therefore, ipso facto violated state false advertising laws. The unifying basis for these dismissals is the courts' refusal to apply the "prior substantiation doctrine" in private class actions; this body of law has become an important arrow in defense counsels' quivers.

Fraker v. Bayer Corp. In *Fraker*, a 2009 class action brought under California's Consumer Legal Remedies Act (CLRA),[14] Unfair Competition Law (UCL),[15] and False Advertising Law (FAL),[16] the Eastern District of California dismissed the plaintiff's allegations that the Bayer Corporation lacked substantiation for its "One-A-Day WeightSmart" vitamin supplement advertising claims, holding that the failure to possess a reasonable basis consisting of prior substantiation is not in and of itself a cognizable claim under California law.[17]

The plaintiff in *Fraker* filed her class action complaint against Bayer a little less than two years after the FTC concurrently filed and settled a lawsuit against Bayer alleging violations of the FTC Act.[18] The FTC settlement, which was memorialized in a consent decree, prohibited Bayer from, among other things, advertising unsubstantiated claims regarding the ability of One-A-Day WeightSmart to enhance metabolism or promote weight loss. The class action complaint challenged advertising disseminated after the FTC consent decree, stating that One-A-Day WeightSmart "increased metabolism, enhanced metabolism through its EGCG [Epigallocatchin Gallate (an extract of green tea)] content, helped prevent weight gain associated with age-related metabolism decline, and helped users control their weight by enhancing their metabolism." The plaintiff alleged that those claims violated the consent decree because they were not substantiated by reliable scientific evidence and, in turn, violated the CLRA, UCL, and FAL.[19]

Bayer moved to strike a number of factual allegations that were taken from the complaint and consent decree in the FTC proceeding on the grounds that the paragraphs were "lifted" directly from documents from other court proceedings in violation of the plaintiff's attorney's duty "to assure that 'the factual contentions have evidentiary support after a reasonable opportunity for further investigation of discovery' as required by Rule 11(b)(3) of the Federal Rules of Civil Procedure."[20] Bayer also moved to dismiss on similar grounds, i.e., that the plaintiff failed to allege any factual predicate for her claims other than those derived solely from the FTC's complaint and the consent decree.[21] The court granted both motions.[22]

In its analysis, the court called the plaintiff's complaint an "attempt to shoehorn an allegation of violation of the [FTCA] . . . into a private cause of action," and recognized that the FTC, not private plaintiffs, retains exclusive jurisdiction over ensuring that advertising claims are substantiated: "[T]he [FTC] Act vests remedial power solely in the Federal Trade Commission and *a regulation under the FTCA does not create a private right of action.*"[23] The court further elaborated that a private plaintiff cannot avoid her obliga-

tions to plead and prove that an advertisement is false or misleading by styling the claim as one for unsubstantiated advertising:

> To successfully allege a claim for false advertising, *Plaintiff has the burden to plead and prove facts that show that the claims that Defendants made in connection with [the] product are false or misleading.* Plaintiff has provided no authority for the proposition that the absence of substantiation of an advertising claim is, itself, falsity or somehow misleading. . . . [T]he court is unwilling to make that leap. *If Plaintiff is going to maintain an action against Defendant for false or misleading advertising, then Plaintiff will be required to adduce evidence sufficient to present to a jury to show that Defendant's advertising claims with respect to [the] Product are actually false; not simply that they are backed up by scientific evidence.*[24]

Fraker holds that false advertising plaintiffs bear the burden to plead and present facts—independent of FTC complaint allegations or settlement terms—that show the challenged advertising claims are false or misleading. Plaintiffs cannot simply allege that the defendant's claims lack substantiation and seek to shift the burden onto the defendant to show otherwise under the CLRA, UCL, or FAL.

