Has the FTC Changed the Game On Advertising Substantiation?

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A COMPETITOR INTRODUCES A sports drink that claims to provide increased energy without caffeine by utilizing a recently discovered plant in the Brazilian rainforest. Your marketing department decides to develop a copycat product and you give them the green light to make similar claims based upon (1) two published clinical studies on the competitor's product, and (2) the fact that the active ingredients in the two products are identical in both quantity and quality. Without telling you, the marketing department decides to give the copycat product better positioning by adding several antioxidants. You find out about the new antioxidants (and your marketing department's plans to rely on them) one week before your company plans to launch the new product. You call the marketing team into your office to tell them that the claims may no longer be substantiated. If they want to avoid risking FTC scrutiny they either have to reformulate the product and take the antioxidants out or delay the launch for months or perhaps years while two clinical studies are conducted on a product containing the new plant and antioxidants.

Seem unlikely? Maybe not. In two recent consent orders involving dietary supplements and supplement drinks,[1] the FTC appears to have changed its enforcement strategy and possibly modified its substantiation standard with regard to health claims and foods. These consent orders require that companies conduct two double-blind, placebo-controlled clinical studies on humans using the advertised product or an "essentially equivalent" product to substantiate certain types of claims. Whether these orders modify the substantiation standard and impose new burdens on companies is now an open question, which firms must consider going forward.

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Overview of the FTC's Substantiation Requirements and Health Claims

History of the "Reasonable Basis" Standard for Substantiation. The FTC's 1972 decision in the *Pfizer* case established the baseline requirements for substantiation. In that decision, the FTC held that an advertiser must have a "reasonable basis" for making objective claims—in other words "substantiation."[2] The FTC identified various factors used to determine the amount of substantiation necessary to constitute a reasonable basis for a particular claim:

> (1) the type and specificity of the claim made—e.g., safety, efficacy, dietary, health, medical; (2) the type of product—e.g. food, drug, potentially hazardous consumer product, other consumer product; (3) the possible consequences of a false claim—e.g., personal injury, property damage; (4) the degree of reliance by consumers on the claims; [and] (5) the type, and accessibility, of evidence adequate to form a reasonable basis for making the particular claims.[3]

Since *Pfizer*, the FTC has elaborated on these requirements. In 1974, the FTC held that the failure to have a reasonable basis for objective claims was deceptive under Section 5 of the FTC Act.[4] Then, in 1977, the FTC subsequently observed that it was "well-established" that a marketer making a product claim represents that it "has a reasonable basis for so doing, and that the assertion does not constitute mere surmise or wishful thinking on the advertiser's part."[5]

In 1983 the FTC memorialized the reasonable basis standard in its Advertising Substantiation Policy Statement. The Policy Statement made clear that the standard was intended to be quite flexible. If the ad included an express or implied statement of the amount of support for a claim (e.g., "studies show," "tests prove," "doctors recommend," or depictions of people in lab coats), the FTC would expect the advertiser to have at least that level of support for its claim. Without a reference to a certain level of support, the Policy Statement suggested that the FTC would essentially conduct a cost/benefit analysis to determine what constituted required substantiation and, for the most part, reiterated the *Pfizer* factors:

> The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.[6]

As former FTC Chairman Robert Pitofsky noted, the Commission designed this balancing analysis to recognize that "protection of consumers against advertising fraud should not be a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn will facilitate an efficient and reliable compet-

itive market process."[7] Further, the Policy Statement required that firms have substantiation before disseminating a claim, and "the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers."[8]

The "Competent and Reliable" Standard for Health Claims. For claims relating to health and safety, as well as many claims regarding product efficacy, the FTC has defined the reasonable basis requirement as "competent and reliable scientific evidence."[9] The Commission has further explained in decisions and consent orders that this standard requires

> tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.[10]

This definition recognizes that different types of claims require differing levels of evidence and defers to experts in the field for the answer. As FTC publications have noted, "The FTC gives great weight to accepted norms in the relevant fields of research and consults with experts from a wide variety of disciplines."[11] The relevant question is whether those skilled in the profession regard the proffered evidence as an appropriate way to obtain accurate and reliable results.

