HAS THE FTC CHANGED THE GAME ON ADVERTISING SUBSTANTIATION?

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I. Introduction

A. In two recent consent orders involving dietary supplements and supplement drinks,[1] the FTC appears to have modified its enforcement policy with regard to health claims and foods. These 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 practitioners must consider going forward.

II. Overview of the FTC's Substantiation Requirements and Health Claims

A. History of the "Reasonable Basis" Standard for Substantiation

1. The FTC established the baseline requirements for substantiation in its 1972 decision in *Pfizer, Inc.*, in which it held that an advertiser must have a "reasonable basis" for making objective claims—in other words "substantiation."[2]

2. In *Pfizer, Inc.*, the FTC identified the various factors used to determine the amount of substantiation necessary to constitute a reasonable basis for a particular claim. These factors include:

   a) The type and specificity of the claim made – e.g., safety, efficacy, dietary, health, medical.

   b) The type of product – e.g. food, drug, potentially hazardous consumer product, other consumer product.

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[1] *See* FTC v. Iovate Health Scis. 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 [Complaint and Stipulated Final Judgment available at Attachment A & B]; Nestlé HealthCare Nutrition, Inc. FTC File No. 092-3087, Agreement Containing Consent Order (July 14, 2010), *available at* http://www.ftc.gov/os/caselist/0923087/100714Nestléorder.pdf [Complaint and Consent Order available at Attachment C & D].

[2] Pfizer, Inc., 81 F.T.C. 23, 86 (1972) [Attachment E].

c) The possible consequences of a false claim – e.g., personal injury, property damage.

d) The degree of reliance by consumers on the claims.

e) The type, and accessibility, of evidence adequate to form a reasonable basis for making the particular claims.[3]

3. Since *Pfizer*, the FTC has elaborated on these requirements.

a) 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]

b) In 1977, the FTC further held 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]

4. In 1983, the FTC issued an Advertising Substantiation Policy Statement, which memorialized the reasonable basis standard.

a) The Policy Statement emphasized that the standard was intended to be flexible.

b) If an advertisement 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.

c) If an advertisement did not include an express or implied statement of the amount of support for a claim, 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.

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[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)).

d) The Commission's determination of what constitutes a reasonable basis depends on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include:

(1) The type of claim.

(2) The product.

(3) The consequences of a false claim.

(4) The benefits of a truthful claim.

(5) The cost of developing substantiation for the claim.

(6) The amount of substantiation experts in the field believe is reasonable.[6]

e) 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 competitive market process."[7]

f) 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."

B. The "Competent and Reliable" Standard for Health Claims

1. 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."[8]

2. The Commission has defined this standard in the following manner.

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[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) [Attachment F].

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

[8] Novartis Corp., 127 F.T.C. 580, 725 (1999) [Attachment G].

a) [T]ests, 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.[9]

3. The above definition acknowledges that different types of claims require differing levels of evidence and defers to experts in the field for the answer.

4. The FTC also "gives great weight to accepted norms in the relevant fields of research and consults with experts from a wide variety of disciplines."[10]

5. Thus, the relevant question is whether those skilled in the profession regard the proffered evidence as an appropriate way to obtain accurate and reliable results.

6. The randomized, double-blind, placebo-controlled clinical trial has become the gold standard for health claims substantiation because for many types of health claims, this test is the only methodology that experts in the field accept as yielding accurate and reliable results. 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.[11]

7. Although, some have attacked it as too vague, the competent and reliable scientific evidence standard has largely stood the test of time,.[12]

8. The Commission has largely rejected more stringent standards modeled on the FDA's approach to regulation of new prescription drugs. Except in very limited circumstances (e.g., "establishment" claims -- i.e. claims that

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[9] *Id.*

[10] 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 [Attachment H].

[11] *See e.g.*, FTC v. QT, Inc., 512 F.3d 858, 861 (7th Cir. 2008).

[12] 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.

certain benefits have been scientifically proven),[13] the Commission has not required FDA-like standards.

9. Under the FDA's approach, 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."[14] Thus, multiple clinical trials addressing the same claims might be required before claims are allowed.

10. 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.[15]

C. The FTC's Loss in *Lane Labs*

1. In 2007, the flexibility inherent in the "competent and reliable" standard came back to haunt the FTC in the *Lane Labs* litigation.

2. In that case, the FTC alleged that Lane Labs violated an earlier consent order[16] when it made claims about a calcium supplement and a supplement intended to improve male fertility without competent and reliable scientific evidence.

3. The *Lane Labs* Trial

   a) 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

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

[14] Novartis Corp., 127 F.T.C. 580, 725 (1999) ("profession" refers to those with scientific expertise in the relevant area) [Attachment G].

[15] *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/v060014FTCStaffCommentstotheFDAReDocketNo2006-0066.pdf; Federal 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.

[16] 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.

a scientific expert for each of its challenged claims. The FTC's experts pointed to other studies that did not support the claims, and also criticized the studies proffered by Lane Labs. Their criticisms included the fact that the 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.

4. The Decision in *Lane Labs*

   a) The 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."[17]

   b) The court refused to find a violation of the 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.[18] The court held that asking the company to do more would be unreasonable.[19]

5. The Aftermath of *Lane Labs*

   a) Since its district court loss after trial in *Lane Labs*, FTC Staff stated that that it intended to modify its traditional requirement of "competent and reliable scientific evidence."[20]

   b) The Director of the Bureau of Consumer Protection, David Vladeck, has stated that he would seek more precise order

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

[18] *Id*. at *9-*10.

[19] *Id*.

[20] Mary K. Engle, Associate FTC Director, Advertising Practices, 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.

language as to the amount and type of scientific evidence necessary to support health claims, as well as pursue efforts to harmonize FTC and FDA requirements. He indicated that an "outlier study" even if well conducted should not be sufficient basis for a health claim.[21]

6. The Appeal of *Lane Labs*

   a) On appeal, the Third Circuit remanded the case back to the District Court for a more detailed, claim specific review rather than what the Third Circuit perceived to be a generalized review of the efficacy of the challenged products.[22]

   b) In the decision, the Third Circuit adopted the defense of "substantial compliance." The Court held that to assert the defense a party must show that it "has taken all reasonable steps to comply with the valid court order" and has "violated the order in a manner that is merely 'technical' or 'inadvertent.'"

D. The *Iovate* and *Nestlé* Standard

1. In two recent consent orders in *Iovate* and *Nestlé*, the FTC has proposed new language for respondents more precisely defining what "competent and scientific evidence" will be required to substantiate health-related product claims.

2. *Iovate* and *Nestlé* define, "competent and reliable scientific evidence" as the following for certain types of claims.

   a) "[A]t 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

[21] David C. Vladeck, Director, Bureau of Consumer Protection, Fed. Trade Comm'n, Remarks at the Council for Responsible Nutrition 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.

[22] FTC v. Lane Labs-USA, Inc., No. 09-3909 (3rd Cir. Sept. 14, 2010) [Attachment I].

scientific evidence, are sufficient to substantiate that the representation is true."[23]

3. "Essentially equivalent" is defined as follows:

   a) "[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 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."[24]

4. These new requirements do not apply to all claims for the products covered by the orders in *Nestlé* and *Iovate* (defined as the "Covered Product(s)").

5. The new definitions apply to the following two specific types of claims.

   a) Weight loss claims (including rapid weight loss).

   b) 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.

6. For health claims generally, *Nestlé* and *Iovate* 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.

7. While the requirement itself is not completely new, there are at least three significant changes.

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[23] 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 [Attachment B]; 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 [Attachment D].

[24] *Iovate*, *supra* note 23, at 4 [Attachment B]; *see also Nestlé*, *supra* note 23, at 3 [Attachment D].

a) First, in the past, the Commission has been content with defining the "competent and reliable" standard very broadly in consent order and then determining that clinical studies are required only after the advertiser makes a claim about the same product. Now, the FTC is making that determination in a consent order rather than waiting to reach that determination during the course of investigating a specific claim or claims.

(1) *Example*: In the past if a firm made a misleading claim that 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.

(2) Now, the FTC states up front in the original order the specific proof that a firm must have to be "competent and reliable scientific evidence.

(3) In sum, advertisers will no longer have two chances to litigate whether they have provided "competent and reliable scientific" evidence to support their claims.

b) Second, the ***Nestlé*** and *Iovate* orders 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 an illness.

(1) These cases now impose the following requirements for clinical studies. The clinical study must be:

(a) Double-blind and placebo-controlled;

(b) Conducted on humans using essentially equivalent products; and

(c) Utilize the same form, dosage, and administration as the covered product.

c) Third, the FTC appears to be moving towards the FDA's standards when it comes to certain disease prevention claims. The *Nestlé* and *Iovate* orders suggest that the FTC believes that certain disease prevention claims may only be made if they are approved by the FDA.

8. The influence of *Lane Labs*' on these definitions cannot be overstated. Had that Company's order defined "competent and reliable scientific evidence" in the manner now defined in the *Nestlé* and *Iovate* orders, it could not have relied upon studies of rats or studies of products containing ingredients that differed from its own. Further, the court would have been required to give greater weight to the presence of other, conflicting studies.

9. In a recent consent order that was entered into with *NBTY, NatureSmart LLC and Rexall Sundown, Inc.*, the FTC appears to have reverted back to 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. That case involved claims that major marketers of children's vitamins were making false and unproven claims that their supplements promoted healthy brain and eye development in children.[25]

10. Another recent consent order involving *The Dannon Company, Inc.* adopts the substantiation standard in the *Nestlé* and *Iovate* orders for certain claims related to relieving temporary irregularity or slowing intestinal transit time.[26]

III. Unanswered Questions Moving Forward

A. Does There Have to be a Violation of Section 5 Before The New Requirements Apply?

1. While it is true that respondents can be "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. For example, if a misleading advertisement related

[25] *See* FTC v. NBTY, Inc., NatureSmart LLC, & Rexall Sundown, LLC, Case No. 102-3080 (Consent Order), *available at* http://www.ftc.gov/os/caselist/1023080/101213nbtyagreeorder.pdf.

[26] *See* FTC v. The Dannon Company, Inc, Case No., Case No. 082-3158 (Consent Oorder), *available at* http://www.ftc.gov/os/caselist/0823158/101215dannonagree.pdf.

to a weight loss claim and juice, the order might cover all health claims for beverages.

2. However, it seems unlikely that the FTC is intending to take the position that the level of required substantiation for advertisers who have agreed to Section 5 consent orders is higher than for advertisers not yet subject to a consent order. More likely, advertisers should assume that the new requirements apply irrespective of whether they are subject to a consent order.

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

1. 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 *Nestle* and *Iovate*. However, there may be other types of claims that the FTC may analyze using its new definition. However, it is difficult to predict the extent of the new standard's scope.

2. 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.

3. The benefits of a stricter standard may 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.

4. However, when the product and claims are ones that could in some circumstances be substantiated, the cost/benefit analysis seems reversed. In these cases, 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 agency 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."

5. Given the current uncertainty, advertisers making health claims for food or dietary supplements should consider whether the new standard will apply to them and, if so, how they might 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.

6. Meanwhile, the FTC has not formally revised or repudiated the Dietary Supplement Guidelines.[27] There is much in the 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.

   a) The 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."[28]

   b) The Guidelines 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").

   c) Finally, 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.

7. 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.[29]

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[27] *See* Dietary Supplement Guidelines, *supra* n. 10 [Attachment H].

[28] *See id,* § II.B.3.

[29] 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://wwwarnoldporter.com/resources/documents/FalseAdvertisingDisputesRoundtableMaterials102209.pdf.

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

1. 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 departments. It is not yet clear whether it would suffice to have two different researchers within one research department conduct studies without communicating with each other. While we believe it would likely 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.

D. What Is an "Essentially Equivalent" Product?

1. The provision which 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.

2. An "essentially equivalent" product is defined as one that:

   a) Contains the identical ingredients in identical amounts, except for inactive ingredients such as binders, colors, fillers and excipients; and

   b) Has the same form and route of administration.

3. Thus, 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.

4. An advertiser can avoid the essentially equivalent requirement if it adds additional ingredients to the product beyond those in the product tested and "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."[30]

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

5. However, this carve-out has some limitations.

   a) First, it appears to place the onus squarely on the advertiser to show that the added ingredients do not alter the efficacy of the other ingredients.

   b) 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 could significantly chill product innovation.

6. The FTC will likely 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.

E. Does the First Amendment Have a Role to Play?

1. First amendment challenges to government regulation of misleading commercial speech has met with mixed results.

2. 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 challenges.

   a) *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."[31] 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

[31] 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)).

constitutionally protected commercial speech."[32] Similarly, the D.C. Circuit ruled in a 1999 decision 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.[33]

3. *Pom Wonderful* Litigation

a) 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.[34]

b) POM Wonderful alleged the following in its complaint:

(1) The requirement for FDA preapproval violates its First Amendment claims because it cannot make otherwise truthful, substantiated claims without such approval.

(2) 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 now discarded definition of "competent and reliable scientific evidence."

(3) The FTC has now changed the requisite standard, meaning that it can no longer lawfully make such claims.

(4) The FTC changed its substantiation standard without sufficient administrative due process.

c) The FTC subsequently filed against POM Wonderful, alleging that POM deceptively claimed that its 100 percent pomegranate juice

[32] *Id.* (quoting United States v. Readers' Digest Ass'n, 662 F.2d 955, 965 (3d Cir. 1981).

[33] 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).

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

and supplements will prevent or treat heart disease, prostate cancer, and erectile dysfunction.[35]

d) The result in this litigation will obviously have a significant effect on the future use of this new standard.

IV. Conclusion

A. The FTC has set out to provide greater specificity 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.

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

ATTACHMENT A

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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, Plaintiff, v. **IOVATE HEALTH SCIENCES USA, INC.; IOVATE HEALTH SCIENCES INC.;** and **IOVATE HEALTH SCIENCES GROUP INC.,** now known as **KERR INVESTMENT HOLDING CORP.,** Defendants.	**CASE NO.**

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("FTC"), for its Complaint alleges:

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission

Act ("FTC Act"), 15 U.S.C. § 53(b), to obtain a permanent injunction, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendants' acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a) and 1345, and 15 U.S.C. §§ 45(a), 52 and 53(b).

3. Venue is proper in this district under 28 U.S.C. § 1391(b), (c), and (d) and 15 U.S.C. § 53(b).

PLAINTIFF

4. The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. §§ 53(b) and 56(a)(2)(A).

DEFENDANTS

6. Defendant Iovate Health Sciences Inc. ("Iovate Health") is a Canadian corporation with its principal place of business at 381 North Service Road, Oakville, Ontario L6M 0H4 Canada. At all times material to this Complaint, acting alone or in concert with

others, Iovate Health has advertised, marketed, distributed, or sold a variety of products purported to cause weight loss, including, but not limited to, Accelis and nanoSLIM (collectively, "Iovate Weight-Loss Products"), and other products purported to provide other health benefits, including, but not limited to, Cold MD, Germ MD EZ-Swallow Rapid-Tabs, Germ MD Effervescent Tablets, Allergy MD, and Allergy MD Rapid-Tabs (collectively, "Iovate MD Products") (Iovate Weight-Loss Products and Iovate MD Products collectively referred to as "Iovate Products") to consumers in this District and throughout the United States. Iovate Health transacts or has transacted business in this District.

7. Defendant Iovate Health Sciences U.S.A., Inc. ("Iovate USA") is a Delaware corporation. Formerly, it had a distribution warehouse located at 3880 Jeffrey Boulevard, Blasdell, New York 14219; however, currently, it does not have a United States business address. At all times material to this Complaint, acting alone or in concert with others, Iovate USA has advertised, marketed, distributed, or sold Iovate Products to consumers in this District and throughout the United States. Iovate USA transacts or has transacted business in this District.

8. Defendant Iovate Health Sciences Group Inc., n/k/a Kerr Investment Holding Corp. ("Kerr"), is a Canadian corporation with its principal place of business at 381 North Service Road, Oakville, Ontario L6M 0H4 Canada. Kerr is the parent company of Iovate Health and Iovate USA. At all times material to this Complaint, acting alone or in concert with others, Kerr has advertised, marketed, distributed, or sold Iovate Products to consumers in this District and throughout the United States.

COMMERCE

9. At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS' BUSINESS ACTIVITIES

10. At all times material to the Complaint, Defendants have labeled, advertised, promoted, offered for sale, sold, and distributed to retailers and consumers the following products throughout the United States: 1) Accelis since at least January 2006 until April 2008; 2) nanoSLIM since at least February 2007 until March 2009; 3) Cold MD since at least September 2006 until June 2007; 4) Germ MD EZ-Swallow Rapid Tabs since at least August 2007 until April 2008; 5) Germ MD Effervescent Tablets since at least August 2007 through April 2008; 6) Allergy MD since at least February 2007 until June 2007; and 7) Allergy MD Rapid-Tabs since at least October 2007 until September 2008. Advertisements for these products have appeared on the Internet and various cable television channels. Advertisements also have appeared in nationally circulated magazines.

Defendants' Product Sales

11. At all times relevant to this complaint, the Iovate Products were available for purchase at a wide range of retail stores and over the Internet.

12. Net sales for the Iovate Weight-Loss Products from inception through 2009 totaled approximately $21.3 million. Net sales for Accelis totaled approximately $15 million from 2006 through 2009. Net sales for nanoSLIM totaled approximately $6.3 million from 2007 through 2009.

13. Net sales of Iovate MD Products from inception through 2009 totaled nearly $5.7

million. Net sales for Cold MD totaled roughly $4.1 million for 2006 through 2009. Net sales for Germ MD EZ-Swallow Rapid-Tabs and Germ MD Effervescent Tablets, combined, totaled approximately $792,000 for 2007 through 2009. Net sales for both for Allergy MD and Allergy MD Rapid-Tabs, combined, totaled approximately $781,000 from 2007 through 2009.

Defendants' Product Representations

14. To induce consumers to purchase **Accelis**, Defendants have disseminated, or caused to be disseminated, advertisements, including, but not limited to, the attached Exhibits A through D. Among other things, the advertisements contain the following statements or depictions:

a. Accelis Packaging (*Ex. A*)

Front Panel:

[Holographic picture of woman in bikini. In one image the word "Before" appears with the woman in a light-colored bikini; in the other image the word "After" shows her in a dark-colored bikini. To the left of the holographic picture the following statement appears: **"I LOST 47 lbs. after struggling with my weight for years."**]

Accelis

Fast Weight Loss - Made Easy!

Side Panel:

Accelis Makes Weight Loss Easy, Effective and FAST!

* * *

[Before and after photos of three purported users claiming to have lost 47 pounds in 37 weeks, 24 pounds in 12 weeks, and 29 pounds in 15 weeks.]

* * *

Researchers have discovered an incredible way to help accelerate your weight loss!

b. Accelis Advertisement (*Ex. B*)

She LOST 23 lbs. . . .

* * *

Tunde lost an incredible 24 pounds in just 12 weeks . . .

[Before and after photos of two purported users claiming to have lost 23 pounds in 12 weeks and 47 pounds in 37 weeks.]

CLINICALLY PROVEN KEY INGREDIENT
Doctor-formulated Accelis is a revolutionary scientific breakthrough that fits easily into your hectic routine. . . . Expert researchers believe the clinically proven key ingredient in Accelis produces rapid weight loss by increasing the rate at which your body uses up your blood sugar for energy.

* * *

*In an 8-week study, subjects using the key ingredient in Accelis (3% corosolic acid) lost an average of 10.65 pounds, as compared to subjects using a placebo, who lost an average of only 5.87 pounds. Both groups followed a calorie-reduced diet.

c. Accelis Advertisement (*Ex. C*)

Fast, Easy, Proven Results . . .

"Accelis helped me lose 24 lbs. in 12 weeks! It's really easy."

- Nicole Reuben

FAST* . . . Thanks to the rapid-release liquid softgel technology and a clinically proven ingredient, you experience accelerated weight loss you can see and feel!

* * *

PROVEN . . .

d. Section From Accelis Website (*Ex. D*, p. 1); *see also Ex. B, Ex. C.*

In an 8-week study, **subjects using the key ingredient in Accelis lost an average of 10.65 pounds** while compared to subjects using the placebo who lost an average of 5.87 pounds. . . . Additionally, the researchers noted that half of the subjects using the key ingredient in Accelis lost

greater than 10 pounds! Two exceptional participants had a weight loss greater than 20 pounds!

With Accelis, the study group had almost double the weight loss of the placebo group! The key ingredient in Accelis was found to be effective as a weight-loss product.

15. To induce consumers to purchase **nanoSLIM**, Defendants have disseminated, or caused to be disseminated, advertisements, including, but not limited to, the attached Exhibits E through G. Among other things, the advertisements contained the following statements or depictions:

a. nanoSLIM Packaging (*Ex. E*)

Front Panel:

nanoSLIM

* * *

Powerful Designer Formula For Faster Weight Loss!

* * *

Side Panel:

* * *

In an 8-week clinical study, subjects using the key ingredient in nanoSLIM lost an average of 10.65 lbs., as compared to subjects using a placebo, who lost an average of only 5.87 lbs.

* * *

Back Panel:

Finally, the world's smallest, incredibly powerful weight-loss pill is here! Introducing nanoSLIM – the most discreet, easy-to-use product with the strength and power to deliver faster, more dramatic weight-loss results with diet and exercise! . . . nanoSLIM researchers packed scientifically tested, ultra-effective weight-loss power into the world's smallest weight-loss pill! Today, nanoSLIM is the only product that offers the best of both worlds – powerful, accelerated weight loss and complete ease-of-use!

b. nanoSLIM Website *(Ex. F, p. 1)*

* * *

In one 8-week study, participants using the key ingredient in nanoSLIM lost an average of 10.65 lbs., as compared to participants using a placebo, who lost an average of 5.87 lbs.

* * *

[nanoSLIM] may be small, but it's extremely powerful and its technologically advanced formula will help you lose weight fast!

* * *

Enormously Powerful,
Impossibly Small

* * *

Become A Success Story
What's a great way to see how nanoSLIM can work for you? Sign up for your chance at an endorsement contract.

c. nanoSLIM Website *(Ex. F, p. 2)*

* * *

nanoSLIM - World's Smallest Weight-Loss Solution

- Nano-Engineered for Rapid Absorption & Maximum Effectiveness
- Proven to Cause Faster, More Dramatic Weight-Loss

d. nanoSLIM Advertisement *(Ex. G)*

It's your tiny little secret for faster weight loss!

Lose weight faster . . .

* * *

In fact, in an 8-week study, subjects following a calorie-controlled diet lost an incredible 10.65 lbs. using just the key ingredient in nanoSLIM. Compare that to subjects following the same diet and using a placebo who lost only 5.87 lbs!
With nanoSLIM, you get the best of both worlds – accelerated weight loss and complete ease-of-use.

* * *

Lost 32 lbs. FAST
"I lost 32 pounds and I'm ecstatic. My ultimate goal is to compete in a figure contest so I am on my way now to being in that kind of shape."

- Rebecca Short

16. To induce consumers to purchase **Cold MD**, Defendants have disseminated, or caused to be disseminated, advertisements, including, but not limited to, the attached Exhibits H through M. Among other things, the advertisements contain the following statements or depictions:

a. Cold MD Packaging (*Ex. H*)

Front Panel
[Pictures of a woman blowing her nose into a tissue and a man with his eyes closed holding his head right above his nose at his sinuses]

* * *
Cold MD
Clinically Proven Immune System Support for
▹ 94% Faster Recovery
▹ Clinically Proven Results!

Increased Immune System Resistance by 312%

Back Panel

▹ **The All-in-One Solution**

* * *
Cold MD is an all-in-one formula that delivers clinically proven immune system support. In addition, by supporting your immune system, Cold MD helps you recover an average of 94% faster. In fact, in a rigorous double-blind clinical study reviewed by a medical doctor, the powerful immune system support effects of Cold MD were validated.

▹ **312% Increased Immune System Resistance**
Furthermore, the exclusive formula supports a strong immune system with clinically proven ingredients, which result in 312% greater immune system resistance.

* * *
For increased immune system support in crowded or congested locations, take 1 serving (2 caplets) before entering buses, offices, restaurants, schools, airplanes, trains, or public places.

Just 1 convenient serving a day of 2 non-drowsy EZ-swallow sweet-

coated caplets is all that's needed for ongoing clinically proven immune system support. Why continue to suffer unnecessarily? Cold MD is a clinically proven, all-in-one solution that works fast!

Side Panel

* * *

A clinical study was conducted on the key ingredient combination in Cold MD. Subjects were observed for 2 seasons. In this study, subjects

- Reduced the frequency of episodes by an average of 3.3 vs. 0.8 against placebo (312% greater resistance).

- Reduced the duration of episodes by an average of 3.3. days vs. 1.7 days against placebo (recover 94% faster).

b. Cold MD Advertisement to Retailers (*Ex. I*)

YOUR CUSTOMERS'
ULTIMATE
DEFENSE
Against
Colds & Flu!

[Photo of five individuals wearing white lab coats and stethoscopes. Below a caption reads:]
Meet the MDs in new Cold MD

Americans suffer from one billion colds annually, so it's no surprise millions of your customers will be looking to you for cold and flu protection this season. Fortunately these MDs have the solution.

* * *

Cold MD Provides Clinically Proven Immune System Support for:
- **Increased Resistance to Colds & Flu by 312%**
- **94% Faster Recovery from Colds & Flu**
- **Clinically Proven Results**
- **Maximum Support When Used Daily**

COLDMD: leading the FIGHT against
colds and flu across the nation!

c. Cold MD Advertisement (*Ex. J*)

NEW CLINICAL BREAKTHROUGH!
DOCTOR-FORMULATED & APPROVED

The ULTIMATE DEFENSE
Against Colds & Flu

* * *

New Cold MD is an immune system support formula that increases your immune system resistance by 312 percent and also helps you recover 94 percent faster if you do happen to catch a cold. With results like this, you won't ever want to be without Cold MD. What also makes Cold MD unique is its three lines of defense:

1) Use daily for maximum immune system protection;
2) For added protection, Cold MD can also be taken at the first sign of cold or flu, and additionally;
3) Use before entering crowded or congested areas such as airplanes, buses, offices, restaurants, schools, trains, or other public places where viruses linger for even more protection.

It's that easy! Get new Cold MD and start protecting yourself from colds and flu today!

* * *

Cold MD provides clinically proven immune system support:
✔ Increased Resistance to colds & flu by 312%
✔ 94% Faster Recovery from colds & flu
✔ Clinically Proven Results

d. Cold MD Advertisement (*Ex. K*)

312% GREATER PROTECTION AGAINST COLDS & FLU

[Picture of a man sneezing on another man who is surrounded by a bubble. The picture is on another graphic of floating germs. Under the picture, it reads:]
By taking Cold MD regularly, you increase your body's immune system defense by supporting its ability to quickly neutralize cold-causing viruses that enter your body. The result is enhanced protection against colds and flu.

* * *

✔ 1. Use daily for maximum support;
✔ 2. For added protection, take Cold MD at the first sign of a cold or flu, and;
✔ 3. Take before entering crowded or congested areas for even more

protection.

e. Cold MD Video Ad Storyboard (*Ex. L*)

[Split screen shots of man and woman sneezing into tissues.]
[LARGE SUPER:] Americans suffer 1 billion colds annually.
MALE ANNOUNCER: Americans suffer one billion colds annually. Only your immune system can destroy these viruses.
SUPER: National Institute of Allergy and Infectious Diseases.

[Two women and three men wearing white lab coats; one man also has a stethoscope around his neck.]
DOCTOR: A trusted team of medical doctors now has a way to fight back.

[Picture of Cold MD Box.]
DOCTOR: Introducing new Cold MD: the world's only immune support formula . . .
[Man sneezing on another man in an elevator. Circular germs and saliva leave the sneezing man in the direction of the other man who is surrounded by a bubble. The circular germs bounce off the bubble.]
[LARGE SUPER:] **312% More Resistance!**
DOCTOR: that increases your resistance to colds and flu by 312%.
SUPER: A clinical study of new ingredients reduced the frequency of episodes by an avg. of 3.3. vs. 0.8 against placebo

[Split screen of man and woman sneezing into tissues.]
[LARGE SUPER:] **Recover 94% Faster!**
DOCTOR: With Cold MD you can also recover an
SUPER: A clinical study of new ingredients reduced the duration of episodes by an avg. of 3.3. vs. 1.7 days against placebo

[Split screen of same man and woman who were sneezing previously, but man is smiling and woman is smiling and talking on the phone.]
DOCTOR: amazing 94% faster.
SUPER: A clinical study of new ingredients reduced the frequency of episodes by an avg. of 3.3. vs. 0.8 against placebo

[Same image of five individuals in white lab coats, including man with stethoscope around his neck.]
DOCTOR: We're the MDs in new Cold MD:
SUPER: Individuals have been remunerated.

[Picture of Cold MD Box.]
[LARGE SUPER:] **A Clinical Breakthrough!**
DOCTOR: your ultimate defense against colds and flu.

SUPER: These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease.

[Screen shots of Cold MD box with trademarks for various retailers including Wal Mart, CVS/pharmacy, Vitamin Shoppe, Kmart, and Albertsons.]
[LARGE SUPER:] **A Clinical Breakthrough!**
MALE ANNOUNCER: Get yours at coldmdhelp.com, Wal Mart, CVS and fine retailers everywhere.
SUPER: These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease.

f. Cold MD Website (*Ex. M*, p. 1)

COLD MD – THE ULTIMATE IMMUNE SYSTEM SUPPORT FORMULA

* * *

Cold MD is the world's only immune system support formula that:
- **Increases immune system resistance by 312 percent**
- **Helps you recover 94 percent faster**
- **Has clinically proven results**

* * *

New Cold MD is an immune system support formula that increases your resistance by 312 percent and helps you recover 94 percent faster. In fact, a clinical study on the key ingredient combination in Cold MD™ showed subjects reduced the frequency of episodes by an average of 3.3 vs. 0.8 against the placebo (312 percent greater resistance). In the same study, subjects reduced the duration of episodes by an average of 3.3 days vs. 1.7 days against the placebo (94 percent faster recovery).

17. To induce consumers to purchase **Germ MD EZ-Swallow Rapid-Tabs** and **Germ MD Effervescent Tablets**, Defendants have disseminated, or caused to be disseminated, advertisements, including, but not limited to, the attached Exhibits N through Q. Among other things, the advertisements contained the following statements or depictions:

a. Germ MD EZ-Swallow Rapid Tabs Packaging *(Ex. N)*

Front Panel:
[Several multicolored cartoon germs.]

GERM MD

* * *

Helps Support a Healthy Immune System

* * *

USE WHERE YOU NEED IT MOST:

✔ SCHOOLS	✔ AIRPLANES
✔ OFFICES	✔ SUBWAYS
✔ THEATERS	✔ RESTAURANTS
✔ MALLS	✔ HEALTH CLUBS
	✔ USE DAILY

* * *

Side Panel:

DIRECTIONS FOR USE
Take 1 serving (2 Rapid-Tabs) of Germ MD every day.
In Addition, GERM MD can also be taken:
Before entering crowded or congested locations, e.g., buses, offices, restaurants, schools, airplanes, trains or other public places.

Back Panel:
* * *

▹ **The Power of New Germ MD**
It is not possible to remove germs from your everyday life, but now you can be proactive with new Germ MD EZ-Swallow Rapid-Tabs! Germ MD is your number one immune defense.

b. Germ MD Effervescent Tablets Packaging (*Ex. O*); *see also* Germ MD Advertisement for Retailers (*Ex. P).*

Front Panel:
[Several multicolored cartoon germs.]

GERM MD

* * *

Helps Support a Healthy Immune System

* * *

USE IT WHERE YOU NEED IT MOST:
✔ SCHOOLS
✔ OFFICES

✔ THEATERS
✔ MALLS
✔ AIRPLANES
✔ RESTAURANTS
✔ HEALTH CLUBS
✔ USE DAILY

Side Panel:

DIRECTIONS FOR USE
Drop 2 Germ MD effervescent tablets (1 serving) of Germ MD in a serving of water, let dissolve, and then drink each morning. Take one additional serving later in the day, prior to entering crowded areas such as airplanes, schools, offices, or wherever you need it most.

Back Panel:

* * *

▹ **The Power of New Germ MD**
It is not possible to remove germs from your everyday life – but now you can be proactive with new Germ MD! Germ MD is your number one immune defense.

c. Website for Germ MD Product "Coming Soon" (*Ex. Q*)

[Several multicolored cartoon germs superimposed on different images, specifically, one of a cafeteria with people sitting, one of a crowded area with escalators and stairs, and one of a crowded subway station.]

GERM MD

* * *

Helps to support a healthy immune system

- Germ MD Helps Support a Healthy Immune System
- Medical-Doctor Formulated
- Research-Driven; Backed by Science

* * *

Use Daily Where You Need it Most:
✔ Schools ✔ Airplanes
✔ Offices ✔ Subways

✔ Theaters ✔ Restaurants
✔ Malls ✔ Health Clubs

"GermMD is scientifically formulated to help support your immune system so that you can be proactive."

Dr. Marvin Heuer, U.S. Licensed MD, FAAFP, MD
Scientific Advisory Board Member, Chief
Scientific Officer, Iomedix

18. To induce consumers to purchase **Allergy MD**, Defendants have disseminated, or caused to be disseminated, advertisements, including, but not limited to, the attached Exhibits R through V. Among other things, the advertisements contain the following statements or depictions:

a. Allergy MD Packaging (*Ex. R*)

Front Panel:

[Picture of a woman blowing the seeds off of a dandelion and the seeds blowing in the wind. Another picture of a man, woman, two children, and a dog lying outside in the grass.]

ALLERGY MD
Clinically Proven Immune System Support
▹ **FAST POWERFUL RESULTS WHEN YOU NEED IT!**

* * *

Back Panel:

[Photo of five individuals in white lab coats; three also have stethoscopes around their necks. A caption above the photo reads:]
The Medical Doctors (MDs) In Allergy MD

[A caption under the photo reads:]
MD Scientific Advisory Board (Medical Doctors left to right). . .

▹ **The All-in-One Solution**
Medical doctor formulated and approved **Allergy MD** is an all-in-one

formula with a clinically proven compound scientifically designed to support your immune system in a totally new and powerful way! Many of the other products on the market do not provide both fast and long-lasting effects . . . This is where Allergy MD is completely different. By providing fast, as well as extended immune system support, Allergy MD is non-drowsy, and has powerful effects that last throughout the day.

▹ **The Importance of the Immune System**
Allergy MD is so effective because its key compound promotes the suppression of a specific immuno-active group of molecules known as "leukotrienes". These leukotrienes mediate the immune system reaction in your body. When leukotrienes are elevated, your body manifests a variety of several undesired effects. Allergy MD provides an unprecedented level of immune system support and helps the body suppress the effects of the leukotrienes so you can be at your best.

▹ **Clinically Proven and Doctor Formulated**
Peer reviewed and published clinical research testifies to the power of the key compound in Allergy MD. In one key double-blind, placebo-controlled study, participants demonstrated significant improvements in combating the physiological effects of numerous episode types.

b. Combination Advertisement for Cholesterol MD, Allergy MD and Heartburn MD (*Ex. S*)

* * *
Peer reviewed published clinical research testifies to the power of the key compound in Allergy MD. In one key double-blind, placebo controlled study, participants demonstrated significant improvements in combating the physiological effects of numerous environmental challenges.

c. Advertisement for Allergy MD (*Ex. T*)

[Picture of dandelions with seeds and grass. In the foreground is a picture of the Allergy MD box with a picture of a woman blowing the seeds off a dandelion.]

* * *

The Science behind Allergy MD
With its dual-release formula, Allergy MD helps your body's own immune system to take on whatever Mother Nature blows your way. The key compound in Allergy MD promotes the suppression of leukotrienes, a group of molecules which mediate the immune system reaction in your body so you can rise above the seasonal and environmental challenges you

face.

d. Allergy MD Video Ad Storyboard (*Ex. U*)

[Five individuals wearing white lab coats and stethoscopes around their necks.]
[LARGE SUPER:] **100% Drug-Free Powerful Results**
DOCTOR: Get fast, powerful, long-lasting effects

[Close-up of Allergy MD package being held by individual in a white lab coat and stethoscope.]
DOCTOR: with new Allergy MD.

[3 panels: Allergy MD box spinning in a field of grass with dandelion seed flowers "whooshing" around.]
SOUND EFFECTS: [Panel 1] Whooshing In, [Panel 2] Spinning In, [Panel 3] Out.
[LARGE SUPER:] [Panels 1 & 2] **So Fast – Releases in Seconds!**
[LARGE SUPER:] [Panel 3] **So Powerful – Long Lasting Results!**
DOCTOR: It actually works to quickly support your immune system. So fast, the key ingredient gets released in seconds. So powerful, you can count on long-lasting results.
SUPER: Study participants demonstrated improvements in combating the physiological effects of numerous episode types. Results will vary.

[Allergy MD box with names of retailers (Supercenters and Walgreens) and MD Product website.]
[LARGE SUPER:] **100% Drug-Free Powerful Results**
MALE ANNOUNCER: Get yours at mdproducts.com and stores everywhere.
SUPER: These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

e. Allergy MD Website (*Ex. V, p. 1*)

* * *

Clinically Proven Immune System Support:
. . . New doctor-formulated and approved Allergy MD is a unique all-in-one formula with clinically proven compounds that have been scientifically developed to help support your immune system against seasonal and environmental challenges. . . . Allergy MD helps you overcome seasonal and environmental challenges quickly.

* * *
The Importance of the Immune System

Allergy MD is so effective because its key compound inhibits a specific immuno-active group of molecules known as leukotrienes. These leukotrienes mediate the immune system reaction in your body. When leukotrienes are elevated, your body manifests a variety of several undesired reactions as a result of environmental challenges. By inhibiting the immune-system activating effects of these leukotrienes, Allergy MD provides a level of immune system support so you can rise above the seasonal and environmental challenges you face.

f. Allergy MD Website (*Ex. V, p. 3*)

* * *

How does Allergy MD work with someone's immune system?

Answer: Allergy MD works with your body's immune system to help you fight back against seasonal and environmental challenges. . . .

19. To induce consumers to purchase **Allergy MD Rapid-Tabs**, Defendants have disseminated, or caused to be disseminated, advertisements, including, but not limited to, the attached Exhibits W and X. Among other things, the advertisements contain the following statements or depictions:

a. Allergy MD Rapid-Tabs Packaging (*Ex. W*)

Front Panel:

[Picture of a woman blowing her nose into a tissue. Another picture of flowers with pollen.]

▹ **NON-DROWSY**
▹ **INDOOR-OUTDOOR**
▹ **TRADITIONALLY USED FOR RELIEF FROM ALLERGY SYMPTOMS:**
✔ SNEEZING
✔ RUNNY NOSE
✔ ITCHY, WATERY EYES
✔ HAY FEVER
✔ NASAL CONGESTION

Back Panel:

* * *

▹ **Allergy MD is the All-in-One Homeopathic Solution**
When your allergies flare up, relief can't come fast enough. That's why we are proud to introduce new doctor-formulated homeopathic Allergy MD. Non-drowsy Allergy MD goes to work to relieve your most stubborn allergy symptoms so you can feel better faster!

b. Allergy MD Rapid-Tabs Website (*Ex. X, pp. 1 - 2*)

[Picture of a dandelions with seeds and grass. A man and a woman are standing in the grass smiling.]

* * *

NEW HOMEOPATHIC ALLERGY MD – JUST 1 PER DAY!
Medical doctor formulated Allergy MD uses 100% natural, active ingredients traditionally indicated in homeopathy to give you stimulant-free, non-drowsy, all-season relief from allergy symptoms such as sneezing, runny nose, hay fever, nasal congestion and itchy watery eyes.

* * *

[*Graphic: picture of a woman blowing her nose into a handkerchief or tissue*]

* * *

Allergy MD is Your All-In-One Solution For Allergy Relief!
Allergy MD is the first, all-season, multi-ingredient allergy product that is medical doctor formulated to address the important needs of allergy sufferers. It's a stimulant-free non-drowsy, indoor-outdoor allergy formula that fuses sound scientific architecture with 100% natural, active ingredients to alleviate the toughest allergy symptoms. Allergy MD is fast-acting, long-lasting and so effective that all you need is just 1 per day!

DEFENDANTS' VIOLATIONS OF THE FTC ACT

20. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce.

21. Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of

Section 12 of the FTC Act, 15 U.S.C. § 52, the Iovate Products are "foods" or "drugs" as "foods" and "drugs" are defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b) and (c).

COUNT ONE

False and Unsubstantiated Weight Loss Claims

22. Through the means described in Paragraphs 14 through 15, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits A through G, Defendants have represented, directly or indirectly, expressly or by implication, that:

a. Accelis causes users to lose substantial amounts of weight, including as much as one to two pounds per week;

b. Accelis is clinically proven to cause substantial weight loss;

c. nanoSLIM causes users to lose substantial amounts of weight, including as much as 32 pounds; and

d. nanoSLIM is clinically proven to cause substantial weight loss.

23. The representations set forth in Paragraph 22 are false or were not substantiated at the time the representations were made. Therefore, the making of the representations in Paragraph 22 constitutes a deceptive practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT TWO

False and Unsubstantiated Disease Prevention and Treatment Claims

24. Through the means described in Paragraph 16, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits H through M, Defendants have represented, expressly or by implication, that:

a. Cold MD increases resistance to colds and flu by 312%;

b. Cold MD reduces the duration of colds and flu by 94%;

c. Cold MD protects against colds and flu when taken before entering crowded places such as buses, offices, restaurants, schools, airplanes, or trains; and

d. Cold MD is clinically proven to reduce the frequency and duration of colds and flu.

25. Through the means described in Paragraph 17, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits N through Q, Defendants have represented, expressly or by implication, that:

a. Germ MD EZ-Swallow Rapid-Tabs and Germ MD Effervescent Tablets provide protection against cold and flu germs;

b. Germ MD EZ-Swallow Rapid-Tabs and Germ MD Effervescent Tablets prevent or reduce infection from cold and flu germs and the incidence of colds or flu; and

c. Scientific evidence demonstrates that Germ MD EZ-Swallow Rapid-Tabs and Germ MD Effervescent Tablets prevent or reduce infection from germs and the incidence of colds or flu.

26. Through the means described in Paragraph 18, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits R through V, Defendants have represented, expressly or by implication, that:

a. Allergy MD provides fast and long-lasting relief from seasonal and environmental allergies, including those caused by grasses and plants

whose pollen is spread by the wind; and

b. Allergy MD is clinically proven to provide relief from seasonal and environmental allergies.

27. Through the means described in Paragraph 19, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits W and X, Defendants have represented, expressly or by implication, that:

a. Allergy MD Rapid-Tabs provide relief from hay fever and all-season and environmental allergies, including symptoms such as sneezing, runny nose, itchy and watery eyes, and nasal congestion; and

b. Allergy MD Rapid-Tabs is a homeopathic product.

28. The representations set forth in Paragraphs 24 through 27 are false or were not substantiated at the time the representations were made. Therefore, the making of the representations in Paragraphs 24 through 27 constitutes a deceptive practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

CONSUMER INJURY

29. Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

30. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations

of any provision of law enforced by the FTC Act. The Court, in the exercise of its equitable jurisdiction, may award other ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

(a) Enter a permanent injunction to prevent future violations of the FTC Act by Defendants;

(b) Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and

(c) Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Dated:

Respectfully submitted,

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General Counsel

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ATTACHMENT B

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ATTORNEYS FOR PLAINTIFF
FEDERAL TRADE COMMISSION

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, Plaintiff, v. **IOVATE HEALTH SCIENCES USA, INC., et al.,** Defendants.

CASE NO. 10-CV-587

STIPULATED FINAL JUDGMENT AND ORDER FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed a Complaint for Permanent Injunction and Other Equitable Relief against corporations, Iovate Health Sciences USA, Inc., Iovate Health Sciences, Inc., and Iovate Health Sciences Group, Inc., n/k/a Kerr Investment Holding Corp., pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), alleging deceptive acts or practices and false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The Commission and Defendants have stipulated to the entry of this Order in settlement of the Commission's allegations against Defendants. The Court, having been presented with this Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief ("Order"), finds as follows:

FINDINGS

1. This Court has jurisdiction over the subject matter of this case and, pursuant to the Stipulation in Paragraph 4 below, jurisdiction over all parties. Venue in the United States District Court for the Western District of New York is proper.

2. The Complaint states a claim upon which relief can be granted, and the Commission has the authority to seek the relief it has requested.

3. The activities of Defendants, for purposes of this Order, are in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. The Commission and Defendants stipulate and agree to entry of this Order under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), without trial or final adjudication of any issue of fact or law. By entering into this stipulation, Defendants do not admit or deny any of the allegations set forth in the Complaint, other than jurisdictional facts, to which Defendants are stipulating only as to this action and subsequent actions arising from this action, including enforcement and modification of this Order.

5. Defendants waive all rights to seek judicial review or otherwise challenge or contest the validity of this Order. Defendants also waive any claim that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.

6. This action and the relief awarded herein are in addition to, and not in lieu of,

other remedies as may be provided by law.

7. Pursuant to Federal Rule of Civil Procedure 65(d), the provisions of this Order are binding upon Defendants, and their officers, agents, servants, representatives, employees, and all other persons or entities in active concert or participation with them, who receive actual notice of this Order by personal service or otherwise.

8. This Order reflects the negotiated agreement of the parties.

9. The parties shall jointly be deemed to be the drafters of this Order; the rule that any ambiguity in a contract shall be construed against the drafter of the contract shall not apply to this Order.

10. Nothing in this Order obviates the obligation of Defendants to comply with Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52.

11. The Commission's action against Defendants is an exercise of the Commission's police or regulatory power as a governmental unit.

12. The paragraphs of this Order shall be read as the necessary requirements of compliance and not as alternatives for compliance, and no paragraph serves to modify another paragraph unless expressly so stated.

13. Each party shall bear its own costs and attorneys' fees.

14. Entry of this Order is in the public interest.

ORDER

DEFINITIONS

Unless otherwise specified,

1. "Defendants" means Iovate Health Sciences USA, Inc., Iovate Health Sciences,

Inc., and Iovate Health Sciences Group, Inc., n/k/a Kerr Investment Holding Corp., and their successors and assigns.

2. "Iovate Products" means, collectively, Cold MD, Germ MD EZ-Swallow Rapid-Tabs, Germ MD Effervescent Tablets, Allergy MD, Allergy MD Rapid-Tabs, nanoSLIM, and Accelis.

3. "Commerce" means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. "Adequate and well-controlled human clinical study" means a human clinical study that is randomized, double-blind, placebo-controlled, and conducted by persons qualified by training and experience to conduct such study.

5. "Covered Product" means any dietary supplement, food, or drug, including, but not limited to, the Iovate Products.

6. "Essentially Equivalent Product" means 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 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.

7. "Endorsement" means as defined in 16 C.F.R. § 255.0(b).

8. "Food" and "drug" means as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

9. "Dietary supplement" means:

a. any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or

b. any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

10. The term "including" in this Order means "including without limitation."

11. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

PROHIBITED REPRESENTATIONS: DISEASE CLAIMS

IT IS HEREBY ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any drug or dietary supplement, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including

through the use of a product name, endorsement, depiction, or illustration, any representation that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that such product:

A. Reduces the risk, incidence, or frequency of colds or flu;

B. Prevents colds or flu;

C. Protects against colds or flu in crowded places;

D. Reduces the severity or duration of colds or flu;

E. Provides relief from hay fever; or

F. Provides relief (including fast or long-lasting relief) from seasonal, all-season, or environmental allergies;

unless the representation is non-misleading and such product: is subject to a final OTC drug monograph promulgated by the Food and Drug Administration (FDA) for such use, and conforms to the conditions of such use; remains covered by a tentative final OTC drug monograph for such use, and adopts the conditions of such use; or is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use.

II.

PROHIBITED REPRESENTATIONS: WEIGHT-LOSS CLAIMS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and

enjoined from making, or assisting others in making, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product:

A. Causes weight loss; or

B. Causes rapid weight loss;

unless the representation is non-misleading and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Section, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of the Covered 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. Defendants shall have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III.

PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including

through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under Sections I or II of this Order, about the health benefits, performance, or efficacy of any Covered Product, other than claims regarding bodybuilding and exercise performance (e.g., increased muscle mass or body mass, increased strength and power, improved weight training performance, increased work-out intensity, improved muscle endurance, or improved muscle recovery), unless the representation is non-misleading, and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

IV.

PROHIBITED REPRESENTATIONS REGARDING TESTS OR STUDIES

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of any product name or endorsement, the existence, contents, validity, results,

conclusions, or interpretations of any test or study, in connection with any representations covered by Sections I through III of this Order.

V.

PROHIBITED REPRESENTATIONS REGARDING HOMEOPATHIC DRUGS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product is a homeopathic drug unless:

A. Such product is recognized as such by the *Homeopathic Pharmacopoeia of the United States*; and

B. The representation is true and not misleading.

VI.

FDA APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order shall prohibit Defendants from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VII.

MONETARY JUDGMENT AND CONSUMER REDRESS

IT IS FURTHER ORDERED that:

A. Judgment is hereby entered in favor of the Commission and against Defendants in the amount of five million, five hundred thousand dollars ($5,500,000.00), which shall be paid to the Commission by electronic funds transfer within twenty (20) days of the date of entry of this Order and in accordance with instructions provided by the Commission.

B. In the event of default on any obligation to make payment under this Order, interest, computed pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for ten (10) calendar days beyond the date that payment is due, the entire amount shall immediately become due and payable. Defendants shall be jointly and severally liable for all payments required by this Subsection and any interest on such payments.

C. All funds paid to the Commission pursuant to this Order shall be deposited into an account administered by the Commission or its agents to be used for equitable relief, including, but not limited to, consumer redress, and any attendant expenses for the administration of such equitable relief. In the event that direct redress to consumers is wholly or partially impracticable or funds remain after the redress to consumers is completed, the Commission may apply any remaining funds for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any funds not used for such equitable relief shall be deposited in the United States Treasury as disgorgement. Defendants shall have no right to challenge the Commission's choice of remedies under this Part. Defendants shall have no right to contest the manner of distribution chosen by

the Commission. No portion of any payment under the judgment herein shall be deemed a payment of any fine, penalty, or punitive assessment.

D. Defendants relinquish all dominion, control, and title to the funds paid to the fullest extent permitted by law. Defendants shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise.

E. Defendants agree that the facts as alleged in the Complaint filed in this action shall be taken as true without further proof in any bankruptcy case or subsequent civil litigation pursued by the Commission to enforce its rights to any payment or money judgment pursuant to this Order, including, but not limited to, a nondischargeability complaint in any bankruptcy case. Defendants further stipulate and agree that the facts alleged in the Complaint establish all elements necessary to sustain an action pursuant to, and that this Order shall have collateral estoppel effect for purposes of, Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S. C. § 523(a)(2)(A). For all other purposes and with respect to all other parties, Defendants' stipulation in this Section shall have no effect. It is specifically agreed and acknowledged that this Section is not intended to be, nor shall it be, construed as an admission of liability by Defendants with respect to the allegations set forth in the Complaint with respect to any claims or demands by any third parties.

F. In accordance with 31 U.S.C. § 7701, Defendants are hereby required, unless they have done so already, to furnish to the Commission their taxpayer identifying numbers, which shall be used for the purposes of collecting and reporting on any delinquent amount arising out of Defendants' relationship with the government.

G. Proceedings instituted under this Part are in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law, including any other proceedings the Commission may initiate to enforce this Order.

VIII.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order.

A. Within ten (10) days of receipt of written notice from a representative of the Commission, Defendants shall submit additional written reports, which are true and accurate and sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and provide entry during normal business hours to any business location in Defendants' possession or direct or indirect control to inspect the business operation;

B. In addition, the Commission is authorized to use all other lawful means, including, but not limited to:

1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, 45 and 69; and

2. having its representatives pose as consumers and suppliers to Defendants, their employees, or any other entity managed or controlled in whole or in part by Defendants, without the necessity of identification or prior notice; and

C. Defendants shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

Provided however, that nothing in this Order shall limit the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

IX.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Order may be monitored:

A. For a period of three (3) years from the date of entry of this Order, Defendants shall notify the Commission in writing of any changes in the corporate structure of Defendants or any business entity that a Defendant directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this Order, including, but not limited to: incorporation or other organization; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; or a change in the business name or address, at least thirty (30) days prior to such change, *provided* that, with respect to any proposed change about which Defendants learn less that thirty (30) days prior to the date such action is to take place, the Commission shall be notified as soon as is practicable after obtaining such knowledge.

B. One hundred twenty (120) days after the date of entry of this Order and annually thereafter for a period of five (5) years, Defendants each shall provide a written report to the FTC, which is true and accurate and sworn to under penalty of perjury, setting forth in detail the

manner and form in which they have complied and are complying with this Order. This report shall include, but not be limited to:

1. A copy of each acknowledgment of receipt of this Order, obtained pursuant to the Section titled "Distribution of Order"; and

2. Any other changes required to be reported under Subsection A of this Section.

C. Defendants shall notify the Commission of the filing of a bankruptcy petition by any Defendant within fifteen (15) days of filing.

D. For the purposes of this Order, Defendants shall, unless otherwise directed by the Commission's authorized representatives, send by overnight courier all reports and notifications required by this Order to the Commission, to the following address:

Associate Director for Enforcement
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
RE: *FTC v. Iovate Health Sciences USA, Inc.,* Civil Action No._____

Provided that, in lieu of overnight courier, Defendants may send such reports or notifications by first-class mail, but only if Defendants contemporaneously send an electronic version of such report or notification to the Commission at: DEBrief@ftc.gov.

E. For purposes of the compliance reporting and monitoring required by this Order, the Commission is authorized to communicate directly with Defendants.

X.

RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of six (6) years from the date of entry of this Order, Defendants and any business of which any Defendant is a majority owner or otherwise directly or indirectly manages or controls the business, and their agents, employees, officers, corporations, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby restrained and enjoined from failing to create and retain the following records:

A. Accounting records that reflect the cost of products covered by Sections I through III of this Order sold, revenues generated, and the disbursement of such revenues;

B. Personnel records accurately reflecting: the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;

C. Customer files containing the names, addresses, phone numbers, dollar amounts paid, quantity of products covered by Sections I through III of this Order purchased, and description of products covered by Sections I through III of this Order purchased;

D. Complaints and refund requests relating to products covered by Sections I through III of this Order (whether received directly, indirectly, or through any third party) and any responses to those complaints or requests;

E. Copies of all advertisements, promotional materials, sales scripts, training materials, websites, or other marketing materials utilized in the advertising, marketing,

promotion, offering for sale, sale, or distribution, of products covered by Sections I through III of this Order;

F. All materials that were relied upon in making any representations contained in the materials identified in Subparagraph 5 above, including all documents evidencing or referring to the accuracy of any claim therein or to the benefits, performance, or efficacy of any products covered by Sections I through III of this Order, including, but not limited to, all tests, reports, studies, demonstrations, or other evidence that confirms, contradicts, qualifies, or calls into question the accuracy of any claim regarding the benefits, performance, or efficacy of any products covered by Sections I through III of this Order, including complaints and other communications with consumers or with governmental or consumer protection agencies;

G. Records accurately reflecting the name, address, and telephone number of each manufacturer or laboratory engaged in the development or creation of any testing obtained for the purpose of manufacturing, labeling, advertising, marketing, promoting, offering for sale, selling, or distributing any products covered by Sections I through III of this Order;

H. Copies of all contracts concerning the manufacturing, labeling, advertising, marketing, promotion, offering for sale, sale, or distribution of any products covered by Sections I through III of this Order; and

I. All records and documents necessary to demonstrate full compliance with each provision of this Order, including, but not limited to, copies of acknowledgments of receipt of this Order required by the Sections titled "Distribution of Order" and "Acknowledgment of

Receipt of Order" and all reports submitted to the FTC pursuant to the Section titled "Compliance Reporting."