Franulovic v. Coca Cola Co. In *Franulovic v. Coca Cola Co.*,[25] the plaintiff asserted a New Jersey Consumer Fraud Act (NJCFA)[26] claim against Coca Cola on behalf of a class of consumers, alleging that the company engaged in fraudulent and deceptive marketing of its "Enviga" green tea soft drink in violation of the NJCFA. Specifically, the plaintiff challenged the veracity of Coca Cola's advertisements, which stated that drinking three cans of Enviga daily would lead to weight loss.

The U.S. District Court for the District of New Jersey granted Coca Cola's motion for summary judgment and denied the plaintiff's motion for leave to file a fourth amended complaint, which, among other things, asserted that Coca Cola advertised Enviga as a calorie burning drink without prior substantiation.[27] Specifically, the proposed fourth amended complaint alleged that "Coke made [the challenged weight loss claims] without adequate prior substantiation for them," and that the "weight-loss representations for the product (whether express or implied) cannot be substantiated because the small number of studies that exist are conflicting and inadequate to substantiate the representations."[28] In opposition to the plaintiff's motion for leave to amend, Coca Cola argued, among other things, that the plaintiff bears the burden under the NJCFA to affirmatively prove that the challenged representation is false; the plaintiff cannot shift the burden to the defendant to prove that the claim, in fact, is true and substantiated.[29]

The district court held that the proposed amendment to include a claim that Coca Cola did not have substantiation to support the challenged weight loss claims would be futile because "the [NJCFA] does not recognize this theory of liability."[30] The Third Circuit affirmed, holding that "[n]o New Jersey or Third Circuit decision has applied the prior substantiation theory to the [NJCFA], and we, therefore, decline to do so here."[31]

Pelkey v. McNeil Consumer Healthcare. In *Pelkey v. McNeil Consumer Healthcare*,[32] the U.S. District Court for the Southern District of Florida rejected a plaintiff's attempt to transform an FDA warning letter into a Florida Deceptive and Unfair Trade Practices Act (FDUTPA)[33] violation. In *Pelkey*, the FDA issued a warning letter advising McNeil Consumer Healthcare that its "Listerine Total Care Anticavity Mouthwash" advertising was misleading in violation of the FDCA. One week later, the plaintiff filed a class action alleging that McNeil falsely and deceptively advertised Total Care Anticavity in violation of the FDUTPA. Citing only the FDA warning letter, the plaintiff alleged that Total Care "does not 'fight unsightly plaque above the gum line' [as advertised] and, therefore, is false and not substantiated under the FTC standards applicable to FDUPTA."[34]

The district court granted the defendant's motion to dismiss the FDUTPA claim, holding that the plaintiff could not base its claim on mere allegations that the defendant lacked substantiation for its mouthwash advertising claims. The court agreed with McNeil's argument that the plaintiff "cannot base her claims on an allegation that Total Care is misbranded under the FDCA as this is a federal statute for which no private right of action exists," and held that the "FDCA does not create a private right of action."[35] In other words, under Florida law, a plaintiff cannot state a FDUTPA violation based on an allegation that an advertiser does not have substantiation for a challenged advertising claim.

Chavez v. Nestlé USA, Inc. In *Chavez v. Nestlé USA, Inc.*, the Central District of California dismissed a class action complaint which claimed that Nestlé violated California's UCL and FAL based on alleged deceptive marketing and advertising practices in connection with its "Juicy Juice Immunity and Brain Development" beverages.[36] The plaintiff in *Chavez* alleged that Nestlé's immunity and brain development claims about its Juicy Juice beverages were false and deceptive because they were unsubstantiated. Nestlé moved to dismiss, arguing that false advertising claims cannot be based upon a lack of substantiation; the court agreed and dismissed without leave to amend.