The randomized, double-blind, placebo-controlled clinical trial is the gold standard for health claims substantiation. For many types of health claims, it is the only methodology that experts in the field accept as yielding accurate and reliable results. On occasion, however, the Commission or courts have permitted health claims to be substantiated through lab testing or through medical literature.[12] Accordingly, the Commission has challenged some claims under the competent and reliable scientific evidence standard based on allegations that no reliable controlled clinical trials were conducted.[13]

This broad "competent and reliable scientific evidence" standard has largely stood the test of time, although, occasionally, some have attacked it as too vague.[14] Indeed, the Commission has largely rejected adopting as a baseline rule more stringent standards modeled on the Food and Drug Administration's approach to regulation of new prescription drugs. Such standards might require clinical trials to substantiate certain types of claims, rather than allowing other methods that use "procedures generally accepted in the profession to yield accurate and reliable results."[15] Moreover, under the FDA's approach, multiple clinical trials addressing the same claims might be required before claims are allowed. However, except in very limited circumstances (e.g., "establishment" claims—i.e., claims that certain benefits have been scientifically proven),[16] the Commission has not required FDA-like standards. In fact, for decades the FTC has urged that the FDA should approach health-related claims as the Commission does, seeking to prevent misleading claims without unduly restricting the flow of truthful information.[17]

Lane Labs. In 2007, the flexibility inherent in the competent and reliable standard came back to haunt the FTC in the *Lane Labs* litigation. There, the FTC alleged that Lane Labs violated an earlier consent order[18] when it made claims about a calcium supplement product and a supplement intended to improve male fertility without competent and reliable scientific evidence. The FTC and Lane Labs presented competing fact and expert testimony during a five-day hearing in federal court in April 2009. Lane Labs relied upon several clinical studies and the testimony of a scientific expert for each of its challenged claims. The FTC's experts pointed to other studies that did not support the claims, and the FTC also criticized the studies proffered by Lane Labs. Their criticisms are familiar to those who practice in this area. They included the fact that Lane Labs' studies were underpowered (i.e., too few participants), used rats instead of humans, that the products had inert ingredients not found in the products tested, and that the studies tested one proposition (increase in bone density) from which the claim (reduced risk of fractures) had to be inferred. The defendant's experts rebutted each of these criticisms.

The district court denied the FTC's motion for contempt, finding that Lane Labs "provided credible medical testimony that the products in question are good products and could have the results advertised."[19] The court refused to find a violation of the consent order where there was simply a difference of opinion among credible experts. Lane Labs "did what they were supposed to do" in seeking expert advice before relying upon scientific articles and peer-reviewed studies attesting to the purported effects of its products.[20] The court held that asking the company to do more would be unreasonable.[21]

The Third Circuit recently reversed the district court in *Lane Labs*.[22] In the opinion, the Third Circuit specifically adopted the defense of substantial compliance, holding that to take advantage of the defense a party must show that it "(1) has taken all reasonable steps to comply with a valid court order, and (2) has violated the order in a manner that is 'technical' or 'inadvertent.'" The case has been remanded to the district court for factual findings as to whether Lane Labs' violations of its order were technical or inadvertent.

