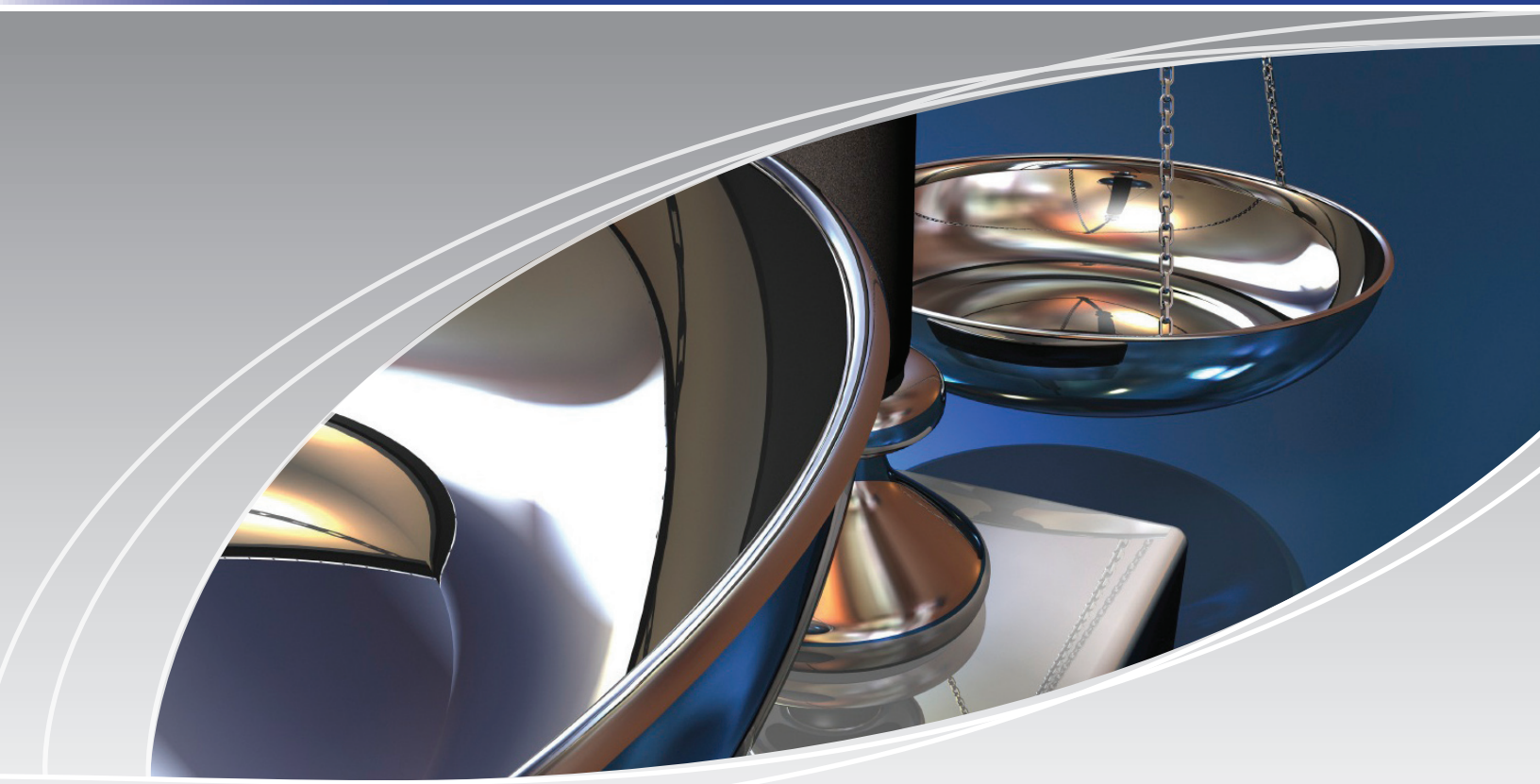

Viewpoints on FDA: Enforcement

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IV. Beating the Heat: What Food & Supplement Marketers Need to Know About the FTC's Summer of Litigation

John E. Villafranco and Katie Bond

When it comes to enforcement, the Food and Drug Administration (FDA) is only one party that food and dietary supplement companies need to consider. While FDA is primarily responsible for safe manufacturing and point-of-sale labeling, the Federal Trade Commission (FTC or Commission) regulates food and supplement advertising.[1] The FTC, since at least 1938, has been an active participant in policing food and supplement ads and seeking consumer redress in the form of injunctions and monetary relief.[2] Additionally, false advertising class actions or other suits from private entities almost invariably follow FTC press releases and other announcements of enforcement action.