Relying on the Eastern District of California's *Fraker* decision, the *Chavez* court held that "false advertising claims cannot be based upon a lack of substantiation."[37] The court reasoned that "[p]laintiff 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.*"[38]

As in *Fraker* and *Pelkey*, the *Chavez* court recognized that to rule otherwise would impermissibly shift the burden of proof to defendants in false advertising cases to show that their advertising claims, in fact, are substantiated. Specifically, relying on a California Court of Appeal decision, the court

explained that "'there is no basis in California law to shift the burden of proof to a defendant in a representative false advertising and unlawful competition action. We conclude further that the [California] Legislature has indicated an intent to place the burden of proof on the plaintiff in such cases.'"[39]

Precision IBC, Inc. v. PCM Capital, LLC. Although the four cases discussed above arose in the context of class actions alleging violations of state false advertising and consumer protection laws, there is a well-recognized history of courts refusing to apply the prior substantiation doctrine in Lanham Act[40] litigation as well. A prime example is the Southern District of Alabama's decision in *Precision IBC, Inc. v. PCM Capital, LLC*.[41] In that case, the plaintiff filed a Lanham Act complaint alleging that the defendant-competitor in the intermediate bulk container (IBC) market (1) advertised that stainless steel tanks imported from China (like the ones used by the plaintiff), were "lower quality" and had "serious quality issues"; (2) advised consumers that they should "stay away from" and not "take the chance" with Chinese IBCs; and (3) warned consumers that the "risks borne of using such units far outweigh the apparent savings." The plaintiff claimed that the defendant's statements were false and misleading.

The defendant argued that for the plaintiff to prevail on its Lanham Act claim, it must prove falsity, not just a lack of pre-existing substantiation.[42] In support of its position, the defendant relied heavily upon the following passage from McCarthy on Trademarks and Unfair Competition:

> The issue has arisen as to whether an advertising claim . . . without preexisting data in support of its truthfulness is necessarily false under [the Lanham Act]. . . . [T]he majority rule is that plaintiff must prove falsity, not just a lack of preexisting substantiation. The burden is on plaintiff to prove that the challenged ad is false or misleading, not merely that pre-advertising clinical or market tests in support of each advertising claim were improperly conducted. The advertising claims may be true even though the testing basis for the claims may not support them.[43]

The Southern District of Alabama agreed with the defendant's argument and, like the *Fraker*, *Franulovic*, *Pelkey*, and *Chavez* courts, concluded that to prevail on its Lanham Act claim, "the plaintiff must prove falsity, not just a lack of pre-existing substantiation."[44]

Conclusion

Both the FTC and FDA are stepping up enforcement against national advertisers, and are basing challenges on the failure to substantiate health and safety claims for myriad consumer products and services through consent orders and warning letters.[45] In response, private plaintiffs have filed a number of recent state law consumer protection and false advertising class actions, which do little if anything more than lift allegations directly from the FTC pleadings and FDA warning letters. The plaintiffs in those cases typically paint the agencies' documents as containing legal "conclusions" and "findings" of unsubstantiation which, in turn, are sufficient to state a claim for false advertising. Courts, however, have uniformly rejected this characterization. Defendants in consumer class actions and false advertising litigation can avail themselves of the courts' refusal to apply the prior substantiation doctrine to claims brought by private plaintiffs and take advantage of this strong defense. Unless and until plaintiffs are able to plead facts—as opposed to just piggybacking off of the agency actions—this defense is likely to carry the day. ■

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1 Theodore V.H. Mayer, *Recent Developments and Current Trends in United States Class Action Law*, 826 PLI/Lit 313, 325 (May 24, 2010) (citing Federal Judicial Center, The Impact of the Class Action Fairness Act of 2005 on the Federal Courts 4 (4th interim report 2008)) ("Among the most remarkable trends from the period between 2001 and 2007 [was] . . . the continuing growth of consumer-protection or consumer-fraud class actions, which increased by more than 150 percent and now account for 20 percent of all federal class actions.").