Since its loss in *Lane Labs*, FTC staff has stated that it intended to modify its traditional requirement of "competent and reliable scientific evidence."[23] The Director of the Bureau of Consumer Protection, David Vladeck (a seasoned public interest litigation lawyer), has also stated that he would seek more precise order language as to the amount and type of scientific evidence necessary to support health claims, as well as pursue efforts to harmonize FTC with FDA requirements. He indicated that an "outlier study," even if well conducted, should not be sufficient basis for a health claim.[24]

The *Iovate* and *Nestlé* Standard

In its recent consent orders in *Iovate* and *Nestlé*, the FTC has proposed more specific language for respondents that precisely defines what "competent and scientific evidence" those companies must show going forward to substantiate health-related product claims. The *Iovate* and *Nestlé* orders provide

that for certain claims, "competent and reliable scientific evidence" is defined as:

> at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.[25]

"Essentially equivalent" is defined as:

> a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the covered product; provided that the product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.[26]

In the case of *Nestlé* and *Iovate*, these new requirements do not apply to all claims for the products covered by the order (defined as the "Covered Product(s)"). For health claims generally, the two orders retain the traditional definition of "competent and reliable scientific evidence," although the language has been modified slightly to make clear that any evidence must be evaluated in light of the body of evidence as a whole. The new definitions are reserved for two specific types of claims—(1) weight loss claims (including rapid weight loss), and (2) claims that a product reduces the duration of acute diarrhea in children up to the age of thirteen or reduces absences from daycare or school due to illness.

The FTC has in the past required two clinical trials to substantiate certain claims, so that requirement itself is not new. There are, however, at least three significant changes.

First, the FTC is now imposing this detailed requirement up front in a consent order. Consistent with the goal of maintaining a flexible standard, the Commission historically has been content with defining the "competent and reliable" standard very broadly in consent orders and then determining that clinical studies are required only *after* the advertiser (now under order) makes a claim about the same product that the FTC had investigated for scientific support.[27] For example, if in the past a firm made a misleading claim that a product cured cancer, it likely would sign a consent order requiring "competent and reliable scientific evidence" for any cancer claim; if the firm made subsequent claims, the FTC would then pursue a contempt action against the firm for violating the original order and (1) litigate whether the advertiser's proof met the general "competent and reliable scientific evidence" standard that appeared in the original consent order, or (2) reach a subsequent settlement that would further define "competent and reliable scientific" evidence. Under this old approach, the Commission could determine—in consultation with experts—that the "competent and reliable scientific evidence" standard required, for example, two double-blind, placebo-controlled clinical studies.

Now, however, it appears in the *Nestlé* and *Iovate* orders that the FTC has changed course by stating up front in the original order (rather than leaving it to be litigated and/or negotiated after the fact in subsequent proceedings) the specific proof that a firm must have to be "competent and reliable scientific evidence." The FTC has effectively taken away the opportunity for advertisers to have a second bite at the apple when it comes to litigating whether they have adduced "competent and reliable scientific" evidence to support their claims.

Second, as noted above, the *Nestlé* and *Iovate* orders also can be read as imposing new or more rigorous substantive standards in the case of weight loss claims and claims that a product reduces the likelihood of illness (in this case, acute diarrhea in children up to the age of thirteen). In these instances, the clinical studies must be double-blind, placebo-controlled, and conducted on humans using essentially equivalent products (defined as a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the covered product (i.e., the product which is the subject of the consent order)). As the consent orders state, the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.

Third, the FTC appears to be moving in the FDA's direction when it comes to certain claims. The *Nestlé* and *Iovate* orders suggest that the FTC believes certain disease prevention claims relating to cold and flu, hay fever, and allergies may only be made if they are approved by the FDA. The FTC has indicated that it has conferred with the FDA on this new requirement.[28]

Lane Labs' fingerprints can be seen all over these definitions. Had that company's order defined "competent and reliable scientific evidence" in the detailed manner now defined in the *Nestlé* and *Iovate* orders, Lane Labs could not have relied upon studies of rats or studies of products containing ingredients that differed from its own. Further, the district court would have been required to give greater weight to the presence of other, conflicting studies.

Unanswered Questions

The FTC's new substantiation definition potentially has significant ramifications for advertisers. Many questions, however, remain unanswered.

Does There Have to Be a Violation of Section 5 First Before These New Requirements Apply?