XI.

DISTRIBUTION OF ORDER

IT IS FURTHER ORDERED that, for a period of three (3) years from the date of entry of this Order, Defendants shall deliver copies of the Order as directed below:

A. Defendants shall deliver a copy of this Order to: (1) each of its principals, officers, directors, and managers; (2) all of its employees, agents, and representatives who engage in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure set forth in Subsection A of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Order upon Defendant. For new personnel, delivery shall occur prior to their assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A of the Section titled "Compliance Reporting," delivery shall be at least ten (10) days prior to the change in structure.

B. Defendants shall secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery, from all persons receiving a copy of the Order pursuant to this Section.

XII.

ACKNOWLEDGMENT OF RECEIPT OF ORDER

IT IS FURTHER ORDERED that Defendants, within five (5) business days of receipt of this Order as entered by the Court, shall submit to the Commission a truthful sworn statement acknowledging receipt of this Order.

XIII.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED:

Dated: July 29, 2010

Richard J. Arcara
UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR THE FEDERAL TRADE COMMISSION:

THEODORE H. HOPPOCK
DEVIN W. DOMOND
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Attorneys for Plaintiff

FOR THE DEFENDANTS:

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By: KALMAN MAGYAR, Counsel

IOVATE HEALTH SCIENCES, INC.
By: KALMAN MAGYAR, Counsel

IOVATE HEALTH SCIENCES GROUP, N/K/A KERR INVESTMENT HOLDING CORP.
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Attorneys for Defendants

ATTACHMENT C

0923087

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

In the Matter of	)	
	)	**DOCKET NO.**
NESTLÉ HEALTHCARE NUTRITION, INC.,	)	
a corporation.	)	

COMPLAINT

The Federal Trade Commission, having reason to believe that Nestlé HealthCare Nutrition, Inc., a corporation ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Nestlé HealthCare Nutrition, Inc. is a Delaware corporation with its principal office or place of business at 12 Vreeland Road, Florham Park, New Jersey 07932-0697.

2. Respondent has labeled, advertised, promoted, offered for sale, sold, and distributed BOOST Kid Essentials to consumers.

3. BOOST Kid Essentials is a "food" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

4. The acts and practices of respondent, as alleged herein, have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

5. Respondent has disseminated or caused to be disseminated advertisements for BOOST Kid Essentials, including but not limited to the attached Exhibits A through E. These advertisements contain the following statements and depictions, among others:

A. **Television Advertisement**: "Straw Power" (Complaint Exhibits A1 (Storyboard) and A2 (Video))

(A girl pops into frame and takes a big enjoyable sip of Kid Essentials.)

Female Announcer: Introducing NEW Boost Kid Essentials, the only nutritionally complete drink that gives kids the power of immune strengthening probiotics.

ON SCREEN: *L. reuteri Protectis* has been clinically shown to help strengthen the immune system when consumed daily. For more information about clinical trials involving *L. reuteri Protectis*, go to www.kidessentials.com.

(The girl runs along playfully as the straw twirls around her. She encounters a boy who sneezes. The straw quickly forms a protective barrier around her. The girl continues on her way and as she approaches a basketball net, the straw forms stairs for her to step up on.)

ON SCREEN: muscle-building protein

Female Announcer: Plus the power to grow strong – with muscle-building protein and 25 vitamins and minerals.

(She takes a shot and hits a perfect swoosh.)

ON SCREEN: 25 vitamins & minerals

(Cut to straw popping back into drink box. The vortex of wellness swirls around the box, highlighting product attributes.)

ON SCREEN: Immunity strengthening probiotics/7 g protein/25 vitamins & minerals

Female Announcer: NEW Boost Kid Essentials: complete nutrition for your child's healthy growth, and probiotics clinically shown to help strengthen the immune system.

(The straw bends forwards, and probiotics titles emerge, followed by animated probiotic bubbles and a twirling arrow.)

ON SCREEN: Probiotic straw/Clinically shown to help strengthen the immune system

(Close up of the girl grabbing the drink box and enjoying another sip)

Female Announcer: And that means the power to do anything is possible every day.

(She finishes her sip, turns and skips out of frame.)

ON SCREEN: Boost Kid Essentials Nutritionally Complete Drink KidEssentials.com....

B. **Product Packaging** (Exhibit B)

Front Panel:

BOOST®

Kid Essentials

Nutritionally Complete Drink

Immunity Protection*

Patented PROBIOTIC straw

Nutritionally Complete Drink with PROBIOTICS to **Help Keep Kids Healthy...*

Side Panel:

Complete, Balanced Nutrition for Your Child's
Healthy Growth and **Strong Immune System**!
BOOST® Kid Essentials provides complete, balanced nutrition for kids 1-13. Only BOOST Kid Essentials has the vitamins and minerals kids need plus immune-supporting probiotics and antioxidants to help keep them healthy!...

Talk to your pediatrician about using BOOST Kid Essentials as a supplement with a meal or as a snack. To learn more about immunity, probiotics, and antioxidants, visit www.kidessentials.com...

C. **Internet Website www.kidessentials.com** (excerpt) (Exhibit C)

FAQ:

Q: What exactly do probiotics protect my kids from?

A: Probiotics are healthy bacteria that must be consumed in order to build up in our digestive system - in the lining of the GI tract. While they occur throughout nature, they are less likely to be present in large numbers in our own GI tract, and therefore need to be consumed to derive a benefit. They help balance and keep the levels of bad bacteria in check. Most importantly, they help keep our immune system healthy by increasing disease-fighting antibodies.[1,2]

References:
1. Tuohy KM *et al.* Using probiotics and prebiotics to improve gut health. *DDT* 2003;8(15):692-700.
2. Isolauri E *et al.* Probiotics: effects on immunity. *Am J Clin Nutr* 2001;73(suppl):440S-50S.

Q: Are probiotics effective against viruses?

A: Yes, certain probiotics have been shown to help fight viruses such as Rotaviral diarrhea.[1] *Lactobacillus reuteri Protectis* (the probiotic found in BOOST Kid Essentials Drink) has been shown to reduce the duration of diarrheal illness in children[3] and reduce the number of days that infants miss daycare due to illness.[2]

References:
1. Szajewska H *et al.* Probiotics in gastrointestinal diseases in children: hard and not-so-hard evidence of efficacy. *J Pediatr Gastroenterol Nutr* 2006;42 (5):454-75.
2. Weizman Z *et al.* Effect of a probiotic infant formula on infections in child care centers: comparison of two probiotic agents. *Pediatrics* 2005;115;5-9.
3. Shornikova AV *et al.* Bacteriotherapy with Lactobacillus reuteri in rotavirus gastroenteritis. *Pediatr Infect Dis J.* 1997;16:1103-7.

Q: Are probiotics safe for my young child?

A: Absolutely. The safety and efficacy of probiotic use has been documented for 100 years all around the world. Probiotic supplemented infant formula has been available for over 15 years, in over 30 countries. *Lactobacillus reuteri Protectis* specifically has been thoroughly tested in infants, children and adults and has shown to be safe and effective.

D. **Pamphlet Advertisement to Health Care Practitioners** (Exhibit D)

Front Cover:

The essential facts: a comparison of **BOOST® Kid Essentials Nutritionally Complete Drink** with probiotic immunity protection vs. **PediaSure®.*** ***Only* BOOST Kid Essentials Drink provides immune-supporting probiotics** in its patented straw to help keep kids healthy....

Inside Pamphlet:

....**The immunity support every kid needs.**
Only BOOST® Kids Essentials Nutritionally Complete Drink delivers ***immunity-supporting probiotics***. PediaSure® does not.
Clinical studies of *L. reuteri Protectis* showed the following:

***Faster* Resolution of Acute Diarrhea In Young Children**
[Depiction of a bar graph showing that 81% of patients in a control group had watery diarrhea compared with 26% of patients in the treatment group on day 2 of treatment]
Adapted from Shornikova *et al.*[1]

***Fewer* Absences Among Infants From Child Care**
[Depiction of a graph showing a 67% relative risk reduction of absences among infants from child care]
Adapted from Weizman *et al.*[2]

***Fewer* Days with Fever Among Infants**

[Depiction of a graph showing a 79% relative risk reduction of days of fever among infants]

Adapted from Weizman *et al.*[2]...

Back Cover:

Strong growth and immunity protection every child deserves....

Only BOOST Kid Essentials Drink's patented straw offers the immune support of the probiotic *L. reuteri Protectis*. Studies in *L. reuteri Protectis* demonstrate the ability to support the body's defenses, resulting in reduced sick days, fever, and the duration of diarrhea.[1,2]...

1. Shornikova A *et al. Lactobacillus reuteri* as a therapeutic agent in acute diarrhea in young children. *JPGN* 1997;24(4):399-404.
2. Weizman Z *et al.* Effect of a Probiotic Infant Formula on Infections in Child Care Centers: Comparison of Two Probiotic Agnes. *Pediatrics* 2005;115(1):5-9.

E. **People Magazine Advertisement** (Exhibit E)

First Page:

Do your kids
have the
power?

[Depiction of Boost Kid Essentials package with the probiotic straw, which reads:
NEW!
BOOST
Kid Essentials
Nutritionally Complete Drink
Immunity Protection*
Patented PROBIOTIC Straw
*Nutritionallly Complete Drink
with PROBIOTICS to Help
Keep Kids Healthy]

Second Page:

The power of immune-strengthening probiotics[1,2]

Probiotic straw to help keep kids healthy

[Depiction of the probiotic straw (continued from the previous page) forming a complete circle around a girl, while a boy sneezes in her direction]

1. Weizman Z et al. Effect of a Probiotic Infant Formula on Infection in Child Care Centers: Comparison of Two Probiotic Agents. *Pediatrics* 2005; 115(1) 5-9.
2. Shornikova AV et al. Lactobacillus reuteri as a therapeutic agent in acute diarrhea in young children. JPGN 1997;24(4);399-404.

Third Page:

The power to grow strong
25 vitamins & minerals
7g of muscle-building protein

[Depiction of the probiotic straw (continued from the previous page) forming stairs for the girl to climb, as she tosses a basketball into a basketball hoop]

Fourth Page:

The power
to do anything!
Every day.

NEW BOOST® Kid Essentials
Nutritionally Complete Drink:

- Immune-strengthening probiotics in the straw
- 25 vitamins & minerals + 7g of protein to support healthy growth
- Kid preferred taste vs. Pediasure®...

6. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through E, among others, respondent has represented, expressly or by implication, that drinking BOOST Kid Essentials:

A. Prevents upper respiratory tract infections in children;

B. Strengthens the immune system, thereby providing protection against cold and flu viruses; and

C. Reduces absences from daycare or school due to illness.

7. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through E, among others, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6 at the time the representations were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made. Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.

9. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A, C, and D, among others, respondent has represented, expressly or by implication, that clinical studies prove that drinking BOOST Kid Essentials:

A. Reduces the general incidence of illness in children, including upper respiratory tract infections;

B. Reduces the duration of acute diarrhea in children up to the age of thirteen; and

C. Strengthens the immune system, thereby providing protection against cold and flu viruses.

10. In truth and in fact, clinical studies do not prove that drinking BOOST Kid Essentials reduces the general incidence of illness in children, including upper respiratory tract infections, reduces the duration of acute diarrhea in children up to the age of thirteen, or strengthens the immune system, thereby providing protection against cold and flu viruses. Therefore, the representations set forth in Paragraph 9 were, and are, false or misleading.

11. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, this _____ day of _____, 2010, has issued this complaint against respondent.

By the Commission.

Donald S. Clark
Secretary

ATTACHMENT D

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	**FILE NO. 092 3087**
NESTLÉ HEALTHCARE NUTRITION, INC., a corporation.	)	**AGREEMENT CONTAINING CONSENT ORDER**

The Federal Trade Commission ("Commission") has conducted an investigation of certain acts and practices of Nestlé HealthCare Nutrition, Inc., a corporation ("proposed respondent"). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Nestlé HealthCare Nutrition, Inc., by its duly authorized officers, and counsel for the Federal Trade Commission that:

1. Proposed respondent Nestlé HealthCare Nutrition, Inc. ("Nestlé HCN") is a Delaware corporation with its principal office or place of business at 12 Vreeland Road, Florham Park, New Jersey 07932-0697.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.

3. Proposed respondent waives:

   a. Any further procedural steps;

   b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

   c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it will be publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time frame provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent's address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the draft complaint and consent order. Proposed respondent understands that it may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" means Nestlé HealthCare Nutrition, Inc., a corporation, its successors and assigns and their officers, and each of the above's agents, representatives, and employees.

2. "Commerce" means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. "Adequate and well-controlled human clinical study" means a human clinical study conducted by persons qualified by training and experience to conduct such study. Such study shall be randomized, and, unless it can be demonstrated that blinding or placebo control cannot be effectively or ethically implemented given the nature of the intervention, shall be double-blind and placebo-controlled.

4. "Covered product" means BOOST Kid Essentials, any drink product containing probiotics, or any nutritionally complete drink, other than infant formula, medical foods, and any

product not sold primarily through conventional retail channels.

5. "Essentially equivalent product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, flavors, preservatives, 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 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.

6. "Dosage" means the quantity of the substance taken in or absorbed over a specified, biologically relevant time period to achieve the intended effect.

7. The term "including" in this order means "without limitation."

8. The terms "and" and "or" in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that such product prevents or reduces the risk of upper respiratory tract infections, including, but not limited to, cold or flu viruses, unless the representation is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that such product:

A. Reduces the duration of acute diarrhea in children up to the age of thirteen; or

B. Reduces absences from daycare or school due to illness;

unless the representation is non-misleading and, at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that

substantiates that the representation is true. For purposes of this Part, competent and reliable scientific evidence shall consist of 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. Respondent shall have the burden of proving that a product satisfies the definition of essentially equivalent product.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, other than representations covered under Parts I or II of this order, about the health benefits, performance, or efficacy of any covered product, unless the representation is non-misleading, and, at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

IT IS FURTHER ORDERED that nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VI.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VII.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and other employees having primary responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent Nestlé HCN, and its successors and assigns, shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent Nestlé HCN, and its successors and assigns, learn less than thirty (30) days prior to the date such action is to take place, respondent Nestlé HCN, and its successors and assigns, shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall, within sixty (60) days after service of this order file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which respondent has complied with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports.

X.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and

the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this 18th day of May, 2010.

NESTLÉ HEALTHCARE NUTRITION, INC.

By: _____
KEVIN L. GOLDBERG, ESQUIRE
HEAD OF LEGAL
Nestlé HealthCare Nutrition, Inc.

_____
LEWIS ROSE, ESQUIRE
DANA ROSENFELD, ESQUIRE
KELLEY DRYE & WARREN LLP
3050 K STREET, NW
WASHINGTON, DC 20007
202-342-8400
Counsel for Nestlé HCN

_____
KAREN MANDEL
Counsel for the Federal Trade Commission

APPROVED:

_____
MARY K. ENGLE
Associate Director
Division of Advertising Practices

_____
DAVID C. VLADECK
Director
Bureau of Consumer Protection

ATTACHMENT E

81 F.T.C. 23, 1972 WL 127465 (F.T.C.)

FEDERAL TRADE COMMISSION (F.T.C.)

IN THE MATTER OF
PFIZER INC.

ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket 8819.

Complaint, July 6, 1970
Decision, July 11, 1972.

Order affirming the hearing examiner's initial decision dismissing the complaint against a New York City manufacturer of a nonprescription product recommended for use on minor burns and sunburn.

Opinion of the Commission resolves the general issue that the failure to possess a reasonable basis for affirmative product claims constitutes an unfair practice in violation of the Federal Trade Commission Act.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Pfizer Inc., a corporation, hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent Pfizer Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located at 235 East 42nd Street, in the city of New York, State of New York.

PAR. 2. Respondent is now, and for some time past has been engaged in the manufacturing, advertising, offering for sale, sale and distribution of a preparation for sunburn treatment called ‘Un-Burn’ and other proprietary drugs and products to retailers for resale to the public.

PAR. 3. In the course and conduct of its business as aforesaid, respondent now causes, and for some time past has caused, its said products, when sold, to be shipped from its plants and facilities to purchasers thereof located in various states other than the state of origination, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said products in commerce, as ‘commerce’ is defined in the Federal Trade Commission Act.

PAR. 4. In the course and conduct of its business as aforesaid, respondent has made and continues to make in print advertisements, including product packages and labels, and other promotional material and in television and radio broadcasts transmitted by television and radio stations located in various States of the United States and in the District of Columbia having sufficient power to carry such broadcasts across the state lines, numerous statements and repre-

sentations respecting the pain relieving properties of said product when used by persons suffering from sunburn.

Typical and illustrative of said statements and representations, but not all inclusive thereof, are the following:

In radio and television broadcasts:

1. New Un-Burn actually anesthetizes *nerves* in sensitive sunburned skin.

2. Un-Burn relieves pain *fast*. Actually *anesthetizes nerves* in sensitive sunburned skin.

3. Sensitive skin * * * Sunburned skin is sensitive skin. Sensitive sunburned skin needs * * * UN-BURN. New UN-BURN contains the same local anesthetic doctors often use. * * * Actually anesthetizes nerves in sensitive sunburned skin. I'll tell you what I like about UN-BURN. It's the best friend a blonde ever had! * * * I'm a blonde * * * and I know what it means to have sensitive skin. Why, I'm half afraid of moon burn! That's why I'm mad about UN-BURN. It stops sunburn pain in * * * less time than it takes me to slip out of my bikini. That's awfully nice to know when you're the sensitive type. * * *

On labels: 'UN-BURN' comprehensive treatment for 'sunburn' * * * relieves pain * * * anesthetic. * * *

PAR. 5. By making the above-quoted statements, and others similar thereto, but not expressly set forth herein, respondent represents, and has represented, directly or by implication, that each of the statements respecting the pain relieving properties of the said product has been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements.

PAR. 6. In truth and in fact, the aforesaid statements respecting the said product, 'Un-Burn,' have not been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements.

Therefore, the representation as set forth in Raragraph Five hereof was and is false, misleading and deceptive.

PAR. 7. The making of any statement or representation, directly or by implication, that Un-Burn will actually anesthetize nerves in sensitive sunburned skin, or any other statement or representation regarding the performance or effectiveness of such product, when such statement or representation is not supported by prior, fully documented, adequate and well-controlled scientific studies or tests is in itself an unfair practice.

PAR. 8. Respondent at all times mentioned herein has been and now is in substantial competition in commerce with individuals, firms and corporations engaged in the sale and distribution of sunburn remedies of the same general kind and nature as that sold by respondent.

PAR. 9. The use by respondent of the aforesaid misleading and deceptive statements, representations and practices has had, and now has, the capacity and tendency to mislead members of the purchasing public into the purchase of substantial quantities of respondent's product. As a result thereof, substantial trade has been and is being unfairly diverted to respondent from its competitors.

PAR. 10. The aforesaid acts and practices of respondent, as herein alleged, were and are all to the prejudice and injury of the public and of respondent's competitors and constituted, and now constitute, unfair methods of competition in commerce and unfair and deceptive acts and practices in commerce in violation of Section 5 of the Federal Trade Commission Act.

Mr. Edward F. Downs and *Mr. Stuart Lee Friedel* supporting the complaint.

Mr. Roy L. Reardon, Mr. William J. Manning, Mr. Melvyn L. Cantor, Mr. Charles E. Koob, of *Simpson Thacher & Bartlett*, New York, New York, and *Mr. Charles F. Hagen* for respondent.

INITIAL DECISION BY WALTER K. BENNETT, HEARING EXAMINER

APRIL 16, 1971

PRELIMINARY STATEMENT

This proceeding brought by the Federal Trade Commission by complaint filed July 15, 1970, charges respondent Pfizer Inc., with violation of Section 5 of the Federal Trade Commission Act. [FN1]

The alleged factual basis for the charge is two-fold: (1) that respondent has advertised and sold its sunburn remedy 'Un-Burn' in commerce without having made adequate and well-controlled tests prior to such advertising to determine the efficacy of the product to support the claim that it anesthetizes nerves in sensitive sunburned skin and stops pain fast and (2) that it falsely implied by its advertisements that it had conducted such adequate and well-controlled tests.

On August 5, 1970, the hearing examiner scheduled a prehearing conference for August 18, 1970, setting up the requirements that motions should be made returnable at such conference.

Prior to answer and by motion papers filed August 13, 1970, respondent sought a cancellation of the prehearing, a postponement of the time to answer and a motion to dismiss and to certify to the Commission

Argument on the motions, initially scheduled for August 25, 1970, was held September 21, 1970, and they were disposed of by written order filed the same day and not appealed. Among other matters, the order held that there was merely a matter of law involved, which should not be certified, and that the allegations of the complaint were adequate to require a full evidentiary hearing before the matter could be determined.

Respondent's answer filed October 6, 1970, admitted that it was incorporated and did business as alleged and had advertised the product 'Un-Burn' as charged although it denied that such advertising was typical or continuing. It denied its advertisements made the implications alleged and that it has knowledge or information that the claims had not been substantiated by adequate and well-controlled scientific studies or tests. Respondent admitted it was in competition with others but denied any violation of law or that its action had the effect of misleading the public. Then, the answer asserted six affirmative defenses in effect alleging: that respondent had not acted recklessly and in disregard of human health and safety; nor unreasonably; that the complaint was defective because it had not alleged the untruthfulness of respondent's advertising; that the claims were true; that the Commission had no authority to impose a requirement beyond the requirements of the Commissioner of the Food & Drug Administration; and that there was no public interest in continuing the proceeding because respondent had submitted an adequate and well-controlled test demonstrating that its claims for 'Un-Burn' were true.

On October 9, 1970, there was a prehearing conference primarily regarding the scheduling of proposed discovery and possible simplification of issues. The conference culminated in an order dictated on the record (Tr. 116–121). [FN2]

On November 16, 1970, respondents filed a motion under Rule 3.36 (b) for the issuance of a subpoena to the Commission. This was denied by order dated November 25, 1970. In the meantime, the parties had been attempting to define certain of the issues and by December 1, 1970, had reached an impasse on the issue of the meaning of 'adequate and well controlled scientific tests.' On December 1, 1970, respondents filed a motion to: (1) require complaint

counsel to define ‘adequate and well controlled;’ (2) secure reconsideration of the orders denying issuance of a subpoena to the Commission; (3) postpone trial.

A second prehearing conference was held December 3, 1970, to hear respondent's motion, it having proved impossible to meet the schedule proposed following the October 9, 1970, conference.

At the December 3rd conference, the meaning of adequate and well-controlled scientific tests was canvassed as well as the necessity for additional discovery. It was decided that the formal hearings would have to be postponed and respondent was given an opportunity to submit a new motion for a subpoena.

On December 14, 1970, following the submission of a new motion for a subpoena to the Commission, the undersigned issued an order calling for limited production of Commission documents at the formal hearings.

Further motions were made regarding scheduling due to the unavailability of the professional witnesses. A hearing in Miami, Florida and a postponement of a few days was accordingly ordered. (Orders dated January 13, 1971 and January 15, 1971.) In addition respondent made an informal suggestion concerning the order of proof, *i.e.*, that the issues of the implications from the advertising be first determined. This was rejected on the basis of complaint counsel's objection.

Hearings commenced January 20, 1971, in Washington, D.C. and concluded February 22, 1971. One witness was heard in Miami, Florida by consent of both parties and because of his inability to be present in Washington, D.C. There were also brief adjournments of the sort customary in judicial proceedings to meet the convenience of the expert professional witnesses taken by consent.

Counsel were most cooperative in production and authentication of documents, in the prelisting of witnesses and in the submission in advance of *curricula vitae* of the experts. Four expert witnesses were called by counsel supporting the complaint and over 70 exhibits were offered. Respondents called three officials and six experts and marked over 100 exhibits. Complaint counsel recalled one expert on rebuttal.

After the conclusion of complaint counsel's case-in-chief respondent moved to dismiss. [FN3] The hearing examiner then reserved decision (Tr. 809, 814–826). Respondent's motion to dismiss at the conclusion of complaint counsel's case is now denied because at the time of that motion all inferences favorable to complaint counsel had to be drawn and the evidence offered by respondent had to be disregarded.

BASIS OF DECISION

This decision is based on the entire record, including the proposed findings and conclusions of the parties. All findings of fact not expressly, or in substance, adopted are denied as erroneous, immaterial or irrelevant. in accordance with Rule 3.51(b), references are made to the specific pages of the principal supporting items of evidence in the record. The citations to the principal supporting portions of the record, however, are not intended to exclude other portions of the record, all of which have been carefully considered in light of the demeanor of the witnesses and their consistency or inconsistency with contemporaneously written documents.

We now set forth our findings of facts, conclusions and proposed order. In the interest of convenience, we first dispose of those findings which are admitted by answer before proceeding to contested ones.

FINDINGS OF FACT

The following findings are based on admissions in the answer.

A. *Admitted Findings*

1. Respondent Pfizer Inc. (sometimes referred to herein as Pfizer), is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located at 235 East 42nd Street, in the city of New York, State of New York (C1, A1; CPF 1; RPF 1.2).

2. Respondent is now, and for some time past, has been engaged in the manufacturing, advertising, offering for sale, sale and distribution of 'Un-Burn,' which is recommended for use in connection with minor burns, including sunburn, and further has been engaged in the manufacturing, advertising, offering for sale, sale and distribution of other proprietary drugs and products to retailers for resale to the public (C2, A2; see CPF 2).

3. In the course and conduct of its business as aforesaid, respondent now causes, and for some time past has caused, its said products, when sold, to be shipped from its plants and facilities to purchasers thereof located in various states other than the state of origination, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said products in commerce, as 'commerce' is defined in the Federal Trade Commission Act (C3, A3; CPF 3; see RPF 1.3).

4. In the course and conduct of its business as aforesaid, respondent has made in print advertisements, including product packages and labels, and other promotional material and in television and radio broadcasts transmitted by television and radio stations located in various States of the United States and in the District of Columbia having sufficient power to carry such broadcasts across the state lines, numerous statements and representations respecting the pain relieving properties of said product when used by persons suffering from sunburn.

Some of said statements and representations, but not all inclusive thereof, are the following:

In radio and television broadcasts:

a. New Un-Burn actually anesthetizes *nerves* in sensitive sunburned skin.

b. Un-Burn relieves pain *fast*. Actually *anesthetizes nerves* in sensitive sunburned skin.

c. Sensitive skin * * * Sunburned skin is sensitive skin. Sensitive sunburned skin needs * * * UN-BURN. New UN-BURN contains the same local anesthetic doctors often use. * * * Actually anesthetizes nerves in sensitive sunburned skin. I'll tell you what I like about UN-BURN. It's the best friend a blonde ever had! * * * I'm a blonde * * * and I know what it means to have sensitive skin. Why, I'm half afraid of moon burn! That's why I'm mad about UN-BURN. It stops sunburn pain in * * * less time than it takes me to slip out of my bikini. That's awfully nice to know when you're the sensitive type * * *

On labels: [UN-BURN' comprehensive treatment for [FN4] 'sunburn' * * * relieves lieves pain * * * anesthetic. * * * (C4, A4; see CPF 4).

5. Respondent at all times mentioned herein has been and now is in substantial competition in commerce with individuals, firms and corporations engaged in the sale and distribution of sunburn remedies of the same general kind and nature as that sold by respondent (C8, A8; CPF 10).

B. *Contested Findings*

The following findings are based on the hearing examiner's evaluation of the evidence:

No Implication of Tests from Advertising

6. On the basis of all of the evidence offered with respect to the advertising of the product Un-Burn and having carefully observed the pictures and sound reproduced from T.V. advertising (CX 1–13) it has not been established to the satisfaction of the hearing examiner that respondent has represented directly or by implication, that each of the statements respecting the pain relieving properties of the said product had been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements. While the hearing examiner

does not consider himself bound in any way by the expert testimony of Dr. Joseph G. Smith, a psychologist called by respondent, Dr. Smith's analysis (see Tr. 752 *et seq.*) was both lucid and convincing on the issue of the lack of implication from the advertising matter that 'adequate and well-controlled scientific tests' had been conducted prior to issuance of the advertising material (Tr. 729–798, particularly 752–762, 795–796, 797–798). Moreover, quite apart from Dr. Smith's testimony, the hearing examiner perceived no such representations or implications from the advertising materials either viewed one by one or considered as a whole. In addition Mr. Ross the (CX 1–13) president of the Leeming Division of Pfizer said he had reviewed consumer reaction and there was none to that effect (Tr. 615–617; see RPF III). The most the advertising implied was that the product could work as represented.

Development of Un-Burn

7. As described by Henry L. Ross, Jr., president of the Leeming Division of Pfizer, the concept of the product Un-Burn was first presented to Pfizer by an advertising agency in the form of a package with a design and the name 'Un-Burn' (Tr. 597). Thereafter, a decision was made to develop a product in the sunburn remedy field that would use the name and design suggested (Tr. 598). The company took a careful look at the products on the market in that category and particularly the product Solarcaine (Tr. 599). The company decided to go ahead because a profitable product seemed feasible and it would fulfill a need for a product to be sold principally during the summer which was a slack season for Pfizer (Tr. 599). Mr. Ross approved the use of the topical anesthetics benzocaine and menthol after receiving assurances from the medical people that the advertising claims could be supported by these two active ingredients at the level selected to put into the product (which was patterned closely after Solarcaine the market leader (Tr. 600)), and that all available literature had been thoroughly reviewed and favorable conclusions had been reached on their efficacy as a topical anesthetic (Tr. 600–601).

8. The parties have stipulated that if appropriate named individuals were called from named competing companies they would testify that the following products containing benzocaine had been on the market since the date set opposite the name and that the product was recommended for the treatment also set opposite the name.

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

(Stipulation 2/10/71; Tr. 1136–1138; RPF 2.8.)

9. James W. Jenkins, vice president in charge of the research and development sections of Pfizer-Leeming/Pacquin Divisions, (Tr. 647) testified concerning the formulation of the product Un-Burn by his division and the extent of research and testing done (Tr. 644–727). One of the first things done was to make a drugstore survey of the products already on the market (Tr. 648). These included: Dermoplast, Surfacaine, Pontocaine, Mediquik, Bactine, Lanacane, Campho Phenique, Johnson and Johnson First Aid Spray, Johnson and Johnson First Aid Cream, Safeguard, Solarcaine Spray, Solarcaine Lotion, Unguentine Spray, Unguentine Ointment and Nupercainal (Tr. 649; RPF 2.9). He found that benzocaine and menthol were prominently used in these products and that the marketing people regarded Solarcaine as the market leader (Tr. 649). Initially Pfizer had contemplated producing a 'cosmetically elegant' product to compete with Johnson's First Aid Cream and Noxzema. This contained benzol alcohol and menthol as active ingredients for the anesthetic effect (Tr. 650). A cream using these ingredients was developed in the spring of 1966 and tested in a very small test on the beach that summer (Tr. 651). In the fall of 1966, however, the marketing group determined that an aerosol caine product should be produced with benzocaine and menthol as the active ingredients (Tr. 651). These active ingredients were later incorporated in the cream and in a lotion so that by the time in the summer of 1969 that the product was distributed nationally, benzocaine and menthol were the active ingredients in all Un-Burn products (Tr. 653). Benzocaine was selected because of the drugstore survey and because of a literature search that 'told us that it was an efective and safe and esthetic ingredient to be used in this type of product.' Further it was discussed with Dr. Carlozzi of the Pfizer medical staff (Tr. 652). Menthol, also used, was chosen because it was reported in medical literature as a local anesthetic and antipruritic (a product to stop itching (Tr. 652)).

Tests Conducted on Un-Burn Prior to Marketing

10. Marketing tests to determine acceptability by consumers were made in 1967, in the fall of 1968, and in the winter of 1968–69 in Florida (Tr. 653–654). In addition under Dr. Jenkins' supervision considerable safety testing was done on animals, a prophetic patch test was done on humans and there was testing with human serum of the antiseptic qualities of the product. A test was also conducted by injecting guinea pigs to determine whether any ingredient of the Un-Burn base interfered with the anesthetic action of the benzocaine (Tr. 655; CX 16–67.) Tests were conducted on the formulations leading up to the final product as well as on the final formulation (Tr. 656). Those on the final formulation included: a report on tests by an independent laboratory as to the anti-bacterial effectiveness of the lotion, aerosol and cream with human serum (Tr. 651–659; CX 48, 51, 61); two reports of guinea pig wheal tests on the aerosol and lotion (Tr. 657; CX 40, 50); three skin irritation tests on rabbits for the lotion, aerosol and cream (CX 52, 53, 67; Tr. 662–663); Draize Eye irritation tests conducted on rabbits with the aerosol (CX 54), the lotion (CX 55) and the cream (CX 66; Tr. 657); and prophetic patch tests on 100 human subjects to determine whether the ingredients were capable of producing primary irritation or sensitivity of the skin (CX 56; Tr. 657, 666–667). After describing the tests Dr. Jenkins (Tr. 659–667) testified that in his opinion they were adequate and well-controlled scientific tests demonstrating that there was no safety hazard in the use of the product and that it would support the claim of anti-oacterial activity (Tr. 668; RPF 4.8). With respect to the efficacy of the ingredients benzocaine and menthol, Dr. Jenkins said he caused a survey to be made of the Pfizer library on references to benzocaine and menthol, that he reviewed the literature surveyed, discussed the matter with the medical director of Pfizer, and reached the conclusion that the tests made and historical information reviewed establish the safety and efficacy of the product (Tr. 672–673). Dr. Michael Carlozzi, the medical director of Pfizer, corroborated Dr. Jenkins and expressed the opinion that the literature reviewed and the clinical experience of the medical profession justified Pfizer's reliance upon such sources for the efficacy of benzocaine and menthol rather than conducting unnecessary efficacy tests (Tr. 1097–1099, 1125–1126). He also pointed out that as part of the guidelines for panels on drug efficacy (RX 110; Tr. 1106–1108) the experience and informed judgment of the members of the panel were part of the criteria to be considered (Tr. 1108–1109, 1119–1122).

Government Criticism of Adequacy of Pfizer Tests

11. Counsel supporting the complaint as part of their case offered all of the tests performed by Pfizer (CX 16–69) and also the advertising and labeling used (CX 1–16). Then they attacked the adequacy of the testing for efficacy by calling their 4 expert witnesses.

12. The first Commission witness, Dr. Harry M. Robinson, Jr. (Tr. 223–285) is a practicing physician in Baltimore and a professor of dermatology with thirty years experience in the field. [FN5] He is also an expert in testing drugs and evaluating tests (Tr. 225, 238). He had not however done specialized research in the field of topical anesthetics or sunburn (Tr. 230) and had done no adequate and well-controlled scientific studies on benzocaine or menthol or any other sunburn preparation (Tr. 236).

13. Over objection by counsel for respondent Dr. Robinson testified that he had examined the tests done by Pfizer (CX 16 thru 68) and that in his opinion the tests conducted were not adequate to prove that: Un-Burn anesthetizes nerves in sensitive sunburned skin; relieves sunburn fast; stops sunburn pain; is a comprehensive treatment for sunburn; is an anesthetic when used on sunburned skin; is so effective in relieving sunburn pain that persons with sensitive skin such as a fair-skinned blonde girl need not fear or worry about being exposed to the sun (Tr. 240–241).

14. Dr. Robinson was then asked (Tr. 241–270) concerning each of the tests (CX 16–68) made by respondent (despite the objection that some were on earlier formulations (Tr. 242–245)). As to each, he responded that they were not adequate to establish that Un-Burn anesthetized nerves in sensitive suburned skin but (except for the consumer research study (CX 68)) were all safety tests. The consumer research study was not adequate because it was not controlled (Tr. 269–270). As clarified on cross examination the tests were of five types: skin irritation, eye irritation, antibacterial, prophetic patch and guinea pig wheal tests (Tr. 271). They were largely safety tests to determine whether

the product to be marketed is safe (Tr. 273) and the testing done was sound (Tr. 273) and adequate for the purpose of showing that there was no hypersensitivity produced in humans, and no eye irritation or skin irritation in animals (Tr. 271–278). One type of test to determine anesthesia in animals was inadequate because not topically applied but injected (Tr. 250, 255, 259, 265–266). Another type of test having to do with consumer reaction (Tr. 269) Dr. Robinson dismissed as inadequate because pain is subjective and mere yes and no answer was insufficient to determine the anesthetic quality of anything (Tr. 269–270). He suggested a polygraph test might be required (Tr. 270) but on cross examination he stated he had never seen a polygraph used on tests regarding sunburn (Tr. 279). He also indicated that a single blind study was worthless (Tr. 280).

15. On the basis of Dr. Robinson's testimony and before the next witness took the stand, the parties stipulated (Tr. 288) that the witness's testimony would be that the tests described in the following exhibits were not designed to prove that Un-Burn anesthetizes nerves or relieves the pain of sunburn (CX 16–23, 25–38, 41–49, 51–56, 59–69, all numbers being inclusive) and that accordingly these exhibits did not establish those facts. [FN6] Identical stipulations were made as to the other two witnesses called by counsel supporting the complaint (Tr. 318, 501). [FN7]

16. The second Commission witness, Dr. John Adriani, (Tr. 289–313) is a specialist in surgery, anesthesiology, and pharmacology. He is chief of the anesthesia services of Charity Hospital in New Orleans, Louisiana, and is also professor in both Tulane University School of Medicine and Louisiana State School of Medicine (Tr. 290–291). He was for four years Chairman of the Advisory Committee of the United States Food and Drug Administration on Anesthetics and Respiratory Drugs (Tr. 292) and was also a member of the Committee of the Secretary of the United States Department of Health, Education and Welfare on the Evaluation of the Task Force Report on Prescription Drugs (Tr. 292–293). He does laboratory testing in the pharmacology department laboratory at Louisiana State University and performs climcal pharmacology testing at Charity Hospital (Tr. 291). He acts as consultant to the Food and Drug Administration's Bureau of Medicine. And, he has done extensive editing and publication of medical journal articles and texts (Tr. 294). [FN8] Dr. Adriani has been testing drugs including local anesthetics for some 35 years (Tr. 296).

17. Dr. Adriani said he was familiar with the ingredients in Un-Burn and that he had tested products which had some or all of such ingredients (Tr. 295–298). He said animal tests would have to be followed by tests on humans because animal studies in relief of sunburn were not adequate (Tr. 298). He stated he had examined Commission Exhibits 24, 39, 40, 50, 57 and 58 (Tr. 300, 301). He was shown the T.V. program CX 4 (Tr. 303–304) via projector equipped with sound and testified that the testing ‘positively’ did not support the claims in the advertising (Tr. 308) because the product was sprayed on the subject in the movie and injected in the tests (Tr. 308) and that the injection has no ‘correlation at all’ with the topical (sprayed on) application (Tr. 310). He then testified as to each test that it did not substantiate the claims (Tr. 311–312). Moreover, none was reasonably designed to prove and did not prove that Un-Burn when used topically will anesthetize nerves in sunburned skin or relieve sunburn pain (Tr. 312). There was no cross examination (Tr. 313).

18. The Commission's third witness was Dr. William Thomas Beaver (Tr. 318–373). Dr. Beaver is a Clinical Pharmacologist, and as such specializes in the effects of drugs in living systems (Tr. 319). He is also a Doctor of Medicine and is Associate Professor in Georgetown University where he teaches medical students and staff and does research. His major area of interest is pain relieving drugs and the design of experiments demonstrating the efficacy of drugs in man (Tr. 320). [FN9] From 1963 to 1967 he was a research associate at Sloan-Kettering Institute for Cancer Research and was almost exclusively involved in doing drug studies in analgesics. He was also a member of the National Academy of Science, National Research Council panel on relief of pain, drug efficacy study (Tr. 320) which was one of those engaged in the review of drugs for efficacy under the auspices of the Food and Drug Administration (Tr. 320–323). He acts also as consultant to the Food and Drug Administration (Tr. 324) and has had experience in designing and reviewing protocols for tests (Tr. 325).

19. Dr. Beaver after reading the T.V. storyboard (CX 11) was asked concerning the tests described in CX 25, 39, 40, 50, 57, and 58. Before testifying on these he was subjected to an extensive voir dire examination attempting to determine just what standards he used in evaluating the tests *i.e.*, those of the F.D.A. or those of the dictionary definition

of adequate and well-controlled (Tr. 328–341). He was guided according to his testimony by general principles accepted by the community of clinical pharmacologists that at the moment coincided with the F.D.A. principles (Tr. 330). Dr. Beaver then testified that the tests did not substantiate the claims in the advertising because: (1) the study was on animals and could not be extrapolated with any degree of confidence to human beings; (2) the study deals with interdernal injection and could have a totally different result from topical application; (3) he could not be sure of the identity of the material tested with Un-Burn (Tr. 343–345). He then described what in his opinion would be an adequate test (Tr. 351–356). This included: (1) use of human subjects; (2) production of the sunburned condition; (3) comparison with a placebo of essentially the same formulation without the anesthetic, applied at random; (4) development of a standard for the amount of sunburn; (5) use of double blind approach so that neither the subject or the tester could identify which was the active product and which the placebo; (6) reading on the pain on stimulation or at rest over a time period; (7) adequate number of subjects; (8) calculation to determine that differences in recorded scores was not due to chance (Tr. 351–356). A motion was made to strike this testimony because it was based on the FDA standard. This was denied on the basis of a voir dire examination (Tr. 356–367). On cross examination Dr. Beaver testified that on panels of National Academy of Sciences and the National Research Council, some panels accepted the informed judgment of the panel members as to the effectiveness of drugs (Tr. 372). On the panel on which he served, the panel members insisted upon studies although in some cases they assumed the adequacy of the test reported when the documentation was not entirely clear (Tr. 369–371). A motion to strike Dr. Beaver's testimony was denied because in the hearing examiner's opinion Dr. Beaver's description of the tests required came within the dictionary definition of adequate and well-controlled (Tr. 374).

20. Dr. Harvey Blank was the final expert called by the Commission. He is a Doctor of Medicine and specializes in dermatology (Tr. 502–592). He is a professor and chairman of the department of dermatology of the University of Miami School of Medicine (Tr. 502). [FN10] Previously he had been associate medical director of Squibb Institute of Medical Research and it was his duty to help in the development of products, to set up and evaluate tests, and to advise Squibb Pharmaceutical Company (Tr. 503–504). He is experienced in testing drugs and evaluating tests and has tested preparations recommended for sunburn pain (Tr. 505). He was chairman of the panel of the drug efficacy study of the National Research Council for the Food and Drug Administration to evaluate drugs for use on the skin (Tr. 506).

He described preliminarily the types of tests, agreed that testing on human beings was necessary because of the difference between animal skin and human skin and indicated that in skin preparations for the relief of itching, for example, many ingredients had a soothing effect and care must be taken to determine whether the active or anesthetic ingredients do more than the product without the active ingredients (Tr. 509, 510).

21. Dr. Blank then compared the claims made by the TV commercial (CX 10) with the tests described in Commission Exhibit 24. After an extensive voir dire examination (Tr. 511–522) in which Dr. Blank indicated he utilized the FDA standard plus some other considerations in making his evaluation, he testified that the test described in CX 24 did not substantiate the TV claims because of the following principal reasons: first, the product was injected and not administered topically and second, you cannot transfer studies on a guinea pig to man without confirmation. He also said the same objections applied to the tests described in CX 24, 39, 40, 50, 57, and 58 (Tr. 522–523). With regard to the reason why there is a difference between injection and topical application Dr. Blank explained that the skin was a barrier that most agents do not penetrate in any substantial amount and therefore in testing drugs to be applied to the skin you have to know whether the product will go through the skin (Tr. 524–526).

22. On cross examination Dr. Blank refused to state whether the panel he chaired had exercised the right to rely on the experience of the panel members in approving drugs for efficacy because the panel report had not been released (Tr. 530). The hearing examiner upheld this refusal (Tr. 537, 548). The doctor said that in preliminary discussions the panel chairmen were informed they had that right to utilize previous experience rather than insisting upon adequate and well-controlled scientific tests (Tr. 535). There was also an attempt to have the report of the panel produced. The hearing examiner ruled that this must be done by motion for a subpoena to the Department of Health, Education and Welfare (Tr. 555). It was then brought out that the witness had refused to talk with counsel for respondent because he was given very short notice at an inconvenient time (Tr. 558). His folder of papers to which he referred during his

direct testimony was examined by the hearing examiner and ordered produced (with the exception of one document which dealt with another company and with enzymes (Tr. 559–562)). After examining the file respondent offered a report submitted in April 1959 under the witness' administrative supervision (Tr. 563). This is marked RX 99A-K and is an unpublished report to Plough Inc., regarding the product Solarcaine with correspondence relating thereto. The University of Miami was paid a fee for the study (Tr. 568). The documents were received in evidence (Tr. 570). It was established that in 1959, Dr. Blank approved a letter and report attesting to the efficacy of Solarcaine, a Benzocaine product (RX 99F). (It will be recalled that Solarcaine was one of the products Un-Burn was developed to compete with and to emulate (Tr. 599)).

23. On redirect examination Dr. Blank indicated that he thought the results which had been obtained were from the use of an occlusive patch (Tr. 575) placed over the lotion because of lack of action without it (Tr. 573).

24. On recross, although Dr. Blank reiterated that a patch had to be used to get the anesthesia (Tr. 576), he said he did not tell Plough Inc., that they were going to have to tell people to use patches on top of the lotion when they used it (Tr. 576) and he admitted that he had written Plough that their product ‘had a distinct pain relief, cooling and soothing properties which relieved the discomfort of minor sunburn and other minor burns and such localized sensations as itching, tingling, and so on.’ (Tr. 577.) He also admitted there was nothing in his letter which told Plough the product had to be applied with the aid of a patch (Tr. 577–578) and further admitted that the test he used (RX 99 A-E) was not adequate by present standards (Tr. 579). He testified, however, that the test had no relevance to Un-Burn (Tr. 580). He then testified that he and his associates had tested Un-Burn spray and cream in the past four or five months but that he had not published the result of the test or reduced it to writing in any form (Tr. 580). With regard to the Plough product (Solarcaine) he found ‘down [sic] at that time’ that the product ‘containing benzocaine was effective on normal skin and produced an effect in fifteen minutes' and advised Plough ‘that the products worked’ knowing that Plough was going to sell the product to the public (Tr. 581–582). On further redirect examination, Dr. Blank said that he and his associates had tested Un-Burn by techniques now used for anesthesia of the skin, *i.e.*, instead of pricking the skin with a needle which allowed the lotion to penetrate the skin barrier they were now using a hot beam of light to determine whether or not anesthesia is produced (Tr. 583). On tests he conducted on Un-Burn he testified ‘that even after one hour of application it was impossible to detect any anesthesia with Un-Burn’ (Tr. 585). On recross, Dr. Blank admitted that he had known he was to testify (Tr. 585) and had told counsel supporting the complaint about the tests which had been conducted on associates (Tr. 586–587). He further admitted that the test was preliminary and that he did not consider it to be an adequate and well-controlled scientific study and test of the efficacy of Un-Burn (Tr. 588). The test was made only on three people repeated many times but ‘we got no effect so we didn't go on’ (Tr. 589). The three subjects performed the test on themselves (Tr. 590) and there was no written protocol or written result (Tr. 591). Dr. Blank did not tell Plough Inc., at any time that he had modified his conclusions expressed in the report sent to it (Tr. 592). Although invited to make a further statement the witness indicated that he did not feel in necessary to do so (Tr. 592).

Summary Finding on Evidence Introduced in Complaint Counsel's Case-in-Chief

25. At the conclusion of complaint counsel's case-in-chief it had been established that respondent Pfizer Inc., had advertised, on TV and in other media with interstate coverage, that Un-Burn anesthetizes nerves in sensitive sun-burned skin and relieves pain fast. It was also established *prima facie* from the testimony of the experts called that the tests conducted by Pfizer prior to marketing were not adequate to determine the efficacy of the product on human beings but merely determined its safety and its efficacy as an antibacterial agent.

There was inconclusive evidence concerning the efficacy of the product apart from the adequacy of the tests. And, evidence that on undamaged skin a topical anesthetic would not penetrate to the nerve endings.

It was conceded that the product was sold in interstate commerce and that it was in competition with other products produced by others.

Findings Relating to Respondent's Affirmative Defenses

We shall now consider the facts relating to respondent's six affirmative defenses under the following three headings: *No Recklessness or Disregard of Safety; Truth of Respondent's Advertising Claims; Propriety of Reliance on Historical and Clinical Experience*.

No Recklessness or Disregard of Safety

26. As heretofore described in Finding number 10 hereof, respondent made elaborate test on both animals and humans at all stages of the development of the product to insure that it was safe to use and would not cause undue irritation or sensitivity. Complaint counsel's first expert witness, Dr. Harry M. Robinson, Jr., made this very clear after his detailed analysis of the tests that were conin that regard. Respondent's officials in charge of development also testified that Pfizer had conducted tests to insure the safety of the product and described them in detail (Tr. 668). There was no proof offered that cast any doubt on the safety of the product in normal usage.

Truth of Respondent's Advertising Claims

27. Respondent bases its claim that its product Un-Burn anesthetizes nerves and stops pain fast on three types of proof: first, its review of the medical and pharmaceutical literature concerning the active ingredients benezocaine and menthol; second, the clinical experience of its experts and their knowledge of the history of the acceptability of these drugs as topical anesthetics; and, third, a test conducted after the commencement of this proceeding. We deal with each of these separately under ensuing subheadings.

Review of the Medical Literature

28. Henry L. Ross, Jr., the president of Leeming Division of Pfizer, who was director of marketing at the time of the development of Un-Burn (Tr. 597) testified that he was assured by Pfizer's medical people that the claims it planned to use could be supported by the two active ingredients at the level selected to be put into Un-Burn, which was patterned closely to Solarcaine, and he was further assured that all available literature or information on the two active ingredients had been thoroughly reviewed and favorable conclusions reached as to the efficacy of the ingredients as topical anes thetics (Tr. 600–601; see also 605). He reiterated this position on cross examination and added that they had found products which had made these same claims with the same active ingredients for many, many years (Tr. 618–620). He specifically claimed that as to active ingredients, Un-Burn was the same as Solarcaine, the leader in the field (Tr. 620). He also took the position that in the case of these well known ingredients a review of the literature was equivalent to testing and that if he put out a product containing ingredients listed in the literature it works (Tr. 629–630).

29. James W. Jenkins, a doctor of philosophy in chemistry, who was vice president of Research and Development of Pfizer's Leeming/Pacquin Divisions (Tr. 647) and responsible for quality control and testing, corroborated Mr. Ross (Tr. 652) and said he had discussed the problem with Dr. Carlozzi of the medical staff and that the literature search ‘told us it was an effective and safe and esthetic ingredient’ (Tr. 652). Dr. Jenkins ordered a survey at the library at the Parsippany laboratory to be made, got a list of references and reviewed them himself adding an additional reference (Tr. 670). The references pertaining to benzocaine and menthol included:

Grollman, Pharmacology and Therapeutics;
The Merck Index;
Goodman and Gillman;
Remington's Practice of Pharmacy;
Journal of Pharmacology and Experimental Therapy, Harry;
Principles and Practice of Modern Cosmetics;

Greenberg & Lester 'Handbook of Cosmetic Materials';
Journal of American Pharmaceutical Associates—an article;
Abbott Laboratories—Technical Bulletin on Benzocaine;
The Dispensatory of the United States of America. (Tr. 671).

As a result of the safety and other tests, his review of the literature and his discussions with Dr. Carlozzi, the medical director of Pfizer, Dr. Jenkins gave his opinion that the testing done was sufficient to establish the safety and efficacy of Un-Burn (Tr. 672–673).

On cross examination Dr. Jenkins testified that the literature examined had no test data just simple statements (Tr. 705) and admitted that he was a specialist in neither dermatology or anesthesiology (Tr. 710). He also said he had read one article (CX 96) that indicated in part that no clinical studies had been made of the relative suitability of many of the established local anesthetics for use on burns (Tr. 713) but it did not change his opinion about Un-Burn (Tr. 714).

30. Dr. Michael Carlozzi, the medical director of Pfizer (Tr. 1090–1134), a graduate of Long Island College of Medicine, obtained experience as a medical officer during World War II and has had extensive experience in the medical departments of several pharmaceutical companies (Tr. 1091). [FN11] He testified that he had advised Pfizer that Un-Burn would be effective in alleviating sunburn pain, based on the facts: that they were incorporating benzocaine and menthol agents which had been available for decades and had been in widespread use as topical anesthetic agents; that they were accepted as such by standard textbooks and by the clinical experience of the medical profession (Tr. 1097). The fact that other such products were on the market also had an influence in his decision (Tr. 1097, see also Tr. 1098). He consulted Dr. George Clinton Andrews' work on dermatology (RX 87) and several other standard textbooks (Tr. 1128).

31. Dr. William Beaver who was called by complaint counsel on rebuttal attested to the fact that the National Formulary and the U.S. Pharmacopoeia, United States Dispensatory, Goodman and Gillman, and Merck Index were standard reference works used by doctors and pharmacists (Tr. 1274–1279).

Clinical Experience of Respondent's Experts

32. Dr. norman Orentreich who conducted a post-complaint test on Un-Burn and whose qualifications are later described, testified with regard to his use of benzocaine in his personal practice (Tr. 848) and by other dermatologists (Tr. 847). He said that it had been in use as a local topical anesthetic since at least the turn of the century (Tr. 848) and that it was his opinion that it works by interfering with the conducting of impulses along the nerves or anesthetizes them (Tr. 848). He said that the opinion that benzocaine was an effective topical anesthetic was taught in medical school as early as 1948 (Tr. 850). He gave similar testimony regarding menthol (Tr. 853–854).

33. Dr. Norman Kanoff (Tr. 1037–1087), whose qualifications are also later described, testified that he used benzocaine in his practice and it was recognized as a topical local anesthetic by him and by other doctors for at least 50 years (Tr. 1043–1044). He explained what sunburn was (Tr. 1040) and its effect on the permeability of the skin (Tr. 1040–1043) and expressed the opinion that benzocaine acted on the nerve endings themselves to interfere with the conduct of nerve impulses and anesthetized them (Tr. 1043) and he would recommend it to relieve skin pain (Tr. 1044). He said he was also familiar with menthol and that it was recognized as an antipruritic and mild anesthetic and used by him and by other doctors (Tr. 1044). He admitted on cross examination that some accepted drugs had later been proved ineffectual (Tr. 1065). He also admitted he could not be certain his patients did what he recommended (Tr. 1060–1061) and that mild sunburn was self-limiting and would get better if not treated at all (Tr. 1082).

34. Dr. Robert A. Berger (Tr. 1142–1171), a specialist in dermatology; [FN12] has been in practice since 1959. He is assistant professor at Mount Sinai Hospital and was formerly associated with teaching at University Hospital of New York and Bellevue Hospital (Tr. 1144). He sees some 12,000 patients in private practice and another 3,000 in the hospitals (Tr. 1145). He described what sunburn is and stated his opinion that sunburned skin was damaged skin (Tr.

1146). He also said that the pain of sunburn was irritation of nerves and nerve endings in the upper layers of skin (Tr. 1147). He described benzocaine as a topical anesthetic agent used in creams, sprays and ointments and recognized as such in his speciality (Tr. 1147). It has been in use for over 50 years (Tr. 1198). He also described menthol as an antipruritic agent and also to a degree an anesthetic agent (tr. 1148). Both benzocaine and menthol are used by doctors (Tr. 1148–1149). Dr. Berger has used benzocaine and menthol in his practice and often advised patients by telephone on first aid for sunburn to use an over-the-counter product with benzocaine (Tr. 1150). He said it was his opinion that it penetrated the skin (Tr. 1151). On cross examination Dr. Berger said he had not conducted blood tests to determine whether menthol or benzocaine penetrated the skin and were present in the blood stream (Tr. 1156). Dr. Berger also admitted he did not know that patients followed his advice but thought it was reasonable to assume they did (Tr. 1158, 1159, see also 1169–1171). He agreed that there were drugs which had been used and gained acceptance which were later found to be ineffective (Tr. 1164). On redirect examination he reiterated that in his opinion there was adequate medical support for Pfizer's claims regarding Un-Burn in May 1969 (Tr. 1168–1169).