2 The Stanford Law School Securities Class Action Clearinghouse in cooperation with Cornerstone Research recently reported that the number of new federal securities class action filings generally has declined over the past several years and continued in the first half of 2011. Cornerstone Research, *Securities Class Action Filings: 2011 Mid-Year Assessment* (August 2011), *available at* http://securities.stanford.edu/clearinghouse_research/2011_YIR/Cornerstone_Research_Filings_2011_Mid_Year_Assessment.pdf. *See also* Seth Aronson, Roberta H. Vespremi, and Madeline Zamoyski, *Developments and Trends in Securities Litigation: 2009–2010*, 1832 PLI/Corp 363, 367–68 (Oct. 14, 2010) (providing statistics for recent securities class action filings). This is not surprising given that, typically, a securities fraud class action plaintiff must produce evidence showing that the challenged misrepresentation specifically caused the decrease in value of a security, *see* Dura Pharms. v. Broudo, 544 U.S. 336 (2005), and, with the general decline in the price of securities across the board due to the recession, it is becoming increasingly difficult for a plaintiff to meet her burden.

3 *See, e.g.*, FTC Press Release, *Dietary Supplement Maker to Pay $5.5 Million to Settle FTC: FTC Challenges Claims That Supplements Cause Weight Loss and Treat or Prevent Colds, Flu, Allergies, and Hay Fever* (July 14, 2010), *available at* http://www.ftc.gov/opa/2010/07/iovate.shtm ("The Commission files a complaint when it has reason to believe that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The complaint is not a finding or ruling that the defendants have actually violated the law. A stipulated final order is for settlement purposes only and does not constitute an admission by the defendants of a law violation."); FTC Press Release, *Nestlé Subsidiary to Settle FTC False Advertising Charges; Will Drop Deceptive Health Claims for BOOST Kid Essentials: Case Involving Drink for Kids Is Agency's First Challenging Deceptive Probiotic Advertising* (July 14, 2010), *available at* http://www.ftc.gov/opa/2010/07/nestle.shtm (same).

4 For example, two recent false advertising consumer class actions filed on the heels of FTC settlements resulted in settlements where just over 2% of the total settlement funds were paid out to consumers. The attorneys' fees awards in these cases, on the other hand, ranged between approximately 15.4% and 29% of the total settlement funds.

5 *See* Martin H. Redish & Uma M. Amuluru, *The Supreme Court, the Rules Enabling Act, and the Politicization of the Federal Rules: Constitutional and Statutory Concerns*, 90 Minn. L. Rev. 1303, 1319 (2006) (explaining that "the costs of these settlements will be passed on to consumers"); *see also* Stillmock v. Weis Markets, Inc., 385 Fed. App'x 267, 281 (4th Cir. 2010) ("the substantial costs associated with settlement will inevitably be passed on to consumers—the very ones whom Congress sought to protect.").

6 15 U.S.C. § 45.

7 81 F.T.C. 23 (1972).

8 *FTC Policy Statement Regarding Advertising Substantiation, appended to*

Thompson Medical Co., 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987), *available at* http://www.ftc.gov/bcp/guides/ad3subst.htm.

[9] 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]").

[10] Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc., 107 Cal. App. 4th 1336, 1349–50 (2003) (internal citations omitted).

[11] 21 U.S.C. §§ 301 et seq.

[12] Food & Drug Admin., *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act* (Dec. 2008), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm.

[13] James T. O'Reilly, Food and Drug Administration § 6:2 (3d ed. July 2007).

[14] Cal. Civ. Code §§ 1750 et seq.

[15] Cal. Bus. and Prof. Code §§ 17200 et seq.

[16] *Id.* §§ 17500 et seq.

[17] Fraker v. Bayer Corp., No. 08-1564, 2009 WL 5865687, at *2, *7 (E.D. Cal. Oct. 6, 2009).

[18] Miles Inc., FTC No. C-3323 (1991).

[19] *Fraker*, 2009 WL 5865687, at *1.

[20] *Id.* at *3.

[21] *Id.* at *6.

[22] Although the court dismissed the complaint without prejudice, about a month later, the parties stipulated to a dismissal with prejudice. *See Fraker*, FTC Docket Nos. 33 and 34.

[23] *Fraker*, 2009 WL 5865687, at *7 (emphasis added).