Many are asking if the *Nestlé/Iovate* substantiation standards apply to everyone or just to companies already operat-

ing under the same or similar consent orders. While it is true that respondents often are "fenced in"—that is, the prohibited conduct goes beyond the scope of the alleged violation—such fencing in typically occurs with respect to the nature of the products or claims covered by the order. In other words, if a misleading advertisement related to a weight loss claim and juice, the order might cover all health claims for beverages. We do not believe, however, that the FTC is intending to take the position that there is one level of required substantiation for advertisers who have agreed to consent orders under Section 5 and another, lesser standard for those advertisers who have not yet been subject to a consent order.

Nor would having a different substantiation standard for companies who are signing consent orders likely make sense from a policy perspective. Imposing the new substantiation requirement only on consent order respondents would mean that two companies could make the same claim but the type of substantiation required to substantiate the claim would differ for each. More likely, advertisers should assume that the new requirements apply irrespective of whether they are subject to a consent order. Indeed, an FTC official suggested as much in an interview last Spring.[29]

What Types of Claims Are Covered by the New Substantiation Requirements?

At a minimum, the new requirement likely applies to weight loss claims and claims relating to the duration of acute diarrhea and reducing children's absences from school since these are the claims covered by the existing orders in *Nestlé* and *Iovate*, which have the new definition of "competent and reliable scientific evidence." However, there may be other types of claims that the FTC may analyze using its new definition. If so, however, the scope of the new standard is difficult to predict.

Determining in advance the necessary quantity and quality of substantiation for claims is an exercise in trying to balance risk: setting too strict a standard discourages innovation and consumer communications while too lenient a standard could allow misleading claims leading to consumer harm. Perhaps the benefits of a stricter standard outweigh the harm when the product and claims at issue are ones that are unlikely to be truthful in any circumstance (e.g., "lose weight while you watch TV"). In that situation, there is little risk of inadvertently suppressing innovation or consumer communication and significant risk that misleading claims might otherwise be made.

However, when the product and claims are ones that could in some circumstances be substantiated, the cost/benefit analysis seems reversed. In this scenario, product innovation and communication of truthful information to consumers might be overly discouraged while the heightened standard would do little to further prevent the communication of misleading information. This is particularly the case because even without the heightened standard the FTC is still free to take the position—as it has many times in the past—that two clinical studies are required to substantiate the claim under the more traditional definition of "competent and reliable scientific evidence."

Given the current uncertainty, anyone making health claims for a food or dietary supplement should carefully consider whether the new standard will apply to them and, if so, how to meet it. Of course, some claims, such as the benefits of fiber, may be so well accepted that additional clinical studies are not needed. However, advertisers attempting to substantiate food health claims through clinical studies may want to verify that the studies meet the FTC's new requirements, including that the studies were conducted on humans, utilized the same or an essentially equivalent product, and are defensible in light of the entire body of relevant scientific evidence.

At the same time, the FTC has not formally revised or repudiated the Dietary Supplement Guidelines.[30] Those guidelines state that the "FTC will consider all forms of competent and reliable scientific research when evaluating substantiation," though noting that "as a general rule, well-controlled human clinical studies are the most reliable form of evidence."[31] They also do not dismiss the possible relevance of animal and in vitro studies or reliance on only a single clinical trial (noting that the "quality of studies will be more important than quantity"). And while they caution advertisers to make sure that differences between their products and those tested in clinical trials do not affect efficacy, they do not put the onus on the advertiser to show that differences between the added and tested products are inconsequential. In short, there is much in these guidelines that seems inconsistent with the FTC's current stance on the meaning of "competent and reliable scientific evidence" in the context of at least some dietary supplement claims. At least one FTC official has remarked that while the FTC intends to proceed initially through consent orders, it intends ultimately to modify the Dietary Supplement Guidelines.[32]

How Should "Conducted by Different Researchers, Independent of Each Other" Be Interpreted?