Over the past two decades, the majority of FTC false advertising actions against dietary supplement and food advertisers have resulted in settlements.[3] The past several months, however, have seen a record number of litigated decisions, including the following:

- ***FTC v. Direct Mktg. Concepts***, Civ. No. 04-1136-GAO (D. Mass. Aug. 13, 2009) (corporate and individual defendants barred from disseminating deceptive claims, including claims to treat or cure cancer, diabetes, and other diseases; defendants ordered to pay almost $70 million in consumer redress);
- ***FTC v. Lane Labs-USA, Inc.***, Civ. No. 00-cv-3174, slip op (D.N.J. Aug. 11, 2009) (corporation and two individuals held not liable for violating prior FTC orders that prohibited deceptive claims for supplements and other health products; FTC had sought $24 million civil penalty);
- ***In re Daniel Chapter One***, FTC Docket No. 9329 (Aug 5, 2009) (corporation and individual officer barred from disseminating misleading cancer treatment claims and ordered to send corrective letter to past customers); and
- ***FTC v. MedLab, Inc., Civ***. No. C-08-00822 SI (D.N.Cal. June 23, 2009) (corporate defendants and individual barred from disseminating deceptive weight loss claims and ordered to pay almost $2.7 million in consumer redress).

These recent decisions, in many ways, reinforce what has been known for years—that certain strong weight-loss claims and claims about serious diseases are of high risk. Two of the cases, *Direct Mktg. Concepts* and *Daniel Chapter One*, may raise the stakes for making such claims, but the lesson remains the same. One of the recent cases, *Lane Labs*, however, stands apart from the others and serves as a rare example of an FTC loss in a health products case. Although *Lane Labs* was a contempt case, and thus on different legal ground than most enforcement cases, it is nevertheless significant. This article reviews each of the four recent decisions and highlights what advertisers, consultants, attorneys, and others working with foods or dietary supplements need to know – regarding these cases – in crafting and substantiating advertising claims or defending advertising in enforcement proceedings or private litigation.

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1 *See, e.g.*, FTC, *In the Matter of Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body: Proposed Rule*, at 1 n.1 (Aug. 27, 1998) (citing FTC-FDA Liaison Agreement, 4 Trade Reg., Rep. (CCH) ¶ 9851).

2 *See Annual Report for the FTC for the Fiscal Ended June 30, 1938*, at 2-4, 47-48 (1938), http://www.ftc.gov/os/annualreports/ar1938.pdf (discussing expanded powers over "unfair or deceptive acts or practices" under Wheeler-Lea Act; noting that 38 of 188 new cases on deceptive advertising involved "medicinal and food preparations and devices").

3 *See, e.g.*, FTC, *Dietary Supplement Advertising Cases 1984-July 15, 2003*, http://www.ftc.gov/bcp/reports/dietadvertisingcases.shtm.

Claims for Treating or Preventing Diseases Remain High Risk

Except with agency pre-approval, FDA prohibits claims that foods and dietary supplements "diagnose, mitigate, treat, cure or prevent disease."[4] The FTC does not prohibit disease claims for foods and dietary supplements, but due to the potential health consequences, requires a high level of substantiation:

> Claims that, if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof [than other claims]. For that reason, an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that benefit. The FTC will closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.[5]

Numerous prior settlements and enforcement sweeps reflect the FTC's position on disease claims. The FTC, for example, launched "Operation Cure-All" in 1997, along with FDA, state, Canadian, and Mexican regulators.[6] This multi-year initiative led to at least 18 FTC cases targeting products marketed for treating HIV/AIDS, arthritis, diabetes, multiple sclerosis, and other serious diseases and conditions.[7] Two of the recent cases, *Direct Mktg. Concepts* and *Daniel Chapter One*, reinforce the FTC's enforcement approach on disease claims and suggest that, now, the stakes are likely even higher than ever before.