35. Dr. James W. Burks (Tr. 1174–1202), a practicing dermatologist and clinical professor of dermatology at Tulane University Medical School, [FN13] testified that he saw 80–100 patients with sunburn in his office each year but that most of his sunburn practice was over the telephone (Tr. 1177, 1179). In his practice as a whole he sees some 20,000 patients a year (Tr. 1179). He said sunburned skin was damaged skin that was no longer intact and that this was caused by chemical damage to the small cells of the skin (Tr. 1177–1178).

Dr. Burks said benzocaine had been used by doctors since the 1800's and was one of the first anesthetics used by dermatologists and it is used today for the treatment of topical skin problems particularly those that itch (*i.e.*, a form of nerve irritation) (Tr. 1180). He prescribes benzocaine both for those who call at his office and those who call on the phone, particularly the latter because they can get one of the caines, Solarcaine, or Un-Burn without a prescription at 2:00 a.m. (Tr. 1181). Dr. Burks also gave a similar opinion concerning menthol and its uses as a mild anesthetic and antipruritic agent (Tr. 1181). It is also used by doctors and by Dr. Burks for relief of itching, burning, stinging or discomfort of the skin because of its cooling or anesthetic effect (Tr. 1182). In the armed forces during the doctor's experience in New Guinea in World War II, benzocaine lotion was one of the two topical remedies that the army supplied. It was of great service (Tr. 1183).

The Post-Complaint Tests and Criticism Thereof

36. Dr. James W. Jenkins, vice president of Pfizer's Leeming/Pacquin Division, identified a test (RX 84) which was run by Dr. Orentreich in October and November 1970 (some three months after issuance of the complaint) (Tr. 674), based on a test plan or a protocol in the preparation of which he had collaborated with Dr. Orentreich (Tr. 674). Dr. Jenkins testified that in his opinion the study was both adequate and well-controlled and explained his reasons (Tr. 676). The product to be tested and the placebo were coded. Dr. Jenkins retained the code until after the study was completed, then caused it to be handwritten on the first page of the report (Tr. 677). The placebo was the same as the active product with the benzocaine and the menthol removed (Tr. 679). Dr. Jenkins calculated the results arithmetically and determined that taking all subjects in each case the active ingredient was more effective than the placebo (Tr. 680). In the case of particular individuals tested on the aerosol:

17 found the active more effective
1 found no difference
1 favored the placebo over the active (Tr. 680).

In the case of the lotion:

19 found the active more effective
2 favored the placebo over the active (Tr. 680).

Dr. Jenkins also calculated the results by test intervals and reached a comparable conclusion (Tr. 681). He summarized the results by saying that ‘Un-Burn aerosol and Un-Burn lotion proved to be effective in relief of pain from sunburn’ (Tr. 682). In his cross examination, he indicated he was relying on Dr. Orentreich's experience in testing (Tr. 716) and he could not supply detailed information concerning the number of subjects or just how the tests were conducted (Tr. 716–718).

37. Dr. norman Orentreich who was responsible for the post-com-plaint study on Un-Burn testified with respect to it (Tr 855 *et seq.*). Dr. Orentreich is an associate professor of Clinical Dermatology in New York University College of Medicine. [FN14] He has been active in medical societies and has written numerous articles. He is director of the Orentreich Medical Group consisting of four qualified dermatologists. It handles some 40,000 patients a year of which he sees some 20,000. He described in technical terms what sunburn was and how it damaged the skin (Tr. 838–843). He also indicated that it diminished the barrier function of the skin (Tr. 843–847) so that it became more permeable. He stated that in his opinion benzocaine was capable of penetrating the skin and anesthetized the nerves (Tr. 848). He also stated that menthol was a standard topical antipruritic agent and had a coolant as well as a direct anesthetic action (Tr. 853).

Testifying with regard to the test identified by Dr. Jenkins, Dr. Orentreich said it had been conducted under his supervision with coded products so neither he nor any of his staff knew which were active products and which placebo (Tr. 856). The 22 subjects selected were from within the doctor's medical group with a broad spectrum of caucasian skin types who were able to discriminate and be objective about their subjective responses (Tr. 856–858). A tested and specially designed lamp was used to closely resemble sunlight and inflict a small area of sunburn at a constant distance. Subjects were each given the same 2-minute exposure (which had been predetermined to cause a substantial first degree sunburn on all types) on five different approximately 1 x 1 inch square areas on their backs, sufficiently separated so there was no leakage of effect from one site to another (Tr. 858–861). Four of the sunburned areas each got an application from one of the four coded products. The fifth area was left as a control (Tr. 862). Then each area was stroked from the unburned skin over the burned area and the reaction was compared with the control, there was also random cross checking. The control area was rated 4 and the response from the other areas 4 if no change. The response from treated area was rated 3 if there was mild discomfort; 2 if moderate diminution of discomfort; 1 if marked diminution of discomfort; and 0 if there was no discomfort at all (Tr. 863). This testing was done a sufficient number of times, trying to fool the individual, to get reproducible data. The data was tabulated and submitted in the report (Tr. 863). after he code was broken Dr. Orentreich said the conclusion he reached was that the active ingredients were more effective than the placebo. This verified what he already knew, that the product would be effective for sunburn discomfort (Tr. 864). In the doctor's opinion he test was an adequate and well-controlled scientific test which substantiates the claim that Un-Burn actually anesthetizes nerves in sensitive sunburned skin (Tr. 864–865).

37a. On cross examination of Dr. Orentreich it was brought out that he knew that there was a question about the advertising claim for Un-Burn and that he was to design a test to determine whether the product would stop pain and anesthetize nerves (Tr. 874). He indicated that Mr. edwards of his organization probably submitted an outline of the technique of testing (Tr. 875); but, that he himself was involved in setting up the procedure (Tr. 876). The number of subjects was determined by Pfizer's willingness to pay (Tr. 876–879) and Dr. Orentreich assumed that was on the basis of the statistical evaluation by Pfizer (Tr. 877) because there were three series of tests (Tr. 877). Dr. Orentreich said he thought there were 15 different subjects and that some had participated in more than one series of tests (Tr. 878). He averred that neither the subjects or the testers whom he identified knew which was the placebo and which the active product though of course they knew which was aerosol and which lotion (Tr. 882). The actual tests were conducted by two nurses under Mr. Edwards supervision and the results were recorded by Miss Connor (Tr. 882–883). Dr. Orentreich maintained general supervision (Tr. 883). The subjects were all female; two-thirds were nurses, others were laboratory technicians or medical secretaries; and they received extra compensation for their participation (Tr. 886). Their age range was 21–40 (Tr. 887) and about 2/3 were fair and light skinned, 1/3 on the dark side (Tr. 887). He also described the details of how exposure was made, how far apart the areas of exposure were, how the lamp was constructed and operated and how it had been pretested (Tr. 888–890). He described the pain produced by the lamp and the reasons for testing after a 16-hour period (Tr. 890–894). He expressly stated that the burn caused was above-minimum and a discomforting advanced first-degree burn just short of blister formation (Tr. 895–896). He explained how the products were applied or randomized (Tr. 896) and that a mask was used to insure that the areosol spray was localized. The lotion was applied in a constant fashion (Tr. 897). He did not think the menthol and its removal caused the placebo to smell differently from the active product (Tr. 898). He testified that he was satisfied that the subjects had no preconceived notions of which product was applied to each site (Tr. 899). He indicated that the

tests were made within a 16–18 hour range after the injury was inflicted and justified that time period and interval (Tr. 900–1002). [FN15] Dr. Orentreich also described in detail how the subjects were stroked with an orange stick to cause pain and how the subjects responded and were cross checked by additional strokings (Tr. 1003–1007). He said there was no measuring instrument on the stroking and no study of each of the subject's tolerance to pain but that in his opinion the technique used was sufficiently standard to create meaningful data (Tr. 1008). The cross examination then drew attention to a number of responses by subjects where the response was slight or was the opposite of the study as a whole (Tr. 1009–1016). The doctor explained that there was an effect from the aerosol spray but that it was a fleeting effect so that an active ingredient was necessary (Tr. 1017). He said no blood samples were taken to determine whether the benzocaine was in the blood stream (Tr. 1017). He explained however, that he was of the opinion that the test established that Un-Burn anesthetized nerve ends (Tr. 1019) and gave a technical explanation of why this was so (Tr. 1020–1021). He further explained that while benzocaine did not penetrate the skin rapidly placing it on the surface has a prolonged reservoir effect (Tr. 1022). He said that the percentage of benzocaine was 1/2 percent in the lotion and almost 1 percent in the spray but that when the spray equilibrated with the skin surface there was a concentration of about 12 percent and 3 percent in the lotion (Tr. 1022). Dr. Orentreich explained that the placebos gave some relief because they prevented exposure to the air or had a cooling effect; but, that the study showed the active ingredients had an additional positive effect (Tr. 1024). Dr. Orentreich said he had not written an article because the test had just been done and was not done for that purpose (Tr. 1025–1026). He said he might sit down with a statistician and see if the latter thought it was statistically adequate. He did not, however, do the test for that purpose and was told it was statistically significant (Tr. 1026).

38. On redirect examination, Dr. Orentreich testified that no one knew of the identity of any of the coded products (Tr. 1027–1028); that the tests for a subjective response were recognized tests (Tr. 1028) that the placebo effect here was due in part to the properties of the base as well as to the psychological effect (Tr. 1029–1030); and, that the cost of a visit to a dermatologist to get a prescription drug was sufficiently high so that most persons with sunburn used an over-the-counter preparation (Tr. 1031–1032). Mr. Cantor, of counsel for respondent, during the re-cross examination stated that he had written the code equivalents on the face of RX 84 on December 17, 1970, and that was the first time the code was broken (Tr. 1033). The witness testified that he had not gone over the details of the test with Pfizer but that during his conference with Dr. Jenkins there were discussions on how one could design a test that would show that the active agent worked (Tr. 1034). On questions by the examiner, the witness stated that there was a single application of the medication and testing for responses after certain periods of time (Tr. 1035).

39. Dr. Norman Kanoff testified that he thought Dr. Orentreich's test established that Un-Burn relieved sunburn pain (Tr. 1055, 1084). He said, however, that he could not ascertain certain factors from the report itself (Tr. 1066–1069) but placed reliance on the test because Dr. Orentreich, who had been his colleague at New York University for 15 years, had done the testing (Tr. 1086).

40. Dr. Robert A. Berger testified that Dr. Orentreich's study indicated that benzocaine penetrated sunburned skin while in his opinion it would not penetrate normal skin (Tr. 1151).

41. Dr. James W. Burks testified that he thought the testing done by Dr. Orentreich (Exhibit 84) was adequate to substantiate that benzocaine will penetrate sunburned skin and anesthetize nerves (Tr. 1188).

42. Dr. David Salsburg, a Doctor of Philosophy from the University of Connecticut [FN16] and an expert statistician employed by Pfizer Pharmaceuticals, testified regarding the statistical significance of Dr. Orentreich's tests (RX 84). Using an arbitrary determination of the onset of activity (Tr. 1210) and the Paired T test, he determined that there was considerably less than a five percent chance that the results found by the study were due to chance (Tr. 1214). From his calculations he reached the conclusion ‘in lay language—that the Orentreich study provides statistically significant evidence that the Un-Burn formulation will do better than its carrier alone, in both lotion and aerosol, in terms of speed of action, of anesthetizing effect, and duration of activity.’ (Tr. 1215).

43. On cross examination, Dr. Salsburg testified that he was a probabilist in that he did not believe that anything

proved anything but that the study 'provided strong evidence that the Un-Burn formulation does work.' (Tr. 1216). He said his arbitrary selection of a point for the onset of activity was done in accordance with standard statistical procedure (Tr. 1223–1224). He also testified regarding the results shown on particular subjects. On redirect examination, Dr. Salsburg indicated that in his opinion there was a statistical probability that the observations were done in a truly random fashion (Tr. 1227). On re-cross, Dr. Salsburg stated that according to his calculations there was only a 1/2 percent chance that his conclusion was in error (Tr. 1229) and that in all probability another experienced statistician would have chosen the same figure for the onset of activity (Tr. 1230). On examination by the undersigned, Dr. Salsburg said he could not tell whether or not the subjects were an adequate sample of the entire population (Tr. 1231) but that question was seldom asked in clinical research (Tr. 1232). He said he could tell that there were a sufficient number of subjects because there were significant results (Tr. 1232). He also said that the chances of getting a result of 16 subjects finding a preference for Un-Burn by pure chance was 0.2 percent (Tr. 1234).

44. Dr. William Beaver was recalled by counsel supporting the complaint on rebuttal (Tr. 1242–1318). He testified he had formed an opinion concerning the adequacy of Dr. Orentreich's test (RX 84; Tr. 1243). On voir dire examination, it was made clear that his opinion was based on the test paper alone as he had neither read nor heard about Dr. Orentreich's testimony concerning the study (Tr. 1243–1244).

It was his opinion that he could not tell whether the study was adequate to demonstrate whether the inclusion of benzocaine in the formulation enhanced the efficacy of the product because the description of the methods used was not adequate (Tr. 1246). The specific criticisms and answers which would have been found it Dr. Orentreich's and others' testimony had been considered were:

1. There was no description of the exact nature of the placebo and the active product so that he could be assured that the study was double-blind (Tr. 1247). Dr. Orentreich testified that the study was double-blind and Dr. Jenkins concerning the placebo).
2. The exact nature of the coding of the medications is not shown. Were the same containers used over and over or did each individual have his own set (Tr. 1248). (Dr. Orentreich made it clear that neither subject nor testers knew what was placebo and what active and in any event Dr. Beaver did not regard this defect as fatal (Tr. 1248).
3. The nature of the test preparation. It is not clear whether it produced a condition comparable to naturally occurring sunburn (Tr. 1249). (Dr. Orentreich testified that they had pretested the lamp and that the burn given was just under 2nd degree).
4. How were the test squares laid out (Tr. 1249). (Dr. Orentreich testified in detail concerning this).
5. How were the test medications assigned to various areas. Were they truly on random fashion (Tr. 1249). (Dr. Orentreich testified as to this and Dr. Salsbourg testified that the results indicated statistically that the application was made in a random fashion).
6. How were the test areas compared against the control area and what were the criteria for response (Tr. 1250). (Dr. Orentreich testified with respect to this at some length).
7. There was no statistical analysis (Tr. 1251). (Both Dr. Salsburg and Dr. Jenkins testified with respect to the statistical results).
8. There was no description of how the measured effect was elicited (Tr. 1251). (Dr. Orentreich covered this thoroughly on both direct and cross examination).

45. In light of the fact that the criticisms made of Dr. Orentreich's study were all covered by the latter's testimony or other testimony introduced in the case, Dr. Beaver's testimony based solely on the test paper itself simply did not rebut the other testimony concerning the adequacy of the test. Accordingly, Dr. Orentreich's test must be regarded as adequate to establish that Un-Burn anesthetizes nerves in sunburned skin and relieves sunburn pain.

Propriety of Reliance on Historical Data and Clinical Experience

46. In regard to the drug efficacy studies conducted for the Food and Drug Administration, expert witnesses for both counsel supporting the complaint and counsel for respondent were in agreement that the judgment of the physicians on the panel could be considered in evaluating the efficacy of drugs (Dr. Carlozzi—Tr. 1101–1108; RX 110; Dr.

Blank—Tr. 532–534; Dr. Beaver—Tr. 371–372, Tr. 1281).

47. Dr. Norman Orentreich, who had conducted the post-complaint test (CX 84), expressed the opinion that it was reasonable for Pfizer to make the claim that Un-Burn anesthetizes nerves in sensitive sunburned skin on the basis of the safety and other tests it had conducted and on the state of medical learning as of May 1969 (Tr. 866). Among the reasons given were that 'benzocaine has for seventy years, at least, been considered an effective topical anesthetic. I think that for a time students were taught it was the only effective topical anesthetic' (Tr. 867). He then analyzed the testing done and stated 'you had every reason to believe that it was reasonable that you had a safe and effective preparation' (Tr. 867–868).

48. Dr. Norman Kanoff, who had conducted the prophetic patch test (CX 56; Tr. 1045) which is one of the safety tests relied on by respondent, is a specialist in dermatology, a graduate of Georgetown School of Medicine and an associate professor of dermatology at New York University [FN17] and director of Dermatology in New York Polyclinic Hospital (Tr. 1037–1039). He stated that the test he conducted was adequate and well-controlled and described how it was conducted (Tr. 1045) and that the other thests conducted (CX 40, 48, 50, tests conducted (CX 40, 48, 50, adequate for the purpose for which they were conducted (Tr. 1045) and that based on the tests and the state of medical learning in May 1969, it was reasonable for Pfizer Inc., to make the claims it did in its advertising (Tr. 1047–1049). One of the reasons was there was 'generally accepted medical knowledge concerning the active ingredients' (Tr. 1049). He also testified that the clinical experience of practitioners is the ultimate test (Tr. 1049).

49. After reviewing the tests made by Pfizer, Dr. Robert A. Berger expressed the opinion that it was not necessary to run efficacy tests to make the claims made by Pfizer because the tests made showed safety, lack of irritation and sensitivity to allergic reaction and because the active ingredients have been in existence for many years, are present in many competitive formulations, and there is reference to them in the literature and much clinical experience as to their efficacy (Tr. 1153). He said that clinical experience in his opinion was what counted because the goal is to achieve a clinical result (Tr. 1154).

50. Dr. James W. Burks testified that the tests made by the Pfizer Company were adequate for the purpose for which they were conducted (Tr. 1182) and that in his opinion based on a review of the tests and the state of medical learning in May of 1969 it was reasonable for Pfizer to claim that Un-Burn would anesthetize nerves in sensitive sunburned skin (Tr. 1183–1184). He said that he thought the tests were enough, if not more than enough, to establish the safety and lack of complications (Tr. 1084). He said he believed that clinical experience was the final test of the value of a drug and that investigative findings were purely supportive (Tr. 1185). He said in the case of these topical anesthetics the doctors and the patients know they work (Tr. 1185).

On cross examination Dr. Burks said he based his opinion on the state of medical learning on the first training he had and on the books he had studied. Benzocaine was listed as one of the most useful anesthetics of the skin (Tr. 1190). He also reiterated that if a drug was used for 50 to 70 or 100 years and was not found to be dangerous but highly effective it would make it unnecessary to do any investigative work (Tr. 1193). He also acknowledged the placebo effect (Tr. 1194) and said it gave relief in 'direct proportion to the enthusiasm of the one that gives it' (Tr. 1194). If you believe in the product you are prescribing it rubs off on the patient (Tr. 1195). While acknowledging he could not control the patient he assumes that when he tells a patient at 2:00 a.m. to get a certain preparation that indicates the patient gets it, puts it on and if he doesn't call back the doctor assumes the product worked (Tr. 1197). He also distinguished between the topical anesthetic benzocaine which was useful to ease reliably mild discomfort in sunburn and an anesthetic to prevent any feeling in an operation (Tr. 1199). With regard to the concentration, 1 or 2 percent is effective to permit the patient to get enough dulling effect to be able to sleep (Tr. 1200–1201).

51. Dr. William Beaver was recalled by counsel supporting the complaint on rebuttal and was asked concerning the efficacy of clinical experience. He testified that clinical experience alone in his opinion was not medically acceptable evidence of a drug's ability to stop sunburn pain unless the medication dramatically, immediately and invariably stopped the pain (Tr. 1258). Having previously testified that he could not tell from reading the responses whether they

were dramatic cnough or not he was not permitted to testify whether or not the responses were sufficiently dramatic in the case of Un-Burn (Tr. 1264–1266).

Summary Finding on Respondent's Defenses

52. At the conclusion of respondent's case it was established that:

a. There was no implication from the advertising that adequate and well-controlled tests had been made.

b. Sunburned skin is not undamaged skin and has greater permeability than undamaged skin.

c. Recognized medical literature and the medical practice of dermatologists for between 50 and 70 years regarded the active ingredients in Un-Burn as efficacious for the relief of sunburn pain.

d. It was reasonable for respondent to rely on such clinical experience and medical literature for the efficacy of Un-Burn without making adequate and well-controlled scientific tests to determine its efficacy, since there had been adequate and well-controlled scientific tests to determine its safety.

e. Following the issuance of the complaint, respondent caused a test to be made by Dr. Orentreich's organization that conforms to the requirements for adequate and well-controlled testing. This test showed that it was much more probable than not that Un-Burn was more effective than its base materials in relieving sunburn pain.

Summary Finding on Complaint Counsel's Rebuttal

53. The testimony offered on robuttal was inadequate to counter the proof offered by respondent.

REASONS FOR DECISION

As pointed out in the order declining to dismiss the complaint or to certify the question to the Federal Trade Commission, [FN18] it is very clear that the Commission not only possesses the authority to determine what facts constitute an unfair trade pactice but that it is its duty to maintain a vigilant watch over commerce to prevent new types of corrosive practices that impede fair competition.

Accordingly, nothing in this decision denigrates the Commission's power to declare that it is an unfair trade practice for a pharmaceutical company to advertise that its product has a particular effect unless the company has made certain by a reasonable [FN19] investigation made prior to the issuance of the advertising that such an effect can reasonably be expected to be produced.

Unlike the usual case of false advertising, there is no charge here that the claims made in the advertising are not wholly accurate. The charge is: (1) that the advertisement implies that adequate and wellcontrolled scientific tests were made prior to the advertising and (2) that it is an unfair practice to advertise the product without having made adequate and well-controlled scientific tests as to its efficacy.

Having viewed the T.V. presentation with a projector and listened to the simultaneous sound recording device several times, as well as having studied the texts in evidence, the hearing examiner failed to observe anything that would reasonably [FN20] imply that prior adequate and well-controlled scientific tests were conducted to determine the effectiveness of the product Un-Burn as charged in the complaint. Dr. Smith, the expert called by the respondent, reinforced the hearing examiner's judgment by a careful and logical analysis. There was no rebuttal evidence offered. We now consider the second charge that it is an unfair practice to advertise a product like Un-Burn unless prior to the advertising, adequate and well-controlled scientific tests were conducted to determine the product's efficacy to anesthetize nerves and stop sunburn pain.

In the opinion of the undersigned, the practice in this instance should not be held to be an unfair practice because the active ingredients of Un-Burn, benzocaine and menthol, have for a great many years been recognized as effective topical local anesthetics in medical and pharmaceutical literature and have been in continuous use by doctors specia-

lizing in dermatology for the topical relief of sunburn pain for many years. There was no reckless disregard of the safety of the users, because carefully controlled tests were made first on animals and then on humans to determine that the product was safe, non-irritating and non-sensitizing. It was also established by an animal test that the base into which the active ingredients were compounded did not inhibit the anesthetic effect of the active ingredients.

Clearly, no prior adequate and well-controlled scientific test was made on human beings to determine whether the product was efficacious in human beings. Thus, the allegations of the complaint in this regard were established. And, if it were not for the fact that for between 50 and 70 years the medical profession and particularly those doctors who specialized in dermatology had been successfully using the active ingredients in Un-Burn, benzocaine and menthol, to relieve sunburn pain, clearly an order should properly be issued because to advertise an untried remedy without adequate testing would be as the Commission charged an unfair trade practice.

However, to take the position that a particular type of test must be made, wholly disregards the value of the clinical experience of a number of experts in the dermatology field of medicine such as those called by respondent. Moreover, such a position would appear to repudiate clinical experience entirely and to insist that laboratory testing be substituted in all instances where advertising is involved. This would submerge the art of medicine in a sea of laboratory tests. There was no dispute that the ingredients were used by doctors for the purpose claimed. Accordingly, it does not seem reasonable to suppose that the Federal Trade Commission would deliberately take a position disregarding clinical experience particularly since that position would be contrary to the position taken by the Food and Drug Administration in the adequacy testing of drugs (See RX 110). It would seem, therefore, that the Federal Trade Commission under its announced policies would defer to the agency that is specifically charged by Congress with determining the adequacy and safety of drug products. [FN21] We assume that knowledge of the clinical use of the product by dermatologists was not brought to the attention of the Commission at the time of the issuance of this complaint.

Of the utmost significance is the fact also that the evidence introduced demonstrated that the product is in all probability quite effective to relieve sunburn pain. So, it would be an exercise in futility to prevent claims being made without proof when now such proof has been made.

Only one doctor called by counsel supporting the complaint claimed that on test (which was concededly preliminary), he found Un-Burn ineffective. The same doctor some years before (using method of testing which he now criticizes) had told one of respondent's principal competitors in this field that its product Solarcaine was effective. He has not withdrawn such advice. Respondent's product was designed to emulate Solarcaine and used much the same ingredients.

After the complaint was issued by the Commission, moreover, respondent caused a test to be conducted that in the opinion of the undersigned was adequate to establish that the product was probably effective to relieve sunburn pain by anesthetizing nerves. The only criticism of the test completely disregarded the testimony given by the doctor who had conducted the test and by the statistician who attested to its statistical validity. The criticism was founded solely on the text of the unpublished report.

On the basis of the evidence as a whole, therefore, particularly the evidence of clinical use which presumably was not before the Comission when it issued the complaint; and on the basis of the postcomplaint testing we are of the opinion that the public interest would not be served by the entry of a cease and desist order in this case.

CONCLUSIONS

1. The Commission has jurisdiction over the person of respondent and over the subject matter of this proceeding.

2. The evidence failed to establish that the advertising reasonably implied that adequate and well-controlled scientific tests had been made prior to the issuance of the advertising.

3. The evidence failed to establish that the product was not effective to produce relief from sunburn pain.

4. While the evidence established that no adequate and well-controlled scientific tests were conducted to determine the efficacy of the product prior to the issuance of the advertising, the medical literature and well-recognized clinical experience demonstrated that the ingredients in the product had been considered efficacious by specialists in the field of dermatology for between 50 and 70 years and it was reasonable for the respondent in those special circumstances to make claims based on such historical and clinical proof and to test only for safety. The safety tests were adequate and well-controlled.

5. It would thus in the opinion of the hearing examiner not be in the public interest under the peculiar facts established in this proceeding, particularly those developed after the complaint was filed, to issue a cease and desist order.

6. The following order should be issued.

ORDER

It is ordered, That the complaint herein be and the same is hereby dismissed.

OPINION OF THE COMMISSION

BY KIRKPATRICK, *Commissioner:*

I. THE PROCEEDINGS

On July 15, 1970, the Federal Trade Commission issued its complaint alleging that Pfizer, Inc., had violated Section 5 of the Federal Trade Commission Act. Respondent Pfizer contested the allegations of this complaint and the matter was assigned to a hearing examiner for a hearing. The hearing examiner decided that the Commission's staff counsel had failed to establish that an order to cease and desist should issue. Counsel supporting the complaint have appealed the examiner's decision to the Commission. Upon consideration of the record of the proceedings before the hearing examiner, the examiner's initial decision, and the briefs and arguments of the parties, the Commission has decided that the decision of the hearing examiner should be affirmed.

II. THE COMPLAINT

The Commission's staff counsel, who have the burden of proving the allegations of the complaint, challenge certain advertising by Pfizer for the product ‘UN-BURN,’ a nonprescription product recommended for use on minor burns and sunburn. The complaint cited the following radio and television advertising for Un-Burn as typical and representative:

> New Un-Burn actually anesthetizes *nerves* in sensitive sunburned skin.
>
> Un-Burn relieves pain *fast.* Actually *anesthetizes nerves* in sensitive sunburned skin.
>
> Sensitive skin * * * Sunburned skin is sensitive skin * * * Sensitive sunburned skin needs * * * UN-BURN. New UN-BURN contains the same local anesthetic doctors often use * * * Actually anesthetizes nerves in sensitive sunburned skin. I'll tell you what I like about UN-BURN. It's the best friend a blonde ever had! * * * I'm a blonde * * * and I know what it means to have sensitive skin. Why I'm half afraid of moon burn! That's why I'm mad about UN-BURN. It stops sunburn pain in * * * less time than it takes me to slip out of my bikini. That's awfully nice to know when you're the sensitive type * * * [FN1]

The complaint alleges that the foregoing advertising claims were not substantiated by Pfizer by ‘adequate and well-controlled scientific studies or tests prior to the making of such statements.’

Based on these facts, complaint counsel set forth charges alleging two separate and distinct violations of Section 5 of the Federal Trade Commission Act—first, a charge of unlawful deception, and second, a charge of unlawful unfairness. The deception charge alleged that Pfizer's advertising constituted a *deceptive practice* in representing to consumers that 'each of the statements respecting the pain-relieving properties of the said product has been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements.' The unfairness charge rests upon the proposition that it is an *unfair practice* to make advertising claims of this nature lacking adequate and well-controlled studies or tests.

III. DECEPTION

Section 5 of the Federal Trade Commission Act provides that deceptive acts or practices in commerce are unlawful. In Section 5 advertising cases, the requisite 'acts or practices' have usually taken one of three forms: (1) advertising containing direct representations, (2) advertising containing representations which reasonably may be said to be implied by the advertising, or (3) advertising which fails to disclose material facts. The Commission may utilize its accumulated 'expertise' in analyzing the facts of each case to determine what direct and implied representations are contained in advertising. [FN2] Its expertise is also utilized in evaluating what facts are material to consumers, and thereby to determine the situations in which material facts have not been disclosed. A sufficient showing of deception is made if there exists a 'capacity to deceive. [FN3]' In evaluating the capacity of an advertisement to deceive, the net impression of the advertisement, evaluated from the perspective of the audience to whom the advertising is directed, is controlling.

It is against the foregoing regulatory framework that the deception charge in this case must be viewed.

While there were many direct representations contained in the Un-Burn advertising, they are not being challenged. Thus, unlike most deceptive advertisting cases, the truth or falsity, or deceptiveness, of advertising claims such as '*New* Un-Burn,' or 'actually anesthetizes nerves,' or 'relieves pain fast' is *not* an issue in this proceeding. The complaint does charge, however, that respondent's advertising, both directly and by implication, represented that each of the statements respecting the pain-relieving properties of Un-Burn *has been substantiated* by respondent by adequate and well-controlled scientific studies or tests *prior* to the making of such statements.

Complaint counsel have not undertaken to prove explicit deception, but rather are relying solely upon the Commission's expertise to find that the implied representation is reasonably contained in the advertising, and that it has the capacity to deceive consumers. [FN4] Complaint counsel argue that Un-Burn's advertising *implied* that—*each* statement in advertising—respecting pain-relieving properties—has been substantiated—by respondent—by adequate—and well-controlled—scientific tests—or studies—conducted *prior* to the making of such statements. Thus, we are urged, for example, to make the following distinctions: (1) between 'pain-relieving properties,' and other claims of product efficacy, content, speed and method of operation; (2) between substantiation 'by respondent,' and substantiation which may have been 'by' someone else (competitors, doctors, consumers, independent laboratories, etc.); (3) between a very precise type of substantiation ('adequate and well-controlled scientific studies or tests'), and other possible standards of substantiation (*e.g.*, adequate substantiation, usual and customary steps, reasonable basis, reliable, comprehensive, etc.); (4) between 'scientific studies or tests' and other possible bases for substantiation, such as medical literature, clinical experience, consumer experience; and (5) between 'prior' testing and a reasonable basis for belief, or subsequent tests.

Complaint counsel argue that respondent's advertising represented to consumers that Un-Burn is a drug which actually anesthetizes nerves in sensitive sunburned skin, and which will provide fast and total relief of sunburn pain. Complaint counsel cite the phrase 'anesthetizes nerves fast' and the advertising references to doctors as statements which consumers will associate with scientific proof of the product's efficacy and as implying medical approbation of Un-Burn. In response, respondent argues that the total setting of the ad, the frivolous nature of the dialogue, the use of a bikinied

model, and the general ‘aura of sexiness' prevent the ad, taken as a whole, from carrying the scientific overtones argued by complaint counsel.

Complaint counsel's sixth proposed finding of fact would hold that respondent represented by implication that the statements that Un-Burn anesthetizes nerves in sensitive skin and stops sunburn pain fast have been substantiated by respondent by ‘adequate evidence’ prior to the making of such statements. Complaint counsel's seventh proposed finding of fact, on the other hand, goes further. It is there argued that by representing that they had ‘adequate evidence’ to substantiate their advertising claims, respondent thereby impliedly represented that they possessed adequate and well-controlled scientific studies or test which substantiated such claims. The Commission does not believe that such an implied representation can reasonably be found in respondent's advertising.

IV. UNFAIRNESS

The Commission's jurisdiction to proscribe ‘unfair’ commercial practices has been utilized frequently as an independent basis for Commission action. [FN5] Most often the term is coupled, perhaps in an effort to add direction and content, either to the deceptive or to the restrictive aspects of the practice in question. [FN6] The Commission, of course, has been delegated the power by Congress to give definition and content to the term ‘unfair practices.’ [FN7] The 1938 Wheeler-Lea Amendment made it clear that this jurisdiction extends to the protection of consumers:

> * * * this amendment makes the consumer, who may be injured by an unfair trade practice, of equal concern, before the merchant or manufacturer injured by the unfair methods of a dishonest competitor. [FN8]

The Commission's responsibilities with regard to unfair trade practices were analyzed in its 1969 *All-State Industries* opinion: [FN9]

> [T]he responsibility of the Commission in this respect is a dynamic one: it is charged not only with preventing well-understood, clearly defined, unlawful conduct but with utilizing its broad powers of investigation and its accumulated knowledge and experience in the field of trade regulation to investigate, identify, and define those practices which should be forbidden as unfair because contrary to the public policy declared in the Act. The Commission, in short, is expected to proceed not only against practices forbidden by statute or common law, but also against practices not previously considered unlawful, and thus to create a new body of law—a law of unfair trade practices adapted to the diverse and changing needs of a complex and evolving competitive system.

The recent *S & H* case sets forth a succinct confirmation of the Commission's jurisdiction over unfair practices:

> [T]he Federal Trade Commission odes not arrogate excessive power to itself if, in measuring a practice against the elusive, but congressionally mandated standard of fairness, it, like a court of equity, considers public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws. [FN10]

In footnoting this statement, the court said:

> The Commission has described the factors it considers in determining whether a practice which is neither in violation of the antitrust laws nor deceptive is nonetheless unfair:
>
> > (1) whether the practices, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common law, statutory, or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive or unscrupulous, (3) whether it causes substantial injury to consumers (or competitors or other businessmen). ‘Statement of Basis and Purposes of Trade Regulation Rule 408 [Unfair or Deceptive Advertising and Labelling of Cigarettes in Relation to the Health Hazards of Smoking].’ 29 Fed. Reg. 8324, 8355 (1964).

An unfairness analysis will take into account many basic economic facts and considerations, and will permit a broad focus in the examination of marketing practices. Unfairness is potentially a dynamic analytical tool capable of a progressive, evolving application which can keep pace with a rapidly changing economy. [FN11] Thus as consumers products and marketing practices change in number, complexity, variety, and function, standards of fairness to the consumer may also change.

Generally, the individual consumer is at a distinct disadvantage compared to the producer or distributor of goods in

reaching conclusions concerning the reliability of product claims. Very often the price of a consumer product is sufficiently low that the cost to the consumer of obtaining relevant product information exceeds the benefits resulting from the increased satisfaction achieved thereby. In other cases, the complexity of a consumer product, and accordingly the large amount of detailed product information necessary to an informed decision, makes the costs of obtaining product information prohibitive. This problem is further magnified by the large number of competing products on the market. [FN12] Thus, with the development and proliferation of highly complex and technical products, there is often no practical way for consumers to ascertain the truthfulness of affirmative product claims prior to buying and using the product. When faced with a vast selection of products to choose from, the typical family unit is not sufficiently large enough, and its requirements are too varied, to allow detailed investigation of the goods to be purchased. The consumer simply cannot make the necessary tests or investigations to determine whether the direct and affirmative claims made for a product are true.

Given the imbalance of knowledge and resources between a business enterprise and each of its customers, economically it is more rational, and imposes far less cost on society, to require a manufacturer to confirm his affirmative product claims rather than impose a burden upon each individual consumer to test, investigate, or experiment for himself. The manufacturer has the ability, the knowhow, the equipment, the time and the resources to undertake such information by testing or otherwise—the consumer usually does not.

Turning to that part of the complaint which challenges respondent's marketing practices as unfair, the Commission is of the view that it is an unfair practice in violation of the Federal Trade Commission Act to make an affirmative product claim without a reasonable basis for making that claim. Fairness to the consumer, as well as fairness to competitors, dictates this conclusion. Absent a reasonable basis for a vendor's affirmative product claims, a consumer's ability to make an economically rational product choice, and a competitor's ability to compete on the basis of price, quality, service or convenience, are materially impaired and impeded. The balance of this opinion will concern itself with an analysis of the reasonable basis standard in relation to the record before us.

The consumer is entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a ‘reasonable basis' for making performance claims. A consumer should not be compelled to enter into an economic gamble to determine whether a product will or will not perform as represented. The economic gamble involved in a consumer's reliance upon affirmative product claims is created by the vendors' activities, and cannot be easily avoided by consumers. Taking a different and analytical perspective and weighing the minimal cost and burden on vendors by requiring that there be a reasonable basis for affirmative product claims against economic losses to consumers which can fairly be ascribed to advertising claims lacking such reasonable basis (losses which are, in a practical sense, unavoidable for the consumer), it is likewise clear that economic fairness requires that this obligation be imposed on vendors. [FN13] The record reflects the fact that the cost to a consumer of a visit to a dermatologist to obtain a prescription drug is sufficiently high that most persons with sunburn utilize an over-the-counter commercial preparation (Tr. 1031–1032). Thus, the consumer is to a great degree dependent on the manufacturer for information concerning products of this type.

In addition, fairness to competitors requires that the vendor have a reasonable basis for his affirmative product claims. A sale made as a result of an unsupported advertising claim deprives competitors of the opportunity to have made that sale for themselves.

This view finds direct support in the recent decision in *Leon A. Tashof* v. *F.T.C.* [FN14] There, the Commission found that a retailer falsely advertised that his products were available at discount prices. The Commission in effect ordered the respondent to stop advertising that he sold any product at a discount price unless he had a reasonable basis for such a claim. In view of this retailer's past history, the Commission prescribed a specific type of ‘reasonable basis'—the Commission ordered that the respondent, before advertising that he sells at discount prices, must take a statistically significant survey to demonstrate that prevailing market prices are substantially above respondent's prices. In affirming the Commission's decision, the Court expressly noted that this order subjected the respondent to civil penalties if the respondent advertises discount prices without having taken the survey, *even if the advertisement is true*. The

unfairness analysis in the Commission's *All-State Industries* [FN15] case is also directly on point.

> *When a seller knows, but the buyer does not know*, that the debt contracted by the buyer in making a credit purchase will be assigned to a third party, *the buyer may be entering into a transaction quite different in its characteristics from the one the buyer imagines he is entering*. * * * In this circumstance, we find it palpably unfair for a seller who routinely assigns instruments of indebtedness executed by his purchasers to third parties to fail to disclose to his purchasers that such transfer is contemplated and may result in a substantial alteration of the buyer's rights and liabilities. (Emphasis added.)

In summary, the Commission concludes that the making of an affirmative product claim in advertising [FN16] is unfair to consumers unless there is a reasonable basis for making that claim.

This standard, it should be noted, focuses in large part on the adequacy of the underlying evidence, and is not solely a 'reasonable man' test. It thus rounds out the *Kirchner* case, which suggested that an advertiser '* * * should have in his possession such information as would satisfy a reasonable and prudent businessman, acting in good faith, that such representation was true.' This test evaluates both the reasonableness of an advertiser's actions and the adequacy of the evidence upon which such actions were based.

The question of what constitutes a reasonable basis is essentially a factual issue which will be affected by the interplay of overlapping considerations such as (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; (5) the type, and accessibility, of evidence adequate to form a reasonable basis for making the particular claims. More specifically, there may be some types of claims for some types of products for which the only reasonable basis, in fairness and in the expectations of consumers, would be a valid scientific or medical basis. The precise formulation of the 'reasonable basis' standard, however, is an issue to be determined at this time on a case-by-case basis. This standard is determined by the circumstances at the time the claim was made, and further depends on both those facts known to the advertiser, and those which a reasonable prudent advertiser should have discovered. Such facts should be possessed *before* the claim is made.

In like manner, the criteria listed above will serve as a touchstone for evaluating those instances in which the Commission is unlikely to proceed against advertisers for failure to have support for an advertisement. In the past, the Commission has recognized that there is a category of advertising themes, in the nature of puffing or other hyperbole, which do not amount to the type of affirmative product claims for which either the Commission or the consumer would expect documentation. In *Kirchner*, [FN17] we held that advertising an inflatable swimming aid as 'invisible' is harmless hyperbole.

> True, as has been reiterated many times, the Commission's responsibility is to prevent deception of the gullible and credulous, as well as the cautious and knowledgable (see *e.g.*, *Charles of the Ritz Dist. Corp.* v. *F.T.C.*, 143 F.2d 676 (2d Cir. 1944)). This principle loses its validity, however, if it is applied uncritically or pushed to an absurd extreme in respect of every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feebleminded. Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim. Perhaps a few misguided souls believe, for example, that all 'Danish pastry' is made in Denmark. Is it, therefore, an actionable deception to advertise 'Danish pastry' when it is made in this country? Of course not. A representation does not become 'false and deceptive' merely because it will be unreasonably misunderstood by an insignificant and unrepresentative segment of the class of persons to whom the representation is addressed. If, however, advertising is aimed at a specially susceptible group of people (*e.g., children*), its truthfulness must be measured by the impact it will make on them, not other to whom it is primarily directed.

In this case, complaint counsel is aparently challenging the reasonableness of the basis for two specific affirmative product claims made for Un-Burn: (1) Un-Burn actually anesthetizes nerves in sunburned skin, [FN18] and (2) Un-Burn stops pain fast. [FN19]

The Standard of Reasonableness

Complaint counsel's unfairness charge basically urges that the only reasonable basis for performance or effectiveness representations for a drug or medical product would be fully documented, adequate and well-controlled scientific studies or tests. Complaint counsel deny that a reasonable basis could be found in the medical literature, clinical experience, or general medical knowledge. Respondent, on the other hand, argues that it possessed a reasonable basis to support its affirmative product claims, and therefore did not need to take the additional step of obtaining controlled scientific test. Respondent rested its defense on the proposition that the complaint set forth too narrow a view of the type of support required to make affirmative product claims, and contended that there was in fact a reasonable basis for making the questioned claims for Un-Burn.

On appeal, complaint counsel argue that courts have held that the only form of evidence which is adequate and reliable to sustain claims for a drug such as Un-Burn is adequate and well-controlled studies or tests. In support of this proposition, complaint counsel cite cases which hold, based upon a reading of statutory language and the pertinent legislative history, that the Food and Drug Administration validly issued administrative regulations establishing criteria for adequate and well-controlled clinical investigations for determining drug efficacy. [FN20] Having disclaimed at trial any relationship between FDA standards of drug efficacy and the definition of ‘adequate and well-controlled scientific studies or tests' as set forth in their complaint, however, complaint counsel cannot now attempt to rely, directly or indirectly, on those FDA standards. Complaint counsel have rested their case squarely on the ‘ordinary dictionary definitions' of the words ‘adequate and well-controlled scientific studies or tests'—it is, accordingly, on this basis that the Commission must evaluate their argument and the record evidence. [FN21]

Adequate and Well-Controlled Scientific Studies or Tests

Complaint counsel argue that the only reasonable basis for making efficacy and performance claims for a drug such as Un-Burn would be adequate and well-controlled scientific studies or tests conducted prior to the marketing of the product. Thus, a primary issue at trial was the existence or non-existence of such studies or tests. It is clear that Pfizer's *safety* testing was not designed to, and did not in fact, support the affirmative *efficacy* representations made for the product (I.D., pp. 9–10 [p. 33 herein]). Respondent's pre-marketing tests consisting of *injections* of benzocaine could not indicate the probable anesthetic effect of a *topical* application of this substance (Tr. 259, 308, 344, 522). The tests for the product's *antiseptic* effects do not lend any support to the *anesthetic* effects claimed (Tr. 288, 311). Nor were the tests on guinea pigs sufficient to substantiate the efficacy of the product on human beings (Tr. 726). The hearing examiner found, and the record amply supports his determination, that Pfizer did not conduct adequate and well-controlled scientific studies or tests *prior* to marketing Un-Burn to substantiate the efficacy claims for Un-Burn (I.D., pp. 17, 35 [pp. 40, 54 herein]).

More generally, the record in this matter is clear that for a test, standing alone, to provide a reasonable basis for an affirmative product claim, the test should be an adequate and well-controlled scientific test (I.D., pp. 10–17 [pp. 33–40 herein]; Tr. 330–331, 351–356). Such a test should be conducted on human beings, not on animals (Tr. 298, 343, 351, 509, 522). A pre-existing test protocol is usually essential to an adequate test (Tr. 296, 345, 1065). The record also indicated the strong desirability of double-blind scientific tests (Tr. 280, 370).

Some time *after* the present proceeding was instituted, respondent did undertake to conduct an adequate and well-controlled test of Un-Burn's efficacy (Tr. 676). This was the test conducted by Dr. Orentreich (Tr. 647; I.D. 30 [p. 51 herein]). While there was some argument as to whether this test actually met the standards of an adequate and well-controlled scientific test (O.A. 14–15) [FN22] it seems clear that it was designed to be such (Tr. 674–676, 864–865). The Orentreich test stands in marked comparison to the tests undertaken by respondents prior to marketing, and graphically demonstrates the insufficiency of such premarketing tests to support the efficacy claims made for the product (Tr. 716, 863, 1116, 1188, 1215, 1226). Even assuming that the Orentreich test did establish that Un-Burn

actually anesthetizes nerves, [FN23] the fact that this test was not conducted *prior* to making the affirmative product claims for Un-Burn precludes it from being considered as a defense to the violation charged in this complaint. In order to have had a reasonable basis, the tests must have been conducted prior to, and actually relied upon in connection with, the marketing of the product in question. Nor does the fact that the product subsequently performed as advertised indicate that there is a lack of public interest in the matter. [FN24] The fundamental unfairness results from imposing on the consumer the unavoidable economic risk that the product may not perform as advertised; that is, at the time of sale, neither the consumer nor the vendor have a reasonable basis for belief in the affirmative product claims.

It is thus clear that the tests conducted by Pfizer did not provide a reasonable basis for the making of these performance claims. The tests were not adequate and well-controlled scientific tests conducted prior to the making of the efficacy representations.

> [T]o take the position that a particular type of test must be made, wholly disregards the value of the clinical experience of a number of experts in the dermatology field of medicine such as those called by respondent. Moreover, such a position would appear to repudiate clinical experience entirely and to insist that laboratory testing be substituted in all instances where advertising is involved. [FN25]

As a question of fact, based on the evidence in this record, the Commission finds that complaint counsel have failed to demonstrate that the only reasonable basis for these affirmative product claims would be adequate and well-controlled scientific studies or tests. It is accordingly necessary to consider, as a matter of fact, the other bases put forth by respondent in support of their ‘reasonable basis' defense.

Composition of Competing Products

As one of the factors in the argument that there existed a reasonable basis for the product claims in question, respondent alleges that it surveyed competing product on the market to determine (1) the ingredients in such products, and (2) the advertising claims which were being made for such products. Respondent apparently reasons that since the ingredients in Un-Burn are substantially identical to those competing products, [FN26] it is permissible to make the same advertising claims as are made for such competing products—or at least those which have not been challenged as false by a government agency (Tr. 1116, 1130, 1162). The restatement of this argument is sufficient to refute it. The Commission clearly can give no weight to this type of argument in evaluating whether there was a reasonable basis for respondent's claims.

The fact that apparently there did exist a valid efficacy test for a competing product of similar composition which was known to and verified by respondent, however, might have provided a reasonable basis for similar efficacy claims for Un-Burn (CX 99; Tr. 562–573; O.A. 24). [FN27] The evidence with regard to this particular test, however, falls substantially short of constituting an adequate test for the particular anesthetic claims made for Un-Burn. Nor is there sufficient evidence that Pfizer knew of, and relied upon, this test in marketing Un-Burn.

Medical Literature

Respondent urges that its search of the medical literature contained in Pfizer's library, prior to marketing Un-Burn, provided a reasonable basis for the Un-Burn efficacy representations. While complaint counsel do not meet this argument directly, their argument that the *only* reasonable basis would be scientific studies or tests encompasses this point. In oral argument, however, complaint counsel did concede that medical literature containing reports on adequate and well-controlled tests might be sufficient.

The record evidence is sufficient to demonstrate to the Commission that medical literature might, in some instances, be sufficient basis for making affirmative product claims (Tr. 671, 704, 713, 1054, 1108, 1118, 1128).

Closely allied with medical literature as a reasonable basis, would be the general state of medical knowledge at the time the claims were made, regardless of how that knowledge is ascertained (Tr. 1049, 1097, 1134; I.D. 20–23 [pp.

42–45 herein], 30–32 [pp. 51–52 herein]). Thus, the examiner found that:

> Recognized medical literature and the medical practice of dermatologists for between 50 and 70 years regarded the active ingredients in Un-Burn as efficacious for the relief of sunburn pain. (I.D. 32 [53 herein].)

Persuasive in this regard is the fact that the NAS-NRC panels utilized by the Food and Drug Administration were permitted to recognize as probative reports on studies contained in the medical and scientific literature (RX 110, p. 5; HX 1; Tr. 369, 371, 535).

The guidelines for these NAS-NRC panels [FN28] set forth the following basis for judgments as to drug efficacy:

> The judgments of the Panels will be based on the following criteria: (1) factual information that is freely available in the scientific literature, (2) factual information that is available from the FDA, from the manufacturer or other sources, or (3) on the experience and informed judgment of the members of the Panels. (See also, Tr. 535.)

These guidelines later discuss one instance where scientific literature alone could provide the basis for a judgment as to effectiveness:

> It is anticipated that substantial evidence for the effectiveness of many of the drugs assigned to a Panel will be found to be well-documented in the scientific literature familiar to the members of the Panel. In these cases, the Panel may be prepared to make its recommendations and to support them by citations from the scientific literature alone.

In a later section, the guidelines discuss other types of evidence of effectiveness:

> IX. *Some Special Considerations*
>
> In the deliberations of the Panels, issues will almost certainly arise as to considerations other than factual evidence, that should be weighed in arriving at judgments on effectiveness. The significance of many of these factors will vary widely in different classes of drugs and of the indications. No general guidelines for these can be offered. As these questions arise, however, Panel chairmen are invited to present them to the Policy Advisory Committee together with any suggestions as to the manner in which they might be resolved.
>
> A few general issues can, however, be anticipated.
>
> * * *
>
> D. *Wide Usage*
>
> There will likely be cases in which a Panel is in doubt as to the sufficiency of evidence of effectiveness of a drug that has gained repute among practicing physicians or that has been in wide use for a period of years. It will be quite in order for the Panel to draw attention to these facts in recording its judgment as to effectiveness.
>
> * * *
>
> F. *Subjective Evaluations*
>
> The informed judgment and experience of the members of the Panels in valid evidence contributory to the final decision on the efficacy of a drug for the indications presented. In justifying its decision, however, the Panel is expected to delineate the extent to which it is supported by the substantive evidence available for its review.

Complaint counsel's burden in this proceeding is that of demonstrating that respondent's actions in reliance upon the medical literature did not provide a reasonable basis for the affirmative product claims. Complaint counsel for example, could have offered evidence or argument that: (1) respondent's search of the medical literature was of such a limited scope that it was unreasonable, or (2) the conclusions drawn by respondent from the medical literature actually reviewed were unreasonable, or (3) the ‘testimonial’ quality of the medical literature was not sufficient basis for the product claims. [FN29] Complaint counsel's insistence that the medical literature specifically report on actual tests fails to address itself to, or satisfy, their burden in this regard. [FN30] Complaint counsel's primary evidence on this point was the rebuttal testimony of Dr. Beaver, who basically showed a possible conflict in the medical literature. This

does not satisfy the burden of proof resting on complaint counsel on this issue.

Clinical Experience

Respondent's final argument is that the clinical experience of the medical profession in itself provides a reasonable basis for making efficacy claims for Un-Burn. Again, in view of complaint counsel's primary focus on the necessity for scientific tests, the Commission is not in a position to definitely evaluate whether clinical experience as to benzocaine and menthol would provide a reasonable basis for assuming its efficacy. It was clear from the evidence of record, however, the 'clinical experience' covers a wide range of circumstances and must be carefully analyzed and evaluated, including consideration of the type of ailment being treated. Accordingly, the reasonableness of clinical experience must be evaluated as a factual issue in each case (Tr. 1083, 1097, 1108, 1122, 1185, 1253, 1258, 1263, 1300). In this regard, the relevant inquiry is into a respondent's knowledge of, and reliance upon, clinical experience *prior* to making the product claims in question. Thus, Pfizer's witness as to clinical experience, who were contacted by Pfizer only in preparation for trial, are irrelevant to the issue (*See I.D.*, pp. 20–23 [pp. 42–44 herein]).

Respondent's Efforts to Provide A Reasonable Basis for Affirmative

Pfizer's director of Marketing testified that he took three measures to satisfy himself as to the efficacy of the product Un-Burn. First, he received 'complete assurance' from Pfizer's medical people that the claims he planned to use for Un-Burn could be supported by the two active ingredients in the quantities in which they were to be used in the product. He was assurred that the way a topical anesthetic works is to anesthetize nerves and thereby stop pain (Tr. 605). He was also assured by the 'medical people' that the product was patterned very closely after the market leader, Solarcaine. Secondly, he was assured that all available literature or information on these two active ingredients had been thoroughly reviewed and favorable conclusions derived from this review as to the efficacy of the ingredients as topical anesthetics. Finally, he personally reviewed all competitive advertising to satisfy himself that Pfizer would not be claiming anything more than other products with the same active ingredients. The director of marketing testified that Pfizer did not conduct tests on humans to determine whether the efficacy claims could be supported, but consciously 'accepted another method of satisfying' themselves by going over the history of the ingredients. No specific tests were conducted on human beings to prove that Un-Burn anesthetizes nerve ends (*I.D.*, pp. 10, 19 [pp. 33, 41 herein]; Tr. 623–624).

The Pfizer medical official responsible for testing all new Pfizer products, testified that two efficacy tests were run on Un-Burn:

1. Testing with regard to the antibacterial properties of the product, and
2. The guinea pig wheal tests.

These latter tests involved the injection of Un-Burn into guinea pigs. His conclusions as to the results of Pfizer's testing on Un-Burn were as follows:

> [T]he products passed the safety and efficacy tests. The tests demonstrated that there were no safety hazards pertaining to the products, and that the antibacterial activity of the product would support the antiseptic claim, and finally, the guinea wheal test demonstrated to us that the active ingredient, one of the active ingredients, benzocaine, was not inactivated by anything in the formulations. (Tr. 668).

As a result of the safety and other tests, his review of the literature, and his discussions with Dr. Carlozzi, the medical director of Pfizer, Dr. Jenkins gave his opinion that the testing done was sufficient to establish the safety and efficacy of Un-Burn (*I.D.*, p. 20 [p. 42 herein]; Tr. 672–673).