The new definition requires that the two studies be conducted by "different researchers, independent of each other." Some food companies have their own in-house research department, in part in an effort to control costs. If two different researchers within their research department conduct studies without communicating with each other, will this suffice or must the company hire at least one outside researcher? While we think it is likely it will suffice, this is also a question that FTC staff almost certainly would be willing to address either at the time a company is about to sign a consent order or during the compliance process.

What Is an "Essentially Equivalent" Product?

The provision that has the greatest potential to create uncertainty and discomfort is the requirement that any clinical studies must be conducted on the advertised product or an "essentially equivalent" product, which is defined as one that (1) contains the identical ingredients in identical amounts, except for inactive ingredients such as binders, col-

ors, fillers and excipients, and (2) has the same form and route of administration.

In other words, if a company has conducted two clinical studies on its existing product but wants to create a line extension by changing a flavor or creating a low-fat variety, the clinical studies may no longer be studies of an "essentially equivalent" product. Of course, there is an escape hatch. An advertiser can avoid the essentially equivalent requirement if it added additional ingredients to the product beyond those in the product tested and if "reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product."[33]

However, this carve-out has several limitations. First, it seems to place the onus squarely on the advertiser to show that the added ingredients do not alter the efficacy of the other ingredients. Second, if a company changes the product in any other way, for example, going from a yogurt to a drink, or removes an active ingredient unrelated to the active ingredients for the relevant claim, the carve-out does not apply, and the company has to do two new clinical studies. This provision, perhaps more than any of the others, seems like it could significantly chill product innovation.

This may, however, be a worst-case scenario. No doubt over time the FTC will fine-tune this definition as it gains practical experience with it. The Commission can also exercise prosecutorial discretion in those instances where the alleged violations seem trivial or nonmaterial. Finally, the Commission may well interpret the carve-out liberally in most instances and instead wield the "essentially equivalent" product definition as a more lethal weapon against those companies that market products with seemingly little regard for significant differences between the tested and advertised products.

Does the First Amendment Have a Role to Play?

First Amendment challenges to government regulation of misleading commercial speech have met with mixed results. The FTC's practice of "fencing in,"—e.g., including within an order products that were not themselves the subject of the allegedly misleading speech—has been upheld against First Amendment challenge. For example, in 1982 the Ninth Circuit held that such a practice was permissible, stating that "'[e]ven truthful commercial speech can be regulated if the government's interest in regulation is substantial and if the regulation directly advances that interest and is not more extensive than necessary."[34] The court further noted that "[a]ny remedy formulated by the FTC that is reasonably necessary to the prevention of future violations does not impinge upon constitutionally protected commercial speech."[35] The D.C. Circuit ruled in a 1999 decision, however, that before the FDA could ban allegedly misleading dietary supplement claims, the First Amendment required the Agency to consider whether the use of disclaimers could cure any alleged deception.[36]

Most recently, POM Wonderful filed a declaratory judgment action against the Commission, alleging that it has been asked to sign a consent order containing the new substantiation language, discussed above, but that the new requirements violate its First and Fifth Amendment rights, as well as the FTC's own procedural requirements.[37] As stated in the complaint the FTC subsequently filed against POM, the Commission is alleging that POM deceptively claimed that its 100 percent pomegranate juice and supplements will prevent or treat heart disease, prostate cancer, and erectile dysfunction.[38] POM argues that the requirement for FDA preapproval violates its First Amendment claims because it cannot make otherwise truthful, substantiated claims without such approval. POM further alleges that its Fifth Amendment rights have been violated because it has invested substantial time and resources in developing substantiation for its claims under what it now believes is the FTC's newly discarded definition of "competent and reliable scientific evidence." POM alleges that the FTC has changed the requisite standard, meaning that it can no longer lawfully make such claims. Finally, POM alleges that the FTC changed its substantiation standard without sufficient administrative due process. Whether POM is successful in its challenge will obviously have a significant effect on the future use of this new standard.