In *Direct Mktg. Concepts*, the FTC alleged that defendants violated Sections 5 and 12 of the Federal Trade Commission Act (FTC Act) by disseminating two infomercials containing false and misleading claims for two products, Coral Calcium and Supreme Greens.[8] In a previous 2008 summary judgment order, the same court found the defendants liable for claiming that 1) Coral Calcium treats or cures cancer, Parkinson's disease, heart disease, and various autoimmune diseases; 2) Coral Calcium has an absorption rate of 100 percent within 20 minutes; 3) scientific research published in *JAMA* and the *New England Journal of Medicine* supports the efficacy of Coral Calcium; 4) Supreme Greens treats, cures, or prevents cancer, heart disease, arthritis, and diabetes; 5) Supreme Greens causes weight loss; and 6) children, persons on medications, and pregnant women can safely take Supreme Greens. Following the summary judgment order, the defendants reached a settlement, for liability purposes, on two additional counts: 1) the Supreme Greens infomercial employed a deceptive news program format; and 2) defendants'"autoship" billing and delivery system constituted an unfair practice.

The recent decision finalized permanent orders against the defendants and awarded monetary relief, which the court provided as disgorgement. Courts are split on whether to consider defendants' ability to pay in disgorgement cases. The court in *Direct Mktg. Concepts* found ability to pay irrelevant, given what it called the defendants'"proclivity for siphoning off funds" and "creative record keeping."[9] The court calculated the amount of disgorgement based on net revenues received by the defendants. It equated this amount with "net consumer loss."[10] Although, in terms of substance, *Direct Mktg. Concepts* is largely a typical FTC supplements case, it is notable for the sheer amount of monetary relief: almost $70 million between four corporations and three individuals.

The court's previous summary judgment decision also was notable in that the court appeared to accept the FTC's argument that health-related efficacy claims require controlled clinical trials:

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4 *See* 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93; http://www.fda.gov/Food/LabelingNutrition/LabelClaims/StructureFunctionClaims/default.htm ("FDA is likely to interpret the dividing line between [structure/function] claims and disease claims in a similar manner for conventional foods as for dietary supplements").

5 FTC, *Dietary Supplements: An Advertising Guide for Industry*, at 21 (1998).

6 *See* Press Release, FTC Testifies on the Internet Sale of Prescription Drugs From Domestic Web Sites (Mar. 27, 2003), http://www.ftc.gov/opa/2003/03/onlinepharm.shtm.

7 *See id.*

8 On August 14, 2009, defendants filed an appeal which is pending.

9 *See FTC v. Direct Mktg. Concepts*, Civ. No. 04-1136 GAO, at 19.

10 *See id.* at 20.

> [T]he FTC cites numerous courts that [according to the FTC] "have consistently found or upheld that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of health-related efficacy claims." While it seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims, it is not firmly accepted by the courts how many studies must be offered.[11]

In many cases, including not only this case but also *Daniel Chapter One* (discussed *infra*), and last year's *FTC v. Nat'l Urological Group*, the FTC has advanced a broad rule that health-related claims require controlled clinical testing.[12] A 2008 circuit court decision found in favor of the FTC in an advertising case, but included strong dicta rejecting any suggestion that health-related advertising *per se* requires controlled clinical testing. Writing for the Seventh Circuit, Chief Judge Easterbrook elucidated the limiting power of underlying statutory law:

> Some passages in [the lower court decision in *FTC v. QT*] could be read to imply that any statement about a product's therapeutic effects must be deemed false unless the claim has been verified in a placebo-controlled, double-blind study . . . .
>
> *Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies.* The Act forbids false and misleading statements, and a statement that is plausible but has not yet been tested in the most reliable way cannot be condemned out of hand. The burden is on the [government] to prove that the statements are false. . . . Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable *how much* the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. *Placebo-controlled, double-blind testing is not a legal requirement for consumer products.*[13]