Inasmuch as complaint counsel's argument did not go directly to the reasonableness of these actions, we lack a sufficient basis for a finding in this regard. In future cases, we would be interested in both the qualifications of the medical and scientific advisors, and some showing that their judgments were rendered on an informed and unbiased basis. Also properly considered here would be the issue of whether reliance upon medical literature and clinical evidence as to the separate ingredients in Un-Burn is appropriate, or whether additional consideration must be given to (1) the combination of ingredients as they appear in the final product, and (2) the various conditions of use to which the

product can reasonably be expected to be subjected, including variations as to skin types and degrees of sunburn. The Commission is not, moreover, convinced of the reasonableness of respondent's attempts to rely upon clinical experience as to the efficacy of benzocaine and menthol in general, to support the specific degree of efficacy (‘anesthetizes' nerves, ‘stops' sunburn) claimed for Un-Burn. [FN31]

Evidently respondent made no written report setting forth the actions which were taken to support the existence of a reasonable basis for its advertising claims. Such a report, if made in good faith prior to marketing, if reasonable in scope and approach, [FN32] and if reasonably clear as to the evidentiary basis for the specific claims in question (be they scientific tests, specified medical references, or specific clinical evidence), would certainly have, in itself, gone a considerable distance in demonstrating the existence of a reasonable basis for their affirmative product claims.

V. REMAINING ISSUES

Respondent raises a number of collateral arguments which should be noted. First, respondent argues that ‘fairness' is an unconstitutionally vague standard upon which to base a Commission order. Second, a holding based on fairness would violate the First Amendment to the Constitution. Third, the Food, Drug, and Cosmetic Act implicitly limits the Commission's Section 5 jurisdiction in certain circumstances. Fourth, the ‘focusing of Congressional attention’ on this proceeding was inconsistent with the Fifth Amendment. The Commission finds none of these arguments persuasive.

VI. CONCLUSION

Having reviewed the record, initial decision, briefs and argument in this proceeding, the Commission has determined that the hearing examiner's dismissal of the complaint should be affirmed. The divergent approaches of complaint counsel and counsel for respondent, both to the appropriate legal standard and to the facts of this case, resulted in the issue simply not being satisfactorily joined.

While the Commission finds that respondent failed in its attempt to demonstrate affirmatively the existence of a reasonable basis for its Un-Burn advertising, the evidence is not sufficient to prove that respondent in fact *lacked* a reasonable basis for its advertising claims. The record evidence is simply inconclusive with regard to the adequacy of the medical literature and clinical experience relied upon by respondent, and with regard to the reasonableness of such reliance.

While this failure of proof might be cured by a remand, the Commission does not believe further proceedings are warranted in the public interest. The reformulation of the legal standard from ‘adequate and well-controlled scientific studies or tests' to ‘reasonable basis' might warrant an extensive trial *de novo*, and the advertising in question has already long been discontinued. The significance of this particular case lies, therefore, not so much in the entry of a cease and desist order against this individual respondent, but in the resolution of the general issue of whether the failure to possess a reasonable basis for affirmative product claims constitutes an unfair practice in violation of the Federal Trade Commission Act. As to that issue, the foregoing opinion expresses the views of the Commission. In view of these circumstances, the Commission has determined to affirm the order and initial decision of the hearing examiner except to the extent inconsistent with this opinion.

Commissioner MacIntyre concurs as to the result reached by the majority.

Commissioner Jones concurs in the statement of law applicable to this case as laid out in the opinion, but in light of the opinion and the record in this matter, dissents to the disposition of the case since it deprives respondent of an opportunity to seek a court review of the issues involved.

FINAL ORDER

This matter having been heard by the Commission upon the appeal of counsel supporting the complaint from the hearing examiner's initial decision, and upon briefs and oral argument in support thereof and in opposition thereto, and the Commission, for the reasons stated in the accompanying opinion, having denied the appeal:

It is ordered, That the order of the hearing examiner be affirmed, and that, except to the extent inconsistent with the accompanying opinion, the examiner's initial decision be, and it hereby is, adopted ad the decision of the Commission.

It is further ordered, That the complaint be, and it hereby is, dismissed.

Commissioner MacIntyre concurs as to the result reached by the majority. Commissioner Jones concurs in the statement of law applicable to this case as laid out in the opinion, but in light of the opinion and the record in this matter, dissents to the disposition of the case since it deprives respondent of an opportunity to seek a court review of the issues involved.

FN1 15 U.S.C. 45.

FN2 The following abbreviations will sometimes be used:
C. Complaint
A. Answer
Tr. Transcript
CX Complaint Counsel's Exhibit
RX Respondent's Exhibit
CPF Complaint Counsel's Proposed Findings
RPF Respondent's Proposed Findings
(In citing proposed findings the references therein are deemed to be included)

FN3 Tr. 809 For convenience of the witnesses, three of respondent's witnesses were called prior to the argument of the motion. Their testimony accordingly is disregarded in denying the motion.

FN4 After the conclusion of their case counsel supporting the complaint conceded that the words in brackets should be out of the case (Tr. 811).
It should be noted that both records and T.V. sound tape are available in evidence and it is respectfully suggested to any reviewing authority that the actual tape projection rather than the foregoing quotations be observed in order that proper inferences may be drawn (see Tr. 211–212).

FN5 His *curriculum vitae* was received as Exhibit 70 (Tr. 223).

FN6 At Tr. 288 line 18, the numbers CX 25–38 are omitted but they were inserted the following day by stipulation (Tr. 318).

FN7 By direction and in the interests of expedition the transcript of January 26, 1971, starts with p. 500 rather than 375 because the last page number was not available to the reporter at Miami.

FN8 His complete *curriculum vitae* is marked CX 71.

FN9 Dr. Beaver's *curriculum vitae* is Exhibit 72 (Tr. 320).

FN10 His *curriculum vitae* is marked Exhibit 73 (Tr. 503).

FN11 His *curriculum vitae* is RX 106 (Tr. 1091).

FN12 His *curriculum vitae* is Exhibit 107 (Tr. 1143).

FN13 His *curriculum vitae* is Exhibit 104 (Tr. 1176).

FN14 His *curriculum vitae* is in evidence RX 105 (Tr. 833–834).

FN15 In the transcript the number 900–1000 was used on one page presumably for the convenience of the typists.

FN16 His *curriculum vitae* is Exhibit 103 (Tr. 1204–1205).

FN17 His *curriculum vitae* was received as RX 108 (Tr. 1037).

FN18 Order dated September 21, 1970. See particularly p. 3 citing *FTC* v. *Brown Shoe Company*, 384 U.S. 316, 321 (1966) and *FTC* v. *Texaco*, 393 U.S. 223, 225 (1968).

FN19 See order of September 21, 1970, p. 2, 3 and the cases there cited.

FN20 The implication clearly must be within the bounds of reason, *FTC* v. *Colgate-Palmolive Co., et al.*, 380 U.S. 374 (1965).

FN21 It will be recalled this in the matter of *National Association of Women's and Children's Apparel Salesmen*, Docket 8691 [76 F.T.C. 1082], the Commission deferred to the decision of NLRB under similar conditions.

FN1 As recommended by the hearing examiner in his initial decision, during the oral argument before it the Commission observed the TV commercials being challenged, and listened to the radio tapes. (See I.D., pp. 6–7 [p. 30 herein]. CX 4, 5, 6, 7.) These advertisements for Un-Burn contain two primary representations: (1) Un-Burn will actually anesthetize nerves in sunburned skin; (2) Un-Burn will stop sunburn pain fast.

FN2 *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374 (1965).

FN3 See Gellhorn, *Proof of Consumer Deception Before the Federal Trade Commission*, 17 Kansas L. Rev. 559 (1969).

FN4 (O.A. Tr. p. 4). Complaint counsel frame their argument in the following terms:

> '[I]t is obvious that (1) because respondent's advertising clearly represented that Un-Burn is a drug that will stop sunburn pain fast (Tr. 779), (2) because the public believes that an advertise cannot make false claims about his product (Tr. 774, 776, 778), (3) because the public expects a product to work (Tr. 778, 779), and (4) because the public expects a manufacture to have evidence that his product will work as claimed (Tr. 778, 779, 780, 781), respondent did in fact represent in its advertising that each of the statements respecting the pain relieving properties claimed for Un-Burn had been substantiated by respondent with adequate and reliable evidence and that this evidence was obtained prior to the making of such statements.' (Complaint counsel's appeal brief, pp. 5 & 6.)

FN5 *Cf. All-State Industries, et al.*, Docket No. 8738 (April 1, 1969), 423 F.2d 423 (1970), *cert. denied*, 400 U.S. 828 (1970); *FTC* v. *R. F. Keppel & Bros., Inc.*, 291 U.S. 304 (1934); *Wolf* v. *FTC*, 135 F.2d 564 (7th Cir. (1943)); *First Buckingham Community, Inc.*, Docket 8750 (May 20, 1968) [73 F.T.C. 938]; *Chemway Corporation*, Docket C–1945 (June 14, 1971) [78 F.T.C. 1250].

FN6 See, *e.g., Topper Corporation, et al.*, Docket C–2073 (November 1, 1971) [79 F.T.C. 681].

FN7 *FTC* v. *Sperry & Hutchinson*, Docket 8671 (June 1968), *rev'd*, 432 F.2d 146 (5th Cir. 1970), *rev'd*, 405 U.S. 233 (March 1, 1973).

FN8 H.R. Rep. No. 163, 75th Cong. 1st Session, p. 3 (1937).

FN9 Slip opinion at p. 11.

FN10 *Federal Trade Commission* v. *Sperry & Hutchinson Co., supra*.

FN11 See *FTC* v. *Standard Education Society*, 86 F. 2d 692, 696 (2d Cir. 1936), *rev'd on other grounds*, 302 U.S. 112 (1937) (Hand, J.):

> '[The Commission's] powers are not confined to such practice as would be unlawful before it acted; they are more than procedural; its duty in part at any rate, is to discover and make explicit those unexpressed standards of fair dealing which the conscience of the community may progressively develop.'

FN12 In the over-the-counter drug field, for example, it has been estimated that there are between 100,000 and 200,000 products available. (Statement of Dr. Charles C. Edwards, Commissioner, Food and Drug Administration, in Hearings Before the Subcommittee on Monopoly of the Select Committee on Small Business, 92d Congress, 1st Session, May 25, 1971, Part 1.)

FN13 *Compare* Fletcher, *Fairness and Utility in Tort Theory*, 85 Harv. L. Rev. 537, 542 (1972).
'Reasonableness is determined by a straightforward balancing of costs and benefits. If the risk yields a net social utility (benefit), the victim is not entitled to recover from the risk-creator; if the risk yields a net social disutility (cost), the victim is entitled to recover. The premises of this paradigm are that reasonableness provides a test of activities that ought to be encouraged and that tort judgments are an appropriate medium for encouraging them.'
This balance admittedly gives more consideration to the producers' interests than does the test suggested by Adam Smith: '[T]he interest of the producer ought to be attended to only so far as it may be necessary for promoting that of the consumer.' Smith, *An Inquiry Into The Nature and Causes of the Wealth of Nations*, 625 (Modern Library Edition, 1937).

FN14 437 F.2d 707 (D. C. Cir. 1970).

FN15 *All-State Industries*, Docket No. 8738 (slip opinion, pp. 13–14), *aff'd*, 423 F.2d 423 (1970), *cert. denied*, 400 U.S. 828 (1970).

FN16 This standard pertains only to advertising representations, and does not deal with the question of whether the mere fact of marketing a product implies or requires that certain standards of safety and health must be met. *Cf. Chemway Corporation*, Docket C–1945 (June 14, 1971) [78 F.T.C. 1250]; *H. W. Kirchner*, 63 F.T.C. 1282 (1963).

FN17 63 F.T.C. at 1290.

FN18 Complaint, Paragraph 4.

FN19 CX 4–7; Complaint, Paragraph 4.

FN20 *PMA* v. *Richardson* (D. Del. 1970). *Upjohn Co.* v. *Finch*, 422 F.2d 944 (6th Cir. 1970).

FN21 This precludes consideration, in connection with this particular case, of the FDA's activities in defining the scientific content of 'adequate and well-controlled clinical investigations.' See HX–1; 35 Fed. Reg. 3073 (February 17, 1970), 35 Fed. Reg. 7250 (May 8, 1970).

FN22 The nature and intricacy of the debate on the adequacy of this test leads to the view that the Commission's role should simply be one of attempting to determine the existence and general quality of the tests and a threshold determination as to the reasonableness of reliance thereon, rather than an attempt to conclusively determine the adequacy of the tests.

FN23 One definite obstacle to such a finding is the fact that this test undertook to compare the effectiveness of Un-Burn with the noneffectiveness of a placebo, rather than to compare Un-Burn's effectiveness with the level of effectiveness claimed by Pfizer's advertising (See, Tr. 680–682, 1215).

FN24 *Compare* *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 388 (1965). A false representation violates Section 5 even if the misstatement in no way affects the qualities of the product. The concern is 'with methods designed to get a consumer to purchase a product, not with whether the product, when purchased, will perform up to expectations.' In short, the focus is upon the method of marketing. *See also*, *Philip Morris, Inc.*, Docket 8838 (March 12, 1971) (marketing practices which allegedly constitute safety hazards are challenged as allegedly unfair); *FTC* v. *Algoma Lumber Co.*, 291 U.S. 67 (1934).

FN25 I.D., p. 35 [67 herein].

FN26 This argument is weakened by the fact that apparently no scientific analysis was made to determine whether the competing products had the same formula as Un-Burn (Tr. 703).

FN27 Such claims, of course, cannot imply that respondent's product is unique or different from the competing product in question.

FN28 Guidelines for the Drug Efficacy Study of the National Academy of Sciences-National Research Council, August 1966 (RX 110; I.D., p. 30 [pp. 50–51 herein]).

FN29 Complaint counsel's argument was misdirected to some degree, to any medical literature which a witness may have reviewed (Tr. 1312; CCRB 2; *Compare I.D.*, p. 19 [pp. 41–42 herein]).

FN30 Thus, we do not reach several significant issues pertinent to this point, *e.g.*, did the medical literature deal with the Un-Burn ingredients in the same combination and amounts as they appear in the final formulation of Un-Burn (O.A., 4, 16); is chemical equivalence sufficiently indicative of therapeutical equivalence (tr. 1081, 1116, 1117, O.A. 12); are authors' opinions and conclusions sufficient, or must the actual underlying tests be described; or whether the medical literature will ever be capable of supporting product claims which relate to a condition which varies so widely among the people it affects as does sunburn.

FN31 The Orentreich test evaluated the efficacy of Un-Burn only in comparison to a placebo—it did not attempt to determine whether nerves were 'actually anesthetized' or sunburn pain had in fact 'stopped.' (CCRB 3–4.)

FN32 The issue of whether an advertisement has appropriately formulated the standard of what constitutes a 'reasonable basis' remains a separate question of fact. See discussion at pp. 16–17 [pp. 66–67 herein], *supra*.

81 F.T.C. 23, 1972 WL 127465 (F.T.C.)
END OF DOCUMENT

ATTACHMENT F

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).

Introduction

On March 11, 1983, the Commission published a notice requesting comments on its advertising substantiation program.[1] To facilitate analysis of the program, the notice posed a number of questions concerning the program's procedures, standards, benefits, and costs, and solicited suggestions for making the program more effective. Based on the public comments and the staff's review, the Commission has drawn certain conclusions about how the program is being implemented and how it might be refined to serve better the objective of maintaining a marketplace free of unfair and deceptive acts or practices. This statement articulates the Commission's policy with respect to advertising substantiation.

The Reasonable Basis Requirement

First, we reaffirm our commitment to the underlying legal requirement of advertising substantiation-that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated.

The Commission intends to continue vigorous enforcement of this existing legal requirement that advertisers substantiate express and implied claims, however conveyed, that make objective assertions about the item or service advertised. Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers. That is, consumers would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true.[2] Therefore, a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.

Standards for Prior Substantiation

Many ads contain express or implied statements regarding the amount of support the advertiser has for the product claim. When the substantiation claim is express (e.g.., "tests prove", "doctors recommend", and "studies show"), the Commission expects the firm to have at least the advertised level of substantiation. Of course, an ad may imply more substantiation than it expressly claims or may imply to consumers that the firm has a certain type of support; in such cases, the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers.

Absent an express or implied reference to a certain level of support, and absent other evidence indicating what consumer expectations would be, the Commission assumes that consumers expect a "reasonable basis" for claims. 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. Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses.

One issue the Commission examined was substantiation for implied claims. Although firms are unlikely to possess substantiation for implied claims they do not believe the ad makes, they should generally be aware of reasonable interpretations and will be expected to have prior substantiation for such claims. The Commission will take care to assure that it only challenges reasonable interpretations of advertising claims.[3]

Procedures for Obtaining Substantiation

In the past, the Commission has sought substantiation from firms in two different ways: through industry-wide "rounds" that involved publicized inquiries with identical or substantially similar demands to a number of firms within a targeted industry or to firms in different industries making the same type of claim; and on a case-by-case basis, by sending specific requests to individual companies under investigation. The Commission's review indicates that "rounds" have been costly to both the recipient and to the agency and have produced little or no law enforcement benefit over a case-by-case approach.

The Commission's traditional investigatory procedures allow the staff to investigate a number of firms within an industry at the same time, to develop necessary expertise within the area of investigation, and to announce our activities publicly in circumstances where public notice or comment is desirable. The Commission intends to continue undertaking such law enforcement efforts when appropriate. However, since substantiation is principally a law enforcement tool and the Commission's concern in such investigations is with the substantiation in the *advertiser's* possession, there is little, if any, information that the public could contribute in such investigations. Therefore, the Commission anticipates that substantiation investigations will rarely be made public before they are completed.

Accordingly, the Commission has determined that in the future it will rely on nonpublic requests for substantiation directed to individual companies via an informal access letter or, if necessary, a formal civil investigative demand. The Commission believes that tailored, firm-specific requests, whether directed to one firm or to several firms within the same industry, are a more efficient law enforcement technique. The Commission cannot presently foresee circumstances under which the past approach of industry-wide rounds would be appropriate in the ad substantiation area.

Relevance of Post-Claim Evidence in Substantiation Cases

The reasonable basis doctrine requires that firms have substantiation before disseminating a claim. The Commission has on occasion exercised its discretion, however, to consider supporting materials developed after disseminations The Commission has not previously identified in one document the circumstances in which it may, in its discretion, consider post-claim evidence in substantiation cases.[5] Such guidance can serve to clarify the program's actual operation as well as focus consideration of postclaim evidence on cases in which it is appropriate.

The Commission emphasizes that as a matter of law, firms lacking a reasonable basis before an ad is disseminated violate Section 5 of the FTC Act and are subject to prosecution. The goal of the advertising substantiation requirement is to assure that advertising is truthful, however, and the truth or falsity of a claim is always relevant to the Commission's deliberations. Therefore, it is important that the agency retain the discretion and flexibility to consider additional substantiating evidence, not as a substitute for an advertiser's prior substantiation, but rather in the following circumstances:

- When deciding, before issuance of a complaint, whether there is a public interest in proceeding against a firm;
- When assessing the adequacy of the substantiation an advertiser possessed before a claim was made; and
- When deciding the need for or appropriate scope of an order to enter against a firm that lacked a reasonable basis prior to disseminating an advertisement.

First, using post-claim evidence to evaluate the truth of a claim, or otherwise using such evidence in deciding whether there is a public interest in continuing an investigation or issuing a complaint, is appropriate policy. This does not mean that the Commission will postpone action while firms create post-claim substantiation to prove the truthfulness of claims, nor does it mean that subsequent evidence of truthfulness absolves a firm of liability for failing to possess prior substantiation for a claim. The Commission focuses instead on whether existing evidence that claims are true should lead us in the exercise of our prosecutorial discretion to decline to initiate a law enforcement proceeding. If available post-claim evidence proves that the claim is true, issuing a complaint against a firm that may have violated the prior substantiation requirement is often inappropriate, particularly in light of competing demands on the Commission's resources.

Second, post-claim evidence may indicate that apparent deficiencies in the pre-claim substantiation materials have no practical significance. In evaluating the adequacy of prior substantiation, the Commission will consider only post-claim substantiation that sheds light on pre-existing substantiation. Thus, advertisers will not be allowed to create entirely new substantiation simply because their prior substantiation was inadequate.

Finally, the Commission may use post-claim evidence in determining the need for or appropriate scope of an order to be entered against a firm that lacked a reasonable basis. Thus, when additional evidence offered for the first time at trial suggests that the claim is true, the Commission may frame a narrower order than if there had been no post-claim evidence.

The Commission remains committed to the prior substantiation requirement and further believes that these discretionary factors will provide necessary flexibility. The Commission will consider post-claim evidence only in the circumstances listed above. But, whether it will do so in any particular case remains within its discretion.

Self Regulation Groups and Government Agencies

The Commission traditionally has enjoyed a close working relationship with self regulation groups and government agencies whose regulatory policies have some bearing on our law enforcement initiatives. The Commission will not necessarily defer, however,

to a finding by a self-regulation group. An imprimatur from a self-regulation group will not automatically shield a firm from Commission prosecution, and an unfavorable determination will not mean the Commission will automatically take issue, or find liability if it does. Rather the Commission will make its judgment independently, evaluating each case on its merits. We intend to continue our useful relationships with self-regulation groups and to rely on the expertise and findings of other government agencies in our proceedings to the greatest extent possible.

By direction of the Commission.

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[1] The distinction between pre-claim and post-claim evidence is only relevant when the charge is lack of substantiation. For other chases, such as falsity, when evidence was developed is irrelevant to its admissibility at trial.

[1] 48 FR 10471, March 11, 1983.

[2] Nor presumably would an advertiser have made such claims unless the advertiser thought they would be material to consumers.

[3] Individual Commissioners have expressed differing views as to how claims should be interpreted so that advertisers are not held to outlandish or tenuous interpretations. Notwithstanding these variations in approach, the focus of all Commissioners on reasonable interpretations of claims is intended to ensure that advertisers are not required to substantiate claims that were not made.

[4] The Commission's evidentiary rule, 16 C.F.R. 3.40, has sometimes been interpreted as precluding introduction of post-claim substantiation. In fact, it does not. Section 3.40 only provides a sanction against the introduction of evidence that should have been produced in response to a subpoena, but was not.

ATTACHMENT G

127 F.T.C. 580, 1999 WL 33913005 (F.T.C.)

FEDERAL TRADE COMMISSION (F.T.C.)

***580** IN THE MATTER OF
NOVARTIS CORPORATION, ET AL.

FINAL ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT
Docket No. 9279

Complaint, June 21, 1996

Final Order, May 13, 1999

This final order, among other things, prohibits Novartis Corporation and Novartis Consumer Health, Inc., successors-in-interest to Ciba-Geigy Corporation and Ciba Self Medication, Inc., and the marketers of Dean's Pills, from representing that any over-the-counter analgesic drug is more effective than other over-the-counter analgesic drugs unless they possess and rely upon competent and reliable scientific evidence that substantiates their claims. In addition, the order requires the respondents to include a corrective notice in certain of Doan's advertisements, and to possess and rely upon competent and reliable scientific evidence as substantiation for any claims regarding the efficacy, safety, benefits or performance of any over-the-counter analgesic they market.

Participants

For the Commission: *Theodore Hoppock, Michael Ostheimer, Kevin Bank, Lynne Colbert, C. Lee Peeler*, and *Susan Braman.*

For the respondents: *Michael Denger, Boyd Johnson* and *Phillip Rudolph, Gibson, Dunn & Crutcher*, Washington, D.C.

COMPLAINT

The Federal Trade Commission, having reason to believe that Ciba-Geigy Corporation, and CIBA Self-Medication, Inc., corporations ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Ciba-Geigy Corporation ("Ciba-Geigy") is a New York corporation with its principal office or place of business at 444 Saw Mill River Road, Ardsley, New York.

Respondent CIBA Self-Medication, Inc. ("CIBA Self-Medication"), is a Delaware corporation with its principal office or place of business at 581 Main Street, Woodbridge, New Jersey. CIBA Self-Medication is a wholly-owned subsidiary of Ciba-Geigy.

PAR. 2. Respondents have manufactured, labeled, advertised, offered for sale, sold, and distributed drug products, including Dean's analgesic products, to the public. Dean's analgesic products are ***581** "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PAR. 3. CIBA-Geigy acquired the Dean's analgesic product line in 1987. Between 1987 and 1994, Ciba-Geigy advertised and sold Dean's analgesic products through its CIBA Consumer Pharmaceuticals division. CIBA Self-Medication was

incorporated in December 1994, at which time Ciba-Geigy transferred the assets of CIBA Consumer Pharmaceuticals to CIBA Self-Medication. Since December 1994, CIBA Self-Medication has advertised and sold Dean's analgesic products.

PAR. 4. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PAR. 5. Respondents have disseminated or caused to be disseminated advertisements for Dean's analgesic products, including, but not necessarily limited to, the attached Exhibits A-I. Respondents have disseminated these or substantially similar advertisements for at least eight years. These advertisements contain the following statements and depictions:

A. Doctors measure back pain by how far you can bend. Extra Strength Dean's is made for back pain relief with an ingredient these pain relievers don't have. *[Depiction of large package of Doan's in front of smaller packages of Bayer, Advil and Tylenol]* Doan's makes back pain go away. Extra Strength Doan's. The Back Specialist. *[Superscript: The back specialist]*

[Exhibit A: "Graph" 15-Second Television]

B. Lower back pain. Neck pain. Upper back pain. There are all kinds of back pain. Dean's relieves them all. With a special ingredient these brands don't have. *[Depiction of large package of Doan's infront of smaller packages of Bayer, Advil and Tylenol]*. Relieve back pain with Doan's, the Back Specialist. *[Superscript: The Back Specialist.]*

[Exhibit B: "Black & White Back" 15-Second Television]

C. Now. Back pain doesn't have to ruin another night's sleep. Introducing new Doan's P.M. Doan's starts with a unique pain reliever these brands don't have; *[Depiction of large package of Doan's P.M. and smaller packages of Tylenol, Bayer and Advil] [Superscript: Magnesium Salicylate]* then adds a second ingredient to help you sleep. New Doan's P.M. For nighttime back pain. *[Superscript: For Nighttime Back Pain.]*

[Exhibit C: "Ruin A Night's Sleep" 15-Second Television]

D. If nothing seems to help, try Doan's. It relieves back pain no matter where it hurts. Doan's has an ingredient these pain relievers don't have. *[Depiction of large package of Doan's in front of smaller packages of Bayer, Aleve, Advil and* ***582** *Tylenol.] [Superscript: Magnesium Salicylate]*. Doan's. The back Specialist. *[superscript: The Back Specialist]*

[Exhibit D: "Activity - Pets" 15-Second Television]

E. There are hundreds of muscles in the back. Any one can put you in agony. That's when you need Doan's. *[Depiction of Doan's package on top of packages of Tylenol, Bayer, Aleve and Advil]*. Doan's has an ingredient the leading brands don't. It relieves back pain no matter where it hurts. There are hundreds of muscles in the back. *[Superscript: The Back Specialist]* Doan's relieves them all.

[Exhibit E: "Muscles" 15-Second Television]

F. Doan's. Made for back pain relief. With an ingredient these other pain relievers don't have. *[Depiction of packages of Bayer, Tylenol, and Advil]*.

[Exhibit F: Print Advertisement}

G. Back pain is different. Why use these pain relievers? *[Depiction of packages of Tylenol, Motrin, and Advil]* Doan's is just for back pain.

[Exhibit G: Print Advertisement]

H. BACK PAIN SUFFERERS[:] IT'S EASY TO SEE WHY YOU NEED DOAN'S. These are for all kinds of aches and pains. *[Depiction of packages of Tylenol, Bayer, Motrin, and Advil, with a magnifying glass on the Tylenol package emphasizing Tylenol's labeling indications for use for "the temporary relief of minor aches, pains, headaches and fever."]* Doan's is just for back pain.

[Exhibit H: Print Advertisement]

I. WHY TREAT GENERAL ACHES? *[Depiction of packages of Bayer, Tylenol, Advil, and Aleve]*.

BACK PAIN NEEDS THE SPECIALIST *[Depiction of packages of Regular Strength Doan's, Extra Strength Doan's, and Extra Strength Doan's P.M.]*. DOAN'S. WITH A UNIQUE INGREDIENT THE OTHERS DON'T HAVE.

[Exhibit I: Print Advertisement]

PAR. 6. Through the use of the statements and depictions contained in the advertisements referred to in paragraph five, including but not necessarily limited to the advertisements attached as Exhibits A-I, respondents have represented, directly or by implication, that Doan's analgesic products are more effective than other analgesics, including Bayer, Advil, Tylenol, Aleve, and Motrin, for relieving back pain.

PAR. 7. Through the use of the statements and depictions contained in the advertisements referred to in paragraph five, including, but not necessarily limited to, the advertisements attached as Exhibits A-I, respondents have represented, di-

rectly or by implication, that at the time they made the representation set forth in paragraph six, respondents possessed and relied upon a reasonable basis that substantiated such representation.

***583** PAR. 8. In truth and in fact, at the time they made the representation set forth in paragraph six, respondents did not possess and rely upon a reasonable basis that substantiated such representation. Therefore, the representation set forth in paragraph seven was, and is, false and misleading.

PAR. 9. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices and the making of false advertisements in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

Commissioner Azcuenaga dissenting.

EXHIBIT A

Doan's®
The Back Specialist.

Doctors measure back pain

by how far you can bend.

Extra Strength Doans is made for back pain relief

with an ingredient these pain relievers dont have.

Doan's makes back pain

go away.

Extra Strength Doan's.
The Back Specialist.

EXHIBIT B

Doan's. The Back Specialist.
Relieves all kinds of back pain.

Lower back pain.

(SFX)

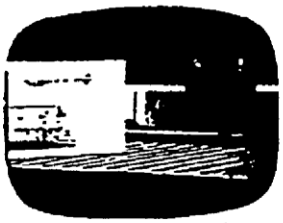
Neck Pain.

(SFX)

Upper back pain.

There are all kinds of back pain.

(Music) Doan's relieves them all.



With a special ingredient these brands don't have.

Relieve back pain with

Doan's.the Back Specialist.

EXHIBIT C

Ruin A Night's Sleep

DOAN'S P.M. RELIEVES BACK PAIN AND HELPS YOU SLEEP

Now. Back pain doesn't have

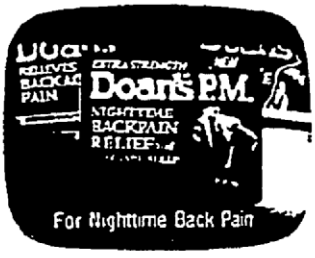
to ruin another night's sleep.

Introducing new Doan's PM.

Doan's starts with a unique pain reliever

these brands don't have

then adds a second ingredient to help you sleep.



New Doan's PM. For nighttime back pain.

EXHIBIT D

DOAN'S

"ACTIVITY-PETS" :15 TV

ANNCR: (VO) He's your best friend.

and he's also

killing your back.

If nothing seems to help.

try Doan's.

It relieves back pain

no matter where it hurts.

Doan's has an ingredient these pain relievers don't have.

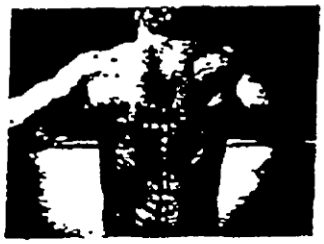
Doan's. The Back Specialist.

EXHIBIT E

DOAN'S

"Muscles - Male 15 TV

AVO. There are hundreds of

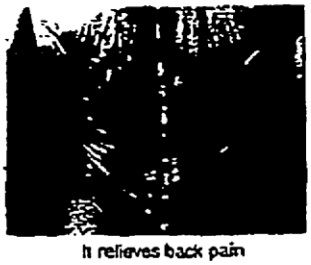


muscles in the back

Any one can put you in agony

That's when you need Doan's.

Doan's has an ingredient the leading brands don't



It relieves back pain

no matter where it hurts.

There are hundreds of muscles in the back.

Doan's relieves them all

EXHIBIT F

EXHIBIT G

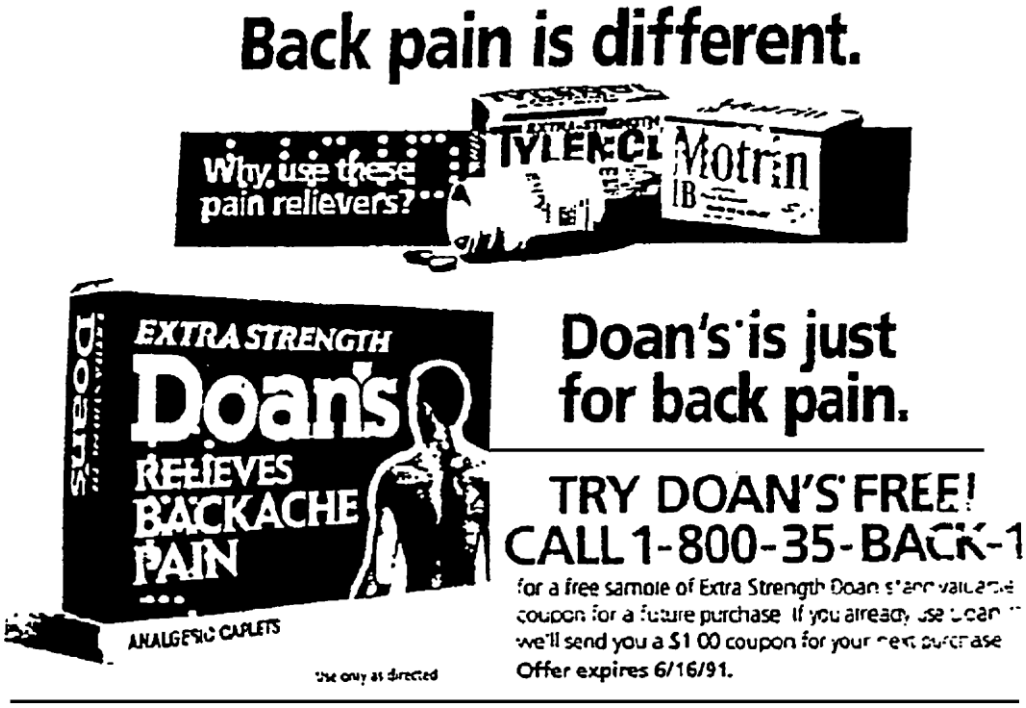
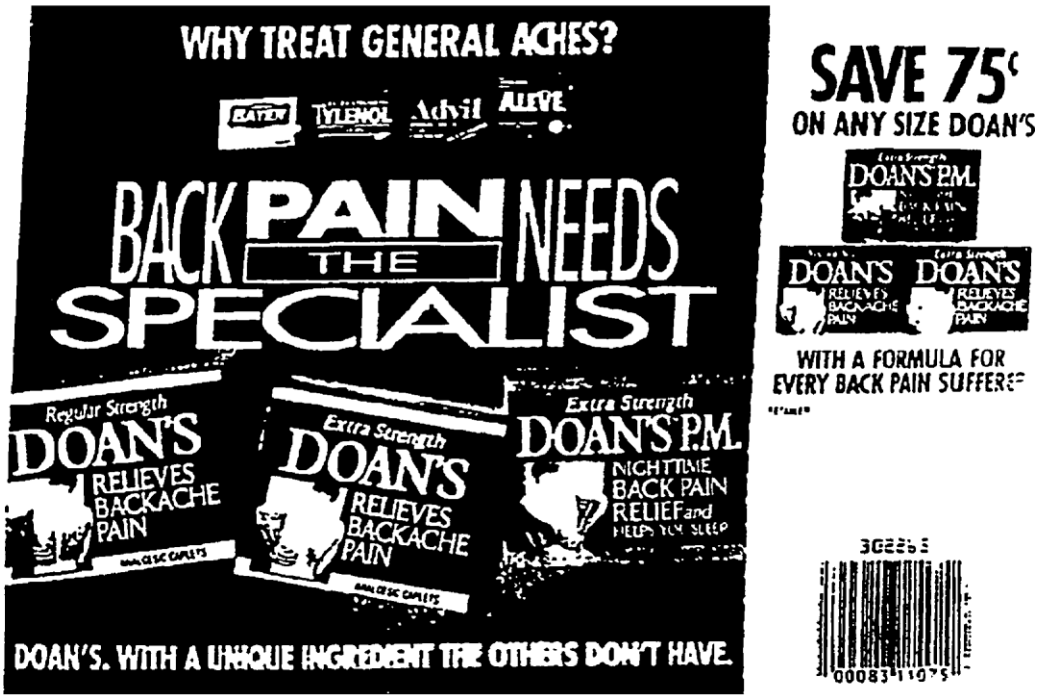


EXHIBIT H

EXHIBIT I



***593** DISSENTING STATEMENT OF COMMISSIONER MARY L. AZCUENAGA

Although I have reason to believe that the respondents have violated Section 5 of the Federal Trade Commission Act as alleged in the complaint, I dissent on the ground that, because the case could have been settled on satisfactory terms, it is not in the public interest to litigate.

INITIAL DECISION

BY LEWIS F. PARKER, ADMINISTRATIVE LAW JUDGE

MARCH 9, 1998

I. INTRODUCTION

On June 21, 1996, the Commission issued its complaint in this proceeding charging that Ciba-Geigy Corporation and Ciba Self-Medication, Inc., now Novartis Corp. and Novartis Consumer Health, inc. ("Novartis" or respondents), successors-in-interest to Ciba-Geigy and Ciba Self-Medication (*see* order dated April 23, 1997), violated Section 5 of the Federal Trade Commission Act.

Novartis manufactures, advertises and sells Doan's analgesic products. The complaint alleges that Novartis has represented, directly or by implication, that these products are more effective than other analgesics, including Bayer, Advil, Tylenol, Aleve, and Motrin, for relieving back pain.

The complaint further charges that Novartis has, by the use of several ads, falsely represented, directly or by implication, that at the time it made its effectiveness claims, it possessed and relied upon a reasonable basis that substantiated them.

After extensive pretrial discovery, trial was held in Washington, D.C. The record was closed on December 5, 1997 and the parties filed their proposed findings on December 19, 1997. Replies were filed on January 16, 1998.

This decision is based on the transcript of testimony, the exhibits which I received in evidence, and the proposed findings of fact and conclusions of law, and answers thereto, filed by the parties, I have adopted several proposed findings verbatim. Others have been adopted in substance. All other findings are rejected either because they are not supported by the record or because they are irrelevant.

***594** II. FINDINGS OF FACT

A. Novartis

1. Respondent Novartis is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its offices and principal place of business located at 556 Morris Avenue, Summit, New Jersey. Respondent Novartis Consumer Health, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 560 Morris Avenue, Summit, New Jersey. Novartis Consumer Health, Inc., is a subsidiary of Novartis Corporation. (*See* Ans ¶ 1; JX 2 ¶ 11.) [FN1]

2. Novartis and Novartis Consumer Health, Inc., (hereinafter, individually and collectively referred to as "Novartis") are successors-in-interest to, respectively, Ciba-Geigy Corporation and Ciba Self-Medication, Inc. (hereinafter individually, and collectively referred to as "Ciba") (JX 2 ¶ 11).

3. On April 23, 1997, upon agreement of the parties, Novartis was substituted for Ciba as respondent in this proceeding. (Order dated March 23, 1997.)

4. Novartis is a subsidiary of Novartis AG, a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland with its office and principal place of business located at Centralbahnstrasse 7, CH-4010 Basel, Switzerland. (*CibaGeigy Limited*, Dkt. C-3725 (March 24, 1997).)

5. Novartis manufactures and sells many over-the-counter ("OTC") products in addition to Doan's, including such well known brands as Ascriptin, Ciba Vision, Desenex, Dulcolax, ExLax, Gas-X, Habitrol, Maalox, Sunkist Vitamin C, Tavist-D, Theraflu, and Triaminic. (*See, e.g.*, CX 401-A; CX 385-Z-36-39.)

6. From January 1987 to December 1994, Ciba-Geigy Corporation was responsible for the marketing and advertising of Dean's analgesic products ("Doan's"). In December 1994, Ciba transferred the Doan's line of products to Ciba Self Medication ("CSM"), a wholly-owned subsidiary. CSM was responsible for the marketing ***595** and advertising of Doan's products from December 1994 to March 24, 1997 (JX 2 ¶ 13). For purposes of the Federal Trade Commission Act, 15 U.S.C. 52, Doan's analgesic products are "drugs" as defined in Section 15 of the Act, 15 U.S.C. 55 (Ans ¶ 2; JX2 ¶ 14).

7. At all relevant times, the acts and practices of Novartis challenged in the complaint have been in or affecting commerce (Ans ¶ 4; JX 2 ¶ 15).

B. Doan's

8. Doan's has been sold in this country for over 90 years and has always been advertised (or "positioned") for the relief of back pain (Peabody Tr. 285-87) (Mr. Peabody is the Director of Marketing Research at Novartis Consumer Health, Inc.).

9. Ciba purchased the Doan's brand in early 1987 from DEP Corporation, which had shortly before acquired the brand from Jeffrey Martin, Inc. (JX 2 ¶ 12; CX 455-A; CX 500 at 19-20 [Russo Dep.]).

10. Ciba purchased the Doan's brand for approximately $35 million (CX 500 at 21-33 [Russo Dep.]) because it believed that Doan's was a brand name with a high level of awareness and potential for expanding sales (CX 501 at 24 [Sloan Dep.]). At that time, Ciba believed that Doan's did not have much of a brand image and was viewed as dated and old fashioned. This view was confirmed by consumer research that Ciba had conducted shortly after acquiring the brand (Peabody Tr. 285).

11. In 1986, before Ciba purchased the Doan's brand, Jeffrey Martin, Inc., was disseminating three different 30-second television commercials for Doan's: "Hollingshead," "Schwartz" (CX 431), and "Drake" (CX 432) (CX 508-Z-2). The creative strategy for these ads was that Doan's "relieves minor muscular back pain." The ads featured hidden camera testimonials with individuals explaining how they got relief from Doan's pills. (*See id.* at Z-2-3; CX 431; CX 432; Mazis Tr. 942-45.)

12. Until late 1987, the only Doan's analgesic product sold was named "Doan's." In the fourth quarter of 1987, Ciba introduced Extra Strength Doan's, containing a larger close of the active ingredient. The original product was renamed "Regular Strength Doan's." (*See* Peabody Tr. 584-85; JX 2 ¶ 18; CX 455-B.) In September 1991, Ciba ***596** introduced Doan's P.M., which contains a sleep aid (JX 2 ¶ 18; CX 455-B).

13. Regular Strength Doan's is available in 24 pill or "count" packages, Extra Strength Doan's is available in 24 count and 48 count packages, and Doan's P.M. is available in 20 count packages (CX 455-J) .

14. The active analgesic ingredient in Doan's products is magnesium salicylate (JX 1 ¶ 1). Regular Strength Doan's contains 325 mg of magnesium salicylate and Extra Strength Doan's contains 467 mg of magnesium salicylate (CX 455-B). Doan's P.M. contains 500 mg of magnesium salicylate, as well as 25 mg of diphenhydramine, a sleep aid (CX 368-D; CX 455-B). The recommended dosage for all three Doan's products is two tablets (CX 497 at 40 [Esayian Dep.]; *see also* CX 510-Z-24).

15. Doan's analgesic products are sold at a price premium over general purpose analgesic products (CX 402-F; CX 496 at 23-24 [Caputo Dep.]). This is true for both Doan's factory prices (*i.e.*, the price paid by retailers) and retail prices. (*See* Peabody Tr. 331, 550-52; CX 360-Z-38; CX 497 at 173 [Esayian Dep.].) In 1992, the retail price of a 24 count package of Doan's Regular Strength tablets was $4.32, while 24 count packages of regular strength Tylenol and Bayer tablets sold for $2.61 and $2 .57, respectively, constituting price premiums of 66% and 68%. (*See* CX 360-Z-38; CX 402-F.)

16. Doan's is more expensive relative to other OTC analgesics on a per pill basis (CX 402-F). The largest size packages of Doan's available, depending on the particular version, are 20, 24, or 48 count packages, whereas general analgesics are sold in substantially larger, more economical packages. (*See* CX 368-D-I; CX 402-F; CX 455-J; Peabody Tr. 551.) In 1995, a 24 count package of Doan's Regular Strength cost $.18 per pill, while in 100 count packages, Regular Strength Tylenol cost $.06 per pill, Advil cost $.08 per pill, and private label aspirin cost $.03 per pill (CX 402-F). On this basis, Doan's was sold at a 200% premium over Tylenol and a 500% premium over private label aspirin. With respect to Advil, the recommended dose is only one pill, while the recommended dose of Doan's is two pills. Accordingly, one dose of Doan's cost $.35 versus $.08 for Advil, a premium of over 300%. Doan's premium price may have been a barrier to increased brand usage (CX 501, pp. 89-90; CX 454-C), so Ciba's strategy for marketing it was to "use back pain ***597** specific/special ingredient strategy to justify price premium" (CX 351-Z-27).

C. Doan's And The FDA

17. Product labeling for magnesium salicylate, the active ingredient in Dean's analgesic products, is regulated by the Food and Drug Administration ("FDA"). *Tentative Final Monograph on Internal Analgesic, Antipyretic, Antirheumatic Products for Over-the-Counter Human Use* (53 Fed . Reg. 46,204, Nov. 16, 1988) ("Monograph") (JX 1 ¶ 1).

18. Under the Monograph, an OTC analgesic drug product may be labeled as indicated for the temporary relief of minor aches and pain associated with one or more of the following: a cold, the common cold, sore throat, headache, toothache, muscular aches, backache, premenstrual or menstrual periods or cramps, and arthritis. 53 Fed. Reg. at 46,209. (JX 1-B ¶ 5.)

19. In 1988, when it promulgated the Monograph, the FDA was aware of comments expressing the concern that pain-specific labeling would suggest to consumers that "one product offers unique advantages over another for the specific indications stated on the label" (RX 88.1-Z-7). Despite this view, the FDA permitted pain-specific labeling as an alternative labeling option, concluding that such labeling "May be helpful to consumers to provide them with examples of the general types of pain for which OTC internal analgesic products are useful" (JX 1-B ¶ 5). Many OTC analgesic brands have positioned themselves for or advertised their efficacy for specific indications, such as headaches, arthritis, or back pain relief (R.X 60-A-Z). Dean's specific positioning as a back pain reliever is consistent with the Monograph (JX 1-B ¶ 5; RX 88; RX 88.1) although it has not been FDA approved. (*See* CX 114-A; CX 500 at pp 14, 74-76.)

20. Although the Monograph states that magnesium salicylate is effective for pain relief for several ailments, the only indication for which Novartis has marketed Dean's has been for the relief of back pain (CX 501 at 20 [Sloan Dep.]). The manufacturers of Advil, Aleve, Bayer, Motrin, and Tylenol label their products as providing relief from pain associated with several different problems. (*See* Peabody Tr. 557; *see, e.g.*, RX 114.)

***598** 21. The Monograph does not state that any approved analgesic ingredient is more effective for the relief of back pain than any other approved ingredient (CX 415-A-Z-31) and it does not sanction a company's labeling or advertising of its analgesic product as being more effective for back pain (*id.; see also* Peabody Tr. 588-89; Scheffman Tr. 2643-44).

22. No other brand of OTC analgesic contains magnesium salicylate as its active ingredient (Peabody Tr. 314), but there are no studies demonstrating that it relieves back pain more effectively than acetaminophen, aspirin, ibuprofen or naproxen sodium (CX 584; JX 1 ¶ 9).

D. The Dissemination of Doan's Ads

23. The challenged ads were disseminated in a long-running national ad campaign beginning in May 1988, and continuing through May 1996 (JX 2 ¶¶ 25, 35, 36).

24. Ciba's ad efforts for Doan's products used national television ads and free-standing inserts ("FSI's") and, at times, radio ads disseminated in selected markets (JX 2 ¶¶ 25, 28, 29, 33-36). FSI's are ads appearing in Sunday newspaper supplements with, in some cases, attached discount coupons. FSI's are primarily used by "coupon clippers." During the relevant period Doan's FSI's were redeemed by less than 1% of newspaper subscribers (RX 160-A; Peabody Tr. 486).

25. Over the period 1988 through 1996, Ciba's broadcast ad expenditures for Doan's products totaled approximately $55 million, and its consumer promotion spending for Doan's (including FSI production and dissemination and merchandising materials) totaled about $10 million (JX 2 ¶ 21).

26. The target audience for Doan's ads was backache sufferers who treat their back pain with OTC pain relievers ("sufferers/treaters") within specified age ranges that varied over time (JX 2 ¶ 27). The goals of Ciba's ad and promotion campaign were to maintain the loyalty of existing Doan's users, encourage Doan's users to increase their usage of Doan's pills for treating their backaches, regain lapsed Doan's users, and attract new users who had been using other OTC pain relievers to treat their back pain or who were new to the analgesics market. (*See, e.g.*, Peabody Tr. 150; Stewart Tr. 3608; CX 360-Z-43; CX 455-I; CX 508-O.)

***599** 1. Television Ads

27. Between January 1987 and June 1996, Doan's television ads were disseminated nationally both on network television during daytime and late night hours, as well as on syndicated and cable television during prime time, early evening, weekend, daytime and late night. (*See* JX 2 ¶ 28; CX 370-A-Z-78; CX 371-A-Z-39; Stewart Tr. 3418-19, 3440.) They appeared during

such popular television shows as One Life to Live, The Young and the Restless, General Hospital, Family Feud, Jeopardy, Wheel of Fortune, Cops, Inside Edition, Current Affair, Oprah Winfrey, Rush Limbaugh, and, in 1989, during prime time newscasts (JX 2 ¶ 29; CX 370-A-Z-78). Doan's television commercials appeared on cable stations such as the Cable News Network, Nashville Network, USA Network, Turner Network Television, Turner Broadcasting Service, Weather Channel, and Lifetime (JX 2 ¶ 29). It also bought time on cable television programs with high Southern viewership, such as "Country News Late," "Texas Connection," "Western Block," and "Truck and Tractor" (CX 371-A-Z-79; Stewart Tr. 3438-39).

28. The advertising agencies Hicks & Greist and Ketchum Advertising participated in the creative development, production, and media dissemination of Doan's television commercials from 1987 to April 1993. Jordan, McGrath, Case & Taylor, Inc. ("Jordan McGrath"), another advertising agency, participated in the creative development, production, and media dissemination of Doan's television commercials from April 1993 to June 1996. Ciba gave final approval for all advertising copy and dissemination (JX 2 ¶ 26).

29. The television ads disseminated by Ciba were 15-second spots (JX 2 ¶ 25). According to Jordan McGrath, the rationale for using 15-second ads is that they provide maximum efficiency, afford continuity and build frequency (CX 390-S; *see also* CX 503 at 110-11 [Jackson Dep.]). Ciba's one-time Marketing Director for Doan's testified that 15-second ads are an effective way of advertising the product, because Doan's television commercials had a fairly singular communication point that could be easily made in 15 seconds (CX 499 at 135 [Nagy Dep.]). Doan's competitors apparently disagree, for more than 80% of TV commercials for Tylenol, Advil, Motrin and Aleve were 30 seconds in length or longer in 1984 (JX 2-H ¶ 31; RX 36-Z-27).

***600** 30. For purposes of efficiently purchasing air time for Doan's television commercials, Ciba defined the Doan's target market in terms of the age demographics it believed best described potential Doan's purchasers. From 1988 to 1990, the age demographics of the target audience for Doan's television commercials were adults 35 years of age or older. From 1991 to 1996, the age demographics of the target audience for Doan's television commercials were adults 25 to 54 years of age (JX 2 ¶ 27; Stewart Tr. 3431).

31. Based on estimates by Ciba's ad agencies, from 1988 to 1996 television commercials for Doan's reached 80% to 90% of the Doan's target audience, on average, 20 to 27 times per year (JX 2 ¶ 28).

32. The first ads disseminated by Ciba for Doan's were 15-second versions of the "Hollingshead" and "Schwartz" television commercials developed by Doan's prior owner, Jeffrey Martin, Inc. These ads were disseminated from January 1987 through February 1988. After it introduced Extra-Strength Doan's, Ciba modified these ads by adding tag lines announcing the Extra-Strength product. These revised "Hollingshead" and "Schwartz" (CX 2) ads aired from February through May 1988 (JX 2 ¶ 25; *see also* Mazis Tr. 947; CX 500 at 57-58 [Russo Dep.]; Peabody Tr. 161, 605-607).

33. The first television commercial created by Ciba, "Graph" (CX 2; CX 13), was disseminated from May 1988 through June 1991. A television ad known alternatively as "X-Ray" or "Acetate" (CX 14), which was a variation of the "Graph" ad, was disseminated concurrently with "Graph" from August 1989 through June 1991 (JX 2 ¶ 25).

34. The "Black & White Back" television ad (CX 15) was disseminated from June 1991 through October 1992. A variation of the "Black & White Back" ad known as "Black & White Pan" (CX 7; CX 16) was disseminated from December 1992 through June 1994 (JX 2 ¶ 25).

35. The "Ruin A Night's Sleep" television ad (CX 7; CX 17) was disseminated from January 1992 through August 1992. Subsequently, "Ruin A Night's Sleep - Non-New" (CX 8; CX 18) was disseminated concurrently with "Black & White Pan" from August 1993 through June 1994 (JX 2 ¶ 25).

36. The "Activity-Pets" (CX 8; CX 22) and "Activity—Playtime" (CX 8; CX 10; CX 20) television ads were disseminated concurrently from July 1994 through July 1995 (JX 2 ¶ 25).

***601** 37. The "Muscles" television ad (CX 11; CX 23) was disseminated from August 1995 through May 1996 (JX 2 ¶ 25).

38. The most recent challenged television ad, "Muscles," last aired in May 1996 (JX 2 ¶ 25). Beginning in May 1996, a revised version of the "Muscles" ad, "New Muscles - Male" (RX 17; RX 24-A), and a revised female version, "New Muscles - Female" (RX 18), have been disseminated (RX 5-Z-84, Z-90-92; RX 17; RX 18; RX 24-A).

2. Free Standing Inserts

39. Between 1987 and mid-1996, Ciba disseminated FSI's for Doan's products in Sunday newspaper supplements two to three times per year (JX 2 ¶ 36). One FSI (CX 32-A) was disseminated on May 21, 1989 in newspapers with circulations totaling 34.9 million, and was used twice again, appearing on October 14, 1990 in 45.3 million individual newspapers (CX 29-J) and on September 29, 1991 in 12.6 million individual newspapers (CX 29-Z-4). On June 2, 1991, two different FSI's (CX 29-U; CX 29-W) appeared in 583,000 newspapers and 473,000 newspapers, respectively. On January 8, 1995, another FSI (CX 53-E; CX 544) appeared in 40.3 million newspapers.

3. Radio Ads

40. From March through December 1991, Ciba tested local radio ads for Doan's in five cities: Denver, Nashville, Oklahoma City, Orlando, and Tampa-St. Petersburg-Clearwater. For each twelve-week flight, the tested Doan's radio ads reached an estimated 45% to 52% of the target audience (adults between the ages of 25 and 54) an average of 17 to 20 times each (JX 2 ¶ 33). In 1992, at least three four-week flights of Doan's radio ads were aired in selected markets (JX 2 ¶ 34).

41. From May through September 1993, Ciba tested Spanish language Doan's radio ads (CX 58 [translated as CX 467]; CX 59 [translated as CX 468]; CX 60 [translated as CX 469]; CX 61 [translated as CX 470]; CX 62 [translated as CX 471]; CX 472 [translated as CX 473]; CX 474 [translated as CX 475]; and CX 476 [translated at CX 477]) targeted at Hispanic consumers in Houston. Three Houston radio stations broadcast between twelve and seventeen Doan's ads weekly for ten weeks (JX 2 ¶ 35).

***602** Novartis voluntarily ceased running the challenged ads in May 1996, prior to the issuance of the complaint (Peabody Tr. 442; JX 2-E ¶ 25).