Conclusion

The FTC has set out to provide greater specificity in its consent orders as to what evidence is acceptable in some cases to satisfy its longstanding "competent and reliable scientific evidence" standard for advertising substantiation. Whether the FTC's orders in *Iovate* and *Nestlé* represent a sea change for how companies go about substantiating health claims for foods and dietary supplements or whether it will be mostly business as usual for those companies that have advertised responsibly in the past remains to be seen. Watch for further guidance in the form of additional consent orders, compliance actions, speeches, and perhaps a federal court opinion. In the meantime, companies making such claims would do well to take a hard look at their claims and particularly their substantiation to see how they would hold up under these new definitions. ■

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1 See 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.

2 Pfizer Inc., 81 F.T.C. 23, 86 (1972).

3 *Id.* at 91.

4 Nat'l Dynamics Corp., 82 F.T.C. 488 (1973), *modified*, 85 F.T.C. 391 (1975).

5 Porter & Dietsch, Inc., 90 F.T.C. 770, 866 (1977) (quoting Nat'l Comm'n on Egg Nutrition, 88 F.T.C. 89, 191 (1976), *modified*, 605 F.2d 294 (7th Cir. 1979)).

6 Policy Statement Regarding Advertising Substantiation Program, *appended*

to Thompson Med. Co., 104 F.T.C. 648, 839, 840 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986) [hereinafter Policy Statement].

7 Robert Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV. 661, 671 (1977).

8 Policy Statement, *supra* note 6, 104 F.T.C. at 839.

9 Novartis Corp., 127 F.T.C. 580, 725 (1999).

10 *Id.*

11 FED. TRADE COMM'N, BUREAU OF CONSUMER PROTECTION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 9 (1998) [hereinafter DIETARY SUPPLEMENT GUIDELINES], *available at* http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

12 *See* Rorer v. Am. Home Prods., No. 83 Civ. 7908 (S.D.N.Y. Mar. 7, 1984) (decision finding that claim that product neutralized stomach acid faster was substantiated by neutralizing acid in a beaker as in vivo studies too difficult and imprecise); *Pfizer*, 81 F.T.C. at 69 (claim for topical analgesic could be supported by nonclinical evidence, such as medical literature).

13 *See, e.g.,* FTC v. QT, Inc., 512 F.3d 858, 861 (7th Cir. 2008); Letter from Donald S. Clark, Secretary to Jonathan W. Emord, Esq., Emord & Assocs., Basic Research Denying Petition for Rulemaking (Nov. 30, 2000), *available at* http://www.ftc.gov/os/2000/12/dietletter.htm.

15 Novartis Corp., 127 F.T.C. at 725 ("profession" refers to those with scientific expertise in the relevant area).

16 *See, e.g.*, Am. Home Prods. Corp., 98 F.T.C. 136 (1981).

17 *See, e.g.*, Fed. Trade Comm'n Staff Comments, *In re Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements* (2006), *available at* http://www.ftc.gov/os/2006/04/v060014FTCStaffCommentstothe FDAReDocketNo2006-0066.pdf; Fed. Trade Comm'n Staff Comments, *In re Request for Comment on First Amendment Issues* (2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf; Fed. Trade Comm'n Staff Comments, *In Response to Request for Comments on Proposal to Amend the Rules Governing Health Messages on Food Labels and Labeling* (1988), *available at* http://www.ftc.gov/opp/advocacy/1987/V870027.PDF.

18 Lane Labs-USA, Inc., No. 00-CV-3174, slip op. (D.N.J. June 29, 2000) (Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief), *available at* http://www.ftc.gov/os/caselist/9823558/lanelabsordandsettlement.pdf.

19 FTC v. Lane Labs-USA, Inc, No. 00-CV-3174, 2009 WL 2496532, at *8 (D.N.J. Aug 11, 2009).

20 *Id.* at *9–*10.