[24] *Id.* at *8 (emphasis added and internal citation omitted).

[25] No. 07-0539, 2009 WL 1025541 (D.N.J. Apr. 16, 2009), *aff'd*, 390 Fed. App'x 125 (3d Cir. 2010).

[26] N.J. Stat. Ann. §§ 56:8-1 et seq.

[27] *Franulovic*, 2009 WL 1025541, at *4–7.

[28] Compl., ECF No. 121-1, at ¶¶ 6, 19; *see also id.* ¶ 28 ("There is in fact no substantiation or reasonable basis for claiming that Enviga (or the amounts of EGCG and caffeine in three cans of Enviga) has any effect on caloric balance or weight for the majority of adults, who are not young, healthy, and thin."). The proposed amended complaint also claimed that the study Coca Cola relied upon "neither substantiates nor provides a reasonable basis for the claims made by Coke regarding Enviga." *Id.* ¶ 27.

[29] Def. Opp. to Leave to Amend, ECF No. 124, at 15–16.

[30] *Franulovic*, 390 Fed. App'x at 127.

[31] *Id.* at 128 ("[T]he District Court correctly held that a [NJCFA] claim cannot be premised on a prior substantiation theory of liability"). Importantly, an FTC action or FDA warning letter did not precede the plaintiff's suit in *Franulovic*. As such, it demonstrates that, in addition to follow-on claims, courts will not recognize free-standing prior substantiation claims in private false advertising cases.

[32] No. 10-61853-CIV, 2011 WL 677424, at *4 (S.D. Fla. Feb. 16, 2011).

[33] Fla. Stat. Ann. §§ 501.201 et seq.

[34] *Id.* at *4.

[35] *Id.*

[36] No. CV 09-9192, 2011 WL 2150128, at *5, *7 (C.D. Cal. May 19, 2011).

[37] *Id.* at *5.

[38] *Id.* (emphasis added and quoting *Fraker*, 2009 WL 5865687, at *8).

[39] *Id.* at *6 (quoting Nat'l Council Against Health Fraud, Inc. v. King Bio Pharms., Inc., 107 Cal. App. 4th 1336 (2003)).

[40] 15 U.S.C. §§ 1114–1127.

[41] No. 10-0682, 2011 WL 2728467 (S.D. Ala. July 12, 2011).

[42] *Id.* at *2.

[43] *Id.* (quoting 5 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 27:61 (4th ed.)). The defendant also cited numerous other Lanham Act cases holding that a plaintiff must prove that the challenged claim is false or misleading, not merely that it is unsubstantiated). *See also* Sandoz Pharm. Corp. v. Richardson Vicks Inc., 902 F.2d 222, 229 (3d Cir. 1990) ("Sandoz's invitation to blur the distinctions between the FTC and a Lanham Act plaintiff would require us to ignore the separate jurisprudence that has evolved under each Act, and the sound reasoning that underlies it. We decline the invitation. We hold that it is not sufficient for a Lanham Act plaintiff to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public.").

[44] *Id.*

[45] *See, e.g.*, FTC v. Reebok Int'l, Inc., Case No. 1:11 CV 2046 (N.D. Ohio, Sept. 29, 2011) (Stipulated Final Judgment), *available at* http://www.ftc.gov/os/caselist/1023070/110928reebokorder.pdf; Dannon Corp., FTC File No. 0823158, Agreement Containing Consent Order (Dec. 15, 2010), *available at* http://www.ftc.gov/os/caselist/0823158/index.shtm; FTC v. Iovate Health Sciences USA, Inc., Case. No. 10-CV-587 (W.D.N.Y. July 29, 2010) (Stipulated Final Judgment), *available at* http://www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf; Nestlé HealthCare Nutrition, Inc., FTC File No. 092-3087, Agreement Containing Consent Order (July 14, 2010), *available at* http://www.ftc.gov/os/caselist/0923087/100714nestleorder.pdf.