E. The Claims Conveyed By The Challenged Ads

42. Several expert witnesses were called by the parties to testify about significant issues in this case -- the claims conveyed by the challenged ads, their materiality, and the need for corrective advertising if the complaint's allegations were upheld.

1. Complaint Counsel's Experts

a. Dr. Michael B. Mazis

43. Dr. Mazis is a tenured Professor of Marketing at The American University in the Kogod College of Business Administration (Mazis Tr. 923,925; CX 417-A, J). Dr. Mazis has taught Principles of Marketing to undergraduates; Marketing and Public Policy to graduate students; marketing research courses to both undergraduates and graduate level students; and consumer behavior courses to undergraduates, graduate level students, and Ph .D. level students (Mazis Tr. 925; CX 417-J).

44. Dr. Mazis received his Doctor of Business Administration from Pennsylvania State University in 1971 with a major in marketing and minors in social psychology and quantitative business analysis (statistics) (Mazis Tr. 924; CX 417-A). From 1971 to 1976, Dr. Mazis was an Assistant Professor and Associate Professor of Marketing at the University of Florida where he taught a variety of courses involving marketing research and consumer behavior (Mazis Tr. 924-25; CX 417-B).

45. From 1976 to 1979, Dr. Mazis served as a full time consultant, first to the FDA's Bureau of Drugs, then in the FTC's Division of National Advertising, and finally as Chief of Marketing and Consumer Research in the FTC's Office of Policy and

Planning (Mazis Tr. 925; CX 417-B). During this period he conducted consumer research and worked on a variety of issues related to advertising and consumer information (Mazis Tr. 925).

46. Dr. Mazis was made a full professor at American University in 1981 (Mazis Tr. 925). From 1980 to 1989, he was the Chair of the Department of Marketing. In 1991, Dr. Mazis was awarded the Kogod College Award for Scholarship (CX 417-J).

***603** 47. Dr. Mazis has published extensively in peer-reviewed journals, including many articles with application to advertising and public policy issues (CX 417-C-H). These include an article regarding copy testing issues in FTC advertising cases and four articles regarding corrective advertising (Mazis Tr. 926-27; CX 417-E-G).

48. Dr. Mazis was awarded a $700,000 grant from the National Institutes of Health to study consumer perceptions of alcohol warning labels (Mazis Tr. 926; CX 417-C) and has served as a consultant to several government agencies, including the FTC, the FDA, the Consumer Product Safety Commission, the Department of Justice and the State of California (Mazis Tr. 926; CX 417-J).

49. Dr. Mazis has served as a consultant to numerous private corporations, has conducted litigation copy testing for Lanham Act cases, and has testified as an expert witness (Mazis Tr. 926, 929). In prior expert testimony that has been accepted by the courts, he has on a number of occasions analyzed advertising and marketing materials on the face of the ad and offered an opinion with regard to what reasonable consumers are likely to take away from such advertising or promotional materials (*id.*, 929, 932).

b. Dr. David W. Stewart

50. Dr. Stewart is a full Professor of Marketing in the Marshall School of Business at the University of Southern California (Stewart Tr. 3390-91; CX 589-A, B, E). He holds the Robert E. Brooker Chair and currently serves as the Chairperson of the Department of Marketing (Stewart Tr. 3391, 3393; CX 589-A-B). Dr. Stewart has taught a variety of graduate and undergraduate level courses related to advertising, advertising and promotional management, consumer behavior, marketing research, market analysis, marketing strategy, product management, and sales management (Stewart Tr. 3393; CX 598-E). Dr. Stewart received his Ph.D. and M.A. in psychology from Baylor University and his B.A. in psychology from Northeast Louisiana University (Stewart Tr. 3391; CX 589-A-B).

51. Dr. Stewart has had a long and distinguished academic career. Prior to his teaching at the University of Southern California, he was employed as an Associate Professor of Psychology and Business at Jacksonville State University from 1978 to 1980, and as an Associate Professor of both marketing and psychology at Vanderbilt from 1980 to 1986 (Stewart Tr. 3392; CX 589-E-F).

***604** 52. Dr. Stewart has authored or co-authored six books on advertising related issues and has written over 70 articles which have been accepted in peer reviewed academic journals (Stewart Tr. 3396; CX 589-A, Z-1-9). His published works have involved the effectiveness of comparative advertising for brands with low market share, the manner in which advertising campaigns wear in and out, the defensive role of advertising for mature brands, and whether sales increases are sufficient to determine whether an advertising campaign has been successful (Stewart Tr. 3397-98). A number of his publications have involved the ARS copy testing methodology used by Research Systems Corporation (Stewart Tr. 3397, 3450).

53. Dr. Stewart has received numerous academic honors during his teaching career. Currently he is the President of the Academic Council of the American Marketing Association and chairman of the Section on Statistics in Marketing of the American Statistical Association (Stewart Tr. 3393-95; CX 589-A, H). He is a past president of the Society of Consumer Psychology of the American Psychological Association (Stewart Tr. 3395; CX 589-A, I). He has won numerous awards, including awards from the American Academy of Advertising for best paper published during 1989 in the *Journal of Advertising* and the best paper published during 1992-1994 in the *Journal of Public Policy and Marketing* (Stewart Tr. 3397; CX 589-A, C-D) .

54. Dr. Stewart has served as the editor, associate editor, or member of the editorial board of numerous academic journals (Stewart Tr. 3397; CX 589-H-J) and has served as a peer reviewer of articles submitted for publication to numerous academic journals (CX 589-J).

55. Dr. Stewart was also employed for two years as the Research Manager for a major advertising agency, Needham, Harper, and Steers (now called DDB Needham) where he managed a research department and was responsible for research, including diagnostic copy testing and communication tests, research regarding markets, and profiling consumers (Stewart Tr. 3391-92; CX 589-A, F).

56. Dr. Stewart has also done extensive consulting work for major corporations in the areas of advertising effectiveness, consumer behavior, and the structure of markets (Stewart Tr. 3398).

57. Dr. Stewart has testified as an expert witness both before the Federal Trade Commission and in U.S. district courts (Stewart Tr. 3399-3400; CX 589-A, T-U). He has previously testified as an expert ***605** in advertising, marketing, marketing research, survey methodology, marketing communication, and branding (Stewart Tr. 3400; CX 589-A).

2. Novartis' Experts

a. Dr. David Scheffman

58. Dr. Scheffman is the Justin Potter Professor of American Competitive Enterprise and Professor of Business Strategy and Marketing at the Owen Graduate School of Management at Vanderbilt University in Nashville, Tennessee (Scheffman Tr. 2513; RX 205-A). He is also a consultant for a national consulting company, Law & Economic Consulting Group, Inc. (Scheffman Tr. 2513, 2515; RX 205-A).

59. Dr. Scheffman teaches courses in marketing, pricing, strategic management, brand equity evaluation and distribution to MBA and executive MBA students (Scheffman Tr. 2516; RX 205-C-D). Dr. Scheffman specializes in industrial organization economics, which uses various theories and tools to evaluate quantitative and qualitative evidence concerning markets and competition (Scheffman Tr. 2513).

60. Dr. Scheffman has a B.S. in mathematics from the University of Minnesota and a Ph.D. from the Massachusetts Institute of Technology in economics (Scheffman Tr. 2512; RX 205-A).

61. Dr. Scheffman worked for the Commission beginning in 1982 (RX 205-B). From 1985 to 1988, he was the Director of the Bureau of Economics, and served as the chief economist on all matters being investigated or litigated by the Commission, including consumer protection matters (Scheffman Tr. 2515; RX 205-B).

62. Dr. Scheffman has co-authored five books and written forty-one articles (RX 205-M-Q). Dr. Scheffman has written articles about the relationship between advertising and product quality, and has authored one book on consumer protection regulation (Scheffman Tr. 2524).

b. Mr. Robert Lavidge

63. Mr. Robert Lavidge was qualified as an expert in consumer survey research, marketing and advertising (Lavidge Tr. 746-47).

64. Mr. Lavidge received a B.A. with highest honors in 1943 from DePauw University, and an M.B.A. with highest honors in 1947 from the University of Chicago (Lavidge Tr. 742; RX 21-A). For over ***606** thirty years, Mr. Lavidge has taught in the areas of marketing and advertising as a member of the adjunct faculty of the Northwestern University School of Management

(Lavidge Tr. 743). Since 1980, Mr. Lavidge has served as a member of the Advisory Council for the University of Chicago Graduate School of Business (RX 21-B).

65. Since 1951, Mr. Lavidge has served as the President of Elrick & Lavidge, one of the largest consumer survey research companies in the country (Lavidge Tr. 739). As President of Elrick & Lavidge, Mr. Lavidge has participated in thousands of surveys, hundreds of which have been offered as evidence in court (Lavidge Tr. 739).

66. Mr. Lavidge has served as the President of the American Marketing Association ("AMA") (Lavidge Tr. 740). Mr. Lavidge also has served as the head of the AMA's Marketing Research Division, the chairman of the Census Advisory Committee and of the Long-Range Planning Committee, and is currently serving as the chair of the AMA's Foundation Board of Trustees, which provides a means for members of the AMA and others in the marketing field to perform public service (Lavidge Tr. 741-42).

67. Mr. Lavidge has been qualified as an expert witness concerning marketing and survey research in excess of forty times (Lavidge Tr. 746).

68. In 1961, Mr. Lavidge wrote an article for the Journal of Marketing entitled, "A Model for Predictive Measures of Advertising Effectiveness" (Lavidge Tr. 744; RX 21-C). This article is credited with introducing the concept of the "hierarchy of effects," has been reprinted in numerous publications over the years, and is regarded as a seminal article by researchers and others studying the functions and effects of advertising (Lavidge Tr. 744; Mazis Tr. 1627).

c. Dr. Jacob Jacoby

69. Dr. Jacoby was qualified as an expert in the fields of consumer behavior, consumer research, social science research methodology, and the comprehension and miscomprehension of advertising (Jacoby Tr. 2921-22).

70. Dr. Jacoby received a B.A. in Psychology in 1961 and a Masters in Psychology in 1963 from Brooklyn College (Jacoby Tr. 2910; RX 4-A). Dr. Jacoby received a Ph.D. in Social Psychology from Michigan State University in 1966 (Jacoby Tr. 2910; RX 4-A).

***607** 71. Dr. Jacoby has taught for over thirty years in the areas of advertising and marketing (Jacoby Tr. 2911-13; RX 4-A). From 1968 to 1981, Dr. Jacoby served as an assistant professor and then professor in the Department of Psychology at Purdue University (Jacoby Tr. 2911; RX 4-A). While at Purdue, Dr. Jacoby taught courses in consumer behavior and research methods (Jacoby Tr. 2911-12). Since 1981, Dr. Jacoby has held an endowed chair as the Merchants Council Professor, Consumer Behavior and Marketing at the Stern School of Business, New York University (Jacoby Tr. 2912; RX 4-A). At New York University, Dr. Jacoby has taught courses in consumer behavior, research methods, and market research, among others, to undergraduates, masters, and doctoral students (Jacoby Tr. 2912-13; RX 4-A).

72. Since 1968, Dr. Jacoby has worked as a consultant for clients including the Commission, the FDA, General Electric, Pillsbury and Proctor & Gamble, among others (Jacoby Tr. 2905-07). As a consultant, Dr. Jacoby has designed well over 1000 studies, hundreds of which have been offered in court (Jacoby Tr. 2907-08), including hundreds of studies focusing on the effects of advertising (Jacoby Tr. 2908).

73. Dr. Jacoby has served as the President of the Consumer Psychology Division of the American Psychological Association (Jacoby Tr. 2917; RX 4-B). Dr. Jacoby has served on the Executive Committee of the Market Research Council (Jacoby Tr. 2918; RX 4-C). Dr. Jacoby also has served as a reviewer of proposals for the FDA and for the National Science Foundation (Jacoby Tr. 2919; RX 4-C).

74. Dr. Jacoby has co-authored seven books and written over 100 articles, including books and articles on deceptive advertising, corrective advertising, the miscomprehension of televised and print communication, and research methodology (Jacoby Tr. 2920).

75. Dr. Jacoby has been qualified as an expert over 100 times in federal court (Jacoby Tr. 2921).

d. Dr. Morris Whitcup

76. Dr. Morris Whitcup was qualified as an expert in marketing and consumer research (Whitcup Tr. 2102). Dr. Whitcup designed, conducted and analyzed two studies for Novartis (Whitcup Tr. 2082).

77. Dr. Whitcup received a B.A. from Yeshiva College (Whitcup Tr. 2085). He subsequently received a Ph.D. in social psychology ***608** from Columbia University in 1977 (Whitcup Tr. 2085; RX 1-A). Dr. Whitcup has over twenty years of professional experience in consumer marketing research (Whitcup Tr. 2085) and has participated in more than 2,500 marketing research studies (Whitcup Tr. 2093; RX 1-A).

78. In 1995, Dr. Whitcup founded Advanced Analytics, Inc., a full-service market research company (Whitcup Tr. 2089; RX 1-A). Advanced Analytics, Inc. is a division of Guideline Research Corporation, one of the top 50 marketing research companies in the world (Whitcup Tr. 2090; RX 1-A).

79. Over the years, Dr. Whitcup has conducted various types of consumer research studies, including tracking studies, communication studies, and attitude studies (Whitcup Tr. 2094-97).

80. Dr. Whitcup has extensive experience conducting consumer research in the pharmaceutical area (Whitcup Tr. 2088; RX 1-A). For example, Dr. Whitcup was involved in a number of studies related to the switch of Aleve from a prescription brand analgesic to an OTC product (Whitcup Tr. 2098). Dr. Whitcup also has been involved in research for the FDA involving packaging and consumer comprehension of labels and packages (Whitcup Tr. 2089).

81. Dr. Whitcup has been qualified as an expert a number of times in court and before the NAD appeals board and the NARB (Whitcup Tr. 2101; RX 1-A).

e. Dr. James Jaccard

82. Dr. James Jaccard is a professor of psychology at the State University of New York at Albany (Jaccard Tr. 1400; RX 122-C). He specializes in social science research methodology, including the design of scientific experiments and surveys and the analysis of the results to draw conclusions about consumer attitudes, behavior, and decision-making (Jaccard Tr. 1401, 1405). In connection with his work in social science research methodology, Dr. Jaccard has taught, applied, and evaluated statistical methodology for analyzing behavioral data (Jaccard Tr. 1401; RX 122-B).

83. Dr. Jaccard received an A.B. in psychology from the University of California at Berkeley in 1971 (Jaccard Tr. 1400; RX 122-C). He received his A.M. and Ph.D. in social psychology from the University of Illinois, Urbana in 1972 and 1976, respectively (Jaccard Tr. 1400; RX 122-C) .

***609** 84. Dr. Jaccard has taught and practiced social science research methodology for more than twenty years (RX 122-C-D). Since 1987, he has served as a professor in the Department of Psychology at the State University of New York, Albany, New York (RX 122-C). Dr. Jaccard has taught graduate and undergraduate courses on research methodology, experimental design, and statistical methods as applied to the analysis of behavioral data (Jaccard Tr. 1402; RX 122-B-C, S).

85. Dr. Jaccard has been a statistical consultant for the federal government and the State of New York, as well as for numerous industries (Jaccard Tr. 1403-04; RX 122-B). Dr. Jaccard also has served as a consulting editor for a number of major scientific journals, and has evaluated statistical analyses of original research (Jaccard Tr. 1404-05; RX 122-B).

86. Dr. Jaccard has authored or co-authored four books addressing statistical methods for evaluating behavioral data. He also

has written numerous book chapters and articles published in peer reviewed academic journals (RX 122-A, B, D to N). In these articles, Dr. Jaccard has developed, explained, and applied statistical approaches for evaluating behavioral data (Jaccard Tr. 1408). Several of Dr. Jaccard's publications have dealt specifically with consumer attitudes and decision-making (Jaccard Tr. 1406, 1408-09).

3. Facial Analysis Of The Challenged Ads

a. TV Ads

87. In the first ad Ciba created for Doan's -- "Graph" -- (CX 13) a voice-over announces that "New Extra Strength Doan's is made for back pain relief." This statement is followed by a depiction of a Doan's package on the left side of the screen and packages of three competing analgesic brands -- Advil, Extra Strength Tylenol, and Bayer -- on the right . The voice-over states: "with an ingredient these pain relievers don't have," as the spotlight on the competing brands is darkened, leaving only the Doan's package clearly visible on the screen.

88. All of the challenged television ads disseminated after "Graph" continued to focus on Doan's special efficacy in relieving back pain, and emphasized that Doan's has an ingredient not found in competing analgesics. The ads, like "Graph," display and then visually diminish competitive analgesics. The same symbolism has ***610** been used by Doan's competitors (RX 60; CX 14; CX 15; CX 16; CX 17; CX 18; CX 20; CX 22; CX 23).

89. "X-Ray" (CX 14) is a variation of the "Graph" ad with the addition of an audio and visual reference to Doan's as "The back specialist." The Ketchum advertising executive who oversaw Doan's advertising from 1987 through 1991 testified that he intended the "back specialist" phrase to create a memorable analogy to a doctor who treats backs only. A conference report summarizing a meeting between Ciba and Jordan McGrath stated with respect to "X-Ray": "Since Doan's is the expert, Doan's works better for back pain" (CX 131-B).

90. The "back specialist" tag line was used in most subsequent Doan's television ads (CX 15; CX 16; CX 20; CX 22; CX 23).

91. In "Black & White Back" (CX 15), the ingredient the other pain relievers don't have is referred to as a "special ingredient," and in the "Ruin A Night's Sleep" ads (CX 17; CX 18) that ingredient is described as "unique." Jordan McGrath's Senior Vice President, who was responsible for the Doan's ads created subsequent to "Ruin A Night's Sleep," but who was not involved in the creation of "Black & White Back," testified that she would not have approved a Doan's advertisement that contained the phrase "with a special ingredient." (*See* CX 504 at 116 [Schaler Dep.].)

92. The final frames of "Activity—Playtime" (CX 20) and "Activity—Pets" (CX 22), Novartis' more recent ads, depict a package of Doan's alongside packages of Advil, Tylenol, Bayer, and a newly introduced competitor, Aleve, while the voice-over states that "Doan's has an ingredient these pain relievers don't have." These ads conclude with the "back specialist" tag line, as does "Muscles" (CX 23).

b. Free Standing Inserts

93. An FSI that first ran in 1989 (and that was disseminated again in 1990 and 1991) features a large Doan's package alongside smaller but clearly visible packages of Advil, Extra-Strength Tylenol, and Bayer (CX 32-A; CX 29-J; CX 29-Z-4). Prominent copy above the packages states: "Doan's. Made for back pain relief." Under this statement, and just above the packages of the competing brands, is the claim "With an ingredient these other pain relievers don't have."

94. One of two FSI's that ran in 1991 headlined: "Back Pain Sufferers -- It's Easy to See Why You Need Doan's" (CX 29-W). This ***611** statement appears directly above packages of Bayer, Extra-Strength Tylenol, Advil, and Motrin. A magnifying glass is superimposed on the packages, highlighting an excerpt from the product labeling for Extra-Strength Tylenol, *i.e.*, that Extra Strength Tylenol is "For the temporary relief of minor aches, pains, headaches and fever." Below the competing packages is the

phrase "These are for all kinds of aches and pains." To the right is a Doan's package accompanied by the words "Doan's is just for back pain." The second FSI features the statement "Back pain is different" above a display of the three competing analgesic packages, with the phrase "Why use these pain relievers?" alongside them (CX 29-U). Directly below is a package of Doan's and the words "Doan's is just for back pain." In a similar vein, a 1995 FSI asks "Why Treat General Aches?" above a display of packages of Bayer, Extra Strength Tylenol, Advil and Aleve (CX 53-E; CX 544). It continues: "Back Pain Needs the Specialist," set above pictures of Doan's packages.

c. Radio Ads

95. In a Spanish radio ad, a woman complains of back pain and a man tells her, "Buy Doan's. It's the medicine that works best when I need back pain relief" (CX 61 [translated as CX 470]). She asks, "And what is it that Doan's has that makes it work so well?" The announcer answers her, "Doan's has a unique ingredient that alleviates pain, and no other pain reliever has it." The ad concludes "Trust Doan's, the back specialist."

96. The claims in its TV, FSI and radio ads that Doan's is special because it has an ingredient other pain relievers don't have, that it is the "back specialist" (*see* CX 131-B) and that it is made for back pain relief clearly carries the message that it is more effective than other OTC analgesics for back pain relief.

d. Expert Testimony

97. Dr. Jacoby testified that it would be inappropriate for an expert to make a facial analysis of the challenged ads (Jacoby Tr. 2945).

98. Dr. Mazis disagreed, and, applying his understanding of consumer psychology and after reviewing certain Ciba strategy and research documents, testified that several Doan's ads made the alleged superiority claim. He stated that "Graph," which refers to an ***612** "ingredient that [other] pain relievers don't have" conveys the message that Doan's is unique and different, and couples this claim with references to back pain, thus conveying the net impression that Doan's is more effective for back pain relief than other pain relievers mentioned in the ad (Mazis Tr. 932, 949-51, 957; CX 508-Z-32).

99. Dr. Mazis gave essentially the same opinion with respect to other Doan's TV ads and FSI's comparing Doan's with other OTC analgesics: "X-Ray" (adding "The Back Specialist") (CX 14; Mazis Tr. 952-54); "Black & White Back" (CX 15; Mazis Tr. 958-60); "Black & White Pan" (CX 16; Mazis Tr. 960-63); "Ruin A Night's Sleep" (CX 17; Mazis Tr. 961-62) and "Ruin A Night's Sleep - Non-New" (CX 17; CX 18; Mazis Tr. 961-63); "Activity—Pets" and "Activity—Playtime" (CX 20; CX 22; Mazis Tr. 964-66); "Muscles" (Mazis Tr. 966-69); FSI, May 1989 (CX 32-A; Mazis Tr. 971); FSI "Back Pain Is Different" (CX 29-U; Mazis Tr. 974); FSI "back pain sufferers" (CX 29-W; Mazis Tr. 974-76); FSI, 1995 (CX 53-E; CX 544; Mazis Tr. 976-78).

4. Novartis' Knowledge Of The Claims Conveyed By The Ads

100. Ciba's Marketing Department knew that advertising claims required substantiation, and that, while the OTC Analgesics Monograph supported efficacy claims, superiority claims would require one or two well-controlled clinical studies (CX 501 at 27-28 [Sloan Dep.]; *see also* CX 499 at 58-59 [Nagy Dep.]). Company officials, members of the Marketing Department, and ad agency executives were unaware of any scientific evidence that Doan's was more effective than other analgesics (*see e.g.*, CX 501 at 8-10 [Sloan Dep.]; CX 496 at 64-65 [Caputo Dep.]; CX 497 at 42 [Esayian Dep.]; CX 498 at 18-19 [Gray Dep.]; CX 499 at 58-59 [Nagy Dep.]; CX 500 at 62 [Russo Dep.]; CX 504 at 48-49 [Schaler Dep.]).

101. In a 1994 letter addressed to the Marketing Director for Doan's, Jordan McGrath's Senior Vice President responsible for Doan's stated: "Doan's cannot support product 'superiority' … nor can it deliver a unique or seemingly superior consumer benefit" (CX 169-D; CX 504 at 136 [Schaler Dep.]).

102. In a "demo exploratory" document attached to a summary of discussions between Jordan McGrath and Ciba regarding creative strategy for 1995, the agency noted:

> ***613** While we would like to *imply* that Doan's provides superior efficacy because of its unique ingredient, we cannot clinically support this since the other brands work equally well as Doan's at relieving back pain.
> (emphasis in original) (CX 147-J.)

103. In a June 1995 response to an inquiry from the Federal Trade Commission, Ciba's Vice President of Marketing responsible for Doan's wrote that there are "no such documents or studies in existence demonstrating that magnesium salicylate relieves back pain more quickly and/or effectively than acetaminophen, aspirin, ibuprofen or naproxen sodium" (CX 584).

104. Despite its awareness that it lacked substantiation, Ciba knowingly and intentionally conveyed in its ads that Doan's was better for back pain than other OTC analgesics, an intention which is shown by the creative strategy upon which the first ads it created were based: "Graph" (CX 13) and "X-Ray" (CX 14). This strategy targeted "adults 35+ who: suffer from backache" and "seek better relief than provided by all purpose pain relievers" and sought to convince them that because Doan's "is made for back pain relief" and "contains a back pain medicine that no leading analgesic product has" it "provides relief from backache that the leading pain relievers may not be able todo" (CX 508-Z-31-32; Peabody Tr. 260-61).

105. Mr. Peabody testified that a reason that Ciba tested Doan's commercials prior to dissemination was to make sure that the ad did not miscommunicate a claim for which Ciba did not have support, and that he became concerned about miscommunication if an ad communicated a claim in copy testing at a 10% to 15% level (Peabody Tr. 149-51), but that he would not be concerned if the target audience was composed of a disproportionate share of users since this group tends to play back a "more favorable message" (Peabody Tr. 617-18).

106. A communication test of the "Graph" ad conducted prior to its production and dissemination informed virtually all of the senior marketing executives at Ciba that it communicated "product superiority" to 38% of respondents (CX 225-C; Peabody Tr. 171-73). This exceeded Mr. Peabody's 10% to 15% miscommunication threshold. An executive summary of the results of this study recommended the production of "Graph," since it had the strengths of the prior ad "as well as communicates product superiority and perceived efficacy" (CX 225-A-D). Dean's 1989 Marketing Plan ***614** repeated the product superiority play-back and described the ad as a "strong execution which effectively communicates product superiority and perceived efficacy" (CX 335-Z-8). Ciba disseminated the "Graph" ad from May 1988 through June 1991 (JX 2 ¶ 25).

107. The report of a 1989 focus group of the "Graph" ad informed Ciba that "[m]entioning the competitive brands by name … appears to create the impression that Doan's may in fact be better than the other brands, thereby promulgating a more favorable predisposition to trying Doan's" (CX 227-Z-3).

108. In September 1990, Ciba commissioned a communication test of three alternative commercial executions to see which best communicated Doan's "Relieving All Kinds of Back Pain" strategy. One of the three ads was the "Black & White Back" ad (CX 15). The test showed that it had a 62% open-ended communication of "superiority over other products" (CX 236-M, Z-67; Peabody Tr. 180). (An open-ended question is one that provides respondents with very little context or structure in order to obtain unprompted answers in respondents' own words (Mazis Tr. 100; Peabody Tr. 165).) The ad was tested prior to its production by the ASI 24-hour delayed-recall methodology (CX 76-A-D; CX 237-A-Z-38; Peabody Tr. 181). A memorandum from the Marketing Research Department to Ciba's senior marketing executives compared ASI test results of "Black & White Back" to an ASI test of "Graph" and reported that "'Black and White Back' does a better job than 'Graph' in establishing Doan's relief/efficacy, quality, and brand superiority" (CX 76-A, C; Peabody Tr. 183-85). A Doan's Marketing Plan also reported, "Our current execution, 'Black & White Back,' is a strong performer …. Communicates backache relief, efficacy and product superiority" (CX 360-Z-100; Peabody Tr. 263). Ciba disseminated the "Black & White Back" ad from June 1991 through October 1992 (JX 2 ¶ 25).

109. A pre-production communications test of the "Ruin A Night's Sleep" ad reported 35% open-ended communication of "superiority over other products" among non-users of Doan's and 15% open-ended communication of "superiority over other

products" among Doan's users (CX 244-F, T; Peabody Tr. 188-89). A report of this study, as well as an executive summary, was distributed to the Marketing Department. Ciba disseminated the "Ruin A Night's Sleep" ad from January 1992 through August 1992, and then disseminated "Ruin A Night's Sleep - Non-New" (CX 18) from August 1993 through June 1994 (JX 2 ¶ 25).

***615** 110. In April 1993, Ciba switched the Doan's account from Ketchum Advertising to Jordan McGrath. Ciba and its new ad agency intended to convey the message that Doan's was more effective for back pain. A December 1993 Conference Report of discussions between Ciba and Jordan McGrath indicates that Ciba and the agency agreed to pursue several executions to "strongly communicate that Doan's has something the others don't have (thereby implying that Doan's is different/better)" and to "more clearly communicate that since Doan's is the expert, Doan's works better on back pain" (emphasis in originals) (CX 131-A-B).

111. In May 1994, Ciba and Jordan McGrath were put on notice regarding an implied superiority claim. Jordan McGrath wrote to Ciba:

> All three Networks are requiring substantiation for the claim "If nothing you take seems to help." The Networks believe that this language implies that Doan's provides superior efficacy vis-a-vis the competitive products shown. … As such, to make this claim, we will need substantiation that Doan's is more effective (due to its Magnesium Salicylate ingredient) at relieving back pain versus the competitors pictured.
>
> Importantly, our Agency council [sic] agrees with the networks.

(emphasis in original) (CX 165-A). Ciba could not provide the networks with substantiation (*see*, CX 166-A; CX 503 at 83-93 [Jackson Dep.]; CPF. ?). The "Activity" ads disseminated later contain language similar to that which the networks disapproved: "If nothing seems to help try Doan's. It relieves back pain no matter where it hurts. Doan's has an ingredient these pain relievers don't have" (CX 20).

112. Further evidence of Ciba's knowledge of its implied superiority claim involves the "Activity-Playtime" (CX 20) ad. At approximately the same time the ad was first disseminated, it was tested by ARS using its 72-hour delayed recall testing methodology (CX 169-A; CX 387-G). Several weeks after "Activity-Playtime" began airing, Jordan McGrath's Senior Vice President responsible for Doan's wrote to Ciba's Marketing Director, notifying her that the ARS testing showed 12% "implied superiority" and stating:

> Doan's cannot support product "superiority" … nor can it deliver a unique or seemingly superior consumer benefit. Hence, it's a challenge for the advertising execution to compensate and persuasively deliver a dimension of competitive "news."

***616** (CX 169-B, D; CX504 at 133-34 [Schaler Dep.]). Several days later, the agency's Vice President Account Supervisor also wrote to Ciba's Marketing Director, telling her:

> "Unfortunately, as we all know, in the Dean's 'Activity' executions our 'unique ingredient' story is not linked to a specific 'back pain relief' claim. Rather our claim 'Doan's has an ingredient these pain relievers don't have,' is used as a copy point that stands by itself with the objective of implied superiority."

(emphasis in original) (CX 170-B; *see* CX 503 at 55-58 [Jackson Dep.]; CX 504 at 143-44 [Schaler Dep.]). Subsequent to this correspondence, no one from Ciba asked that the "Activity-Playtime" ad be modified or withdrawn from dissemination (CX 504 at 135-36 [Schaler Dep.]; CX 503 at 57-58 [Jackson Dep.]). Ciba disseminated the "Activity-Playtime" ad from July 1994 through July 1995 (JX 2 ¶ 25).

113. In a "demo exploratory" attached to a February 1995 Conference Report of a meeting between Ciba and Jordan McGrath regarding the creative strategy for 1995, the agency noted:

> While we would like to *imply* that Doan's provides superior efficacy because of its unique ingredient, we cannot clinically support this since the other brands work equally well as Doan's at relieving back pain.

(emphasis in original)(CX 147-J). Nevertheless, before the "Muscles" (CX 23) ad was produced it was also tested by ARS 72-hour delayed recall testing (CX 265-A; Peabody Tr. 191-93). In that study, 18% of those with related recall played back a "better/best product" claim (*see* CX 265-M; Peabody Tr. 196). A report of this study, as well as an executive summary, was distributed to the Marketing Department (CX 265-A). The executive summary noted that "The conclusion that our product may be better/best is more likely to be conveyed in 'Muscles' than in 'Activity Playtime' …." (CX 265-B). Ciba disseminated the "Muscles" ad from August 1995 through May 1996 (JX 2 ¶ 25).

114. Although comparative advertising may be the optimal technique for the promotion of low-share brands (Stewart Tr. 3459) and although Mr. Peabody denied any intention by Ciba to do so (Peabody Tr. 539), I find that Ciba's advertising campaign created the false message that Doan's was more effective for the relief of back pain than other OTC analgesics. This finding is based on the clear ***617** import of the challenged ads, Dr. Mazis' analysis of them, and Ciba's comments on those ads (F 98, 99, 102, 104, 106, 107-113).

5. Copy Tests Of The Challenged Ads

115. Respondents or their agents performed copy tests in the ordinary course of business on a number of the challenged ads. In addition, complaint counsel commissioned the United States Research Company ("USR") to execute a copy test of two of the challenged ads. These tests support the conclusion that Doan's ads communicated the false message that it was superior to other OTC analgesics for the relief of back pain.

a. Copy Tests Conducted For Ciba

(1) Bruno & Ridgeway Copy Tests Of The "Graph" Ad

116. In March 1988, Bruno & Ridgeway, an independent consumer research company, copy tested the "Graph" ad (CX 2; CX 13), a potential ad, "Twisted," and an ad which was being run, "Hollingshead" (CX 224-E; Peabody Tr. 158). The questionnaires were designed by the staff of Ciba's marketing department and researchers at Bruno & Ridgeway (Peabody Tr. 159-60; CX 502 at 70).

117. This test used the mall intercept method in six geographically dispersed shopping centers. Qualified respondents were taken to a central interviewing room and were shown one of the test ads (Mazis Tr. 996; CX 224-D; Z-97).

118. Qualified respondents included adult back pain sufferers/treaters aged 35 to 64 (CX 224-E, Z-97-98; Mazis Tr. 997; Peabody Tr. 158-59). Respondents were not required to have used or been aware of Doan's for the treatment of backache. These demographics constituted the target audience that Ciba was attempting to reach with its Doan's ads at the time (Peabody Tr. 159). This was an appropriate group of consumers upon which to test these ads (Whitcup Tr. 2383-84; Mazis Tr. 997).

119. A total of 300 copy test respondents were included in this survey (CX 224-E). Each respondent was shown one of the three tested ads which were in a rough, unfinished form. Ciba routinely tested unfinished ads to save the approximately $300,000 it would cost to produce fully three different ads, none of which might ultimately be aired (Peabody Tr. 338-39). In the experience of Ciba's marketing research department, the results obtained from copy testing ***618** rough versions of Doan's ads provided an accurate measure of how those ads would communicate to consumers in finished form (Peabody Tr. 148-49, 338-40; CX 224-Z-99).

120. Approximately 100 respondents were exposed twice to each tested ad (CX 224-E, Z-99; Mazis Tr. 999-1000). Thereafter, they were asked to identify the advertised product, state how likely they were to buy it, and explain why (Questions 7a-8b) (CX 224-Z-100).

121. Respondents were then asked an open-ended question (F 108) (9a) asking what they thought was the main idea of the ad (*id.*; Mazis Tr. 1000-01). Thereafter, respondents were asked another open-ended question (9c) to elicit what other ideas had been communicated to them by the ad (CX 224-Z-101; Mazis Tr. 1002). There is nothing in the questionnaire that would bias the results of the copy test (CX 502 at 74 [Wright Dep.]).

122. In response to question 9a, 18% of the respondents answered that the main idea of the "Graph" ad was "Superior to other products" (CX 224-M; Mazis Tr. 1002). When the results of the "main idea" question (9a) and the "other ideas" question (9c) were netted, 38% of the respondents exposed to the "Graph" ad were coded as answering that it communicated that Doan's was "Superior to other products" (CX 224-M; Mazis Tr. 1003; Peabody Tr. 163-64).

123. The open-ended responses that were coded as "Superior to other products" only included responses that Doan's was "better than/more effective than other products" (CX 224-Z-22; Mazis Tr. 1006; CX 502 at 84 [Wright Dep.]). In their own research conducted for this litigation, the experts for both parties coded such "better than/more effective than other products" responses to mean superior efficacy for back pain, since back pain is the subject of the ads (Whitcup Tr. 2418-23; Jacoby Tr. 3063; Lavidge Tr. 902-03; RX 128-D-E). The "Superior to other products" category is equivalent to the superior efficacy claim alleged in the complaint (Mazis Tr. 1007).

124. A 38% communication of a superior efficacy message in response to open-ended questions is quite high (Mazis Tr. 1009). In its report to Ciba, Bruno & Ridgeway concluded that the "Graph" ad was "successful at communicating the more specific ideas of: … Superiority to other products" (CX 224-K).

125. Respondents' marketing research department recommended "Graph" for finished production since it had many of the same ***619** strengths as "Hollingshead" and communicated product superiority and perceived efficacy (CX 225-D).

126. The "Graph" test did not use a control ad, *i.e.*, an ad that is similar to the tested ad but which is believed not to make the claim that the tested ad is making. The purpose of a control ad is to account for "noise" — responses that come from sources other than the ad's communication (Mazis Tr. 1077-78). For close-ended questions, the results of the control ad are subtracted from the results of the test ad to net out the effects of such noise. (Close-ended questions ask about specific topics and provide the respondent with a finite number of response options such as "yes" or "no" or "more," "same" or "less," *Kraft, Inc.*, 114 FTC 40, 68 (1991).) The results obtained from open-ended questions are usually not deducted from the test ad (Jacoby Tr. 325).

127. Copy testing research done in the ordinary course of business for Ciba did not employ control ads (*id.* at 354-56). Ciba relied heavily upon these copy tests in making consumer research-based business decisions (Peabody Tr. 354-56, 622).

128. The "Hollingshead" ad tested in CX 224 had an Extra-Strength tag line to announce its introduction. Only 7% of the respondents exposed to "Hollingshead" were coded as saying it conveyed a "superior to other products" claim. Thirty-seven percent of them were coded as stating that it communicated extra strength (CX 224-M; Mazis Tr. 1009).

129. Both the "Graph" and "Hollingshead" ads promoted Extra-Strength Doan's. Of the respondents viewing the "Graph" ad, 38% were coded as stating it communicated "Superior to other products," but only 24% were coded as stating it communicated "Extra Strength." Conversely, 7% of the respondents viewing "Hollingshead" were coded as stating the ad communicated "Superior to other products," but 37% were coded as stating it communicated "Extra-Strength" (CX 224-M). There is no correlation between consumer playback of the extra strength nature of the advertised Doan's product and consumer playback of superior efficacy (CX 224-M; Whitcup Tr. 2376-81).

130. Responses to open-ended questions 9a and 9c that were coded as "Extra-Strength" in CX 224 were not included in the "Superior to other products" code (Peabody Tr. 610-12; Whitcup Tr. 2355). Based upon the copy test results, Ciba's marketing research ***620** department concluded that "Extra Strength" was a secondary message for the "Hollingshead" execution. It did not find "Extra Strength" to be a secondary message in the "Graph" ad, which the marketing research department stated "was perhaps due to greater intrusiveness of Extra Strength in Hollingshead" (CX 225-C).

(2) Bruno & Ridgeway Copy Test Of The "Black & White Back" Ad

131. In September 1990, Bruno & Ridgeway copy tested the "Black & White Back" ad (CX 15) and two other potential ads named "Thermography" and "Broadcast News" (CX 236-E-F; Peabody Tr. 174).

132. The purpose of this mall intercept copy test was to test these ads for communication of a new message: that Doan's was effective at relieving all kinds of back pain (Peabody Tr. 357-76; CX 236-E).

133. The target audience in this test was current and lapsed Doan's users (users who had not used Doan's in the previous six months (CX 236-E-F; Peabody Tr. 376).

134. Approximately 100 copy test respondents were exposed to each tested ad (CX 236-Z-44). Each respondent was shown one of the three tested ads in unfinished form (*i d.* at Z-206). The first exposure placed the Doan's ad in the middle of a reel of five commercials. The four ads surrounding the Doan's ad were for products unrelated to analgesics or back pain (CX 236-Z-44, Z-206; Mazis Tr. 1012-13). This "clutter reel" methodology was infrequently used by Ciba (Peabody Tr. 175).

135. After this first exposure, respondents were asked what products they recalled being advertised. For those who recalled a Doan's ad, three open-ended questions (5a-c) were asked to elicit respondents' take-away from the Doan's ad. Respondents were then exposed to the Doan's ad by itself (CX 236-Z-206-07; Peabody Tr. 175-76).

136. Following the second exposure to the Doan's ad, respondents were asked open-ended questions regarding what brand was advertised (questions 7a-b), what was the main idea of the ad (question 8), what other ideas was the ad trying to communicate (question 9), and what, based upon the ad, the respondent would like about the advertised product (questions 10a-b) (CX 236-Z-207-08; Mazis Tr. 1017-18). Open-ended questions 8-10 were not leading (Mazis Tr. 1023; *see* Peabody Tr. 178).

***621** 137. In response to open-ended questions, 5a-c, 46% of the respondents who saw the "Black & White Back" ad gave answers that were coded as "Superiority over other products" (CX 236-J, T; Mazis Tr. 1018; Peabody Tr. 177). Bruno & Ridgeway included a number of groups of comments into this superiority coding category, including "Better/more effective than Tylenol/Advil/aspirin," "Works better than other products," "Best backache medication," and "Works faster than other brands" (CX 236-T, Z-67-68). Dr. Mazis testified that the 46% result was extraordinarily high and demonstrates consumer take-away of the superior efficacy message (Mazis Tr. 1022).

138. Bruno & Ridgeway also netted the "Superiority over other products" responses for all of the open-ended questions (5a-c, 8, 9, and 10a-b) (CX 236-Z-67; Mazis Tr. 1021; Peabody Tr. 179). The result of that netting shows that 62% of the respondents exposed to "Black & White Back" understood it to communicate a superior efficacy claim (CX 236-Y, Z-67; Mazis Tr. 1021; Peabody Tr. 180). Bruno & Ridgeway concluded that this data established that "Black & White Back" "generate[d] high playback of Doan's being superior to other products. …" (CX 236-M) and that it "appear[s] to be highly successful at breaking through clutter" (CX 236-1) . Clutter refers to the other commercials that were shown respondents in this copy test (CX 236-E, 1; Mazis Tr. 1012-13).

139. Sixteen percent of the respondents viewing "Black & White Back" gave an answer to an open-ended question that was coded as "Extra Strength" (CX 236-Z-71). The 16% of responses coded as "Extra Strength" were not included in the "Superiority over other products" coding category (*see* Peabody Tr. 619-22; Whitcup Tr. 2355).

(3) December 1990 ASI Copy Test Of The "Black & White Back" Ad

140. In December 1990, Ciba had a research company, ASI, conduct a copy test on the same "Black & White Back" commercial that was tested in the 1990 Bruno & Ridgeway Copy Test (Peabody Tr. 386-87; RX 98-A-Z-11). Consumer playback was measured 24 hours after exposure to the commercial through telephone interviews (Peabody Tr. 387-88).

***622** 141. The 1990 ASI Copy Test reported that only 3% of the 384 respondents questioned twenty-four hours after exposure to the "Black & White Back" commercial said that it communicated "product superiority" (Peabody Tr. 389; RX 98-H). Similarly, only 1% of respondents played back that Doan's was "more effective/works better" in comparison to other products (Peabody Tr. 390; RX 98-H).

142. Ciba believed that the ASI testing method is closer to a real world viewing situation than the Bruno & Ridgeway method, and, since it measures both communication and recall, that the data from the 1990 ASI Copy Test provided more reliable evidence of the effectiveness of the "Black & White Back" commercial than data from the 1990 Bruno & Ridgeway Copy Test (Peabody Tr. 392, 394-95).

(4) The Bruno & Ridgeway Copy Test Of The "Ruin A Night's Sleep" Ad

143. In October 1991, Bruno & Ridgeway copy tested the "Ruin A Night's Sleep" and "Car Bed" ads (CX 7; CX 17; CX 244-B; Peabody Tr. 185) to determine which of the ads best communicated consumers' response to the new Doan's P.M., a line extension product aimed at people who suffered nighttime back pain (Peabody Tr. 396-97).

144. This copy test used the mall intercept procedure, and it targeted nighttime back pain sufferers/treaters within the past 6 months, aged 25-60, one-half of whom who had ever used Doan's (CX 243-A-C; CX 244-B; CX 245-H; Peabody Tr. 186-87).

145. Respondents were asked open-ended questions and a close-ended question (CX 243-D; Mazis Tr. 1033).

146. Approximately 25% of consumers gave answers that were coded "superiority over other products," a result which Dr. Mazis testified was quite high for open-ended questions. This superiority coding included such responses as "works better than others," "Better than Tylenol," "Better than Advil," "Better than Bayer" (Mazis Tr. 1039-40).

147. Four percent of the respondents reported that the "Ruin A Night's Sleep" ad communicated that Doan's "is the best brand for back pain versus other brands" (Peabody Tr. 405; CX 244-V) and Mr. Peabody claimed that the rest of the 25% superiority playback was linked to the presence of the second sleep ingredient in Doan's ***623** P.M. which was not available in formulations offered by Doan's competitors (Peabody Tr. 405-06).

(5) 1991 ARS Copy Test Of "Ruin A Night's Sleep"

148. In 1991, ARS (F 159) tested the "Ruin A Night's Sleep" commercial and found that only 2% of the 165 backache sufferers reported 72 hours after exposure that it communicated that Doan's was "effective/works/better" and four percent of these respondents reported that the commercial communicated "good product/better/best" (Peabody Tr. 411; RX 89-Z-20). Of the 81 nighttime backache sufferers/treaters included in the test, 7% reported that the commercial communicated "good product/better/best" (Peabody Tr. 412; RX 89-Z-20).

149. In addition, there were no respondents in the 1991 ARS Copy Test who recalled that "Ruin A Night's Sleep" communicated that Doan's P.M. had a "unique combination of ingredients/pain relieving medicine that Advil, Tylenol & Bayer don't have" (Peabody Tr. 414-15; RX 89-P, R, S, T, U).

(6) The 1993 ARS Copy Test Of "Black & White Pan Rev. 15"

150. In 1993, Ciba asked ARS to conduct a copy test of the proposed "Black & White Pan Rev. 15" commercial (Peabody Tr. 436; RX 32-A-Z-33). The ARS testing methodology measures the "persuasion" of a proposed commercial on a scale of one to seven. A score of zero to two is called "inelastic" and predicts a zero percent chance of the proposed advertising generating sales (Peabody Tr. 416-18; Stewart Tr. 3522). A score of two to four is called "low elasticity" and indicates that there is only a small possibility that the advertisement will increase sales (Peabody Tr. 418). A score of four to seven is called "moderate elasticity" and predicts a 50% chance of positive sales response from the advertising (Peabody Tr. 417).

151. Dr. Stewart testified that the ARS persuasion score was a "perfectly appropriate measure" for Ciba to rely upon in determining the effectiveness of its advertising campaign (Stewart Tr. 3516).

152. "Black & White Pan Rev. 15" scored in the low elasticity range of 2.3 to 3.7 on the ARS persuasion scale (Peabody Tr. 437; RX 32-F). Despite this, Ciba ran the "Black & White Pan Rev. 15" commercial (Peabody Tr. 437).

***624** 153. In addition to poor persuasion scores, 4% of the 163 male and female back pain sufferers who viewed "Black &

White Pan Rev. 15" recalled that the commercial communicated "good product/better/best" (Peabody Tr. 438; RX 32-Y). Because playback of "good product" does not necessarily connote superiority, Mr. Peabody testified that the 4% figure overestimated the playback of a more effective claim in the 1993 ARS Copy Test (Peabody Tr. 438-39).

154. One percent of respondents recalled that "Black & White Pan Rev. 15" communicated that Doan's "contains a back pain relieving medicine that no leading analgesic product has" (Peabody Tr. 440; RX 32-M).

(7) The 1994 ARS Copy Test Of "Activity-Playtime"

155. In 1994, Ciba had ARS conduct a copy test of the proposed "Activity—Playtime" commercial. The persuasion scores for it were "abysmally low," *i.e.*, in the 1.5 to 2.1 inelastic range (Peabody Tr. 429; RX 33-J). According to ARS studies, a score in this range would not have any positive impact on Doan's sales (Stewart Tr. 3514).

156. Nevertheless, Ciba decided to run this commercial because the "prior ad we had been running I think at this point was worn out, was equally as ineffective as this one" (Peabody Tr. 429).

157. In addition to the "abysmal" persuasion scores, only 4% of the 201 male and female backache sufferers who viewed the "Activity—Playtime" commercial recalled -- 72 hours after exposure -- that the commercial communicated "works/effective/more effective" (Peabody Tr. 433; RX 33-Z-4). Three percent of these respondents recalled that the commercial communicated "good product/better/best" (Peabody Tr. 434; RX 33-Z-4).

158. Less than 1/2% of respondents recalled that "Activity—Playtime" communicated that Doan's "has an ingredient other pain relievers don't have" (Peabody Tr. 435; RX 33-Z-5). Less than 1/2% of respondents recalled the commercial communicating that Doan's "has a special ingredient others don't have" (Peabody Tr. 435-36; RX 33-Z-5).

(8) The 1995 ARS Copy Test Of "Muscles"

159. In late March and early April 1995, ARS, an independent consumer research provider, implemented a 72-hour delayed recall ***625** test of the "Muscles" ad (CX 11, 23) (CX 265; Peabody Tr. 191). ARS testing is done in a theater-type setting where respondents are pre-recruited to watch two pilot television shows. Prior to viewing the program, respondents are given a depiction of various products in each category in which the brands whose advertisements will be tested compete, and are asked to select one from each product category with the promise that one person will win their selections. They then view the program material, which is interspersed with pods of ads. At the end of the program, the product selection task is done again, with the promise that another respondent will win the products they select (Peabody Tr. 191-93; Stewart Tr . 3450-51).

160. An ARS test includes a total of 12 ads in the one hour of programming shown. The remaining 11 ads are in product categories unrelated to the ad being tested (CX 265-Z-23; Peabody Tr. 194).

161. From the data it obtains comparing the respondents' product selections made before and after exposure to the programming material and ads, ARS calculates a persuasion score for each ad tested. In making this calculation, ARS takes additional factors into account, such as the number of competitors, in the product category and the degree of brand switching in that category. Positive scores are interpreted to mean that the ad will have a net persuasive affect (Stewart Tr. 3450-52; Peabody Tr. 191-93).

162. Seventy-two hours after the ARS test is conducted, respondents are recontacted by telephone. If they can remember an ad for the tested product and give some correct playback from that ad, they are considered to be a "related recaller" of the ad (Peabody Tr. 193; CX 265-Z-23). For evaluative purposes, ARS also provides a "norm" related recall score, which is an average calculated from scores obtained for all ads tested by ARS in the category in which the brand competes (Stewart Tr. 3452-53; *see* CX 265-L). The ARS "norm" against which the Doan's ads were compared was 23%;pl related recall, *i.e.*, whether 23% or more of the respondents recalled the ad and gave some correct playback from it (CX 265-L). Recall above that level was viewed as more memorable than the average ad for the category, which is calculated mostly from 30-second ads. Dr. Stewart

acknowledged that "Muscles," as well as "Black & White Back" and "Activity Playtime," although persuasive, were not memorable (Stewart Tr. 3449, 3452-53).

***626** 163. The persuasion scores for "Muscles" were in the low elasticity range with a low likelihood of generating a positive sales response (Peabody Tr. 441-42).

164. The results reported by ARS for the sample of "male and female back pain sufferers in past year" in the "Muscles" ad test was based upon the entire sample of 143 such respondents. Of that sample, 45% had any related recall of the tested ad and 8% were coded as having said "superiority" was a claim conveyed by the ad (CX 265-M; Peabody Tr. 196; Mazis Tr. 1064-65). As a percentage of the related recallers, however, 18% of the recalling sample took away the "superiority" claim (Mazis Tr. 1065-66; *see* Peabody Tr. 196).

(9) Doan's FSI Mail Panel Communication Test

165. In January 1991, Market Facts, an independent consumer research provider, undertook a communication study of several Doan's FSI's using its mail panel research methodology (CX 238; Peabody Tr. 207-15; CX 502 at 47-49 [Wright Dep.]).

166. The respondents who were surveyed by Market Facts had previously completed a mail panel questionnaire inquiring about backaches and how they are treated (CX 238-Z-126; Peabody Tr. 209). The survey was mailed to the members of the Market Facts mail panel with instructions to give the questionnaire to the person in the household who had completed the previous backache related questionnaire (CX 238-Z-126; Peabody Tr. 208-09). No verification procedure was undertaken to ensure that the individual completing this questionnaire was identical to the one who completed the earlier questionnaire (Peabody Tr. 209-10).

167. One purpose of the mail panel study was to determine the communication effect of five FSI's (CX 502 at 47-48 [Wright Dep.]). Question 5 of the questionnaire asked respondents to rate their agreement or disagreement with a list of statements on a five-point scale, "[b]ased on what this offer [FSI] said about Doan's" (CX 238-Z-128). One of those statements was: "Is better for back pain than other pain relievers" (*id.*).

168. The results of question 5 for the statement "Is better for back pain than other pain relievers" were presented at CX 238-Z-71 (Peabody Tr. 214-15). For an FSI that was identical to CX 32-A and nearly identical to CX 29-J and CX 29-Z-4 (CPF 165), 47.4% of the ***627** respondents strongly or somewhat agreed that the FSI made that claim (CX 238-Z-71; *see* Peabody Tr. 212-13).

169. For FSI's that were substantially similar to CX 29-U and 29-W (CPF 165), 51.5% and 59.0%, respectively, of the respondents strongly or somewhat agreed that the FSI's made the superior efficacy claim (CX 238-Z-71; *see* Peabody Tr. 207-08, 213-14).

b. Dr. Mazis' Copy Test

170. U.S. Research, Inc. ("USR") conducted a mall intercept copy test designed by Dr. Mazis to determine if two of the challenged ads communicated the superiority claim. The Doan's ads tested were "Activity-Playtime" (CX 10) and an FSI entitled "Why treat general aches? Back pain needs the back specialist" (CX 53). Dr. Mazis' use of an FSI was appropriate because it contained an ad message as well as a coupon (Mazis Tr . 976, 1902, 2034-35).

171. The copy test used the "funneling" technique: it asked open-ended questions followed by filtering questions to focus the questioning and minimize guessing, and then close-ended questions (Mazis Tr. 1084-90). The test also used a screener, a main questionnaire, and, to eliminate bias, control ads and control questions (Mazis Tr. 1077, 1087, 1090; CX 419-K-Z-8).

172. USR pretested the main questionnaire to determine if any of the questions were confusing. Some changes were made to the questionnaire (Kloc Tr. 671, 708). USR also validated the test to ensure that there was no interviewer misconduct or cheating (Mazis Tr. 1128).

173. USR's coding department developed proposed codes after review of a portion of the open-ended questions. The codes were developed by professional coders at USR, each of whom had between six and twenty years of experience as coders. To develop the codes, the coders took samplings from each of the open-ended questions to ascertain the thoughts and ideas that respondents gave to those particular questions (Kloc Tr. 694-98). They then combined similar thoughts into categories and created a list of proposed codes. The proposed codes were then reviewed by Dr. Mazis (Mazis Tr. 1069).

174. Dr. Mazis' universe was comprised of men and women, twenty-five to seventy years old who had suffered back pain in the last six months and treated it with an OTC analgesic (CX 419-F; ***628** Mazis Tr. 1070-71). His universe matched target audiences defined by Ciba (*see* JX 2 ¶ 27).

175. Dr. Mazis chose control ads (F 126) for analgesics which focused on back pain and excluded ads that made or implied superiority claims (Mazis Tr. 1079). He decided not to use a Doan's ad purged of superiority features, as did Dr. Jacoby in his study (Mazis Tr. 1079, 1370-72; Jacoby Tr. 2948-49).

176. The control ads were a Motrin TV commercial and an FSI for Nuprin (CX 540; CX 545).

177. The control ads did not include any references to "Extra Strength" while the Doan's ads did, but this language was unlikely to communicate a superiority claim since it was hardly visible in the tested TV ad (Mazis Tr. 1919-20). Furthermore, the "extra strength" language does not carry with it, in most cases, a superiority message (CX 419-Z-76). (*See* F 129, 130, 193.)

178. Dr. Mazis' copy test gradually filtered out those respondents who did not have anything relevant to offer, then asked the qualifying respondents a series of open-ended and close-ended questions (Mazis Tr. 1084-90).