21 *Id.*

22 FTC v. Lane Labs-USA, Inc., No. 09-3909, 2010 WL 4226509 (3d Cir. Oct. 26, 2010).

23 Dan Schiff, *FTC's Pending Claim Substantiation Changes Will Weigh on Small Firms*, THE TAN SHEET, Mar. 1, 2010; Mary K. Engle, Associate Director for Advertising Practices, Fed. Trade Comm'n, Remarks Before False Advertising Disputes Roundtable Webinar, The FTC's Advertising Priorities (Oct. 22, 2009), *available at* http://www.arnoldporter.com/resources/documents/FalseAdvertisingDisputesRoundtableMaterials102209.pdf.

24 David C. Vladeck, Director, Bureau of Consumer Protection, Fed. Trade Comm'n, Remarks Before the Council for Responsible Nutrition's Annual Symposium for the Dietary Supplement Industry, Priorities for Dietary Supplement Advertising Enforcement (Oct. 22, 2009), *available at* http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspeech.pdf.

25 FTC v. Iovate Health Sciences USA, Inc., Case. No. 10-CV-587, slip op. at 7 (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 at 4 (July 14, 2010), *available at* http://www.ftc.gov/os/caselist/0923087/100714nestleorder.pdf.

26 *Iovate*, *supra* note 25, at 4; *see also Nestlé*, *supra* note 25, at 3.

27 *See, e.g.*, KFC Corp., 138 F.T.C. 422, 429 (2004) (decision and order) (defining "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results"). In some cases, the Commission in the past did impose consent order language that informed advertisers that the standard can only be satisfied through the presence of one, or more often, two clinical studies. *See* Removatron Int'l Corp. v. FTC, 884 F.2d 1489, 1498–99 (1st Cir. 1989) (requiring one clinical study to support permanent hair removal claim); Jerome Milton, 3 Trade Reg. Rep. (CCH) ¶ 22, 648 (1987) (requiring one clinical study to support claim of reduced teeth sensitivity to hot and cold and cure cold sores); Walgreen Co., 52 Fed. Reg. 6172, 6173 (1987) (requiring two clinical studies or FDA approval to support claim that over-the-counter analgesics can be substituted for prescription form of the product); Biopractic Group, Inc., 1983–87 Transfer Binder Trade Reg. Rep. (CCH) ¶ 22,201 (1984) (requiring two clinical studies or FDA approval to support claim of remedy for arthritis pain and inflammation); N. Am. Philips Corp., 101 F.T.C. 359 (1983) (requiring two clinical studies required to support claims relating to razor bumps); McCaffrey & McCall, Inc., 101 F.T.C. 367 (1983) (same); Sperry Corp., 98 F.T.C. 4 (1981) (same); AHC Pharmacal, Inc., 101 F.T.C. 40 (1983) (requiring two clinical studies or FDA approval to support acne treatment claim). These cases, however, were the exception rather than the rule.

28 *See* Schiff, *supra* note 23, at 9.

29 *See id.*

30 *See* DIETARY SUPPLEMENT GUIDELINES, *supra* note 11.

31 *See id.* § II.B.3.

32 *See* Schiff, *supra* note 23, at 9.

33 FTC v. Iovate Health Sciences USA, Inc., Case. No. 10-CV-587, slip op. at 4 (W.D.N.Y. July 29, 2010); Nestlé Health Care Nutrition, FTC File No. 092-3087, slip op. at 3 (July 14, 2010).

34 Litton Indus., Inc. v. FTC, 676 F.2d 364, 373 (9th Cir. 1982) (quoting Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980)).

35 *Id.* (quoting United States v. Reader's Digest Ass'n, 662 F.2d 955, 965 (3d Cir. 1981)).

36 Pearson v. Shalala, 164 F.3d 650, 655–60, 661 (D.C. Cir. 1999); *see also* Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002) (same).

37 POM Wonderful v. FTC, Civ. No 1:10-CV-01539 (D.D.C. 2010).

38 POM Wonderful, FTC Docket No. 9344 (2010) (complaint), *available at* http://www.ftc.gov/os/adjpro/d9344/100927admincmplt.pdf.