Judge Easterbrook also noted, "A placebo-controlled study is the best test; something less may do (for there is no point in spending $1 million to verify a claim worth only $10,000 if true) . . . ."[14] Other precedent, including *Lane Labs* (discussed *infra*), appears to support the Seventh Circuit, insofar as other cases have considered the usual "*Pfizer* factors" to determine, on a case-by-case basis, what constitutes appropriate competent and reliable scientific evidence in support of health-related claims.[15] The "*Pfizer* factors" came from the landmark case, *In re Pfizer, Inc.*, which held that the following should be considered: 1) the type of claim, 2) the type of product, 3) the consequences if the claim is false, 4) the benefits of a truthful claim, 5) the ease and cost of developing substantiation for the claims, and 6) the level of substantiation experts in the field would agree is reasonable.[16]

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[11] *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 303 (D. Mass. 2008) (internal citation omitted).

[12] *See Daniel Chapter One*, FTC Docket No. 9329, Compl. Counsel's Pre-Trial Brief, at 23, http://www.ftc.gov/os/adjpro/d9329/090331ccpretrialbrief.pdf; *FTC v. Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145 (N.D. Ga. 2008), Pl.'s Mem. in Supp. of Mot. for Summ. J., at 40.

[13] *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008) (emphasis added except for "*how much*").

[14] *Id.* at 862.

[15] *See, e.g., Am. Home Prod. v. FTC*, 695 F.2d 691 (3d Cir. 1983); *see also FTC Policy Statement Regarding Substantiation*, 49 Fed. Reg. 3099 (Aug. 23, 1984), http://www.ftc.gov/bcp/guides/ad3subst.htm; Letter from Donald S. Clark, Secretary, FTC, to Jonathan W. Emord, Esq., Emord & Associates, P.C. (Nov. 30, 2000), http://www.ftc.gov/os/2000/12/dietletter.htm (stating *Pfizer* factors apply in assessing claim substantiation for dietary supplements).

[16] *See In re Pfizer, Inc.*, 81 F.T.C. 23 (1972) (1972 WL 127465, at *25); *see also FTC Policy Statement Regarding Substantiation*, 49 Fed. Reg. 3099. Particularly if scientific experts do not believe that controlled trials are necessary, imposing such a costly pre-requisite likely proves counter productive to protecting consumers — not to mention at odds with the First Amendment. For a discussion of why the controlled clinical trial model is often inappropriate for establishing nutritional benefits, *see* Sarah Taylor Roller & Robert P. Heaney, *Nutrition in the Prevention and Treatment of Disease, Chapt. 14* (Ann M. Coulston & Carol J. Boushey eds. 2d ed. Acad. Press 2008).

Daniel Chapter One, a decision by FTC Administrative Law Judge (ALJ) D. Michael Chappell, resulted from a recent FTC enforcement sweep, "Operation False Cures," which, thus far, has led to at least 10 other FTC cases.[17] The defendants—the corporate entity, Daniel Chapter One, and an individual officer—sold a shark cartilage product, BioShark, and three herbal formulations, 7 Herb Formula, GDU, and BioMixx. Product websites and catalogs included efficacy and testimonial claims, such as, "Nancy—Cured Breast Cancer in 3 Months—7 Herb and GDU"; "7 Herb eliminates pre-cancerous growth"; "Ancient cancer remedy improved upon"; "Cancer Solution … for any type of cancer."[18] The defendants also promoted their products through newsletters and a call-in radio show, in which the individual defendant and his wife provided health advice. Neither individual is a physician, but they testified that they created Daniel Chapter One based on Biblical scripture, including Genesis 1:29 where, according to the defendants, "it is written that God said he created all things for our food for healing."[19] The ALJ agreed with the FTC that the defendants had disseminated deceptive and unsubstantiated claims that the products at issue treat cancer and assist with recovery from radiation and chemotherapy. The ALJ's order prohibits the defendants from disseminating any future health-related claims without competent and reliable scientific evidence. The order also requires the defendants to send a form letter to customers who bought the products at issue.[20] The letter, in short, summarizes the FTC's findings on the products and urges consumers to talk to their doctors before taking herbal products:

> Very little scientific research has been done concerning shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, Echinacea, and ginseng as a means of prevention, treatment, or cure for cancer in humans. The scientific studies that have been done do not demonstrate that any of these ingredients, which are included in BioShark, 7 Herb Formula, GDU, and BioMixx, are effective when used for prevention or treatment for cancer in humans.
>
> It is very important that you talk to your doctor or health care provider before using any alternative or herbal product, including shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, Echinacea, and ginseng. …[21]

The ALJ rejected the defendants' arguments that their religious affiliations prevented jurisdiction under the FTC Act and protected their speech from government intrusion under the First Amendment. The ALJ found that the First Amendment does not protect false and misleading commercial speech and that jurisdiction was proper, given that the defendants sold products in commerce. Similar to previous cases on disease claims, the ALJ also rejected the defendants' argument that their newsletters and other ads did not convey disease claims given that the pieces included the following disclosure language that is required on supplement labeling: "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease." The ALJ found that, in context, the disclosures were not adequately prominent, and, moreover, the disclosures served to confuse consumers "by interjecting a message that [contradicts] the overall net impression that the [products at issue] do treat cancer."[22]

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[17] *See* Press Release, FTC Sweep Stops Peddlers of Bogus Cancer Cures (Sept. 18, 2008), http://www2.ftc.gov/opa/2008/09/boguscures.shtm. The ALJ decision constitutes an "initial decision." Within 90 days of release, an initial decision becomes a final, binding decision unless a party appeals or the Commission stays the decision for review. *See* 16 C.F.R. §§ 3.51, 3.56.

[18] *Daniel Chapter One*, FTC Docket No. 9329, at 83, 85, 92.

[19] *Id.* at 68.

[20] An ALJ does not have the authority to enter monetary relief; however, the FTC may seek monetary redress, based on a final order, in federal or state court. *See* 15 U.S.C. § 57b. In such a proceeding, the FTC must show that a reasonable person would have known, under the circumstances, that the conduct at issue was "dishonest or fraudulent." *See id.*

[21] *Daniel Chapter One*, FTC Docket No. 9329, at 130.

[22] *Id.* at 96.

Daniel One held that the defendants' claims required clinical testing, but took a more measured approach than *Direct Mktg. Concepts* in reaching that conclusion. Although the decision includes some statements supporting a broad requirement for clinical trials, the ALJ considered the *Pfizer* factors and gave great weight to the opinion of the only medical expert in the case who opined on what constitutes competent and reliable scientific evidence specifically for cancer claims. According to ALJ Chappell, the FTC's expert, Dr. Denis Miller, stated that competent and reliable scientific substantiation includes a "spectrum" of evidence, but that "[o]nly data from well-designed, controlled, clinical trials will substantiate a claim that a new therapy is safe and effective to treat, cure, or prevent cancer."[23]

Taken together, *Direct Mktg. Concepts* and *Daniel One* suggest not only that disease claims remain of high risk, but also that the potential fall-out, now, may be greater than ever before. While FTC consent decrees and settlement orders tend to suspend substantial portions of monetary judgments based on ability to pay, *Direct Mktg. Concepts* provides a pointed example of how a court may impose a very high monetary reward, without regard for defendants' financial situation. Similarly, *Daniel One* shows that, although the FTC has not done so in many past cases, it has the authority to order a range of equitable remedies, including corrective letters and other measures that are bound to have lasting effects on a company's business and good will.

"Red Flag" Weight-Loss Claims Continue to Be High Risk

In *MedLab, Inc.*, the FTC challenged weight-loss claims by four companies and an individual defendant. At issue were 27 ads placed in newspapers throughout the United States between 2005 and 2007. The ads included claims such as "New Skinny Pill!"; "Lose up to 15 pounds a week with the amazing formula that forces your body to release fat!"; "The product works so fast you can actually lose as much as 50% of your excess weight in just 2 weeks"; "New Calorie-Busting Slimming Pill Forces You to Lose Weight Without Diet or Exercise!"; "You only have pounds and inches to lose and a lifetime of slimness to gain"; "Fast, Immediate Results … Guaranteed! Clinical studies prove it."[24] The court held that the ads deceptively conveyed 1) that defendants' products cause "substantial amounts of weight [loss] rapidly, including as much as 15 to 18 pounds per week and as much as 50% of all excess weight in just 14 days, without diet and exercise"; 2) that defendants' products cause "permanent or long-term weight loss"; and 3) that clinical studies supported the product claims.[25] The first two claims found deceptive are among the seven types of claims that the FTC identified in its guidance, *Red Flag Bogus Weight Loss Claims: A Reference Guide for Media on Bogus Weight Loss Claim Detection*.[26] In its guidance, the FTC warned against claims that products can provide the following effects:

- Cause substantial weight loss of two pounds or more a week for a month or more without dieting or exercise;
- Cause substantial weight loss no matter what or how much the consumer eats;
- Cause permanent weight loss (even when the consumer stops using product);
- Block the absorption of fat or calories to enable consumers to lose substantial weight;
- Safely enable consumers to lose more than three pounds per week for more than four weeks;
- Cause substantial weight loss for all users; and
- Cause substantial weight loss by wearing it on the body or rubbing it into the skin.

Although originally intended as a publication to assist media outlets, the *Red Flag* guidance has become a centerpiece of the FTC's enforcement against weight-loss products.[27]

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[23] *Id.* at 55.
[24] *MedLab, Inc.*, Civ. No. C-08-00822 SI, at 3, 6-7, 9-10.
[25] *Id.* at 6-10.
[26] FTC, *Red Flag Bogus Weight Loss Claims: A Reference Guide for Media on Bogus Weight Loss Claim Detection* (2003), http://www.ftc.gov/bcp/edu/pubs/business/adv/bus60.pdf.
[27] *See, e.g.*, Press Release, FTC Launches "Big Fat Lie" Initiative Targeting Bogus Weight-Loss Claims (Nov. 9, 2004), http://www.ftc.gov/opa/2004/11/bigfatliesweep.shtm (announcing actions against defendants who used *Red Flag* claims).

The court in *MedLab, Inc.* accepted the opinion of an FTC scientific expert that the defendants' claims were "clearly outside the realm of plausible science."[28] The court also rejected an argument by the defendants that certain disclosures changed the meaning of the claims at issue. Disclosures present at the bottom of print ads stated, "Results will vary from one individual to another … To achieve best results, you should follow the caloric abatement recommendations, increase activity level and not rely on pill use alone."[29] The court concluded that, in context, the disclaimers were not conspicuous and did not "correct the message of the advertisements, which is, overwhelmingly, that *any* user of this product can lose lots of weight quickly by taking a pill and doing nothing else."[30] The court ordered nearly $2.7 million in monetary relief, and a later injunction barred the defendants from disseminating weight-loss claims without competent and reliable scientific evidence. Like *Direct Mktg. Concepts*, *MedLab, Inc.* calculated damages based on net sales as a measure of the "full amount lost by consumers."[31]

Like in *Direct Mktg. Concepts* and *Daniel One*, the decision in *MedLab, Inc.* shows that, more than ever, marketers should avoid those claims that FTC has challenged again and again. Additionally, the case illustrates that disclosures cannot qualify what is otherwise a false and deceptive claim.

Lane Labs: A Case for the Defense

In January 2007, the FTC filed a complaint in a New Jersey federal court alleging contempt and seeking a $24 million fine against the supplement maker, Lane Labs-USA, Inc., and two individual officers. The FTC argued that the defendants violated prior orders, from 2000, that 1) required competent and reliable scientific evidence in support of health-related claims; 2) prohibited misrepresenting studies or other research; and 3) imposed certain reporting requirements. Following a five-day evidentiary hearing, the court held that the defendants had substantially complied with the order and, thus, could not be held in contempt.[32]