179. USR tabulated the results of each open-ended question separately (Kloc Tr. 704; *see* CX 419-Z-29-37, Z-39-47, Z-49-55, Z-59-63) . It also netted the results of all three open-ended questions for each coding category (Kloc Tr. 705-06; Mazis Tr. 1091-92). This "total ad communication" tabulation lists the total number of respondents who gave a particular response to the open-ended questions, without any double counting (Kloc Tr. 705-06).

180. For each of the two challenged ads shown to respondents in Dr. Mazis's copy test, the following is the percentage who responded in their own words to the open-ended questions (which may understate the total communication (Whitcup Tr. 2829-30)), that the ads communicated that Doan's is more effective than other pain relievers:

	"Total" open-ended communication of superior efficacy based on Q2, Q3b, and Q4b
"Activity-Playtime"	56.7%
"Why treat general aches?" FSI ***629** (Q2: "What does the commercial state or imply about Doan's?") (Q3b: "What reason or reasons does the commercial state for buying Doan's?") (Q4b: "What does the commercial state or imply about Doan's in comparison to other pain relievers?")	40.1%

181. If the results of only the first two, broadest open-ended questions are tabulated, the following is the percentage of consumers who responded that the tested ads communicated that Doan's is more effective than other pain relievers:

	Open-ended communication of superior efficacy based on Q2 and Q3b

"Activity-Playtime"	39%
"Why treat general aches?" FSI	25%

(Mazis Tr. 1095-96). The open-ended responses that were coded as "more effective" for back pain included responses coded that Doan's was "better overall" or "better than other pain relievers" (RX 128-D E; Mazis Tr. 1915-18). Respondents' expert, Dr. Jacoby, also coded "best/better" and "better than other pain relievers" to mean superior efficacy for back pain, since back pain is the subject of the ads (Jacoby Tr . 3063; Mazis Tr. 1920). This is the standard manner in which to code these responses in the context of these ads (Mazis Tr. 1920-21).

182. The magnitude of the superiority responses given in response to the open-ended questions in Dr. Mazis' copy test is extremely high and is consistent with data from the copy tests respondents performed in the ordinary course of business on other challenged ads and FSI's (Mazis Tr. 1093, 1096-97).

183. For each of the two challenged ads shown to respondents in Dr. Mazis' copy test, the following is the percentage of consumers who responded that the advertisement conveyed that Doan's was more effective than other OTC pain relievers for back pain relief in response to close-ended question 5a:

	Total close-ended communication of superior efficacy based on Q5a
"Activity-Playtime"	73.3%
"Why treat general aches?" FSI	57.9%

***630** (Mazis Tr. 1098-99; CX 419-Z-56).

(Q. 5a: "Does the ad state or imply that Doan's is more effective than other over-the-counter pain relievers for back pain relief?")

184. To control for beliefs consumers might have that all back pain claims are akin to superiority claims and for yea saying bias, Dr. Mazis first subtracted the "yea saying" responses (consumers who responded "yes" to 5b, the headache control question) ("Does the ad state or imply that the product is more effective than other OTC products for headaches?") from the total percentage of consumers who took away a "more effective" claim from the test and control ads in response to question 5a. Dr. Mazis then subtracted the result of this calculation for the control ad from the result obtained for the test ad. The use of this double control procedure provides a conservative estimate of the superiority communication conveyed by close-ended question 5a (Mazis Tr. 1087, 1100-01).

185. The superiority playback of the tested ads from the close-ended question 5a, net of controls, is as follows:

	Close-ended communication of superior efficacy based on Q5a net of controls
"Activity-Playtime"	58.0%
"Why treat general aches?" FSI	42.7%

(Mazis Tr. 1100). This magnitude of results confirms that consumers take the challenged superiority claims from these ads (Mazis Tr. 1092).

***631** *c. Dr. Jacoby's Copy Test*

186. Dr. Jacoby designed a survey on behalf of respondents for the purposes of this litigation (RX 5) which measured, in separate sections, both beliefs about Doan's and the communication of selected Doan's ads (Jacoby Tr. 2962, 2971). The belief

portion of this study is discussed below. The copy testing portion of Dr. Jacoby's study measured the communication of two challenged Doan's ads, "Activity-Playtime" and "Muscles." Complaint counsel challenge Dr. Jacoby's conclusion with respect to close-ended question 8(a) ("Based on what the commercial said, showed or suggested, would you say that when it comes to relieving back pain, the advertised brand is as effective, less effective, or more effective than other brands") (RX 5-Z-61) because of "priming" by question 1(d) ("Do you believe any of the brands [of analgesics] that you mentioned [in response to questions 1a-c] is more effective for back pain than any of the other brands you mentioned") (RX 5-Z-57).

187. "Priming" refers to information given or concepts raised in earlier questions in an interview that sensitize respondents to that issue and result in respondents providing that information or concept as an answer to a later question only because they had been primed to think about it by the prior question (Mazis Tr. 1109; Jacoby Tr. 3217-18).

188. Complaint counsel claim that question 1d primed respondents to answer question 8a with the "more effective" response, with the result that the superiority claim playback could have been inflated (Mazis Tr. 1109).

189. Complaint counsel's argument may be valid, but the most significant aspect of Dr. Jacoby's study is the responses to its open-ended questions which provide the most reliable measure of ad communication that can be extracted from it (Mazis Tr. 1108-10). These questions asked for the main idea of the tested ad (Q6a) and what other points or ideas the ad communicated (Q6b).

190. These results provide reasonably reliable data which support the conclusion that the superior efficacy claim was conveyed to consumers by the "Activity-Playtime" and "Muscles" ads.

191. The data reported in RX 5 shows that 35% of the respondents who viewed the "Activity-Playtime" ad took the superior efficacy claim from it based upon their responses to the two open-***632** ended questions (RX 5-Z-123; Jacoby Tr. 3063-64; Mazis Tr. 1111-12). Dr . Jacoby characterized that figure as "high" (Jacoby Tr. 3065).

192. The data reported in RX 5 shows that 19% of the respondents who viewed the "Muscles" ad took the superior efficacy claim from it based upon their responses to the two open-ended questions (RX 5-Z-124; Mazis Tr. 1112).

193. In response to these open-ended questions (Questions 6a-b), only one percent of respondents exposed to the "Activity-Playtime" commercial played back a "strong/extra strength/need fewer" message, while 35% of respondents played back a superiority claim (RX 5-Z-123); Jacoby Tr. 3121-22; Mazis Tr. 1728-29). Similarly, after exposure to the challenged "Muscles" commercial, only 2% of respondents played back a "strong/extra strength/need fewer" message, while nineteen percent played back a superiority claim (R.X 5-Z- 124; Mazis Tr. 1728-29). These data indicate that the "Extra Strength" claim is not the reason respondents are taking a superiority message (*see* Mazis Tr. 1728, 1874, 1922).

194. Dr. Mazis undertook an independent review of the verbatims from the three open-ended questions (6a-b, 7d) in Dr. Jacoby's copy test, adding a third category entitled "Faster" because these responses are properly included in the net superior efficacy take away (Mazis Tr. 1114).

195. Netting the three coding categories across the three open-ended communication questions yields a net superior efficacy take away of 47.9% for the "Activity-Playtime" ad and 22.1% for the "Muscles" ad (CX 453-C-D; Mazis Tr. 1114-15).

d. Mr. Lavidge's Copy Test

196. Mr. Lavidge designed three studies on behalf of respondents for the purpose of this litigation (RX 23) which measured both the communication of certain Doan's ads and beliefs about Doan's (Lavidge Tr . 758-60). The belief portion of the studies is discussed below. The copy testing portion of Mr. Lavidge's studies attempted to measure the communication of the challenged "Muscles" ad and the unchallenged "New Muscles - Male" ad, immediately after exposure and eleven days later (RX 23-E).

197. Mr. Lavidge's three surveys were called Test 1, Test 2, and Test 3 (RX 23-E). Tests 1 and 2 were identical except with regard to the Doan's ad shown; Test 1 showed the challenged "Muscles" ad and ***633** Test 2 showed the modified, "New Muscles - Male" ad. Test 3 was identical in ad exposure to Test 1, but obtained its recall and belief measures between 10 and 12 days after that exposure (Lavidge Tr. 758-59).

198. In Tests 1,2, and 3, respondents were exposed to advertising in the same way. The Doan's ad of interest was included on a socalled "clutter tape" with three other 15-second ads for Bufferin, Advil, and Extra Strength Tylenol Aches & Strains (Lavidge Tr. 758, 844). Each of these ads only promoted the advertised analgesic for the treatment of back pain. These commercials were shown twice and in random order (Lavidge Tr. 776-77; RX 23-F). Prior to this study, Mr. Lavidge had never used the clutter tape methodology, a procedure which was necessary here because of the combination of the belief and communication studies (Lavidge Tr. 759-60, 844-46).

199. All of the ads on the clutter tapes were for OTC analgesics to treat back pain, an unusual procedure, for clutter ads never use a product in the same category as the tested ad (Mazis Tr. 1264-66; Peabody Tr. 175-77).

200. Mr. Lavidge and Mr. Peabody testified that they would not recommend the placement of a Doan's ad in a group of other OTC ads because consumers would have difficulty recalling the Doan's message (Peabody Tr. 156; Lavidge Tr. 849). Thus, their use in the copy test would confuse respondents (Mazis Tr. 1266; Lavidge Tr. 851) with the result that it would likely discourage ad recall (Mazis Tr. 1265-67) Test 3 also discouraged ad recall by delaying questioning until, on average, eleven days after exposure to the clutter tape (Mazis Tr. 1267).

201. Copy tests seeking to determine whether implied claims are made usually ask that question (Mazis Tr. 1269; Whitcup Tr. 2829). Mr. Lavidge's communication question did not do so (Mazis Tr. 1064, 1269).

202. Tests 1, 2, and 3 did not employ close-ended ad communication questions; the result may have been to miss playback of all ad claims (Whitcup Tr. 2829; Mazis Tr. 1994).

203. The use of the clutter tapes, the eleven-day recall methodology in Test 3, the lack of close-ended communication questions and the failure to ask for implied claims, resulted in an understatement of the ads' communication of superiority claims (Mazis Tr. 1265-68).

***634** *F. Substantiation Of The Superiority Claim*

204. According to accepted principles of scientific and medical practice, two well-controlled clinical studies are required to establish the therapeutic superiority of an OTC analgesic over competing OTC analgesics (JX 1 ¶ 6).

205. Although the Advisory Review Panel On OTC Internal Analgesic and Antirheumatic Products and the FDA concluded that magnesium salicylate is safe and effective for the treatment of backache and other pain (Peabody Tr. 313-14), the OTC Analgesic Monograph does not state that any approved analgesic ingredient is more effective for the relief of back pain than any other approved analgesic product (CX 415-A-Z-31).

206. No studies have been conducted regarding the efficacy of any Doan's product or the exact formulation contained in any Doan's product offered for sale to the public (JX 1 ¶ 8).

207. There are no specific studies demonstrating the therapeutic superiority of magnesium salicylate over aspirin, acetaminophen, ibuprofen, or naproxen sodium for the relief of back pain, or for any other approved OTC Analgesic Monograph indications (JX 1 ¶ 9).

208. Ciba's former Vice President of Marketing stated that there are no documents or studies in existence demonstrating that magnesium salicylate relieves back pain more effectively than acetaminophen, aspirin, ibuprofen or naproxen sodium (CX 584; *see also* CX 501 at 22 [Sloan Dep.]).

209. The only scientific review Ciba conducted prior to purchasing the Doan's brand was a review of FDA's OTC Analgesics Monograph (CX 501 at 25 [Sloan Dep.]).

210. Ciba's former Vice President of Marketing testified that during the time he was responsible for Doan's he knew that advertising claims required substantiation and that, while the OTC Analgesics Monograph was sufficient to support basic efficacy claims, superiority claims would require one or two well-controlled clinical studies (CX 501 at 27-28 [Sloan Dep.]). He also stated that he never saw any scientific evidence that Doan's was more effective than other analgesics (CX 501 at 22 [Sloan Dep.]).

211. In 1989, Ciba's legal counsel and the Marketing Manager for Doan's received a memorandum from Ciba's medical division stating that "clinical studies have shown that magnesium salicylate is an effective analgesic and is comparable to aspirin" and that "there are ***635** no clinical studies of Doan's in combination with other over-the counter medications" (CX 71-B; CX 519-A).

212. As part of the network review process, Ciba sometimes received comments from the TV networks that the way a claim was structured might imply superiority and requesting substantiation (CX 501 at 37 [Sloan Dep.]; CX 503 at 86-91 [Jackson Dep.]). Ciba did not provide the networks with substantiation for a superiority claim and, instead, revised its ads or withdrew them from consideration (*see e.g.*, CX 166-A; CX 177-A-B; CX 212-A; CX 501 at 37 [Sloan Dep.]).

213. In a 1994 letter addressed to the then-Marketing Director for Doan's, Jordan McGrath's Senior Vice President responsible for Doan's stated:

> Doan's cannot support product "superiority" … nor can it deliver a unique or seemingly superior consumer benefit. Hence, it's a challenge for the advertising execution to compensate and persuasively deliver a dimension of competitive "news."

(CX 169-D; CX 504 at 136 [Schaler Dep.]).

214. In a "demo exploratory" document attached to a summary of discussions between Jordan McGrath and Ciba regarding creative strategy for 1995, the agency noted:

> While we would like to *imply* that Doan's provides superior efficacy because of its unique ingredient, we cannot clinically support this since the other brands work equally as well as Doan's at relieving back pain.

(emphasis in original) (CX 147-J).

G. Materiality Of The Superiority Claim

215. Dr. Jacoby's study (RX 5) analyzed the impact which the ads "Activity-Playtime" and the old "Muscles" might have on respondents' [consumers'] future purchasing behavior (Jacoby Tr. 3053; RX 5-Z-112).

216. Specifically, after exposure to the commercials, Dr. Jacoby asked respondents the following questions: "Did seeing this commercial influence whether or not you would buy the advertised product in the future?"; "Did it make you more likely to buy this product, or less likely to buy this product?"; and "What is it about what the commercial said, showed or suggested that makes you more likely to buy it in the future?" (Jacoby Tr. 3055; RX 5-Z-112-13).

***636** 217. The percentage of consumers reporting that the test ad made them more likely to buy the advertised product were as follows:

"Activity-Playtime"	25%

"Muscles" (challenged)	30%
"Muscles" (new & not challenged)	35%
Advil	28%
Tylenol Aches & Strains	42%

(RX 5-Z to Z-8).

Based on the measurements taken from these questions, the unchallenged Doan's commercials exerted a slightly greater impact on respondents' purchase decisions than the challenged "Activity-Playtime" and "Muscles" commercials (Jacoby Tr. 3057; RX 5-Z-112-13). The fact that the unchallenged Doan's "Muscles" commercial actually exerted more impact on respondents' purchase behavior is especially telling according to Dr. Jacoby (Jacoby Tr. 3057-58). Similar to the comparison between the two "Muscles" commercials, the Tylenol control commercial had a greater impact on respondents' purchase decisions than any of the Doan's commercials that were shown (Jacoby Tr. 3059-60; RX 5-Z-112).

218. Respondents were then asked what it was about the ad that made them more likely to buy (RX 5-Z-59). In response, only 2% out of 142 (2% of the 122 nonusers of Doan's and 0% of the 20 users of Doan's) who viewed the "Activity-Playtime" commercial attributed this reaction to a supposed claim in the ad that Doan's "works better/best/more/most effective ." Only 3% of the same group indicated that the positive impact on their purchase interest was due to "Activity-Playtime" saying that Doan's had a "special/unique ingredient" (Jacoby Tr. 3058; RX 5-Z-114).

219. Two percent of the respondents who viewed the old "Muscles-Male" commercial indicated that the positive impact on their purchase interest was due to the commercial saying that Doan's "works better/best/more/most effective" (Jacoby Tr. 3059; RX 5-Z-115). Two percent of the same group indicated that the positive impact on their purchase interest was due to old "Muscles" saying that Doan's had a "special/unique ingredient" (Jacoby Tr. 3059; RX 5-Z-115).

220. Based on these measurements, Dr. Jacoby testified that any alleged more effective claim in the challenged Doan's advertising did not have a positive impact on relevant consumers' interest in purchasing Doan's (Jacoby Tr. 3061).

***637** 221. He also concluded that, to the extent that respondents in the Jacoby Study who indicated that the "Activity-Playtime" commercial communicated a more effective claim, the same respondents did not believe that such a claim would positively affect their purchase behavior (Jacoby Tr. 3338-42).

222. Of the 129 respondents who viewed the old "Muscles-Male" commercial, 4.7% reported that the commercial communicated a more effective claim and that the claim exerted a material impact on their purchase intentions (Jacoby Tr. 3341; RX 209-A). After controlling for noise by subtracting the response level from the new "Muscles-Male" commercial, the net amount of respondents who thought the old "Muscles-Male" commercial communicated a more effective claim that exerted a material impact on their purchase intentions was 1.9% (Jacoby Tr. 3341; RX 209-A).

223. Of the 142 respondents who viewed the "Activity-Playtime" commercial, 12.7% reported that the commercial communicated a more effective claim and that the claim exerted a material impact on their purchase intentions (Jacoby Tr. 3340; RX 209-A). After controlling for noise by subtracting the response level from the Tylenol control commercial, the net amount of respondents who thought that the "Activity-Playtime" commercial communicated a more effective claim that exerted a material impact on their purchase intentions was 7.9% (Jacoby Tr. 3341).

224. These data, according to Dr. Jacoby, demonstrate that even to the extent that consumers may have extracted a superior efficacy claim from the "Activity-Playtime" and old "Muscles-Male" commercials, the claims were not material (Jacoby Tr. 3342-43).

225. Furthermore, Mr. Peabody testified that the ARS persuasion scores for "Black and White Pan Rev. 15," "Activi-

ty-Playtime" and "Muscles" would not generate significant sales for Doan's (Peabody Tr. 429, 437, 441-42).

226. Complaint counsel argue that the challenged ads were material because they involve information that is important to consumers and would likely affect their purchasing decisions.

227. Complaint counsel cite the following evidence in support of their claim:

The Bruno & Ridgeway copy test of "Graph" which found that the idea of "superiority" conveyed by the ad "seems to be an important and persuasive idea" to consumers (CX 224-L).

***638** The conclusion of a market research company report discussing "Graph" which "appears to create the impression that Doan's may in fact be better than other brands, thereby promulgating a more favorable predisposition to trying Doan's" (CX 227-Z-3).

The Brand Equity study (CX 25a), (whose conclusions I reject (F 246)), shows that superior efficacy for back pain is an important attribute of OTC analgesics (Mazis Tr. 1618).

The fact that consumers were willing to pay a premium price for Doan's (F 15).

The 80% increase in Doan's dollar sales during the time the challenged ads were disseminated (JX 2 ¶ 17).

Despite the results of Dr. Jacoby's study, I am compelled by the strong presumption of materiality and the evidence cited by complaint counsel to find that the challenged ads were material.

H. The Need For Corrective Advertising

228. Complaint counsel's argument for the imposition of a corrective advertising order claims that: (1) there exists a misbelief about Doan's efficacy, (2) the misbelief was substantially created or reinforced by the challenged advertising, and (3) the misbelief is likely to linger unless respondents are compelled to engage in an advertising campaign which will correct the misapprehension created by Doan's eight year advertising campaign.

229. Complaint counsel argue that the need for corrective advertising can be inferred. They also cite three extrinsic "belief" studies -- the 1987 A&U study, the Brand Equity study, and the NFO study, in support of their argument.

230. Respondents, on the other hand, cite "advertising penetration data" as well as consumer belief studies conducted by Mr. Lavidge and Drs. Jacoby and Whitcup which, they say, lead to the conclusion that corrective advertising is not an appropriate remedy in this case.

1. The Impression Created By Doan's Ads

a. Ordinary Course Of Business Studies

(1) The ASI and ARS Tests

231. The 1990 ASI and 1991, 1993, 1994 and 1995 ARS copy tests revealed low 24 (ASI) and 72 (ARS) hour recall (2% to 8%) by respondents of a "more effective" or "good product/better/best" message (F 140, 148, 150, 155, 159).

***639** 232. Dr. Jacoby testified that if only a small percent of consumers recall a "more effective" or "good product/better/best" message within one to three days after, exposure to a commercial in a test environment, it shows the absence of any widespread lingering misimpression by consumers (Jacoby Tr. 2996-97).

(2) The 1987 Attitude And Usage Study

233. In June and July 1987, Arbor, Inc., an independent consumer research provider, conducted an attitude and usage study ("A&U study") by telephone for Doan's among adults who were back pain sufferers (CX 221-I; Peabody Tr. 134). The A&U

study was undertaken shortly after Ciba purchased the Doan's brand and was conducted to help Ciba understand the product category in which Doan's competed, to determine consumer awareness of the Doan's brand, and to determine the imagery and beliefs analgesic users held for Doan's and the brands with which it competed (CX 221-H; Peabody Tr. 133, 287; Mazis Tr. 979).

234. Question 22 of this study asked respondents to rate each of three selected brands of which they were aware on a list of 14 attributes, including one which stated "Is the most effective pain reliever you can buy for backaches" (CX 221-Z-120; Mazis Tr. 989-90; Peabody Tr. 141).

235. The mean results of respondents' ratings of the four brands (using a 1-7 scale) on the attribute "Is the most effective pain reliever you can buy for backaches" were: Doan's, 4.4; Extra-Strength Tylenol, 5.1; Advil, 4.8; Bayer, 4.2 (CX 221-Z-72). These ratings provide a measure of back pain sufferers/treaters' perceptions about the four brands on that attribute as of the time of the study (Peabody Tr. 141). They show that Doan's was rated below Extra-Strength Tylenol and Advil and about the same as Bayer on this attribute (*id.* at 143).

236. Ciba's marketing research department's analysis of the A&U study results concluded that "Extra-Strength Tylenol is clearly the gold standard for backache pain relief followed by Advil. Bayer and Doan's are consistently perceived weakest" (CX 221-C). That conclusion was based, in part, on the attribute rating for "Is the most effective pain reliever you can buy for backaches" (Peabody Tr. 144). The marketing research department further concluded that "Doan's has a weak image in comparison to the leading brands of analgesics ***640** and would benefit from positioning itself as a more effective product that is strong enough for the types of backaches sufferers usually get" (CX 221-C-D).

237. The results of the Doan's A&U study were used to help create new Doan's advertising. The first new Doan's ad that was created and disseminated after Ciba's receipt of the Doan's A&U study results was the "Graph" ad (Peabody Tr. 146).

(3) The Brand Equity Study

238. In July 1993, five years after the ad campaign at issue in this case began, CLT Research Associates, Inc., an independent consumer research company, implemented a research project called the Brand Equity study for Ciba. The study was conducted, in part, to help Ciba understand the strengths and weaknesses of the Doan's brand and establish the current equity and brand image of Doan's compared to its competitors in the backache market (CX 256-C; Peabody Tr. 217; Mazis Tr. 1042).

239. One purpose of the Brand Equity study was to evaluate how Doan's was perceived on a set of attributes compared to other analgesics used to treat back pain (Mazis Tr. 1042; *see* CX 259-B-C).

240. Question 2b of the study used an answer booklet (CX 259-B; CX 260) which consisted of a list of the 21 attributes and a grid of six boxes adjacent to each of the attributes (CX 260-B). The left hand box was labeled "Unacceptable, brand couldn't be worse," the right hand box was labeled "Ideal, nothing could make brand better," and in the middle above the dividing line between the third and fourth box was the label "Good" (*id.*). Respondents were asked to rate each of a group of analgesic products they were aware of for the treatment of back pain on each of the 21 attributes using this grid (Peabody Tr. 222-23; Mazis Tr. 1047).

241. The report of the Brand Equity study does not contain a detailed discussion of the results of question 2b (Mazis Tr. 1048-49). That data was contained in CX 486 and CX 507, which were massive printouts of the Brand Equity data. CX 480 contains a summary of some of the data obtained from question 2b, taken from those computer printouts.

242. The data in CX 480 is presented separately for users and aware non-users of Doan's, Extra-Strength Tylenol, Advil, and Motrin IB. This is appropriate since it takes account of the "usage ***641** effect" *i.e.*, the tendency of users to rate a product higher than do non users (Mazis Tr. 992, 1055, 1158).

243. The data for both users and aware non-users in CX 480 is presented both in terms of"top box" results and "top two box" results. Top box results are the percentages of respondents giving the highest rating to the product. In this case, top box refers to the proportion marking the boxes labeled "Ideal, nothing could make brand better." Top two box results are the percentage of individuals who selected either the "Ideal" rating or the box to its immediate left. Hypothetically, if the scale were rated from one to six with the "Ideal" box given a rating of six, the top two box figures reflect the percentage of respondents who rated a product with either a five or a six (Mazis Tr. 1051).

244. The following are the ratings of users of the products on the attribute "Being particularly effective for back pain":

	Doan's	ES Tylenol	Advil	Motrin
Top Box	44.7%	20.7%	18.9%	22.6%
Top Two Box	72.7%	50.0%	41.9%	54.7%

(CX 480-A-B).

245. The following are the ratings of aware non-users of the products on the attribute "Being particularly effective for back pain":

	Doan's	ES Tylenol	Advil	Motrin
Top Box	20.0%	7.1%	5.3%	6.6%
Top Two Box	36.0%	27.1%	16.8%	23.0%

(CX 480-C-D).

246. Dr. Mazis testified that the attribute "Being particularly effective for back pain" is similar to the attribute "Is more effective than other OTC pain relievers for back pain relief" (Mazis Tr. 1058). I disagree. "Particularly effective for back pain" probably reflects consumers' association of Doan's with back pain relief. It does not necessarily imply equivalence to the phrase "more effective" and this study, therefore, is not probative on the issue of belief.

***642** *b. The NFO Belief Study*

247. NFO is a marketing research company which provides mail panel research. Mail panel research involves mailing research instruments to individuals, who have previously agreed to serve as survey respondents, for them to complete and return to NFO by mail. Over 500,000 households participate in NFO research projects (Clarke Tr. 8-9).

248. NFO conducts over 3,000 consumer research studies annually using the mail panel methodology for major corporate clients, including 45 of the top 100 companies listed in the Fortune 500 (Clarke Tr. 9). Its research includes tracking studies, consumer attitude studies, advertising studies, concept studies, etc. These corporate clients, including Ciba and Novartis, rely on mail panel research by NFO and its competitors to make business decisions (Clarke Tr. 10; Peabody Tr. 203, 520-21, 196-98, 206-07, 215).

249. A NFO multi-card survey is an omnibus mailing of various questionnaires to a large group of panelists (Clarke Tr. 10). NFO mailed a multi-card questionnaire to 40,000 households (8 panels) in October 1996 on behalf of complaint counsel (Clarke Tr. 10-14; CX 420-H) and prepared a report tabulating the results of that survey (CX 420). The multi-card survey was intended to identify back pain sufferers/treaters who were Doan's users or aware non-users who could be sent a follow-up questionnaire to determine whether they held the belief that Doan's was more effective than other OTC pain relievers for back pain relief (Mazis Tr. 1118; Clarke Tr. 14).

250. None of the additional survey questionnaires that were included in the multi-card mailout with complaint counsel's questionnaire related to OTC medications or pain-related products. NFO received 30,025 completed questionnaires of the 40,000 mailed out (Clarke Tr. 18-20; CX 420-H).

251. Dr. Mazis decided to employ a mail panel to screen for Doan's users and aware non-users because it is a very cost effective method by which to locate users of a niche product like Doan's (Mazis Tr. 1117-18; Clarke Tr. 11; Peabody Tr. 518). Dr. Mazis has had experience using mail panel research and he has found it to provide useful and reliable results (Mazis Tr. 1119).

252. The survey, which was designed by Dr. Mazis (Tr. 1117), used a screening questionnaire to exclude respondents who did not meet the criteria established by him. An identical screening process ***643** was used in Doan's Brand Equity study (Mazis Tr. 1117-20; CX 258-C). Telephone validation of the NFO screening questionnaire was not conducted because there was no interviewer in this mail panel who might engage in misconduct (Mazis Tr. 1128).

253. In December 1996, NFO conducted a follow-up study for complaint counsel to assess beliefs of Doan's users and aware non-users (CX 421-H; Clarke Tr. 32; Mazis Tr. 1121-22, 1129). The sample of this survey consisted of 400 Doan's users and 400 Doan's aware non-users selected on a random basis from the larger population of both groups identified in the multi-card screening survey (Mazis Tr. 1130; Clarke Tr. 34-35). Dr. Mazis excluded consumers unaware of Doan's from his study because they do not hold any opinions about the product (Mazis Tr. 1122). Mr. Peabody confirmed the importance of obtaining data from users of Doan's (Peabody Tr. 377, 398).

254. At the time he designed the NFO belief study, Dr. Mazis planned to analyze the data that he obtained by comparing the belief measures of (1) users of Doan's to users of other analgesics for back plain relief, and (2) aware non-users of Doan's to aware non-users of other analgesics. The purpose of such matched comparisons was to take into account and control for the usage effect (Mazis Tr. 1129, 1158, 1199-1201). Novartis' expert statistician agreed that this sort of paired analysis is appropriate and necessary to remove the impact of the usage effect (Jaccard Tr. 1527-28; *accord* Lavidge Tr. 879).

255. The belief questionnaire presented to the respondents ten attribute statements, including "Is more effective than other over-the-counter pain relievers for back pain relief" (CX 421-Z-12; Mazis Tr. 1131) as well as "Has an ingredient for back pain" and "Is just for back pain." The remaining belief statements were included so as not to focus undue attention on the belief measures of interest, resulting in a list which was unbiased (Mazis Tr. 1134-35).

256. About 20% of respondents gave inconsistent answers, agreeing that the same product was both just for headaches and just for back pain, but Dr. Jaccard agreed that this was no cause for concern about responses to other survey questions (Jaccard Tr. 1539).

257. NFO's analysis of its belief study (CX 421-N-W) was recalculated by Dr. Mazis to exclude those respondents (38) who were unaware of any analgesic other than Doan's. This made the results of the NFO study more balanced (CX 481; Mazis Tr. 1139-40).

***644** 258. The results for three belief statements, "Is more effective than other over-the-counter pain relievers for back pain relief," "Has an ingredient especially for back pain," and "Is just for back pain" are summarized in CX 482 (Mazis Tr. 1147-51). That summary contains an aggregation of the percentages of respondents who agreed with each of those belief statements for each product by combining the data for the "strongly agree," "agree," and "somewhat agree" responses (*id.* at 1148). That data is reported both for users of each product and for aware non-users of each product (CX 482). The results for the belief statement "Is more effective than other over-the-counter pain relievers for back pain relief" are as follows:

	Doan's	Advil	Aleve	Bayer	Motrin	Tylenol
Users	77%	62%	51%	41%	61%	43%
Non-Users	45%	31%	20%	17%	35%	22%

(CX 482).

259. Users of a brand tend to have more favorable beliefs about brands they use. It is inappropriate to look at the overall ratings for each brand by the whole sample regardless of usage, because usage behavior can exert influences on perceptions (Jaccard Tr. 1528). To account for this usage effect, one must compare the beliefs of users of Doan's to the beliefs of users of the other brands. Similarly, the beliefs of Doan's aware non-users must be compared to the beliefs of aware non-users of the other brands. Dr. Mazis conducted a statistical analysis of the NFO data to account for the usage effect.

260. For each of the five comparison analgesic products, Advil, Aleve, Bayer, Motrin, and Tylenol, Dr. Mazis' analysis looked at the subgroup of individuals who used that brand and Doan's ("joint users") (CX 424-A-Z-25; CX 422-A-F; Mazis Tr. 1158-59). Then, for each set of joint users of Doan's and a comparison product, he compared those individuals' beliefs about Doan's to their beliefs about that comparison product (a "user-to-user comparison"). For example, one of the analyses looked at individuals in the NFO sample who used both Advil and Doan's and compared their beliefs about Advil to their beliefs about Doan's (Mazis Tr. 1159-61). A similar analysis was done for each set of joint users (*e.g.*, Aleve and Doan's joint users) (Mazis Tr. 1158-59, 1199-1201). Dr. Mazis conducted a ***645** similar analysis for aware non-users (CX 424-A-Z-25; CX 422-A-F; Mazis Tr. 1159).

261. Dr. Mazis' analysis focused on whether respondents agreed or did not agree that a brand they rated "is more effective than other over-the-counter pain relievers for back pain relief." If the respondent either "strongly agreed," "agreed," or "somewhat agreed" on the seven-point scale, they were treated as an "agreer." If he or she "strongly disagreed," "disagreed," "somewhat disagreed," or "neither agreed or disagreed," that respondent was treated as a "non-agreer." The analysis concentrated on the percentages or proportions of joint users and joint aware non-users "agreeing" that a product was more effective for back pain than other OTC analgesics (Mazis Tr. 1162-63).

262. The following table presents the percentages of joint users who agreed that Doan's or another of the five comparison brands was more effective than other OTC pain relievers for back pain relief.

Among joint users of both Doan's and comparison brand	Doan's is more effective than other OTC pain relievers for back pain relief	Comparison brand is more effective than other OTC pain relievers for back pain relief	Difference in % agreeing
Doan's & Advil	74%	57%	17%
Doan's & Aleve	77%	46%	31%
Doan's & Bayer	70%	33%	37%
Doan's & Motrin	72%	54%	18%
Doan's & Tylenol	76%	48%	28%

(CX 424-Z-16-20; CX 422-E-F; *see* Mazis Tr. 1171-73).

263. On average, the proportions of joint users agreeing that Doan's is more effective for back pain than other OTC analgesics is 26% higher than the proportions agreeing that the other brands are more effective (Mazis Tr. 1173-74).

264. The following table presents the percentages of joint aware non-users who agreed that Doan's or another of the five comparison brands was more effective than other OTC pain relievers for back pain relief .

Among those aware of both Doan's and compar-	Doan's is more effective than other OTC pain re-	Comparison brand is more effective than other OTC	Difference in % agreeing

ison brand but who use neither	lievers for back pain relief	pain relievers for back pain relief	
Doan's & Advil	43%	30%	13%
Doan's & Aleve	41%	19%	22%
Doan's & Bayer	47%	14%	33%
Doan's & Motrin	39%	35%	4%
Doan's & Tylenol	42%	17%	25%

***646** (CX 424-Z-16-20; CX 422-E-F; Mazis Tr. 1175-76).

265. On average, the proportions of joint aware non-users agreeing that Doan's is more effective for back pain than other OTC analgesics was 20% higher than the proportions agreeing that the other brands were more effective (Mazis Tr. 1176).

266. Dr. Mazis conducted a statistical analysis to determine whether the differences in beliefs about Doan's and other brands could have occurred by chance (Mazis Tr. 1178-81).

267. A statistical significance test determines whether the "null hypothesis" of no real difference is rejected. For example, in this case the null hypothesis might be that the proportion of joint users who believe Doan's is superior for back pain is not different than the proportion believing other brands superior. If the null hypothesis is rejected, one concludes that the observed difference is real and did not occur by chance (Mazis Tr. 1178-81; Jaccard Tr. 1421-22).

268. Usually, statistical analysis accepts a result, *i.e.*, rejects the null hypothesis, when the likelihood of that result occurring by chance is less than five percent (Mazis Tr. 1178-79, 1181; Jaccard Tr. 1489). This is referred to as a "p value" of less than .05 (Mazis Tr. 1178-79). The p value is also known as an "alpha level" (Jaccard Tr. 1488-89). Dr. Mazis used .05 as the p value for his analysis of the NFO belief study data (Mazis Tr. 1182).

269. Dr. Mazis's analysis of the NFO belief study data used a "two-tailed" statistical significance test to measure the p value rather than a "one-tailed" approach (Mazis Tr. 1180; Jaccard Tr. 1487).

***647** 270. A "two-tailed" test is equally concerned about a difference in either direction, *e.g.*, whether the percentage of joint users believing Doan's is superior is statistically significantly higher or lower than the percentage believing that the other product is superior (Mazis Tr. 1182). A "one-tailed" test is only concerned with a difference in one pre-determined direction (Mazis Tr. 1183; Jaccard Tr. 1486).

271. A two-tailed test is more conservative than a one-tailed test because using the former makes it more difficult to achieve a p value of .05 or less and, therefore, more difficult to conclude that there is a real difference (Mazis Tr. 1180-81; Jaccard Tr. 1488).

272. Because the issue in this proceeding is only whether there is a disproportionate belief that Doan's is more effective, a one-tailed test would have been appropriate (Mazis Tr. 1183). Dr. Jaccard agreed that the hypothesis at issue is concerned only with a result in that one direction and testified that it might be appropriate to use a one-tailed test to analyze the NFO data (Jaccard Tr. 1485-88).

273. Dr. Mazis calculated that all of the observed differences in the user-to-user comparison for the attribute "more effective for back pain" were statistically significant at the .05 level, as were the p values for four of the five aware non-user to aware non-user comparisons for the attribute "more effective for back pain" (CX 424-Z-16-20; CX 422-E-F; Mazis Tr. 1187-89; Jaccard Tr. 1496-98).

274. Dr. Mazis also analyzed the NFO data by applying the so-called Bonferroni adjustment to correct for experiment-wise error which may occur when statistical analyses involve hypotheses based on multiple statistical tests (Mazis Tr. 1190-94). Even after making these adjustments, the results were not that much different than in his other analysis (Mazis Tr. 1195-96).

275. There is often more than one acceptable statistical model for analyzing a data set (Mazis Tr. 1163; Jaccard Tr. 1484). Dr. Mazis used a repeated measures loglinear statistical analysis to analyze the NFO belief study data (Mazis Tr. 1157). Dr. Jaccard, who has used the loglinear approach to analyze data in his research, reanalyzed the NFO belief study data using a statistical analysis based on the general linear model which makes the assumption that the distribution of the difference scores has "normal" bell-shaped distribution (Mazis Tr. 1166-67; Jaccard Tr. 1484). If the data are not normally ***648** distributed, the results of an analysis based on the general linear model may be unreliable (Jaccard Tr. 1532-33).

276. The results of Dr. Jaccard's re-analysis of the NFO belief study data using the general linear model and mean ratings are consistent with the loglinear model analyses conducted by Dr. Mazis (Mazis Tr. 1839, 1845-46). The loglinear and general linear analyses are also consistent after applying a Bonferroni adjustment for experiment-wise error (Jaccard Tr. 1510; Mazis Tr. 1845-46).

277. Dr. Jaccard also criticized Dr. Mazis' loglinear analysis for collapsing his scale into "agreers v. non-agreers" (Jaccard Tr. 1423-25) rather than using mean scales but other researchers have used this procedure (Peabody Tr. 142-43; Jaccard Tr. 1520-21; Whitcup Tr. 2846-48).

c. Respondents' Belief Studies

(1) The Jacoby Study

278. Dr. Jacoby designed a survey for this litigation to determine whether consumers believe that Doan's is superior in efficacy for back pain relief and, if so, whether the belief arose from Doan's advertising (RX 5).

279. Dr. Jacoby's study included some respondents who were not back pain sufferers and who were unaware of Doan's (Jacoby Tr. 2959, 3138-39, 3140; Mazis Tr. 1120; Lavidge Tr. 770; Whitcup Tr. 2109).

280. Although those who were unaware of Doan's could not express an opinion about its efficacy, Dr. Jacoby included them because they were potential purchasers (Jacoby Tr. 3139, 3377-78).

281. Dr. Jacoby also excluded Doan's non-users (79% of the respondents) because they would have no basis for forming efficacy beliefs except from personal use (Jacoby Tr. 3151).

282. Other exclusions of some respondents for questions about efficacy probably resulted in understatement of those who would have expressed efficacy opinions (RX 5-Z-56-57; Jacoby Tr. 2963, 2965, 3153-54, 2989; Mazis Tr. 1297, 1274-75).

283. Despite these flaws, complaint counsel rely on results of the Jacoby study which indicates that 38% of the Doan's users in the sample believed that Doan's is more effective for the relief of back pain, whereas 23% of Advil users and 17% of Tylenol users believed their brand is superior. Dr. Mazis testified that the results of user-to-***649** user comparisons are consistent with the results of the 1993 Brand Equity study and the NFO belief study, which demonstrated that there is a clear, long-term, disproportionately strong belief that Doan's is more effective for back pain than other pain relievers (Mazis Tr. 1155-57).

284. The survey's questionnaire also presents some problems. Question 1f was an open-ended question directed to respondents who stated that a particular brand was more effective than others for back pain in response to questions 1d-e. It asked those respondents to tell the interviewer what made them say that brand was more effective (RX 5-Z-57). The interviewer was permitted to follow-up only once with the probe, "Anything else" (Jacoby Tr. 3158-59). Dr. Jacoby acknowledged that limiting

the interviewer to one follow-up probe would not fully capture all of the reasons some respondents had for believing one brand was more effective than another. He also agreed that for open-ended questions in this study that he believed to be important, he permitted unlimited probing by the interviewer (Jacoby Tr. 3158-60, 2974-75).

285. In response to question 1f, 8% of the respondents who had previously identified Doan's as more effective for the treatment of back pain gave advertising as a reason they held that belief (RX 5-Z-107), but Dr . Mazis testified that this was not an insignificant amount (Mazis Tr. 1299-1300) given the fact that some consumers are reluctant to admit that they are influenced by advertising (Whitcup Tr. 2805-06; Lavidge Tr. 890-91); furthermore, it is a well known marketing principle that consumers are often not aware that their views are shaped by advertising (Mazis Tr. 1300-03; Lavidge Tr. 890-91; Jacoby Tr. 3194).

286. Dr. Jacoby concluded that the superiority beliefs elicited in his survey for Doan's, Advil and Tylenol were caused by past product usage and not the lingering effects of advertising (RX 5-Z-106; Jacoby Tr. 2984-85). He based this conclusion on the fact that 218 of 220 respondents (99%) who said one of those brands was superior in efficacy for back pain in response to question 1e were users of those brands. However, this result occurred in part because of the design of question 1d which excluded non-users (RX 5-Z-56-57).

287. Question 2b asked users of a particular brand why they used that brand. Eleven percent cited advertising as the reason (Jacoby Tr. 3209-11; RX 5-Z-58). Some of this response may be due to the fact ***650** that Doan's users had a stronger recall of Doan's ads than did users of Tylenol or Advil (Jacoby Tr. 3209-11). Also, the 11% of Doan's users who cited advertising was higher than the 1% or less who cited advertising as the reason they used Tylenol or Advil (*see* RX 5-Z-109).

288. Question 3b asked those respondents who recalled advertising for a brand to state what the advertising communicated. Based on the fact that only 3% of the Doan's users gave responses that were coded as a superior efficacy claim, Dr. Jacoby concluded that there were few, if any, lingering effects of advertising related to the challenged claim (RX 5-Z-58), although he agreed at trial that the fact that respondents played back a general recall of Doan's ads, does not establish that they did not form a superiority belief from their exposure to Doan's ads (Jacoby Tr. 3208-09; *see also* Mazis Tr. 2017-19). He also agreed that people who see an ad can have beliefs based on the ad, hold those beliefs and yet not recall the ad (Jacoby Tr. 3201).

(2) The Whitcup Study

289. Dr. Whitcup designed a survey for this litigation to determine whether consumers believe that Doan's is superior in efficacy for back pain relief and whether any such belief arose from Doan's advertising (RX 2).

290. The universe for Dr. Whitcup's survey consisted of men and women aged 18 and older who were back pain sufferers/treaters within the past year (Whitcup Tr. 2109-10; RX 2-Z-8-10). He did not exclude back pain sufferers/treaters who were unaware of Doan's for the treatment of back pain (Whitcup Tr. 2111). According to Dr. Mazis, this made the universe over inclusive (Mazis Tr. 1273).

291. Dr. Whitcup did not supplement his sample, with the result that only 35 Doan's users were in it, compared with 190 Tylenol users and 121 Advil users (RX 2-Z-49).

292. As a result of the small number of Doan's users in his study, Dr. Whitcup added the letter “c” (“caution small base”) whenever he presented data based on their responses (RX 2-Z-49; RX 2-Q-S, V-W, Z-1).

293. In contrast, Mr. Peabody testified that when Doan's marketing research department wanted to analyze the responses of Doan's users in a consumer research study, it sought a large enough ***651** sample to perform a proper analysis (preferably at least 100 Doan's users per cell) (Peabody Tr. 297).

294. Dr. Mazis testified that because of the small number of Doan's users in this study, the usage effect resulted in understatement of the superiority beliefs for Doan's (Mazis Tr. 1290-91), making the data unreliable. Questions 1a-b and 1c-d, did not

mention back pain, with the result that respondents were primed to think of all-purpose rather than back pain drugs, thus causing an understatement of Doan's awareness caused by advertising (Mazis Tr. 1280-81).

295. The main reason given -- that Dr. Whitcup did not want to poison respondents' minds (Whitcup Tr. 2148-49) -- did not dissuade other experts from referring to "back pain" in their screening questionnaires (CX 420-Z-34; RX 23-Z-398; RX 5-Z-6), although Dr. Jacoby stated that asking respondents first about awareness or use of OTC analgesics for back pain would not poison their minds (Jacoby Tr. 3146).

296. Based upon unaided questions 1c-d of his questionnaire, Dr. Whitcup concluded that awareness of Doan's ads is virtually nil and that they are unmemorable (RX 2-Z-3; *see* Whitcup Tr. 2160) but Dr. Mazis concluded that, because of priming, they understate respondents' recollection of Doan's advertising (Mazis Tr. 1647). Furthermore, Dr. Whitcup acknowledged that a respondent's failure to mention Doan's ads on an unaided basis does not mean that they were unaware of Doan's ads (Whitcup Tr . 1280-81).

297. Question 1f asked respondents who had indicated that they used multiple brands to treat back pain which brand they used most often (RX 2-Z-11). Question 2 asked respondents, if they used only one brand of pain reliever to treat back pain, why they used that brand (*id.* at Z-12). If respondents used more than one brand, they were only asked question 2 with regard to the brand they used most often (*id.% i). Thus, if a Doan's user used another brand more often, he or she was not asked why they used Doan's. This design resulted in question 2 not fully eliciting the magnitude of the belief among the few Doan's users surveyed that Doan's is more effective for back pain relief (Mazis Tr. 1283; Whitcup Tr. 2789). Dr. Whitcup agreed that the underlying questionnaires contain examples of Doan's users who were not asked question 2 but who responded to later questions that Doan's was more effective than other pain relievers for back pain* ****652*** *relief but he argued that most respondents did not mention superiority (Whitcup Tr. 2790-95).*

298. Dr. Mazis concluded, after analyzing the questionnaire, that it biased the outcome toward understating the playback of Doan's related information (Mazis Tr. 1289).

(3) The Lavidge Study

299. Mr. Lavidge designed a survey for this litigation to determine what claims the "Muscles" ad conveyed and whether consumers held a belief that Doan's was superior in efficacy for back pain relief (RX 23).

300. Mr. Lavidge did not limit the universe in this study to Doan's users and aware non-users (Lavidge Tr. 755-56; *see* RX 23-Z-395-98); he included respondents who were not aware of Doan's because they were potential purchasers (Lavidge Tr. 755-56), but Dr. Mazis testified that a belief study for a niche brand like Doan's should not include respondents who are un-aware of the product, and thus could have no beliefs about it (Mazis Tr. 1273). The data collected in this survey shows that 71% of the sample were unaware of Doan's for the treatment of back pain (RX 182) . In contrast, 79% of the sample were aware of (and 70% used) Tylenol; and 68% were aware of (and 59% used) Advil (RX 182). The inclusion of respondents who were unaware of Doan's caused different awareness rates and made it impossible to determine if there is a disproportionate belief regarding Doan's (Mazis Tr. 1273, 1279).

301. Mr. Lavidge's copy test asked belief questions subsequent to the viewing of a clutter tape which included the challenged "Muscles" ad (CX 23) (Tests 1 and 3) or the "New Muscles - Male" ad (RX 24-A) (Test 2) and three other 15-second ads for analgesic products being promoted for back pain relief. Question 13, which was asked after two exposures to the clutter reel, purports to measure beliefs about product efficacy.

302. Exposure to the Doan's ad in the midst of a clutter tape containing three similar back pain-oriented ads for other analgesics does not reflect how consumers are exposed to Doan's ads in natural surroundings (Peabody Tr. 156; Lavidge Tr. 849).

303. The appropriate way to measure whether lingering beliefs exist is to measure them without exposure to an ad (Mazis Tr.

1276). Dr. Jacoby repeatedly testified with regard to the belief study portion ***653** of his methodology that lingering beliefs cannot properly be measured after exposure to an ad (Jacoby Tr. 2962, 2968, 3155).

304. The belief question (13a) began by asking respondents "Do you think any non-prescription pain killer product is more effective in relieving back pain than the other non-prescription products which are sold for that purpose, or don't you have an opinion about that?" For respondents who answered affirmatively, question 13b was asked: "Which non-prescription product do you think is more effective than others in relieving back pain?" This was followed by a question asking what respondents thought made that product more effective (RX 23-Z-401).

305. Question 13a does not provide respondents with a list of brands to be rated on the more effective for back pain attribute, or any other attributes (*id.; see* RX 23-Z-401). This requires respondents to sort through a mental list, a processing requirement that is difficult for many consumers to perform. This form of questioning can result in an understatement of consumer beliefs (Mazis Tr. 1274-76).

306. A better way of asking such a question is to ask respondents what their beliefs are for a list of brands with regard to certain attributes, as was done in the A&U study, the Brand Equity study, and the NFO belief study (Mazis Tr. 1274-75). This procedure is the one most commonly used in the consumer research industry (Mazis Tr. 1274; Peabody Tr. 412).

307. Question 13a uses the term "any non-prescription pain killer product" and 13b uses the term "which non-prescription product" (RX 23-Z-401; Lavidge Tr. 889). Mr. Lavidge acknowledged that the term "product" in both questions was singular and that he was asking respondents to identify only one product they believed to be more effective (Lavidge Tr. 889-90). This question is flawed because it limits respondents to giving only one product when they may believe that more than one are more effective. This is particularly limiting for a niche product such as Doan's, which could be one of multiple products a respondent believes to be more effective, but does not come immediately to mind (Mazis Tr. 1275-76).

308. Novartis' other consumer research experts recognized the problem inherent in such a limitation and permitted respondents to provide multiple products in response to their belief question (RX 2-Z-13; Whitcup Tr. 2811; RX 5-Z-57; Jacoby Tr. 3158). Dr. Whitcup testified that 15% of the respondents answering his belief question ***654** identified multiple brands (Whitcup Tr. 2811). The singular wording of the term "product" in questions 13a-b of the Lavidge study may have resulted in those questions understating the number of products that respondents believed to be more effective for the treatment of back pain.

309. Because there were only a small number of Doan's users in Mr. Lavidge's study, the usage effect probably resulted in the superiority beliefs for Doan's being understated according to Dr. Mazis (Mazis Tr. 1271, 1291).

310. The presentation of the data in the Lavidge study does not break down the superiority belief into those held by users of each product or aware non-users of each product (Mazis Tr. 1271; *see id.* at 1291). Such comparisons are the only reliable way to equalize any usage effects (Mazis Tr. 1158-59, 1199-1200; Jaccard Tr. 1528-29). There is no reliable data or data analysis in RX 23 that permits one to draw any conclusions regarding the existence of a superior efficacy belief with regard to the Doan's product (Mazis Tr. 1272-73; *see id.* at 1295-96). Mr. Lavidge acknowledged this at the hearing (Lavidge Tr. 879).

d. The Creation Of Consumer Misbelief By The Challenged Ads

311. The NFO Belief study shows that Doan's ad campaign created a consumer misbelief about the efficacy of Doan's -- *i.e.*, that Doan's is more effective than other OTC analgesics for the relief of back pain.

312. That belief, however, has no significance unless complaint counsel establish that it has been substantially created or reinforced by the challenged ads (CPF 314).

313. Factors other than advertising, such as experience, word-of-mouth, doctor recommendations and packaging may have played some role in consumer belief about the efficacy of Doan's (Mazis Tr. 1606-09; CX 502 at 123-24 [Wright Dep.]; La-

vidge Tr. 750-52; RX 179), but the evidence leads to the conclusion that advertising was also a factor in the creation of that belief (Mazis Tr. 1201-02, 1609; Stewart Tr. 3468-69).

314. The purpose of Doan's ads was to convince consumers that it was superior to other OTC analgesics for relieving back pain and, to that end, Ciba spent $55 million from 1988 through 1996 for Doan's broadcast ads and $10 million for consumer promotions (JX 2 ¶ 21).

***655** 315. Doan's is a "niche" product which competes in the back pain segment of the OTC analgesics market and its ads target that audience (Stewart Tr. 3478; CX 501 at 68 [Sloan Dep.]). Marketers using niche ads can reach their intended audience with less ad dollars than marketers who target a broader audience (Stewart Tr. 3476, 3478).

316. Doan's ad agencies estimated that it reached between 80 and 90% of its target audience 20 to 27 times per year between 1988 and 1996 (JX 2 ¶ 25; Stewart Tr. 3413-14).

317. For most of the period in which the challenged Doan's ads were aired, Ciba used a "flighting" strategy. Flighting is a common method of scheduling in which the advertiser is on the air for a period of time, and off the air for other periods (Stewart Tr. 3421). Ciba started flighting in 1991 "to increase visibility and reach in order to attract additional users to the brand" (CX 514-C; Stewart Tr. 3420). Flighting works especially well for niche brands if the advertiser's objective is both to persuade new users to try the brand and to reinforce the preferences of current users (Stewart Tr. 3422).

318. Ciba produced 15-second rather than 30-second ads for Doan's after it acquired the brand (JX 2 ¶ 25; CX 508-Z-13). Ingrid Nagy, who was Doan's Business Unit Manager from 1988-1991 and its Marketing Director from 1994-1995, believed that the 15-second format was an effective strategy for Doan's ad campaign (CX 499 at 135 [Nagy Dep.]).

319. One means of determining whether a 15-second ad is as effective as a 30-second ad is to test it in a copy test (Stewart Tr. 3446-47, 3461-62; CX 506 at 87-88 [M. Seiden Dep.]). If a 15-second ad performs as well as a 30-second ad, it makes sense to use it because it costs half as much (Stewart Tr. 3449; CX 506 at 87-88 [M. Seiden Dep.]).

320. Ciba tested the first ad it created for Doan's, "Graph," through an ASI test. It achieved a 19% recall score (Stewart Tr. 3448; CX 335-Z-7). This exceeded the average (or "norm") for 15-second ads for drug and health products by 5% (CX 335-Z-7; CX 120-C). The score equaled the norm for the average 30-second ad in the drug and health products category (Stewart Tr. 3448-49; Peabody Tr. 258; CX 335-Z-7; Mazis Tr. 2010), indicating that "Graph" was as memorable as the typical 30-second ad in the category (Stewart Tr. 3448-49; Mazis Tr. 2010-11).

***656** 321. Ciba tested the second ad it created for Doan's, "Black & White Back," through ASI. This ad also achieved a related recall score of 19% (RX 98-F).

322. Another Doan's ad, "Ruin A Night's Sleep," was tested by ARS in 1991 and achieved a recall score of 42%, 19% above the category average (RX 89-L; Mazis Tr. 2008-09). "Black & White Back Pan" was tested by ARS in 1993 and achieved a recall score of 38%, 15% above the average of the OTC analgesics category. "Activity-Playtime" was tested by ARS in 1994 and achieved a recall score of 34%, 11% above the average (Stewart Tr. 3452-53; CX 393-Z-30). "Muscles" was tested by ARS in 1995 and achieved a recall score of 45%, 22% above the average (*id.*; Peabody Tr. 196).

323. Dr. Stewart testified that these ARS recall scores indicate that the tested 15-second Doan's ads were more memorable than the average for the category, which is calculated mostly from 30-second ads (Stewart Tr. 3449, 3452-53), and he concluded that Ciba's use of 15-second ads for Doan's was a very effective strategy (Stewart Tr. 3462).

324. Dr. Jacoby's study (RX 5) shows that the Doan's advertising campaign was memorable among back pain sufferers/treaters when compared to the more extensive advertising campaigns for Advil and Tylenol during the same period. In the Jacoby study, before exposure to any test ad, respondents were asked about their recall of ads for the brands they used (RX 5-Z-58).

Fifty-two percent of Doan's users said they recalled Doan's advertising (RX 5-Z-111) but only 3% of them recalled any superiority claim in Doan's ads (Jacoby Tr. 2996).

325. Dr. Stewart testified that the only way to differentiate Doan's and affect its market performance is through advertising; and, in fact, the Doan's brand group and its ad agency frequently referred to Doan's as an ad-driven brand (Stewart Tr. 3468). Other statements by Doan's employees and its ad agency confirm that the brand is advertising sensitive (CX 335-D; Peabody Tr. 257; CX 514-C; CX 499 at 82 [Nagy Dep.]; CX 120-A; CX 497 at 38 [Esayian Dep.]; CX 407-A; CX 496 at 104-05 [Caputo Dep.]).

326. Other Ciba documents refer to the crucial role advertising played in the marketing of Doan's and in driving Doan's sales (CX 404-A-B; CX 499-A). The "Doan's 1996 1st Half Brand Update" states: "Dean's support continues to drive strong volume and share performance despite competitive activity." This document also states ***657** that "Doan's advertising has historically improved category performance, as well as Doan's share/volume."

327. Mr. Peabody testified that Doan's P.M. sales were "very sensitive to advertising" (Peabody Tr. 566; *see also* CX 157-B; Peabody Tr. 567; CX 185-E; CX 504 at 138 [Schaler Dep.]; Peabody Tr. 626-27; CX 144-B).

328. ARS also tested "Ruin A Night's Sleep," "Black & White Back," "Activity Playtime," and "Muscles" for persuasion (CX 393-Z-30; RX 98; RX 32; RX 33; CX 265). The persuasion measure is calculated based on the test respondents' choice of a "prize" grocery basket of products the respondents select prior to and after the one hour of "pilot" television shows they view. In calculating the persuasion score, ARS takes additional factors into account, such as the number of competitors in the product category and the degree of switching in the category. Persuasion scores can be negative or positive; a positive score reflects the fact that the ad is having a net persuasive effect on the market, over and beyond what one might expect given various marketplace conditions (Peabody Tr. 191-93; Stewart Tr. 345-52).

329. All of the Doan's ads tested by ARS received positive scores, ranging from 1.5 for "Activity-Playtime" to 6.8 for "Ruin A Night's Sleep" (CX 393-Z-30; RX 89-K). All of the tested ads would be expected to have a net persuasive effect on the market (Stewart Tr. 3452).

330. Dr. Stewart testified that Doan's competes in the analgesics market, which is a "mature market." In such markets, it is difficult to persuade long-time customers to switch brands on the basis of one exposure to a competing ad. For a niche brand in the category, the persuasion scores achieved by the Doan's ads were quite good (Stewart Tr. 3452).

331. The ad which achieved the lowest, but still net positive persuasion score, "Activity Playtime," was very successful in generating sales for Doan's. In this instance the persuasion score was not a good predictor of what occurred in the real world (CX 504 at 55-57, 138 [Schaler Dep.]; Stewart Tr. 3472).

332. Between 1987, when Ciba bought the brand, and 1996, Doan's factory sales have increased by approximately 80%, from $10.2 million to a high of $18.9 million in 1994 (with a small drop from 1994 to 1995) (JX 2 ¶ 17; Mazis Tr. 2026; Stewart Tr. 3469; ***658** Peabody Tr. 141-42). Consumer sales, which were first tracked in 1992, rose from $21.5 million in 1992 to $23.3 million in 1995.

333. Consumer sales of Doan's products increased at approximately the same rate as consumer sales of all analgesic products between 1992 and 1995 (JX 2 ¶¶ 16, 19; Stewart Tr. 3481). This parallel growth occurred even though advertising spending for all analgesic products increased by almost one third during this period, while advertising expenditures for Doan's remained relatively constant (JX 2 ¶¶ 21, 23). Doan's successfully maintained its sales without increasing advertising expenditures by focusing effectively on its niche of back pain sufferers (Stewart Tr. 3481-82).

334. The "contribution" for a brand refers to the amount it contributes to Ciba's profits. "Contribution" is calculated by subtracting the brand's expenses from its sales (CX 496 at 93 [Caputo Dep.]). Doan's contribution to Ciba's profits remained relatively constant between 1990 and 1997, delivering approximately 22 to 25% of sales as contribution (Peabody Tr. 549-50).

This percentage equaled or exceeded the contribution from Ciba's other OTC pharmaceutical brands (CX 496 at 93 [Caputo Dep.]; CX 401-A-B).

335. In "mature" product categories such as analgesics, a central purpose of advertising is to retain current users. This is because the overall market for the products in the category may not be growing appreciably. In these categories, sales increases are not the only measure of the success of an advertising campaign. A key criterion for success of the advertising is whether it is succeeding in maintaining share, particularly in the case of a competitive onslaught (Stewart Tr. 3467; Mazis Tr. 1202; CX 597).

336. Since Ciba acquired Doan's, several new entrants have entered the back pain specific category (which consists of analgesics that are marketed only for back pain) and the general analgesics category (CX 393-R; CX 97-B). Despite these competitive pressures, Doan's was able to maintain and even increase its sales (Stewart Tr. 3468).

337. Doan's responded to these competitive entries partially through the use of advertising (Stewart Tr. 3434-37; Mazis Tr. 2028-32). When Nuprin Backache was introduced in the first half of 1993, Ciba's media planners increased Doan's television advertising budget by approximately $500,000 to respond to this competitive threat (CX 357-B; Mazis Tr. 2033-34; Stewart Tr. 3434). Similarly, when Bayer Select Backache was introduced, Ciba increased spending to ***659** run more advertising during the introductory period for Bayer Select (CX 378-K; Stewart Tr. 3434-35). Doan's Marketing Director wrote that both the Nuprin Backache and Bayer Select Backache products were unsuccessful because Doan's used a "consistent, strong advertising campaign to defend and even build share in the face of these competitors" (CX 399-B). Both products had been withdrawn from the market by 1996 (CX 496 at 24 [Caputo Dep.]).

338. At the time that Aleve was being introduced in mid-1994, Ciba directed its advertising agency to include the Aleve package in the competitive "set" in the "Activity" commercials that were then being produced. Ciba carefully tracked the entry of Aleve and consulted with its advertising agency regarding the most appropriate ways to defend Doan's during Aleve's introduction (CX 168-A-M).

339. Drs. Mazis and Stewart testified that the numerous references in the Doan's marketing and strategy documents to the fact that the brand is advertising driven, indicates that the challenged ads must have played an important role in sustaining and growing the Doan's brand (Mazis Tr. 2026; Stewart Tr. 3408-09).

340. It is not surprising that the challenged ads were successful, because academic research has shown that ads for low share brands which include explicit comparative references to high share brands in the same category are very effective. Such ads succeed in attracting more attention to the low share brand and increase purchase intention for the low share brand relative to the high share brand. This comparative reference strategy was employed in all of the challenged Doan's ads (Stewart Tr. 3458-61; CX 595-A-L; CX 596-A-I).

341. The advertising campaign for Doan's was a highly successful one for a niche brand (Stewart Tr. 3485).

342. Dr. Stewart testified that the ad expenditures for Doan's, the media strategies employed, and the type of ads that were used, created or reinforced consumers' beliefs that Doan's is more effective than other analgesics for back pain (Stewart Tr. 3485-86).

e. Consumer Research Into The Creation Of The Superiority Belief

343. The NFO study shows that more Doan's users and aware non-users believe that Doan's is superior for back pain than do those users and aware non-users of other brands who believe those brands are superior (CPF 347-52, 395-429). The similarity in the beliefs of ***660** users and aware non-users is evidence that Doan's advertising played a role in creating and reinforcing that superiority belief, since by definition the beliefs of aware non-users about Doan's stem from factors other than their usage experiences with the product (Mazis Tr. 1203-08; CX 502 at 123-25 [Wright Dep.]). And, the superiority beliefs among Doan's users cannot be explained by usage experience because of the inability of consumers to evaluate the comparative efficiency of

analgesics (CPF 546-47).

344. Further evidence that advertising created or reinforced superiority beliefs is that Doan's users and aware non-users have beliefs that track other claims conveyed by Doan's advertising --Doan's "has an ingredient especially for back pain" and "just for back pain" (Mazis Tr. 1210-18).

345. The NFO belief study demonstrates that there is a strong and disproportionate belief among both Doan's users and Doan's aware non-users that Doan's "has an ingredient especially for back pain" and "is just for back pain." In that study, survey respondents rated their levels of agreement or disagreement with these attributes for each of the brands of OTC back pain relievers of which they were aware (CX 422-A-D).

346. Dr. Mazis conducted the same statistical paired comparison analyses regarding these attributes, looking at joint users and joint aware non-users, that he conducted for the attribute "more effective for back pain than other OTC analgesics" (CX 424-G-K, Q-U; CX 422-D; Mazis Tr. 1208). Across the five user-to-user comparisons, the proportions of joint users agreeing that Doan's "has an ingredient especially for back pain" is on average 54% higher than the proportions agreeing that each of the other brands (Advil, Aleve, Bayer, Motrin, or Tylenol) has that attribute (*see* CX 424-A-U; CX 422-C-D). Across the five aware non-user-to-aware non-user comparisons, the proportions agreeing that Doan's "has an ingredient especially for back pain" is on average 46% higher than the proportions agreeing that each of the other brands has that attribute. For the attribute "just for back pain," on average 62% more joint users and 54% more joint aware non-users agreed that Doan's has that attribute (*see* CX 424-G-K; CX 422-A-B). Each of the differences in beliefs among every user-to-user and aware non-user-to-aware non-user comparison is large and highly statistically significant (Mazis Tr. 1209).

***661** 347. The eight year advertising campaign claiming that Doan's "has an ingredient especially for back pain" and that it "is just for back pain" played a substantial role in the creation or reinforcement of beliefs that mirror those claims (Mazis Tr. 1217). Mr. Peabody testified that Doan's advertising is likely one of the sources of the beliefs that Doan's "has an ingredient especially for back pain" and that it "is just for back pain" (Peabody Tr. 226-28) and Dr. Mazis concluded that consumers would not infer that a product had a special ingredient for back pain simply from the fact it is only advertised and marketed for back pain (Mazis Tr. 1621). The fact that the ads created beliefs consistent with these claims further supports the conclusion that they played a role in creating or reinforcing the belief that Doan's is more effective for back pain than other OTC analgesics (Mazis Tr. 1217; *see id.* at 1057-58; *see also* CX 480-A-D; Mazis Tr. 1054-58 (1993 Brand Equity Study)).

348. The 1987 A&U study and the 1996 NFO belief study measured the beliefs of users and aware non-users of Doan's, Extra-Strength Tylenol, Advil, and Bayer regarding the product attribute "most effective" (the A&U study) and "more effective" than other OTC pain relievers for back pain relief (CX 421-Z-12; CPF 383).

349. Since the A&U study was conducted just before the challenged ads were disseminated (CPF 326, 336), Dr. Mazis felt that comparing its results with those of NFO's 1993 belief study, which took place six months after they were abandoned, would permit him to determine if beliefs among users and non-users of these products had changed over the years and to measure the impact of the Doan's ad campaign on consumer beliefs (Mazis Tr. 1219-20).

350. I agree with respondents' experts that Dr. Mazis' comparison of these two studies is unsound since there are a number of differences in the methodologies and questions used in the 1987 A&U study and 1996 NFO study that could be responsible for the change in reported attribute ratings (Jaccard Tr. 1461-73; RX 133-B-E).

351. These include: (1) a difference in the wording of the key attribute in the two studies (CX 221-Z-120; CX 421-Z-12); (2) differences in the structure of the studies' questionnaires (Jaccard Tr. 1462-71); (3) differences in the response dimensions (how much attributes "applied" to a brand v. how much respondents "agreed" that the attributes described the tested brands)(Jaccard Tr. 1465; RX 133-B); and, (4) differences in the studies' response scales (Jaccard Tr. 1465-67; Jacoby Tr. 3021-22; RX 133-C). 662

***662** 352. The methodologies of the studies were also different. The 1987 A&U study was a telephone survey; the NFO

study was a mail survey (Jaccard Tr. 1468-69; RX 133-C).

353. Finally, the samples in the two studies differed in terms of the nature of respondents' back pain (*i.e.*, suffered "in an average six month period" versus "on a regular basis"), the usual type of treatment (*i.e.*, "prescription or non-prescription medication" versus "over-the-counter medication"), and respondents' role in the purchase of the treatment product. Other key demographic variables -- such as age, gender, income, education, occupation, geographic location, and household size -- are not specified in the 1987 A&U study and could have varied from the demographics of the sample surveyed in the 1996 NFO Mail study. These many differences between the samples of respondents surveyed in the two studies could account for the discrepancy in respondents' attribute ratings (Jaccard Tr. 1470-71; RX 133-D, D)

354. Given the many differences in the questions, response dimensions, response scales, methodology, and samples in the 1987 A&U study and the 1996 NFO Mail study, I find that the attempted comparison of the two studies to draw inferences regarding the impact of the challenged advertising on consumer beliefs has no methodological merit (Jaccard Tr. 1577-78; RX 133-A).

f. The Lingering Effect Of The Challenged Ads

355. The challenged ads which were widely disseminated for several years communicated a message which created a disproportionate belief in the target audiences that Doan's is superior to other OTC analgesics for back pain.

356. Dr. Jacoby testified about the lingering effects of advertising in *American Home Prods.*, 98 FTC 283 (Initial Decision). He stated that beliefs concerning attributes that had been stressed in analgesic product ads can endure long after they have ceased (*American Home Prods.*, 98 FTC at 293 (IDF 59 2) (Initial Decision). Dr. Jacoby also testified that among users of an analgesic product that was advertised as superior to its competitors, that superiority belief would linger long after the cessation of the advertising because product usage will continually reinforce that image (*id.* at 284).

357. The NFO belief study was conducted in December 1996, six to seven months after the last challenged ad was disseminated (Mazis Tr. 1254-55; CX 421-H; JX 2 ¶ 25), and it shows, according to ***663** Dr. Mazis, that a strong superior efficacy belief lingered, and is likely to linger (Mazis Tr. 1254-55).

358. Dr. Mazis' conclusion is echoed by three empirical studies of the lingering effect of ads. The first study, authored by Kinnear, Taylor and Gur-Arie, was a follow-up study of the effect of a Commission corrective advertising order in *RJR Foods, Inc.*, 83 FTC 7 (1973). The purpose of the study was to measure the change in consumers' beliefs regarding the fruit juice content of Hawaiian Punch (Mazis Tr. 1257-59; CX 536-N-O).

359. This research continued for eight and one-half years (Mazis Tr. 1259; CX 536-N) and found that the percentage of the tested population that held the factually correct belief, the result the corrective advertising was intended to achieve, increased from 20% to 40% in a year's time, improved to 50% by the fifth year, and increased to 70% after eight years. This data shows that advertising based beliefs that are imbedded in consumers' minds can last a very long time, even in the face of corrective advertising. Such ad-created beliefs would have remained at even higher levels for a longer period of time, if the challenged advertising had ceased and no corrective advertising was required (Mazis Tr. 1259-61).

360. Two studies of the corrective advertising order in Listerine --one conducted by Armstrong, Russ, and Gurol and the other by Dr. Mazis, -- tracked the effect of the corrective advertising requirement over time. These studies showed a reduction of between 11% and 20% in the false beliefs over the course of the approximately one and one-half year corrective advertising effort, according to Dr. Mazis, and support the conclusion that embedded advertising-based beliefs do not change quickly, even in the face of corrective advertising (Mazis Tr. 1261-63).

III. CONCLUSIONS OF LAW

A. Introduction

Doan's has been marketed for over 90 years. Ciba purchased the Doan's brand in early 1987 for approximately $35 million because it believed that Doan's could be successfully marketed if its old fashioned image could be changed (F 8-10).

The so-called Attitude & Usage study ("A&U") which was conducted for Ciba shortly after its purchase of Doan's tested consumer awareness of Doan's and its competitors (F 233). Among ***664** other things, the study concluded that Doan's should position itself "as a more effective product." The results of this study convinced Ciba to embark on the eight year comparative ad campaign which featured the challenged ads (F 236-37).

B. The Challenged Ads Conveyed The Superiority Claims

1. Legal Standard

Section 5 of the FTC Act prohibits material and deceptive representations or omissions which are likely to mislead reasonable consumers into unwarranted beliefs about the advertised product. *Cliffdale Associates, Inc.*, 103 FTC 110, 164-65 (1984). *Appeal dismissed sub nom. Koven v. FTC* No. 84-5337 (11th Cir. Oct. 10, 1984) ("Deception Statement").

The Commission deems an ad to convey a claim if consumers, acting reasonably under the circumstances, would interpret it to convey that claim, even if a challenged, misleading claim is accompanied in the same ad by non-misleading claims. *Kraft, Inc.*, 114 FTC 40, 120 n.9 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (199 3); *Thompson Medical*, 104 FTC at 789 n.7, 818 (1984).

Both express and implied ads may be deceptive, *Fedders Corp. v. FTC*, 529 F. 2d 1398, 1402-03 (2nd Cir.), *cert. denied*, 429 U.S. 818 (197 7), and intent to convey a claim need not be established, *Kraft, Inc.*, 114 FTC at 121; however, if an advertiser intends to make a claim, it is reasonable to conclude that the ads make that claim. *Thompson Medical*, 104 FTC at 791.

2. Facial Analysis

Despite Dr. Jacoby's and respondents' argument to the contrary (F 97), the Commission has often held that facial analysis of a challenged ad may be the basis for concluding that it conveys a challenged claim to consumers, and that extrinsic evidence of its meaning is not necessary. *Kraft, Inc.*, 114 FTC at 121; *Thompson Medical*, 104 FTC at 789.

Facial analysis of the challenged ads supports the conclusion that they make a claim of superior efficacy by referring to Doan's as the "back specialist" which has an ingredient not found in competing analgesics (F 88-89, 91, 93). *See American Home Products Corp. v. Johnson & Johnson*, 654 F. Supp. 568 (S.D.N.Y. 1987).

***665** Dr. Mazis also concluded that several of the challenged ads made the superiority claim. For example, he testified that the "Graph" ad, which refers to an "ingredient that [other] pain relievers don't have" conveys the message that Doan's is unique and different, and coupling the claim with references to back pain, conveys the net impression that Doan's is more effective for back pain relief than other pain relievers mentioned in the ad (F 98).

3. Copy Test Evidence

Methodologically sound copy tests of challenged ads are often resorted to as evidence of the messages which they convey. *Thompson Medical*, 104 FTC at 790.

The parties rely on two kinds of copy tests: Those which were conducted in the ordinary course of business by or for Ciba, and those which were designed and administered for purposes of this proceeding.

Prior to their dissemination, the "Graph," "Black & White Back" and "Ruin A Night's Sleep" ads were copy tested by Bruno & Ridgeway, a consumer research company.

If its "main idea" and "other idea" questions are netted, the copy test of the "Graph" ad indicates that 38% of respondents exposed to it were coded as answering that it communicates the claim that Doan's was "Superior to other products" (F 122), a quite high response to open-ended questions (F 124). *Stouffer Food Corp.*, Dkt 9250 (Sept. 26, 1994).

The "Black & White Back" copy test found that 46% of the respondents who saw this ad gave answers that were coded as "superiority over other products." If responses to all of the open-ended questions are netted, 62% of the respondents took away a superior efficacy claim (F 137-38).

The copy test for the "Ruin A Night's Sleep" ad produced similar results: 25% of respondents gave answers that were coded "superiority over other products" (F 146).

The 1991 copy test of the challenged FSI's revealed that between 47% and 59% of respondents strongly or somewhat agreed that Doan's is better for back pain than other pain relievers, a response whose magnitude confirms that the claim was conveyed (F 168-69). *See Thompson Medical*, 104 FTC at 797, 805-06 (22% of those ***666** viewing the ad believed Aspercreme contained aspirin). *See also Warner-Lambert*, 86 FTC 1398, 1504 (1975).

U.S. Research conducted a mall test of a Doan's ad, "Activity-Playtime" and an FSI. Fifty-seven percent of the "Activity-Playtime" and 40% of the FSI respondents took the superior efficacy claim from these ads (F 180). *See also* F 181, 183, 185.

The part of Dr. Jacoby's copy test for respondents which measured the communication of the challenged ads "Activity-Playtime" and "Muscles" showed that 35% of the respondents viewing "Activity-Playtime" and 19% of those viewing "Muscles" took away the superiority claim from open-ended questions (F 191-92).

The results of the copy tests relied on by complaint counsel provide solid evidence that the challenged ads conveyed the superiority message, as did Ciba's dissemination of ads which it knew conveyed a false superior efficacy claim. *ABSI*, Dkt 9275, slip op. at 40 (March 3, 1997); *Thompson Medical*, 104 FTC at 7 91. (If an advertiser intends to make a particular claim, it is reasonable to interpret the ads as making that claim.) Furthermore, the ads were a significant factor in creating the superiority belief (F 342). *Warner-Lambert*, 86 FTC at 1503.

C. The Superior Efficacy Claim Is Unsubstantiated

The parties have stipulated that two well controlled clinical studies are required to substantiate a superiority claim for an analgesic like Doan's. JX 1 ¶¶ 6, 9; *see Thompson Medical*, 104 FTC at 822-825. The parties also stipulated that there are no scientific studies demonstrating the therapeutic superiority of magnesium salicylate (Doan's active ingredient) over aspirin, acetaminophen (the active ingredient in Tylenol), ibuprofen (the active ingredient in Advil and Motrin) or naproxen sodium (the active ingredient in Aleve) for the relief of back pain. JX 1 ¶ 9. Nothing in the FDA analgesics monograph supports the superior efficacy of magnesium salicylate. Respondents knew that they possessed no substantiation for the superior efficacy claim (F 101, 102, 103).

***667** *D. The Superior Efficacy Claim Is Material*

For deception to occur the challenged representation or omission must be material, *i.e.*, likely to affect consumer choice or conduct with respect to a product.

Respondents' ads make claims regarding the efficacy or comparative efficacy of Doan's. They may be considered presumptively material because they relate to the central characteristics of that product, Deception Statement, 103 FTC at 18 2, because

they involve an important health claim, *Kraft, Inc.*, 114 FTC at 135-36, and because respondents intended to make a superior efficacy claim (F 104).

E. Corrective Advertising Is Not Warranted

In *Warner-Lambert*, 86 FTC at 1499-1500, the only litigated case in which corrective advertising was ordered, the Commission stated with respect to Listerine's forty-year deceptive ad campaign:

> [I]f a deceptive advertisement has played a substantial role in creating or reinforcing in the public's mind a false and material belief which lives on after the false advertising ceases, there is clear and continuing injury to competition and to the consuming public as consumers continue to make purchasing decisions based on the false belief. Since the injury cannot be averted by merely requiring respondent to cease disseminating the advertisement, we may appropriately order respondent to take affirmative action designed to terminate the otherwise continuing ill effects of the advertisement. 86 FTC at 1499-1500.

There is strong academic support for the imposition of corrective ads in the appropriate circumstances (F 356, 358-60), and the NFO belief study shows that a superior efficacy belief lingered for six months after the last challenged ad was disseminated (F 357).

However, given the difference between the length of time that the false Doan's and Listerine ads ran, there is no certainty that the belief at issue requires corrective advertising and I reject Dr. Mazis' contrary conclusion (F 357) as well as complaint counsel's claim that the need for a corrective advertising order can be inferred.

In fact, there are indications in the record that the belief in Doan's superiority may be transitory.

The ASI and ARS copy tests reveal low 24 and 72 hour recall (2% to 8%) by respondents of a "more effective" or a "good product/better/best" message (F 231-32) and Dr. Jacoby testified that this shows that the ads did not create any widespread, lingering ***668** misimpression by consumers. Dr. Whitcup and Dr. Stewart testified that Doan's ads were not memorable, a further indication that the effect of the ads which they analyzed will not linger for a substantial period of time (F 162, 296)

That the remedy sought by complaint counsel is drastic [FN2] is shown by the Commission's failure to enter a corrective advertising order in cases where some or all of the conditions for doing so existed. *See e.g .*, *Bristol Myers Co.*, 102 FTC at 21 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984), *cert. denied*, 469 U.S. 1189 (19 85); *Sterling Drug, Inc.*, 102 FTC 395 (1983), *aff'd*, 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 470 U.S. 1084 (19 85); *American Home Prods. Corp.*, 98 FTC 136 (1981), *aff'd as modified*, 695 F.2d 681 (3d Cir. 1982).

The parties agree that not every case of deception warrants corrective advertising: some unique circumstances must exist before that remedy is adopted. Complaint counsel have not shown what is memorable about an ad campaign, which, while successful in retaining market share (F 333), created no significant increase in sales (JX 2-B, ¶¶ 16, 19; Scheffman Tr. 2543-46).

I therefore reject corrective advertising as an appropriate remedy in this case.

F. The Appropriate Order

1. Introduction

Because respondents' violations were serious, deliberate, and transferable, a comprehensive "fencing-in" order is appropriate. *See* *Thompson Medical*, 104 FTC at 843 -44.

2. The Violations Were Serious And Deliberate

The challenged ads ran for eight years and were extensively disseminated (F 23). Total expenditures of the campaign were sizeable -- $55 million for broadcast advertising and $10 million for consumer promotions (JX 2 ¶ 21).

***669** The challenged claims were health related and consumers suffered economic injury because Dean's products are significantly more expensive than other OTC analgesics (F 15).

Consumers could not evaluate the efficacy of Doan's and could not make informed decisions about purchasing the product. *Thompson Medical*, 104 FTC at 834; *American Home Prods v. FTC*, 695 F.2d at 707.

Ciba's violations were serious and deliberate, for it designed ads which it knew would convey a superiority message which was unsubstantiated (F 100-113).

3. The Violations Are Transferable

Ciba's violations -- false and unsubstantiated superiority claims--are transferable to other OTC analgesics and an order prohibiting transference is appropriate. *Sears & Roebuck*, 676 F.2d at 394-95.

4. The Injunctive Provisions Of The Notice Order

The injunctive provisions of the proposed order are necessary and appropriate to address respondents' violations.

Part I of the proposed order addresses the specific violation in this case, requiring competent and reliable scientific substantiation for any claim that any OTC analgesic is more effective than any other OTC analgesic for pain relief. It specifies that the substantiation required for these claims must include at least two well-controlled clinical studies. This is the appropriate standard for comparative efficacy claims for OTC analgesics. *Thompson Medical*, 104 FTC at 821-26, 832.

Part II of the proposed order contains the fencing-in relief, prohibiting unsubstantiated efficacy, safety, benefits, or performance claims for any OTC analgesic drug.

Part III of the proposed order contains a "safe harbor" provision for claims approved by FDA under a tentative or final monograph, or pursuant to an approved new drug application.

Parts IV-VIII consist of standard compliance, record keeping and sunsetting provisions.

***670** IV. SUMMARY

A. The Federal Trade Commission has jurisdiction over the advertising of Dean's analgesic products under Sections 5 and 12 of the Federal Trade Commission Act.

B. Respondents disseminated advertisements for Doan's analgesic products that falsely represented to reasonable consumers that Doan's analgesics products are more effective than other analgesics for relieving back pain.

C. At the time respondents made these representations, they did not possess or rely upon a reasonable basis that substantiated such representations.

D. Respondents' representations were material.

E. The acts and practices of respondents as herein found were all to the prejudice and injury of the public and constitute unfair and deceptive acts and practices and false advertisements in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

F. The accompanying order is necessary and appropriate under applicable legal precedent and the facts of this case.

FN1. Abbreviations used in this decision are:
Cplt: Complaint
Ans: Answer
CPF: Complaint Counsel's proposed findings
RPF: Respondents' proposed findings
CX: Commission Exhibit
RX: Respondents' Exhibit
JX: Joint Exhibit
Tr.: Transcript of the proceeding
F: Finding of fact

FN2. Although both corrective advertising and affirmative disclosure are forms of fencing-in relief…, the standard for imposing corrective advertising is significantly more stringent than that for an affirmative disclosure.… [which] requires only that the disclosure be 'reasonably related' to the alleged violations. In my view, it is important to distinguish between corrective advertising and affirmative disclosures because the Commission should not evade the more demanding standard for corrective advertising where it is clearly applicable.
California SunCare, Inc., 61 Fed. Reg. 64521, at 64523-24 (Dec. 5, 1996) (Statement of Commissioner Roscoe B. Starek, III) (concurring in part, dissenting in part) .

ORDER

For purposes of this order:

1. "*Doan's*" shall mean any over-the-counter analgesic drug, as "drug" is defined in the Federal Trade Commission Act, bearing the Doan's brand name, including, but not limited to, Regular Strength Doan's analgesic, Extra Strength Doan's analgesic, and Extra Strength Doan's P.M. analgesic.
2. "*Competent and reliable scientific evidence*" shall mean 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.
3. "*Advertisement*" shall mean any written, oral or electronic statement, illustration or depiction which is designed to create interest in the purchasing of, impart information about the attributes of, publicize the availability of, or effect the sale or use of goods or services, whether it appears in a brochure, newspaper, magazine, free standing insert, marketing kit, leaflet, circular, mailer, book insert, ***671** letter, catalogue, poster, chart, billboard, public transit card, point-of-purchase display, package insert, package label, product instructions, electronic mail, website, homepage, film, slide, radio, television, cable television, program-length commercial or "informercial," or in any other medium.

I.

It is ordered, That respondents Novartis Corporation, and Novartis Consumer Health, Inc., corporations, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Doan's or any other over-the-counter analgesic drug, in or affecting commerce, as "drug" and "commerce" are defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that such product is more effective than other over-the-counter analgesic drugs for relieving back pain or any other particular kind of pain, unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific

evidence that substantiates the representation. For purposes of Part I of this order, "competent and reliable scientific evidence" shall include at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, each of whom is qualified by training and experience to conduct such studies, independently of each other.

II.

It is further ordered, That respondents Novartis Corporation, and Novartis Consumer Health, Inc., corporations, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any over-the-counter analgesic drug in or affecting commerce, as "drug" and "commerce" are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication, regarding such product's efficacy, ***672** safety, benefits, or performance, unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IV.

It is further ordered, That for a period of five (5) years after the last date of dissemination of any representation covered by this order, respondents, or their successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials that were relied upon in disseminating such representations; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

V.

It is further ordered, That respondents shall:

A. Within thirty (30) days from the date of entry of this order, provide a copy of this order to each of their current principals, officers, directors and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this order; and

B. For a period often (10) years from the date of entry of this order, provide a copy of this order to each of their future principals, officers, directors, and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this order who are associated with them or any subsidiary, successor, or assign, within three (3) days after the person assumes his or her position.

***673** VI.

It is further ordered, That respondents shall notify the Commission at least thirty (30) days prior to any proposed change in their corporate structures, including, but not limited to, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or affiliates, or any other corporate change that may affect compliance obligations arising out of this order.

VII.

It is further ordered, That this order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

VIII.

It is further ordered, That respondents shall, within sixty (60) days from the date of entry of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing setting forth in detail the manner and form in which they have complied with this order.

***674** OPINION OF THE COMMISSION

BY ANTHONY, *Commissioner*.

This case is about a company that chose to market an over-the-counter ("OTG") analgesic by advertising that the product was superior to others in the treatment of back pain without any basis for that claim. Respondents Novartis Corporation and Novartis Consumer Health, Inc. [FN1] (collectively "Novartis") appeal from an Initial Decision and Order of Administrative Law Judge Lewis F. Parker (the "ALJ"), holding that superiority claims in advertisements for Doan's products were material and therefore deceptive in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. 45 , 52. Complaint counsel cross-appeals the ALJ's decision not to order a corrective advertising remedy.

We affirm the ALJ's holding that the unsubstantiated superior efficacy claims for back pain relief were material and thus deceptive. We reverse the ALJ's holding regarding corrective advertising. We agree with the ALJ's findings and conclusions to the extent that they are consistent with those set forth in this opinion, and, except as noted herein, adopt them as our own. [FN2]

I. FACTUAL BACKGROUND

Novartis Corporation is a New York corporation and Novartis Consumer Health, Inc. is a Delaware corporation. Both are subsidiaries of Novartis AG, a Swiss corporation, and successors-in-interest to Ciba-Geigy Corporation and Ciba Self-Medication, Inc. (collectively "Ciba"). [FN3] JX 2A ¶ 11. [FN4] In addition ***675** to the Doan's line, Novartis manufactures and sells other OTC products. [FN5]

Doan's has been marketed and sold for over 90 years and has always been advertised as a backache product. IDF 8; Peabody Tr. 286. The active analgesic ingredient in the Doan's products is magnesium salicylate. IDF 14; JX 1 ¶ 11. While no other brand of OTC analgesic contains magnesium salicylate as an active ingredient, IDF 22; Peabody Tr. 314, there are no scientific studies demonstrating that magnesium salicylate is more efficacious than other analgesics.IDF 22; JX 1 ¶ 9. The Food and Drug Administration (the "FDA") regulates product labeling for Doan's pursuant to its *Tentative Final Monograph on Internal Analgesic, Antipyretic, Antirheumatic Products for Over-the-Counter Human Use* (the "Monograph"). Under the Monograph, an OTC analgesic drug may be labeled as indicated for the temporary relief of minor aches and pain associated with one or more of the following: cold, sore throat, headache, toothache, muscular aches, backaches, and arthritis. JX 1 ¶ 5.

Doan's is a relatively small player in a large market. In 1987, the total advertising spending for all OTC analgesic products was $299 million; for the first half of 1996 it was $351.1 million. JX 2D ¶ 23. Doan's advertising expenditures were a small fraction (1 to 3%) of the total analgesic advertising spending from 1988 to 1996. JX 2E ¶ 24. Between 1988 and 1994, Doan's share of the back pain advertising spending ranged from 8 to 12%. *Id.* Doan's analgesic products sell at a significant price premium over general purpose analgesic products at both the factory level (the retailer's purchase price) and the retail level (the consumer's purchase price). IDF 15.

After Ciba acquired the Doan's line in 1987, it commissioned a study, the Attitude and Usage Telephone Study (the "A&U Study"), CX 221, to find out how consumers perceived Doan's and to direct future marketing efforts. *See* Peabody Tr. 133-34. The A&U Study surveyed users of the Doan's product and non-users who were aware of the product. After analyzing the results of the A&U Study, Ciba's Marketing Research Department concluded that "Doan's has a weak image in comparison to the leading brands of analgesics and *would benefit from positioning itself as a more effective product* that is ***676** strong enough for the types of backaches sufferers usually get." CX 221-c,d (emphasis added). It further concluded that "Extra-Strength Tylenol is clearly the gold standard for backache pain relief followed by Advil. Bayer and Doan's are consistently perceived weakest." CX 221-c.

Ciba used the results from the A&U Study to create a new Doan's advertising strategy. Peabody Tr. 146. The strategy of this new campaign was to compare Doan's to other general analgesics. Comparative claims for small-share niche brands like Doan's are especially effective according to one of complaint counsel's experts, Dr. David Stewart. Stewart Tr. 3457. Specifically, Dr. Stewart explained that explicit comparative references made by low-share brands attract more attention to, and increased purchase intention for the low-share brand relative to the high share brand. Stewart Tr. 3458-59.

Ciba's marketing plans showed that its goals were to maintain its existing customers, to regain lapsed users and, of course, to attract new users. *See* CX 335-z-12; CX 343-z-65; CX 351-z-59. In the fourth quarter of 1987, Ciba introduced "Extra Strength Doan's," containing a larger dose of the active analgesic ingredient, and renamed the original product "Regular Strength Doan's." After its introduction, the Extra Strength product captured more than half of the Doan's product sales. JX 2B ¶18. In September 1991, Ciba introduced Doan's P.M., which contains a sleep aid.

Increasingly, Doan's faced competition from new back pain products, general analgesics, and private label brands. *See* CX 335-d; CX 343-f; CX 351-c; Peabody Tr. 146. The marketing plans outlined strategies to deal with such competition. For example, in August 1992, Ketchum Advertising prepared a "Doan's Defense Plan" intended to respond to the anticipated 1993 introduction of Nuprin Backache. *See* CX 357. The 1996 Marketing Plan reports that in 1994 Ciba regained its 1993 loss. CX 400-h.

To send its message, Ciba used national television ads and, to a lesser extent, free standing inserts ("FSIs"). Ciba disseminated FSIs in Sunday newspaper supplements two to three times per year. JX 2I ¶36. From 1987 through 1996, Ciba spent $55 million for broadcast ads and $10 million for FSIs. JX 2C ¶21. Doan's television ads appeared nationally both on network television and on syndicated and cable television. *See* JX 2F ¶28. The television ads were 15-second commercials. JX 2E ¶25. Ingrid Nagy, Doan's Business Unit Manager ***677** from 1988 to 1991 and its Marketing Director from 1994 to 1995, believed that 15-second ads were effective because of the fairly singular communication point of the ads. IDF 29; CX 499 at 135 [Nagy Dep.]. In addition, Ciba disseminated the television ads through a righting strategy [FN6] during 26 weeks of the year. Based on estimates by Ciba's advertising agencies, from 1988 to 1996, television commercials for Doan's reached 80% to 90% of the Doan's target audience, on average, between 20 and 27 times per year. JX 2F ¶28. Finally, for short periods in 1991 and 1993, Ciba tested radio ads including Spanish radio ads in Houston. JX 2I ¶¶34, 35.

II. PROCEDURAL BACKGROUND

On June 21, 1996, the Federal Trade Commission (the "Commission") issued a complaint alleging that Ciba had violated Section 5 by making unsubstantiated claims in its advertisements (1) that Doan's analgesic products were more effective than

other analgesics, including Bayer, Advil, Tylenol, Aleve, and Motrin, for relieving back pain; and (2) that Ciba possessed and relied upon a reasonable basis to substantiate such claims. During litigation, complaint counsel sought an order requiring that the following corrective notice appear on all advertising and packaging: "Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain." [FN7] Complaint counsel sought to impose a performance standard for determining when the corrective notice was no longer needed. Specifically, the corrective notice would appear until Ciba (now Novartis) submitted consumer survey data to the Commission demonstrating that consumer beliefs had reached a specified level. [FN8]

After extensive discovery and an administrative trial, the ALJ issued his Initial Decision and Order on March 9, 1998. The ALJ found that a facial analysis of the challenged advertisements supports the conclusion that the advertisements conveyed a claim of superior ***678** efficacy for the treatment of back pain. The ALJ concluded that the Doan's superior efficacy claims were presumptively material because they relate to the central characteristics of the product and involve health claims. He also found that the claims cause consumers economic injury because the Doan's products are significantly more expensive than other OTC analgesics. He therefore held the superiority claims to be deceptive in violation of 15 U.S.C. 45 and 52. Further, the ALJ concluded that Ciba intended to make the challenged claims. ID at 63-66.

The ALJ's order prohibits Novartis from making superiority claims for any OTC analgesic drug with regard to the product's ability to relieve back pain or any other particular kind of pain without competent and reliable scientific evidence that includes at least two adequate and well-controlled, double-blinded clinical studies. (Part I) As fencing-in relief, the ALJ's order prohibits Novartis from making any representation regarding any OTC analgesic drug's efficacy, safety, benefits, or performance without competent and reliable scientific evidence to substantiate the claim. (Part II) Finally, the order contains a "safe harbor" for claims approved by the FDA under a tentative or final monograph, or pursuant to an approved new drug application. (Part III).

The ALJ concluded that the record did not support the imposition of a corrective advertising remedy. He noted that a belief study, relied upon by complaint counsel, showed that a superior efficacy belief lingered for six months after the last challenged ad was disseminated. Nevertheless, the ALJ compared the 51 years Warner Lambert ran deceptive Listerine ads to the eight-year Doan's campaign and concluded that there was insufficient evidence that consumer misbeliefs in Doan's superiority for the treatment of back pain would linger in the absence of the remedy. ID at 64. Finally, he rejected complaint counsel's claim that the need for corrective advertising could be inferred.

III. DECEPTION ANALYSIS

A. Legal Standard.

The first issue in this case is whether the challenged Doan's ads were deceptive. Section 5 of the Federal Trade Commission Act prohibits "unfair or deceptive acts or practices in or affecting commerce." 15 U.S .C. 45. Section 12 of the Act declares ***679** dissemination of false advertisements regarding certain categories of products, including drugs, to constitute an unfair or deceptive act or practice under Section 5.15 U.S.C. 52.

As the Commission explained in its policy statement on deception, appended to *Cliffdale Assocs., Inc.* 103 FTC 110, 176-184 (1984) (the "Deception Statement"), a representation is deceptive if it "is likely to mislead the consumer acting reasonably in the circumstances, to the consumers detriment." *Id.* at 176. In practice, the Commission's deception analysis is applied as a three-part test asking whether (1) a claim was made; (2) the claim was likely to mislead a reasonable consumer; and (3) the claim was material. *E.g.*, *Cliffdale Assocs., Inc.* 103 FTC at 165. There is no requirement of intent. *Kraft, Inc.*, 114 FTC 40, 121 (1991) ("Evidence of intent to deceive is not required to find liability."), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (199 3).

The factors and evidence the Commission weighs in assessing the three prongs of the deception analysis are often interrelated. While Novartis' sole question on appeal is whether the ALJ "err[ed] in concluding that the alleged implied superior efficacy claim was material to consumers," [FN9] RAB 7, its claims arguably implicate the other two parts of the test. Therefore, to

address fully Novartis' arguments on appeal, and to provide a context for our discussion of the materiality issue, we briefly discuss the first two elements before considering materiality.

B. The Challenged Ads Conveyed Superior Efficacy Claims.

We first consider whether the challenged ads communicated a superior efficacy claim for the treatment of back pain. In determining what claims may reasonably be ascribed to an ad, the Commission examines the entire ad and assesses the overall net impression it conveys. *Deception Statement*, 103 FTC at 176; *Kraft, Inc.*, 114 FTC at 122; *Thompson Meal Co.*, 104 FTC 648, 790 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

***680** Claims can either be express or implied. Here we are dealing with an implied claim. Implied claims range on a continuum. At one end are claims that are "virtually synonymous with an express claim" and use "language that literally says one thing but strongly suggests another." *Thompson Med. Co.*, 104 FTC at 789. At the other end of the spectrum are claims that use "language that relatively few consumers would interpret as making a particular representation." *Id.*

The Commission's assessment of whether an implied claim is made necessarily begins with the advertisement itself. A facial analysis alone will suffice if it permits the Commission to conclude with confidence that the ad makes the implied claim. *See Stouffer Foods Corp.* 118 FTC 746, 798 (1994); *Kraft, Inc.*, 114 FTC at 121; *Thompson Med. Co.*, 104 FTC at 789. In cases where the claim is not manifest from an examination of the ad, the Commission will look to extrinsic evidence, *Id.* at 799; *Kraft Inc.*, 114 FTC at 121; *Thompson Med. Co .*, 104 FTC at 789. Such evidence might include, for example, the testimony of expert witnesses, market research studies regarding consumer reactions to the use of certain common terms, or consumer surveys. *Kraft, Inc.*, 114 FTC at 121-22. The Commission will carefully assess the quality and reliability of any extrinsic evidence introduced by the parties. *Stouffer*, 118 FTC at 799; Deception Statement, 103 FTC at 176. While methodological perfection is not required, with regard to reliance on copy tests and other consumer surveys, flaws in methodology may affect the weight the Commission gives to such results. *Id.*

1. A Facial Analysis of the Ads Reveals That They Conveyed Superior Efficacy Claims.

Respondent ran the challenged ads over eight years. [FN10] J-X2E ¶25. The "Graph" ad was the first in the new campaign. It begins with a visual of the profile of a person in front of what appears to be graph paper. CX 13. The individual twice attempts to bend over; the second time (after he has implicitly ingested Doan's), he is able to bend farther. The audio portion of the ad states that "Doctors measure back ***681** pain by how far you can bend." The ad then depicts a package of Doan's on the left side of the screen while packages of three competing analgesic brands -- Advil, Tylenol and Bayer -- are displayed on the right. The audio portion concludes: "With an ingredient these pain relievers *don't* have." The spotlight on the other brands is then darkened leaving only a visual of the Doan's package on the screen.

The television ads respondent disseminated after "Graph" continued to emphasize that Doan's has an ingredient not found in competing analgesics while depicting competing products. The "X-Ray" ad introduces an audio and visual reference to Doan's as "the back specialist," and this tag line is also used in several subsequent Doan's ads. CX 14. Respondent began to use the terms "special" and "unique" to modify references to Doan's "ingredient" in "Black and White Back" and "Ruin a Night's Sleep" ads, respectively. CX 15; CX 17.

The superiority themes begun in "Graph" and "X-Ray" continued in subsequent ads such as "Activity Playtime" and "Activity Pets." CX 20; CX 22. As in earlier ads, both depict a package of Doan's alongside other analgesics while the voice-over states, "Doan's has an ingredient these pain relievers don't have." And once again, the ads conclude with the "back specialist" tag line. Respondent repeated similar themes in the challenged "Muscles" ad. CX 23.

The Free Standing Inserts -- color print advertisements included with newspapers -- closely tracked the claims in the television ads . One FSI that first ran in 1989 and again in 1990 and 1991, features a large Doan's package alongside smaller but clearly visible packages of Advil, Extra-Strength Tylenol, and Bayer. CX 32. Copy above the packages states: "Doan's. Made for back

pain relief. With an Ingredient these other pain relievers don't have." *Id.* Other FSIs made similar claims and included depictions of competing brands. *See, e.g.*, CX 33-39.

Based upon a facial analysis of the challenged ads, we find that they clearly conveyed a claim that Doan's is superior to other analgesics, such as Bayer, Advil, Tylenol, Aleve and Motrin, for relieving back pain. The express claims that Doan's is made for back pain and contains a unique or special ingredient that the other featured brands do not have, coupled with the depiction of the other brands, combine to communicate that Doan's is superior to the ***682** competing analgesics for back pain. This message is reinforced by the statement in some ads that Doan's is the "back specialist." The superior efficacy claim is implied, but on the continuum of implied claims, we find the claim so clear as to be nearly express.

2. Extrinsic Evidence Confirms That the Challenged Ads Conveyed Superior Efficacy Claims.

Substantial extrinsic evidence confirms our conclusion that the challenged ads make a superior efficacy claim. We affirm and adopt the ALJ's findings on this point (ID at 62-63), and highlight some of the more persuasive extrinsic evidence.

Several consumer surveys and copy tests show that consumers understood the ads to be making a superiority claim. For example, copy tests on mock-up versions of some of the challenged ads conducted by Bruno & Ridgeway, an independent consumer research company employed by Ciba, showed that approximately 30 to 45% of the consumers tested discerned a superiority message from the ads. [FN11] Likewise, a Mail Panel Communication Test conducted by Market Facts, a firm retained by Ciba to test the 1991 FSIs, revealed that between 47 to 59% of respondents strongly or somewhat agreed that the FSIs indicated that Doan's is better for back pain than other pain relievers. CX 238-z-71. In addition, complaint counsel commissioned U.S. Research ("USR") to conduct a mall intercept copy test to determine if the challenged ads communicated the superiority claim. Fifty-seven percent of the "Activity-Playtime" ad and 40% of the FSI respondents took the superior efficacy claim from the ads. IDF 179, 180; ID at 63.

***683** Ciba prepared these tests in the regular course of business, which indicates that at the time Ciba was running the ads, it was well aware that consumers understood them as conveying a superior efficacy message. Mr. Edward Peabody, the Director of Marketing Research, testified that he became concerned about miscommunication at the 10 to 15% level. Peabody Tr. 150-51. Nevertheless, as noted above, Ciba ran ads from which percentages of 30 to 45% drew a superiority message. While a respondent need not intend to make a claim in order to be held liable, evidence of intent to make a claim may support a finding that the claims were indeed made.

Novartis counters its own commissioned Bruno & Ridgeway test results with results obtained in ASI and ARS copy tests [FN12] that show low percentages of consumers drawing a superiority message from the ads. [FN13] We find that the ARS and ASI test methods likely understate the communication results. These were tests of recall and persuasion administered either one or three days after exposure to the ad. The legal issue in the first prong of deception, however, is whether the claim was made and not whether it was memorable. Forced-exposure tests, like those conducted by Bruno & Ridgeway, where questions are asked when the ad is fresh in the consumer's mind, are more telling regarding whether a particular claim was made. The ARS and ASI tests also tend toward understatement because their questionnaires contain no close-ended questions, and the open-ended questions asked consumers about express claims in the tested ads rather than what the ad implied or suggested. Peabody Tr. 194-95.

In sum, the issue of whether the claim was made is not a close one. While technically an implied claim, respondent's superior efficacy message is plain from a facial analysis of the challenged ads ***684** alone. The extrinsic evidence introduced on this issue provides additional support for our finding that the superiority claims for back pain treatment were made.

C. The Challenged Ads Were Likely to Mislead Reasonable Consumers.

Having concluded that the claims were made, we proceed to consider whether those claims were likely to mislead reasonable consumers. Deception Statement, 103 FTC at 17 7. The applicable standard is whether a claim is *likely* to mislead; proof that

particular consumers were actually deceived is not required. *Kraft, Inc.*, 114 FTC 133; *Cliffdale Assocs., Inc .*, 103 FTC at 165; Deception Statement, 103 FTC at 17 6. Further, "[t]he test is whether the consumer's interpretation or reaction is reasonable." *Id*. The interpretation need not be the only one to be reasonable. For example, a respondent can be held liable where multiple interpretations of a claim are possible, only one of which is deceptive. *Stouffer Foods Corp.*, 118 FTC at 799; *Kraft, Inc.*, 114 FTC at 120-21 n.8; *Thompson Med. Co.*, 104 FTC at 789 n.7. The reasonableness of an interpretation is not contingent upon its being shared by a majority of consumers. A claim would likely mislead a reasonable consumer if at least "a significant minority of consumers" would be deceived by it. Deception Statement, 103 FTC at 177 n.20. Importantly, the Deception Statement adds that an interpretation is presumed reasonable if it is one the respondents intended to convey. *Id.* at 178.

The misleading nature of the superior efficacy claims at issue here is plain. The claims are entirely unsubstantiated. Novartis concedes that no scientific studies demonstrate the therapeutic superiority of magnesium salicylate, the active ingredient in Doan's, over aspirin, acetaminophen, ibuprofen, or naproxen sodium for relief of back pain or any other indications contained in the Monograph issued by the FDA. JX ID ¶ 9. As a general matter, the Commission considers claims regarding the efficacy of analgesics to be adequately substantiated when the claims are supported by the results of two well-controlled clinical studies. *Thompson Med Co.*, 104 FTC at 825. Here, the claim that Doan's is superior to various other OTC analgesics for treating back pain is baseless and, consequently, likely to mislead reasonable consumers.

***685** This conclusion is bolstered by the fact that Ciba intended to make the superiority claim. Ciba knew from its own copy testing data that consumers were taking a superiority message from the ads and that it had no substantiation for such a claim. Indeed, more than a significant minority -- 30 to 45% -- of consumers discerned this superiority message. Yet, Ciba continued to run the ads. This demonstrates that Ciba intended to, and in fact did, convey a superiority message. Therefore, consumers receiving such a message from the ads behaved reasonably in doing so. *See Thompson Med. Co.*, 104 FTC at 79 1.

Our finding of the reasonableness of the deceptive interpretation is further supported by the nature of the product. Analgesics are products the efficacy of which consumers cannot readily judge for themselves. Well-documented phenomena such as the "placebo effect" and the "usage effect" [FN14] make it difficult for consumers to judge accurately the degree of an analgesic's efficacy. Superiority vis-a-vis other types of analgesics is even more difficult to ascertain absent well-controlled clinical trials. Thus, consumers necessarily rely upon manufacturers' representations and behave reasonably when they take those representations to be substantiated and accurate.

D. The Claims Are Material.

Finally, the Commission must determine whether the superior efficacy claim is material. A "material" misrepresentation is one that involves information important to consumers and that is therefore likely to affect the consumer's choice of, or conduct regarding, a product. Deception Statement, 103 FTC at 182 . Materiality is closely related to injury in that when a consumer's choice is affected by a misrepresentation, the consumer, as well as competition generally, is injured. *Id.* at 182-83. However, proof of actual consumer injury is not required. *Kraft, Inc.*, 114 FTC at 134.

The ALJ concluded that the challenged claims were presumptively material, ID at 63-64, and found that the misleading ***686** claims were material based upon this presumption and the record evidence. IDF 227.

On appeal, Novartis argues that the ALJ misapplied the presumption, and improperly evaluated the evidence submitted by the parties. We conclude that the respondent's implied superior efficacy claim was material.

1. The Presumption of Materiality

a. Generally

Novartis and *amicus curiae* Grocery Manufacturers Association argue that the ALJ improperly elevated the presumption of materiality to a virtually irrebuttable conclusion of law. We disagree.

Certain categories of information are presumptively material, including, but not limited to, express claims, claims significantly involving health or safety, and claims pertaining to the central characteristic of the product. Deception Statement, 103 FTC at 182. Similarly, the Commission will infer materiality where the record shows that respondent intended to make an implied claim. *Id.* However, we "will always consider relevant and competent evidence to rebut presumptions of materiality." *Id.* at 182 n.47.

"To establish a 'presumption' is to say that a finding of the predicate fact," here, any of the factors listed above, "produces a required conclusion in the absence of explanation," here, materiality. *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993) (internal quotation marks omitted). In order to rebut the presumption, respondent must come forward with sufficient evidence to support a finding that the claim at issue is not material. Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact-finder could not reasonably find materiality, the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id.* at 516 (noting that after the presumption drops out, "the inquiry … turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals … the parties have introduced"). While the presumption itself is negated by sufficient rebuttal evidence, as previously noted, the predicate facts that gave rise to the presumption are not. These facts remain evidence ***687** from which materiality can be inferred. *See Boise Cascade*, 113 FTC at 975 (1990). However, this evidence is simply part of the entire body of evidence considered. *See also* 21 *Charles Alan Wright and Kenneth W. Graham, Jr., Federal Practice and Procedure: Evidence* §§ 5122 *et seq.* (1977 and 1998 Supp.) (discussing the history and application of presumptions).

b. The Facts Underlying the Presumption

The ALJ applied a presumption of materiality because the challenged claim involves a health issue. He also concluded that the presumption was appropriate in light of evidence that the challenged superior efficacy claim relates to the central characteristic of the product, that is, Doan's ability to relieve back pain. *See, e.g.*, *Sterling Drug*, 102 FTC at 753 (efficacy is "the most important feature of any analgesic"). Novartis admits that the presumption of materiality properly flows from these facts. RAB 46; RRAB 9.

We likewise conclude that these predicate facts -- that the claims go to health [FN15] and to a central characteristic of the product -- both support an initial presumption of materiality and constitute strong evidence that the claims were material. Common sense and experience, along with the Commission's expertise in advertising matters, counsel that respondent's representation that Doan's is more effective than other analgesics in the treatment of back pain was important to consumers considering a purchase and likely affected their decisions as to which product to buy. This requires no great leap.

Along with the "health claim" and "central characteristic" bases for the presumption of materiality, the ALJ found that Ciba's intent to make a superior efficacy claim was evidence that the claim was material and supplied an independent basis for the presumption. ID at 64. Novartis objects to this finding.