The contempt proceeding involved claims for a fertility product and a calcium supplement. Calcium claims at issue included the following: "AdvaCAL has been 'clinically shown to be three times more absorbable than typical calcium carbonate coral calcium supplements'"; "AdvaCAL is the 'only' calcium that can increase bone density"; and "Most of the supplements out there don't have available, digestible calcium." For the fertility product, Ferti Male, the FTC challenged claims that the product had been "clinically shown" to increase sperm production, sperm motility, and semen production. The court considered expert testimony from both the defendants and the FTC on the various studies and research offered in support of the claims. It ultimately found that the defense experts were more persuasive than the FTC's experts. The court appeared, in part, persuaded by the lack of any testimony or evidence showing inefficacy or physical harm from the products: "Neither of the FTC's experts stated that the supplements marketed by Lane Labs are not effective or constitute a health risk to the public."[33] The court, likewise, found that the defendants appropriately sought expert advice on scientific matters and hired a compliance officer following the earlier orders. The court noted, "This is not a case of a company making claims out of thin air."[34] In its findings, the court also recounted testimony from a defense expert who stated, "half of the things on the shelf have no studies," and "[it is] so unusual to have [] studies that it is refreshing."[35]

Unlike other recent cases, the *Lane Labs* decision contains no language suggesting that a certain type or quantity of scientific evidence is *per se* required for health-related claims.[36] The court, rather, accepted the opinions of the defendants'

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[28] *MedLab, Inc.*, Civ. No. C-08-00822 SI, at 10 (internal citation omitted).
[29] *Id.* at 7 (internal citation omitted).
[30] *Id.* at 8.
[31] *Id.* at 16 (internal citation omitted).
[32] Because *Lane Labs* was a contempt proceeding, a "substantial compliance" defense was available. This defense is not available in initial Section 5 and Section 12 enforcement cases.
[33] *Lane Labs-USA, Inc.*, Civ. No. 00-cv-3174, at 13 (internal footnote omitted).
[34] *Id.* at 14.
[35] *Id.* at 10.
[36] The FTC briefing also did not argue for a *per se* rule.

experts on an array of substantiation, including small controlled clinical trials, rat studies, a doctoral thesis, and at least one uncontrolled human trial. Although the court acknowledged some potential flaws in the research, it found that the defendants' experts properly accounted for those points and were convincing on the merits of the overall research. Excerpts from the case illustrate this point:

> All four expert witnesses were credible and knowledgeable in their respective fields of expertise. This Court, however, was more impressed by the testimony of Defendants' experts because their testimony seemed more reasonable and in accordance with the Consent Orders … .
>
> ***
>
> In support of its motion, the FTC engaged in significant discovery and presented a nuanced case that delved into the details of every piece of substantiation offered by Lane Labs. While the FTC's experts identified several questionable aspects to the studies and reports offered by Lane Labs, Lane Labs' experts explained why these concerns do not negate the value of the studies and reports …
>
> ***
>
> The issues raised by the FTC in this action are subject to interpretation. The differences between the expert opinions evidences this fact. The Orders [nevertheless] do not specifically require that which the FTC is arguing was and is required.[37]

In considering whether the defendants misrepresented studies or other research, the court appropriately acknowledged that "misrepresentation" depends on the overall, net impression of ads. The court found that, in general, "the impression created by Defendants' advertisements is that both supplements are good products that will most likely help people who take them."[38] The court also noted, again, that neither of plaintiff's expert went "as far as to say that the products do not work."[39] The court acknowledged one defendant's testimony that "some things slipped through the cracks and that errors were made over a number of years"; nevertheless, it found that "the FTC ha[d] not carried its burden of demonstrating that Lane Labs ha[d] created a false impression" regarding research or studies.[40] Regarding the reporting requirements from the 2000 orders, the court found that, over the years, the defendants had submitted to the FTC multiple detailed and timely reports on its claim substantiation. Against this background, the court observed that it was "disingenuous" and unfair for the FTC to raise concerns for the first time in a contempt proceeding.[41]

While *Direct Mktg. Concepts*, *Daniel One*, and *MedLab, Inc.* show that high-risk areas will remain high risk, *Lane Labs* is the first case in some time where the FTC has not had its way. The case highlights the importance of engaging strong experts and avoiding any claims or products that may risk physical harm to consumers.

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[37] *Id.* at 10, 14, 18.
[38] *Id.* at 15.
[39] *Id.*
[40] *Id.* at 14.
[41] *Id.* at 17.