An advertiser's intent to make a claim generally implies that the advertiser believes that the claim is important to consumers. *See American Home Prods.*, 98 FTC 136, 368 (1981) ("The very fact that AHP sought to distinguish its products from aspirin strongly implies that knowledge of the true ingredients of those products would be material to consumers."), *aff'd*, 695 F.2d 681 (3d Cir. 1982). Thus, the Deception Statement includes intent as a predicate fact giving rise ***688** to a presumption of materiality. 103 FTC at 182, *see also Thompson Med. Co.*, 104 FTC at 816. For express claims, the intent to make the representation is self-evident. In the context of implied claims, however, extrinsic evidence is required to establish an intent to make the claim.

Complaint counsel presents various documents showing that Ciba knew that the ads were conveying a superiority message. Novartis argues that the documents have been taken out of context and offers the testimony of employees who state that Ciba had no intent to make the claim. We find complaint counsel's evidence more credible and compelling and conclude that Ciba

did indeed intend to communicate a superior efficacy message to consumers.

The record is replete with evidence demonstrating that Doan's ads were communicating a superiority claim and that Ciba management was aware of that communication. For example, the Bruno & Ridgeway communication study of the "Graph" ad categorized 38% of consumers exposed to the ad as answering that it communicated that Doan's was "superior to other products." CX 224-m. In a May 1988, memorandum to Ciba regarding the study, Bruno & Ridgeway recommended producing the ad, *inter alia*, because it "communicated *product superiority* and perceived efficacy." CX 225-d (emphasis added). This memorandum was directed to Ciba's Marketing Research Department and circulated to the Group Vice President of Marketing and other senior marketing executives at Ciba. In addition, the 1989 Doan's Marketing Plan prepared by Ciba reported the product superiority interpretation of the ad and described the "Graph" ad as a "strong execution which effectively communicates product superiority and perceived efficacy …." CX 335-z-8.

Communication tests conducted for Ciba on its "Black & White Back," "Ruin A Night's Sleep," and "Activity Playtime" advertisements indicated that they communicated a product superiority claim as well. For example, the Bruno & Ridgeway copy test for "Black & White Back" reported that 46% of respondents recalled a message of superiority over other products. CX 236-j.

In May, 1994, Ciba's advertising agency, Jordan McGrath Case & Taylor, wrote to Ciba indicating that the networks were seeking substantiation for one of the implied superiority claims:

> *All three Networks are requiring substantiation for the claim "If nothing you take seems to help."* The Networks believe that this language implies that Doan's ***689** provides superior efficacy vis-a-vis the competitive products shown …. As such, to make this claim we will need substantiation that Doan's is more effective (due to its Magnesium Salicylate ingredient) at relieving back pain versus the competitors pictured.
>
> Importantly, our Agency coun[sel] agrees with the networks.

IDF 111; CX 165-a. In response, Ciba deleted the words "you take" from the ad copy so that the ad stated "if nothing seems to help." CX 20.

Despite its knowledge that the ads were communicating an unsubstantiated efficacy claim, Ciba continued to disseminate some of the ads until May, 1996, just a month before the Commission's decision to issue a complaint in this matter and well after its investigation had begun.

Novartis argues that Ciba did not intend to make a superior efficacy claim, but rather to distinguish Doan's from other products. Novartis primarily relies on the testimony of former and current Ciba/Novartis managers who stated that Ciba did not intend to make any superiority claims. We are unpersuaded by these *post facto* denials. They ring hollow in the face of the contemporaneous documentary evidence revealing knowledge that a superiority claim was being communicated. *See, e.g., United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 506, 602 (1957).

In sum, we agree with the ALJ that Ciba intended to make the superiority claim and conclude that this intent, along with the predicate facts that the claim goes to health and to a central characteristic of the product, create a presumption, and provide strong evidence, of materiality.

2. Complaint Counsel's Additional Evidence of Materiality

Along with the evidence that gave rise to the initial presumption of materiality, discussed above, the record contains substantial additional evidence supporting a finding that the claim was material. This diverse body of evidence includes consumer survey results, expert testimony, and business records.

a. The Nature of the Claims

The record contains ample evidence showing that superior efficacy claims are important to consumers attempting to choose a

back pain remedy. First, experts for both parties testified that a superior efficacy claim would be important to the back pain sufferer ***690** when choosing an OTC analgesic. Mazis Tr. 1983 (testifying that superior efficacy is the primary reason why consumers choose one analgesic over another); Jacoby Tr. 3371 (testifying that superior efficacy claim would "motivate" back pain sufferers to purchase a product).

Second, the results of a study performed by Dr. Whitcup show the importance of efficacy claims. Dr. Whitcup asked consumers to rate the characteristics of pain relief products. Dr. Whitcup found that efficacy-related responses constituted three of the top four characteristics . RX 2-z-105. These results led Dr. Whitcup to conclude that analgesic products are generally chosen "on the basis of perceived efficacy," along with other factors. RX 2-z-3; Whitcup Tr. at 2815.

Third, several studies and copy tests Ciba commissioned in the ordinary course of business demonstrate the importance of efficacy claims to consumers of back-pain remedies. For example, a study delivered to Ciba management highlights a key finding: "[Doan's] is seen as particularly effective for back pain, and as having a special ingredient.... this specificity is what users are looking for …." CX 256-c (Brand Equity Study, Exec. Summary). Similarly, Bruno & Ridgeway stated in its report on the copy test for the "Graph" ad that superiority "seems to be an important and persuasive idea." CX 224-1. Weiss Marketing Research Co. likewise concluded that the fact that the "Graph" ad created the impression that Doan's is better may persuade people to try Doan's. CX 227-z-3.

b. The Price Premium

Throughout the relevant period, Doan's was priced well above the general purpose analgesics depicted in the challenged ads, including Tylenol, Advil, and Bayer. In 1992, for example, a 24-count package of Doan's cost consumers 66% more than the same size package of Tylenol. IDF 15-16. The existence of this price premium constitutes further evidence of materiality. Deception Statement, 103 FTC at 183.

Respondent argues that these price premiums cannot be linked to the challenged claim because the premium is attributable to Doan's status as a niche brand. RAB 83. However, the challenged ads compared Doan's to general purpose, lower-priced analgesics and not to other similarly priced niche products. Thus, the ads used a misrepresentation in an effort to convince consumers to pay the additional amount for a product similar to general purpose analgesics.

***691** 3. Novartis' Evidence Against Materiality

Novartis offers several arguments to support its contention that the superior efficacy claim was not material. While we find that Novartis submitted a sufficient amount of relevant evidence to rebut the presumption of materiality, the totality of the evidence strongly compels a finding of materiality.

a. Effectiveness of the Ads

Novartis primarily argues that the ads were ineffective in communicating their message to consumers and therefore did not affect consumer purchase decisions (*i.e.*, they were not material). Respondent argues that Ciba ran ads that it knew were ineffective in order to appease retailers who demand manufacturer support for niche brands. [FN16] RAB 56-57. Respondent cites market data for the relevant period that reflect little or no growth in sales or market share and reasons that the superior efficacy claim, therefore, did not affect consumer purchase behavior. [FN17] RAB 71.

In the first place, this claim is irrelevant even if it were true. Materiality is not a test of the effectiveness of the communication in reaching large numbers of consumers. It is a test of the likely effect of the claim on the conduct of a consumer who *has* been reached and deceived . *See* Deception Statement at 182 - 83. The materiality inquiry builds upon the findings from the prior two factors in the deception analysis -- that the claim was made and that it was likely to mislead at least a significant minority of reasonable consumers exposed to the ad. Materiality turns upon whether those consumers who have drawn the claim from the advertisement and been misled by it are also likely to have their conduct affected by the misrepresentation.

In any event, respondent's argument that it ran an eight-year multimillion dollar campaign of ineffective ads is contradicted by the ***692** evidence. Market data demonstrate that the campaign produced positive results. Contrary to Novartis' assertions, Doan's maintained its market share in an extremely competitive environment and enjoyed an 80% increase in dollar sales during the relevant period. [FN18] JX 2B ¶17. Because the number of consumers in the analgesics market in which Doan's competes is not growing appreciably (*i.e.*, the market is "mature"), a business must take customers from another brand in order to increase market share. Stewart Tr. 3467; CX 597. In such markets, maintenance of market share, and not increasing sales, is the primary criterion of success. *Id.* Indeed, Doan's ability to maintain its market share in the mature OTC analgesics market notwithstanding the fact that its advertising budget was much less than those of its competitors, JX 2E ¶24, reveals that the challenged advertising campaign was successful. The fallacy of Novartis' market performance arguments is also shown by Doan's survival and prosperity while other products were introduced and later withdrawn.

Even if Novartis' characterization of the market data were accurate, a history of static performance alone does not support its contention that the challenged ads were ineffective. Market performance is governed by a host of variables, and the materiality inquiry focuses upon a single claim. [FN19] Absent evidence, lacking here, that links market performance directly to the claim or controls for other variables influencing market performance, general market data is not particularly useful in assessing materiality.

b. Puffery

Novartis argues that the challenged claims were not material because they amounted to mere "puffing." RAB 61-64. Respondent posits that if consumers did not take the superiority ***693** claim seriously, the claim could not have misled them into buying the product. We reject this argument [FN20]

The claim that Doan's is more effective than other analgesic products for treating back pain is not a subjective opinion, a matter of personal taste, or a hyperbolic statement that might be deemed "puffery." Rather, it is an objective claim that can be scientifically tested. The implied claim at issue here not only asserts superiority, but specifies in what respect (back pain relief), why (its unique ingredient) and compared to whom (named competitors). CCAB 93-94. This is the opposite of puffery, and the exact type of claim that a consumer would reasonably expect to be substantiated by adequate clinical studies. *See Pfizer*, 81 FTC 23, 64 (1982) (puffing does not include "affirmative product claims for which either the Commission or the consumer would expect documentation").

Respondent also argues that approximately half of all consumers harbor a general belief that no analgesic is any more effective than any other in treating back pain. RAB 65-66. Presumably, respondent's point is that these skeptics would never be swayed by false efficacy claims. Even assuming, for the sake of argument, the accuracy of the statistic and the validity of the claim that a consumer's general belief could not be overcome by specific misrepresentations, the argument still fails. An advertiser does not have to fool all of the people to be found liable; a "significant minority" of consumers is sufficient. Deception Statement, 103 FTC at 177 n. 20. Nor does the existence of some hardened cynics free advertisers to make deceptive claims.

c. Consumer Surveys

Novartis offers various consumer survey results as support for its contention that the claim was not material. For the most part, the results touted by respondent, even assuming flawless methodology, are only marginally probative on the issue of materiality. With respect to the one survey that tested materiality, methodological flaws render its results unreliable.

Respondent first points to the ARS tests, which indicate a low consumer recall of superiority messages between one and three days ***694** after seeing certain ads, as demonstrating that some of the challenged ads were not material. RAB 69-70. As discussed above, these tests asked only about express superiority claims, which were not made. Because the ARS tests did not even ask about implied claims (the only kind of claims at issue), they are hardly helpful. Moreover, materiality does not depend upon whether the claim is remembered by consumers days later. As discussed above, a claim does not have to be memorable to

be material.

Novartis also claims that a study conducted by Dr. Jacob Jacoby in late 1996 shows that the superiority claim was not important to consumers and that the challenged ads were unlikely to cause consumers to purchase Doan's. RAB 76-79; RRAB 23-25. In Dr. Jacoby's study, consumers were shown one of six commercials [FN21] and then questioned. Three of the questions (numbers 5a, 5b, and 5c) pertained to materiality. Question 5a asked: "Did seeing this commercial influence whether or not you would buy the advertised product in the future?" RX 5-z-112. Only those who responded affirmatively preceded to question 5b: "Did it make you more likely to buy this product, or less likely to buy this product?" *Id.* Finally, those who responded "more likely," were asked 5c: "What is it about what the commercial said, showed or suggested that makes you more likely to buy it in the future?" RX 5-z-113. Dr. Jacoby contends that "only a trivial number" of those questioned indicated that the commercials made them more likely to buy the advertised product based upon a claim of superiority or because it had a special ingredient. RX 5-z-120.

Dr. Jacoby's test for materiality was flawed in several ways. First, by asking question 5c only of those who answered questions 5a and 5b in certain ways, Dr. Jacoby's study understated the number of respondents to whom the misrepresentation was material. Questions 5a and 5b ask about the *commercial* rather than the *claim.* Whether a commercial as a whole influences a consumer is not the same issue as whether a claim contained in the commercial is likely to do so. Despite the materiality of a given claim, the commercial containing that claim might fail to influence a consumer for any number of reasons. Because the claim need only be an important factor in the purchase decision, the results for questions 5a and 5b tell us little about the materiality of the superior efficacy claim.

***695** Moreover, once the pool of respondents had been inappropriately filtered through questions 5a and 5b, their number had been drastically reduced. Of the 142 people shown the challenged "Activity Playtime" ad, only 35 were asked question 5c. RX 6-z-39. Similarly, of the 129 people shown the challenged "Muscles" ad, only 36 were asked question 5c. RX 6-z-15. These numbers appear to be too small to be accorded significant evidentiary weight.

Dr. Jacoby's study also understated the number of respondents to whom the superiority claims were material by failing to ask directly whether the superiority claim was important to them. The open-ended nature of question 5c tended to yield a scattershot range of responses. *E.g., RX* 6-z-40. For each of the two challenged ads, seven of the approximately 35 people asked question 5c (roughly 20%) gave responses that Dr. Jacoby interpreted as indicating materiality. RX 6-z-16; RX 6-z-40. These results are almost certainly understated because Dr. Jacoby failed to ask follow-up questions to determine *all* of the aspects of the commercial that made consumers more likely to buy Doan's in the future. As previously noted, in order to be material, a claim does not have to be the *only* factor or the *most* important factor likely to affect a consumer's purchase decision, it simply has to be *an* important factor. By seeking only one response to question 5c for each consumer tested, Dr. Jacoby ignored this fact and thereby undermined his results.

During the administrative trial, Dr. Jacoby sought to buttress his results by performing calculations cross-referencing several other questions included in the survey. While Dr. Jacoby did not explain his methodology in detail, he apparently matched the consumers he interpreted as drawing a superior efficacy claim from the ads (in response to questions 6a, 6b, and 8b) [FN22] with those who stated, in answer to question 5b, that the commercial made them "more likely" to buy the product. *See* RX 209-a. *See* Jacoby Tr. 3061, 3338-343. Based upon these calculations, Dr. Jacoby concluded that for the challenged commercials, the overlap was only 12.7 and 4.7%, respectively. *See* RX 209-a. He reduced these results further by subtracting the percentages obtained from the control ads. *Id.*

***696** This procedure did not salvage Dr. Jacoby's study. The results of Dr. Jacoby's cross-referencing exercise derive from the results obtained from question 5b. That question only tells us which consumers found the commercial persuasive and does not reveal anything about what aspects of the commercial made it persuasive. As explained above, a claim by itself can be material and yet, when viewed in the context of a commercial, fail to persuade a consumer to buy the product. Therefore, question 5b improperly excluded many relevant respondents. As it is, Dr. Jacoby's rcsults show that of the 35 consumers who indicated that they found "Activity Playtime" persuasive, 20 (57%) also drew a superior efficacy claim from the ad. *See* RX 209-a. While one might logically infer that the superior efficacy claim played an important role in making the ad persuasive to many of these

consumers, the flaws in Dr. Jacoby's methodology preclude a definitive and quantified linkage.

Finally, Dr. Jacoby conceded that if a person suffers from back pain and is offered a product that is superior for the relief of back pain compared to other analgesics products, then that person would be motivated to purchase the product. Jacoby Tr. 3371. Thus, even Dr. Jacoby agrees that a superior efficacy claim is likely to affect consumers' purchase decisions.

E. Conclusion

Thus, although we have concluded that the evidence adduced by Novartis requires us to look beyond a simple presumption of materiality, our review of that evidence shows that it ultimately adds little to respondent's side of the scales. Weighing *all* of the available evidence — including the basic and irrefutable fact that the misleading claims of superiority relate to the central characteristic of the product and involve health; the evidence that the claims were intended to affect consumer decisions; and the range of other evidence adduced by both sides — we have no hesitation in concluding that the claims were material. The extensive record amassed in this proceeding strongly confirms the common-sense proposition that efficacy is a pivotal consideration for consumers in selecting an analgesic, and that claims of superior efficacy are highly material to those consumer choices.

***697** IV. CORRECTIVE ADVERTISING

A. Legal Framework For Imposing Corrective Advertising

Corrective advertising is an appropriate remedy if (1) the challenged ads have substantially created or reinforced a misbelief; and (2) the misbelief is likely to linger into the future. *See Warner-Lambert Co . v. F.T.C.*, 562 F.2d 749 (D.C. Cir. 1977, *cert. denied*, 435 U.S. 950 (1978). In such cases, the lingering effects of a deceptive advertisement constitute a "clear and continuing injury to competition and to the consuming public" and justify the requirement of a corrective message. *Warner-Lambert Co.*, 86 FTC 1387 (1975).

It is well sealed that, in analyzing each of these two prongs, we may consider indirect evidence as well as direct evidence. *See, e.g., National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (197 8); *Warner-Lambert Co.*, 562 F.2d at 762; *American Home Prods.*, 98 FTC at 407; Statement in Regard to Corrective Advertising, Trade Reg. Pep. (CCH) ¶ 39,046 (1979) (stating "that the absence of consumer research will not preclude a corrective advertising order if other factors in the evidentiary record indicate that the challenged advertising campaign has created or reinforced consumer beliefs"). Therefore, we reject Novartis' argument that reliance on inferences would be a departure from a "settled understanding" expressed in the corrective advertising case law. RRAB 53.

We also reject the ALJ's holding that corrective advertising is inappropriate absent "certainty" that the misbeliefs will otherwise linger. The proper standard is whether, by a preponderance of the evidence, the misbelief is *likely* to linger. A requirement of certainty that a misbelief will linger would be impossible to satisfy, because certainty about the future is unattainable. [FN23] The ALJ's finding that the false beliefs are not *certain* to linger applies the wrong legal standard.

Finally, we reject respondent's argument that corrective advertising can only be ordered if it is shown that such a remedy is the *only* way to eliminate consumer misperceptions. RRAB 94 (citing *American Home Prods.*, 98 FTC at 411). Contrary to the ALJ's suggestion, corrective advertising is not a drastic remedy. ID at 65. ***698** Requiring the dissemination of a truthful message to counteract beliefs created or reinforced by a respondent's deceptive message is an appropriate method of restoring the *status quo ante* and denying a respondent the ability to continue to profit from its deception.

B. Methodology of Belief Studies

To support a corrective advertising remedy, complaint counsel relies on three consumer belief studies to demonstrate (1) that the challenged advertising campaign created or reinforced misbeliefs harbored by consumers about Doan's, and (2) that those

misbeliefs are likely to linger. Complaint counsel claims: first, that the A&U Study demonstrated that Doan's had a weak image compared to the other leading brands of general purpose analgesics in 1987, before the challenged ads were aired; second, that a Brand Equity Study, conducted mid-way through the campaign in 1993, showed that Doan's was then viewed as particularly effective for back pain and as having a special ingredient -- two claims that were the focus of the new campaign; and third, that a 1996 NFO study, commissioned by complaint counsel for this litigation, showed that users of Doan's and non-users who were aware of Doan's continued to harbor misbeliefs about the superiority of Doan's for back pain six months after the campaign had ended and that the misbeliefs were disproportionately high compared to the beliefs held for other products. One of complaint counsel's experts, Dr. Michael Mazis, also compared the results of these three studies, concluding that Doan's ads created or reinforced a superiority belief.

To counter complaint counsel, Novartis relies on three separate belief studies conducted for this litigation by Mr. Robert Lavidge, Dr. Morris Whitcup, and Dr. Jacob Jacoby. Novartis contends that these studies show that consumers do not have misbeliefs about Doan's. In addition, Novartis contends that the ARS and ASI copy tests and an Aleve Tracking Study, conducted by Ciba when Aleve was introduced into the OTC analgesic market, demonstrate low levels of unaided recall for the Doan's products. Novartis argues that if consumers are unaware of Doan's, they cannot harbor misbeliefs of any kind, and, thus, corrective advertising would be an inappropriate remedy.

***699** The methodology and results of each of these studies are described in Appendix I. [FN24] The Brand Equity, Jacoby, and Lavidge studies used a mall intercept method. The A&U, Aleve Tracking, and Whitcup studies were conducted by telephone. Dr. Whitcup testified that telephone surveys are the most appropriate way of assessing consumer attitudes because their samples are most representative of the total population. [FN25] Whitcup Tr. 2107. Finally, the NFO study used a mail panel method. Mail panel research involves mailing research instruments to individuals who previously have agreed to serve as survey participants. These individuals complete and return the research instrument. The mail panels used by NFO were designed to achieve demographic balance. [FN26] Clarke Tr. 11. NFO panels are especially useful in identifying hard-to-reach consumers because of the large sample size. *Id.*

We initially discuss two criteria that affect the evidentiary value of the parties' consumer belief studies. First, consumer beliefs should be measured without exposing survey participants to the challenged ads. This is because such exposure may elicit the participant's interpretation of the ad rather than his or her beliefs. Second, the universe of participants surveyed should be properly selected to eliminate usage bias and to compare relevant groups. In testing for credence claims about a product, where consumers may have difficulty objectively evaluating the product's performance, the survey should insert controls to counter bias stemming from the use of the product.

1. Exposure to Advertising

All of the studies but one asked participants questions about their beliefs without exposing them to ads. Only the Lavidge study showed consumers television ads for four OTC products prior to questioning. Both complaint counsel's expert, Dr. Mazis, and respondent's expert, Dr. Jacoby, testified that the appropriate way to measure beliefs is ***700** without exposure to ads. Mazis Tr. 1276; Jacoby Tr. 2962, 2968, 3155. By exposing consumers to advertising before asking questions about their beliefs, it is difficult to determine whether the consumers' responses to questions designed to elicit their beliefs reflect their interpretation of the ad or, in fact, their beliefs. We find that the Lavidge study is not probative of consumer beliefs because, contrary to the first criterion, participants were exposed to advertising as part of the study. [FN27] By contrast, the A&U, Brand Equity, NFO, and Whitcup, studies as well as the relevant portions of the Jacoby study were conducted in keeping with this criterion.

2. The Proper Universe

The appropriate universe is crucial to determine the probative value of any consumer survey. An improper universe can render a survey useless. Experts for both parties agreed that in a survey of consumers' beliefs regarding Doan's superior efficacy, the universe should be limited to those who suffer from and treat back pain. Mazis Tr. 1120; Lavidge Tr. 770; Whitcup Tr. 2109. All of the belief studies, with the exception of the Aleve Tracking Study, limited the universe of participants to those who

suffered from back pain and had used an OTC analgesic product within the previous year. Because the Aleve Tracking Study was not confined to backache sufferers, the results are not particularly useful. [FN28]

The experts part company on the question of whether the survey respondents should be aware of the product for which the beliefs are tested. Complaint counsel's expert, Dr. Mazis, concluded that the appropriate universe for testing consumer beliefs about Doan's would include both people who were users of Doan's and people who were aware of, but not users of, Doan's (aware non-users). With such a universe it would be possible to compare the beliefs of users of ***701** Doan's to users of other products. In order to control for usage bias, it is also necessary to compare the beliefs of people who were aware of the product, but not users, with the beliefs of users of the product. Mazis Tr. 1122-23. On the other hand, Novartis' experts contend that a survey limited to participants who are aware of Doan's would not be representative of the relevant population, and would tend to overstate ratings for Doan's relative to other OTC analgesics. Whitcup Tr. 2182. In their belief studies, Novartis' experts included consumers who were unaware of Doan's. Dr. Jacoby testified that this was an important group of consumers because they were prospective consumers and they were the people to whom the advertising is directed. Jacoby Tr. 2937.

On balance, we conclude that the most reliable studies are those that focus on persons who have used Doan's or are aware of the product . Because our inquiry is whether the Doan's ad campaign has created or reinforced misimpressions about the product's efficacy, it makes sense to direct our attention to those consumers who, in fact, have an opinion about Doan's -- which will necessarily be those who are aware of the product. [FN29]

The soundness of this approach is confirmed by consideration of the problem of user bias. Users of a product tend to rate it more highly than do non-users. Mazis Tr. 992. [FN30] This preference may be attributable, in part, to consumers' inability accurately to evaluate the efficacy of certain products -- such as analgesics -- relative to alternatives. *See American Home Prods. Corp.*, 98 FTC at 282 (Initial Decision). Although the Whitcup and Jacoby consumer studies included consumers who were Doan's users (8% in Whitcup universe and 21% in Jacoby) the studies failed to ascertain the number of remaining consumers who were aware of Doan's, making it impossible to compare the beliefs of consumers who use the product to those who are aware of the product, but are not users. Accordingly, the most reliable assessments of consumer beliefs will be based on comparisons of like groups -- *e.g.*, users of one brand to users of another brand; or aware non-users of one brand to aware non-users of another. Only the NFO belief study used such a methodology. The ***702** NFO demonstrated that 77% of Doan's users and 45% of aware non-users believed that Doan's is superior to other brands. [FN31]

C. The Evidence Supports the Imposition of Corrective Advertising.

Having found that the superior efficacy claim was deceptive, and that a relevant universe of consumers believe that Doan's is superior, we must determine whether (1) the ads created or reinforced that misbelief; and, if so, whether (2) that misbelief is likely to linger. We address each of these issues in turn.

1. The Challenged Ads Created or Reinforced Misbeliefs.

A number of factors influence consumer beliefs about and attitudes toward a product, including advertising, use of the product, recommendations by doctors or others, and packaging. Mazis Tr. 1606-09; Lavidge Tr. 750-52. As a general matter, advertising and usage are among the most important of these factors. [FN32] *American Home Prods.*, 98 FTC at 281. But product usage can be a primary source of a consumer's product image "only if the consumer has the ability to discriminate objectively between various similar products. … Thus, if a consumer is unable to evaluate objectively a product's actual efficacy, the role of advertising as a cause of the consumer image is enhanced." 98 FTC at 410 . Because consumers cannot objectively evaluate OTC analgesics, including Doan's, advertising is an important factor in creating and reinforcing beliefs about such products. Mazis Tr. 1609. The Doan's eight-year advertising campaign created and/or reinforced beliefs and made them more salient, understandable, and resistant to change. Mazis Tr. 1205-06. Indeed, such a long campaign could do both, having initially created and later reinforced beliefs.

After the 1987 A&U study showed that Doan's had a weak image, CX 221-c,d, Ciba launched the challenged advertising

campaign, claiming that Doan's was superior to other general purpose analgesics for back pain and that Doan's contained a special ingredient for that ***703** purpose. Consumer survey data, conducted before final production of the ads, showed that consumers were drawing a superiority claim for back pain from the advertising. *See* ID at 62-63. The challenged superiority claims were consistent and made throughout the campaign. In fact, the eight-year campaign presented a focused message of comparative superiority.

The Brand Equity Study, conducted midway through the campaign, provides strong evidence that the advertising had already influenced consumer beliefs. Dr. Mazis' summary of that study shows that users of Doan's put Doan's in the top category for back pain efficacy twice as often as users of Tylenol, Advil and Motrin gave such a rating to the products they used. CX 480-a. Non-users who were aware of the product also rated Doan's more highly than the other brands (though less dramatically so) . CX 480-c. Thus, in five years, the Doan's brand developed from having a weak image to being viewed by users and those aware of the brand as particularly effective for back pain. [FN33]

Moreover, changes in consumer beliefs during that five-year period closely tracked the claims made in the challenged advertising. Mazis Tr. 1057. Dr. Mazis' summary sets out the percentage of users and non-users who were aware of Doan's who believed two attributes claimed in the challenged ads (superiority for back pain and use of a special ingredient) and a third that was not advertised (superiority for all kinds of pain). CX 480-c. Consumers tended to perceive Doan's as particularly effective for back pain and also as containing a unique ingredient. [FN34] Mazis Tr. 1058. The non-advertised attribute (effectiveness for all kinds of pain), however, was not believed by many consumers. CX 480. Accordingly, the Brand Equity Study supports the conclusion that the challenged ads played a substantial role in creating or reinforcing consumer misbeliefs about Doan's.

The results of the NFO belief study similarly show that in 1996, a disproportionately high percentage of Doan's users and aware non-users believed that Doan's was more effective than other OTC pain ***704** relievers for back pain relief. CX 482. Dr. Mazis testified that the Doan's advertising played a significant role in creating or reinforcing the superiority belief. Mazis Tr. 1216-18.

Dr. Mazis also compared the results of the 1987 A&U Study with the 1996 NFO study. He testified that this analysis shows that "superior efficacy" beliefs for Doan's relative to Advil, Bayer, and Tylenol increased (between 0.5 and 1.25 scale points on a seven-point scale) between 1987 and 1996 relative to other brands, as did beliefs that Doan's has a "special ingredient" (between 0.75 and 1.875 points). At the same time, consumer beliefs that Doan's "is safe to use" -- a claim not made in its advertising campaign -- declined in rough proportion to the other products. CX 532-e, h, k; Mazis Tr. 1244-45. Dr. Mazis concluded that this striking pattern, in which changes in consumer beliefs mirrored advertising themes (or their absence), confirms that the ads created or reinforced the misbeliefs. Mazis Tr. 1246. The ALJ rejected Dr. Mazis' comparison of the studies because of the differences in their methodologies and questions asked. IDF 350. While we acknowledge the methodological differences between the studies, we believe that these data nonetheless corroborate the connection between the ads and the misbeliefs. [FN35] *See* IDF 351, 352.

We reject respondent's contention that the Aleve Tracking Study and the Whitcup Study demonstrate a low unaided recall of Doan's advertising, so consumers cannot harbor misbeliefs about Doan's. RRAB 61, 62 . We have already noted that because the Aleve Tracking Study was not confined to back pain-sufferers, its results are not useful. It tends to understate those consumers who may have beliefs about Doan's and did not ask back pain-specific questions. And the results of the Whitcup study are undermined by the small number of Doan's users sampled (35) in contrast to the number of Tylenol users (190) and Advil users (121). RX 2-z-49. Indeed, Dr. ***705** Whitcup himself appended the letter "c" (designating "caution" due to a small base) to data regarding Doan's user responses.

As in its attack on materiality, respondent argues that the Whitcup, Lavidge, and Jacoby studies show that a majority of consumers do not believe that any OTC analgesic brand was more effective than others for relieving back pain, RRAB 63, 64, presumably rendering advertising ineffectual in creating or reinforcing any superior efficacy beliefs. Even if those studies show that a *majority* of consumers so believe, a *substantial number* of respondents remain who believe that one brand may be more effective than others. *See* RX 23-j; RX 2-t; RX 6-j. The results do not shed light on whether the challenged ads created or reinforced misbeliefs in the minds of these remaining consumers.

Novartis also recycles its argument that, even if consumers harbor misimpressions about Doan's, such beliefs are due to Doan's ninety-year positioning as a back-specific analgesic and not to the challenged ads. RRAB 75-77. In fact, however, there is no record evidence to support respondent's speculation. To the contrary, the A&U Study showed that Doan's historical positioning did not have a major impact on consumer beliefs, and that the product's image remained weak prior to the commencement of the ad campaign at issue here. CX 221-c. As the evidence discussed above shows, the ensuing multi-million dollar, eight-year campaign was successful in enhancing the product's image by persuading consumers, incorrectly, of Doan's superior efficacy. In any event, even if that misimpression existed to some degree prior to the ad campaign, the campaign at the very least had the effect of *reinforcing* such beliefs, which to supports a corrective advertising remedy. *See* *Warner-Lambert Co.*, 562 F.2d at 762. In fact, the campaign could have both created and reinforced misbeliefs in that beliefs may have been created and later reinforced.

We likewise reject respondent's argument that complaint counsel failed to establish a link between consumer beliefs and the challenged advertising. Respondent claims that the NFO study is flawed because Dr. Mazis did not ask survey participants whether they were aware of Doan's advertising. RRAB 79. [FN36] While a specific question asking whether participants recalled the challenged advertising might have ***706** been useful, we find that the failure to include such a question was not a fatal flaw. The evidence of parallel changes in consumers' beliefs about Doan's that track the course of the eight-year campaign sufficiently establishes the link between the challenged ads and the resultant misbeliefs.

Respondent further claims that the ads did not create or reinforce misbeliefs because the campaign was ineffective in communicating its superiority message (again repeating a claim employed to attack materiality). Novartis argues that Doan's used a small advertising budget and relied on "worn out" ads. *See* e.g., RAB 16, 23; RRAB 1. Such a campaign, it claims, would be incapable of creating misbeliefs in the minds of consumers that would justify corrective advertising. This line of argument, however, is not only inconsistent with the evidence already discussed regarding the campaign's actual effects but is also belied by Ciba's actions during the campaign, which evince its reliance on the campaign.

Ciba continually refined its marketing plans in response to changing demographic information. Ciba conducted research to define precisely the target audience of backache sufferers and revised its media plans accordingly. For example, after learning that its target audience was disproportionately female and Southern, the yearly marketing plans considered these factors in developing media strategies and ad placement. CX 335-z-14; CX 343-z-64. Ciba's decision to test Spanish radio ads in Houston during short periods in 1991 and 1993 is another example of Ciba's responsiveness to changing demographics. Similarly, when competitors entered the market, Doan's responded through defensive advertising. When Nuprin Backache was introduced in the first half of 1993, Ciba increased Doan's television advertising budget by approximately $500,000. CX 357-b. When Bayer Select Backache was introduced, Ciba increased its spending to run more advertising during the new product's introductory period. CX 378-k. A Marketing Director wrote that Doan's used "a consistent strong advertising campaign to defend and even build share in the face of these new competitors ." CX 399-b.

Finally, Novartis' resort to market share data and statistics wholly fails to show that the ads could not have created or reinforced consumer misbeliefs. Respondent claims that Doan's unit sales actually declined during the relevant period; that even when measured against OTC analgesics used to treat backache, Doan's market share stood at 5%; that Doan's was unable to increase its sales and market ***707** share even after dropping its price, [FN37] and that any increases in factory or consumer dollar sales resulted from the introduction of the Extra Strength and PM lines. RAB 17-19. In fact, the sales volume fluctuated during these years rather than declining and Novartis' expert, Dr. Scheffman, relied upon incomplete data that did not extend beyond 1993. RX 189-a. Volume sales increased by 10% in 1995. CX 402-c; CX 408-h. Further, Doan's share of the total analgesic category grew from 0.8 to 0.9% between 1993 and August 1995, a 12.5% increase, and there was nearly an 80% increase in factory sales. JX 2B ¶17. Moreover, in a mature market, a key criterion for advertising success is maintenance of market share. Stewart Tr. 3467. And, a variety of marketing plans during the relevant period indicate that sales were responding well to ads. CX 360-z-43; CX 393-q; CX 408-i. Accordingly, we conclude that the challenged ad campaign was successful, and that the challenged ads created or reinforced misbeliefs among consumers regarding the superior efficacy of Doan's.

2. The Effects of the Challenged Ads Are Likely to Linger.

We next turn to the question whether the misimpressions caused or reinforced by the challenged advertisements are likely to linger in the absence of corrective advertising.

The NFO study, conducted six months after the ads ceased, demonstrates that 77% of Doan's users and 45% of those who were aware of but did not use Doan's believed that the product was superior to other brands for the treatment of back pain. These percentages are disproportionately high for both groups relative to other brands. [FN38] Thus, the NFO study shows that, for at least six ***708** months after the challenged ads stopped being aired, their effect continued to linger.

A Novartis expert, Dr. James Jaccard, re-analyzed the NFO data, attempting to measure the magnitude of the differences in brand attribute ratings, RX 132 f-o, and to demonstrate that there likely are not meaningful differences in brand efficacy beliefs held by those who use or are aware of Doan's and those who use or are aware of other OTC analgesics. Jaccard Tr. 1427. In fact, Dr. Jaccard's testimony does not undermine the conclusions of Dr. Mazis and the NFO study.

First, Dr. Jaccard has no expertise regarding the OTC analgesic market and does not know whether any of the differences in effectiveness beliefs in the NFO study were significant. Jaccard Tr. 1523. Second, he conceded that traditional null hypothesis testing, as used by Dr. Mazis, is the dominant analytic technique, Jaccard Tr. 1510, and that his own approach is not common. Jaccard Tr. 1444-45. Third, Dr, Jaccard acknowledged that the differences observed in the NFO study might be practically significant. Jaccard Tr. 1450-51.

A number of factors that support the results of the NFO study also support an inference that consumers' false beliefs are likely to endure . *See* *American Home Prods.*, 98 FTC at 411. Specifically, the challenged claims were (1) very salient to consumers (because superior efficacy is among the primary considerations for a consumer in selecting a back pain remedy), (2) clearly and consistently conveyed by the challenged ads, and (3) an integral part of an eight-year campaign. Respondent spent approximately $65,000,000 disseminating these claims, primarily in fifteen-second ads whose primary message was the false superiority claim. The ads reached between 80 and 90% of Doan's target audience approximately 20 to 27 times each year. JX 2F ¶ 28. A likelihood of lingering effects can also be inferred from copy tests, which demonstrated that consumers drew a superiority claim from the Doan's ads after just one or two exposures. [FN39] *See* *Warner Lambert*, 86 FTC at 1470.

***709** Novartis' expert, Dr. Scheffman, testified that any misimpression created by the Doan's ads is not likely to linger due to Doan's insignificant advertising spending and the placement, length, and frequency of the challenged advertising compared to the amount of advertising in the OTC analgesic marketplace. Scheffman Tr. 2612-13. We reject the argument that market share, total sales, or the relative size of the advertising budget determine whether a misbelief is likely to linger. All of these factors go primarily to the purported *magnitude* of the harm created by the deceptive ads and not to the likelihood that the misbelief will linger. [FN40] Moreover, niche marketers who engage in deceptive campaigns should not be immune from a corrective advertising requirement simply because of the relative size of their advertising budget or market shares.

Respondent also contrasts the evidence of lingering misbeliefs in *Warner-Lambert*, in which we ordered corrective advertising, to that in cases where we declined to order corrective advertising. RRAB 96. Novartis argues that we have rejected corrective advertising in three cases where challenged ads were disseminated for a longer period of time than those in this case, where the advertising budget for the challenged campaign was larger, and where there was higher consumer recall of the specific challenged claims. RRAB 47.

We disagree that such a comparison counsels against corrective advertising here. First, we have frequently noted that the amount of evidence in *Warner Lambert* was unusually strong and far exceeded the threshold needed to impose corrective advertising. "We emphasize that we do not believe corrective advertising may only be imposed where there is an evidentiary basis like that in *Warner-Lambert.*" *American Home Prods.*, 98 FTC at 408 n.93 (citations omitted.). [FN41] Second, none of the three cases relied upon by respondent involved comparable evidence to support a corrective advertising remedy. In *Bristol-Myers Co.*, 102 FTC 21 (1983), complaint counsel introduced "no evidence" that misbeliefs would likely linger. *Id.* at 380. We declined to infer a likelihood of lingering solely from the face of the challenged ads. *Id.* Similarly, in *American Home*

Products ***710** *Corp.*, we refused to infer a likelihood of lingering merely from the nature of the ads notwithstanding a total absence of evidence on that issue in the record. [FN42] 98 FTC at 409. In *Sterling Drug, Inc.*, 102 FTC 395 (1983), we found that the misrepresentations had not created or reinforced misbeliefs in light of studies conducted both before and after the challenged campaign revealing the same levels of consumer misbeliefs. [FN43] *Id.* at 798. These cases are easily distinguished from this one, where extensive evidence supports each prong of the corrective advertisement test. [FN44]

Respondent next contends that low unaided brand awareness, evinced by consumer survey testing, demonstrates that the ads did not convince consumers that Doan's is more effective than other brands, [FN45] RAB 39-40, 73-75; RRAB 59, and thus no misbeliefs can linger. The advertising penetration data are not probative. Apart from the serious methodological flaws with the belief studies noted above, [FN46] this low brand awareness -- even assuming it exists -- is relevant only to the magnitude of the harm that respondent's false ads caused, and not to the likelihood that such harm as was caused will linger.

The ALJ found that the ARS and ASI studies, revealing 2 to 8% recall of a "more effective" or a "good product/better/best" message after 24 and 72 hours, suggest that any misbelief may be transitory. ID at 64. We disagree. These were communication studies that asked what the ad said or showed, not what consumers believed about the product. The data from these tests thus do not establish the nonexistence of consumer misbeliefs. Consumers may hold beliefs about a product without recalling advertising that contributed to such ***711** beliefs. *See* Jacoby Tr. 3201. This is especially true with respect to a credence good, such as an OTC analgesic, for which consumers cannot easily evaluate the truth or falsity of claims. Moreover, the studies do not even purport to measure the duration of misbeliefs among those who were, in fact, misled, which is, after all, the relevant inquiry.

The record establishes that consumers held misbeliefs about Doan's superior efficacy, that such beliefs were created by or substantially reinforced by the challenged advertising campaign, and that those beliefs are likely to linger into the future. Therefore, we find that the elements for corrective advertising are satisfied, and that corrective advertising is appropriate and necessary.

Corrective advertising is appropriate for an additional reason. We previously discussed the factors which, separate from the NFO study, support an inference that misbeliefs about the superior claim are likely to linger. Another inference arises under these facts. We cannot turn a blind eye to the obvious relationship between an absolute efficacy claim ("this product works"), which Doan's has been running for ninety years, and a comparative efficacy claim ("this product works better than others") . Given that Novartis' advertising campaign fostered a symbiotic relationship between these two claims, simply to permit Novartis to return to its ninety-year old positioning of Doan's as a backache product makes it all the more likely the misbeliefs will linger -- absent some corrective action.

3. Content of the Corrective Message

Dr. Mazis testified that, as a general matter, proper corrective advertising accomplishes its intended effect of dissipating misbeliefs over time. IDF 358-59. Studies designed to track the impact of corrective advertising imposed in *RJR Foods, Inc.*, 83 FTC 7 (1973) and *Warner Lambert* support this conclusion. IDF 360.

The corrective message should (1) state that Doan's products are effective; (2) correct the lingering misbelief that Doan's products are superior to other products; and (3) permit respondent to continue to advertise Doan's specifically for back pain. [FN47] The following corrective message proposed by complaint counsel satisfies all of these requirements: "Although Doan's is an effective pain reliever, ***712** there is no evidence that Doan's is more effective than other pain relievers for back pain." We find that this slightly longer version of the corrective message is more balanced than the suggested alternatives for shorter television or radio ads. We recognize the FDA monograph allows pain specific advertising and do not want to impede Novartis' ability to make claims specifically allowed by FDA. For all these reasons, the corrective message in the present matter is inevitably somewhat complex.

Both parties conducted studies to test the effectiveness of this corrective message. Dr. Mazis tested the message in FSIs in a telephone survey involving 370 consumers. [FN48] Dr. Mazis concluded that the corrective message was effectively com-

municated with a very low level of miscommunication of the unintended message that Doan's is less effective. [FN49] Dr. Jacoby criticized the study because he did not believe that a mail panel method was appropriate to test the corrective message as a general matter. He also criticized the use of FSIs to test the corrective message since FSIs were not a large part of the advertising campaign.

Dr. Whitcup conducted a study of the same corrective message using a mall intercept methodology with the corrective message placed on the product package. Dr. Whitcup concluded that the corrective message did not convey the intended message to consumers [FN50] -- of the 35% who saw the disclaimer, 10% got it wrong. Dr. Whitcup argued that number to be high given the small number who recalled the disclaimer at all. Accordingly, he concluded that the corrective message did not do a good job of communicating its message. Dr. Mazis criticized the Whitcup study, noting that the ***713** corrective message appeared in a cluttered context. He found that the message was inconspicuous and difficult to read. Mazis Tr. 1353-56.

We find that the Mazis study is probative of the effectiveness of the corrective message. We also find that the Whitcup package study actually confirms the effectiveness of the corrective message. We believe that the different levels of communication between the Whitcup product package study and the Mazis FSI study result from their differences in the conspicuousness of the disclosure and the fact that packages contain a great deal more information than advertising.

Although we have no data to determine at what level the message would be communicated in a 15-second television or radio ad, we believe that the corrective message would be difficult to communicate in such a short ad without unduly restricting respondent's ability to also convey its advertising message. Accordingly, we require that the corrective message appear on all advertising except television and radio ads that are 15 seconds or less in duration. The corrective message must also appear on the product package. Including the corrective message on the product packaging is especially important because, as Dr. Whitcup testified, packaging is a particularly ubiquitous form of advertising in that people have to pick up the product in order to purchase it. Dr. Whitcup also noted that in deciding what product to buy, consumers may compare packages. *See* Whitcup Tr. 2286.

We reject complaint counsel's recommendation that the duration of the corrective message be determined by a performance standard. In *Egglands Best*, we required the corrective message to appear on the package for one year. 118 FTC 340, 357. In *Warner Lambert*, we required the corrective message to appear in all advertising until the respondent had expended a sum equal to the average annual Listerine advertising budget for a ten-year period. 86 FTC 1514-1515. The Court of Appeals affirmed, stating: "[T]he corrective advertising order in this case, by tying the quantity of correction required to the investment in deception, is tailored to serve the legitimate governmental interest in correcting public misimpressions as to the value of Listerine and no more." In a footnote, the court went on to say: "As a result, any imprecision in the order's scope would seem likely to inure to Warner-Lambert's benefit." 562 F.2d 771.

We believe that a hybrid approach -- advertising expenditures and specific length of time -- is the best method for determining when the ***714** corrective message should terminate. If we were to require that the corrective message appear in advertising until Novartis has expended a specific amount of money on advertising, Novartis could choose to advertise for a short period of time in an expensive way. If we were to require the corrective message to appear only for a specific period of time, then Novartis could choose not to advertise for that period of time. [FN51] Accordingly, we order that the corrective message appear for one year on all packaging and advertising, except radio and television ads of 15 seconds or less in duration, and until Novartis has expended on Doan's advertising an amount equal to the average spent annually during the eight years of the challenged campaign. [FN52] In contrast to complaint counsel's proposed performance standard, as the Court of Appeals found in the *Warner Lambert* matter, any imprecision in the scope of the order is likely to inure to Novartis' benefit. [FN53]

Respondent argues that complaint counsel's proposed corrective advertising order violates the First Amendment. RRAB 106. Respondent argues that the corrective message does not convey the intended message and may be confusing. In addition, it argues that the corrective notice will be punitive because it will have a negative influence on consumers' beliefs about Doan's. RRAB 104. Further, it argues that the message would force it to abandon the 15-second ad format. RRAB 110. Finally, it argues that the corrective message "carries an unacceptable risk of forcing Doan's to abandon its back pain specific positioning and thus forcing Doan's off the market." RRAB 106. These arguments rely on respondent's assumption that the corrective message

could be perpetual because of the performance standard suggested by complaint counsel.

We reject these arguments. First, the corrective remedy is of a finite duration. Second, it will not force respondent to abandon 15-second ads because it does not apply to such ads. Third, the corrective message was effectively communicated and is not unduly confusing or misleading. Finally, it is not punitive to require respondent to tell the truth.

***715** We now turn to the specific First Amendment arguments. Respondent asserts that complaint counsel's proposed corrective advertising provision would prevent it from truthful speech and require it to underwrite speech about the merits of other brands. RRAB 107-108. It relies on *Ibanez v. Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136 (1994). That case involved a reprimand by the Florida Board of Accountancy ("Board") of a Florida attorney for including her Certified Public Accountant and Certified Financial Planner credentials in her advertising and other communication to the public. *Id.* at 139-41. The United States Supreme Court noted that the challenged statements were true and that the government had nothing more than speculation or conjecture to support its fear that the listing of her credentials would, in fact, mislead consumers, by implying compliance with the relevant state accountancy regulations. *Id.* at 143, 144-47. In the present matter, we are not dealing with an across-the-board ban on truthful speech as was the case in *Ibanez*, but with commercial speech which was subject to an adjudicative proceeding and was found to be deceptive.

While commercial speech is entitled to First Amendment protection, misleading speech is not protected and may be banned entirely. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 477 U.S. 557 (1980). Nonmisleading commercial speech may be regulated if the regulation meets a three-prong test: (1) the government's interest in regulating the speech must be substantial; (2) the regulation must materially and directly advance these interests; and (3) the regulation must be no more extensive than is necessary. [FN54] *Id.* at 566.

We apply the *Central Hudson* test to the facts of this case. First, the government has a substantial interest in protecting consumers from deception. *See Warner Lambert*, 562 F.2d at 771. Thus, the first prong of the test is satisfied.

With respect to the second prong, we find that the corrective advertising remedy directly and materially advances the aforementioned governmental interest. We have determined that the challenged advertising has created or substantially reinforced misbeliefs in the minds of consumers and that those beliefs are likely to linger into the future. As discussed above, the corrective ***716** advertising remedy we order has been copy tested by both parties, and the results show that it effectively communicates the desired message. Accordingly, we conclude that the corrective advertising remedy advances the governmental interest in preventing future deception by correcting the lingering effects of Doan's past false advertising.

Finally, we conclude that the remedy is no more extensive than necessary. Our order is narrowly drafted to correct the misbelief at issue. We have balanced the need for correcting the lingering misbeliefs of consumers against Novartis' ability to advertise effectively. In doing so, we have been mindful of imposing less restrictive alternatives where appropriate. Therefore, we have specifically exempted television and radio ads whose duration is 15 seconds or less to achieve the proper balance. Accordingly, we find that the last prong of *Central Hudson* has been satisfied.

V. CONCLUSION

After a careful review of the entire record and after consideration of all the arguments made by the parties, we believe that Doan's advertising claims were material, the required elements of corrective advertising have been satisfied, and a corrective advertising remedy is appropriate.

FN1. Novartis is the successor-in-interest to Ciba-Geigy Corporation and Ciba Self-Medication, Inc. On April 23, 1997 the ALJ issued an order, pursuant to the agreement of the parties, substituting Novartis for Ciba as respondent in this proceeding.

FN2. We are in general agreement with the dissent regarding the applicable legal standards. The disagreements are over differing interpretations of the evidence.

FN3. Ciba acquired the Doan's brand from DEP Corporation in early 1987. DEP Corporation had acquired the brand from Jeffrey Martin, Inc. shortly before. JX 2A ¶ 12. From January 1987 to December 1994, Ciba was responsible for the marketing and advertising of Doan's analgesic products. In December 1994, Ciba transferred the Doan's line of products to CSM, a wholly-owned subsidiary. CSM was responsible for the marketing and advertising of Doan's analgesic products from December 1994 to March 1997. JX 2A ¶ 13.

FN4. References to the record are abbreviated as follows:

IDF Initial Decision Finding
ID Initial Decision
Tr. Transaript of Trial Testimony
CX Complaint Counsel's Exhibit
RX Respondents' Exhibit
JX Joint Exhibit
RAB Respondents' Appeal Brief
CCAB Complaint Counsel's Answering and Cross-Appeal Brief
RRAB Respondents' Reply and Answering Brief
CCRB Complaint Counsel's Reply Brief

FN5. These products include Ascription, Ciba Vision, Desenex, Dulcolax, ExLax, Gas-X, Habitrol, Maalox, Sunkist Vitamin C, Tavist-D, Theraflu, and Triaminic. IDF 5.

FN6. In contrast to ads that are aired every week, flights are ads that air for several weeks and then are off the air for several weeks. Peabody Tr. 130.

FN7. For TV, radio, or other broadcast advertisements, Novartis would have the option of substituting either of the following corrective notices: “There is no evidence that Doan's is more effective for back pain relief than other over-the-counter pain relievers;” or “There is no evidence that Doan's is more effective than other pain relievers for back pain.”

FN8. The performance standard was modeled after the 1996 NFO belief study relied upon by complaint counsel in this litigation.

FN9. In its appeal brief, Novartis states that while it “disputes the [ALJ's] finding that the challenged Doan's advertisements conveyed an implied superior efficacy claim to the requisite number of consumers under applicable precedent, it does not challenge that finding for purposes of this appeal.” RAB 6. Novartis repeats that its appeal “challenges only the ALJ's conclusion that complaint counsel established the materiality of the alleged superiority claim,” in its reply brief. RRAB 2. In a footnote, Novartis states that it is not conceding that the claim was communicated. *Id.* 2 n.1. By failing to appeal the issue, however, Novartis *has* conceded the issue for purposes of this litigation.

FN10. Graph (CX 13) ran from May 1988 through June 1991; X-Ray (CX 14) ran from August 1989 through June 1991: Black & While (CX 15) ran from June 1991 through October 1992; Black & While Pan (CX 16) ran from December 1992 through June 1994; Ruin A Night's Sleep (CX 17) ran from January 1992 through August 1992; Ruin A Night's Sleep (CX 18) ran from August 1993 through June 1994; Activity Playtime (CX 20) ran from July 1994 through July 1995; Activity Pets (CX 22) ran from July 1994 through July 1995: and Muscles (CX 23) ran from August 1995 through June 1996. JX 2E ¶ 25.

FN11. Bruno & Ridgeway used a mall intercept methodology where qualified respondents were shown mock-ups of the ads and then asked questions. CX 224-d; Peabody Tr. 160. A mall intercept study is conducted in suburban shopping malls in different cities. Interviewers posted in the mall solicit passersby to participate. Interviewers first determine whether a participant meets the demographic requirements of the study. If so, the participant is shown materials and asked questions. Peabody Tr. 358. Mall intercept studies are sometimes criticized as less demographically balanced than mail panel or telephone surveys

because mall-goers are not necessarily representative of society at large. *See* Peabody Tr. 204. Tests of this nature are referred to as forced-exposure communication tests.

> Thirty-eight percent of the consumers tested indicated that the "Graph" ad communicated, as a primary or secondary message, that Doan's was "superior to other products." CX 224-m. In response to open-ended questions, 44% of the consumers who saw the "Black and White" and gave answers that were coded as "superiority over other products." CX 236-j. If responses to all of the open-ended questions are netted, 62% indicated that at least one ad conveyed a superiority claim. CX 236-m. Similarly, the results for "Ruin A Night's Sleep" ad reported that 23% of Doan's users and 38% of Doan's non-users gave answers that were coded "superiority over other products." CX 244-h, v.

FN12. ASI tests expose consumers to commercials during pilot shows on unused cable channels. The consumer watches one or two pilots with test commercials embedded for Doan's and other products. Twenty-four hours later, consumers are called and asked questions about the ads. Peabody Tr. 181-83. ARS testing is similar to ASI testing except it is done in a theater-like setting, often at a hotel. Three days after seeing the pilot, consumers are called and asked questions about the ads. Peabody Tr. 350-52.

FN13. Specifically, Novartis argues that a 1990 ASI copy test of "Black and White Back" reported that only 3% of the respondents questioned twenty-four hours after exposure to the ad reported that it communicated "product superiority," and that only 1% reported that it was "more effective/works better" in comparison to other products. Peabody Tr. 389; RX 98-h. Novartis also relies on ARS copy test data from 1991, 1993, 1994 and 1995 to show low percentages of consumer recall for a "more effective" or "good product/better/best" message within one to three days after exposure to the ads. RX 89-z-20; RX 32-y; RX 33-z-4; CX 265-z-2,3.

FN14. The "placebo effect" is the tendency of patients to respond favorably to a treatment regardless of the treatment's medical efficacy. *See Thompson Med. Co.* 104 FTC at 715 (Initial Decision.) The "usage effect" is the tendency of users of a product to rate it more highly than non-users of the product. Mazis Tr. 992, 1055-56. Users tend to use a product because they believe it works and thus lend to give it higher ratings than non-users. *Id.*; Jacoby Tr. 2987. This may be attributable, in part, to consumers' inability to evaluate effectively the efficacy of OTC analgesic products they use. *See American Home Prods. Corp.*, 98 FTC at 282 (Initial Decision).

FN15. The record establishes that approximately 50% of adults in the United States suffer from back pain; thus, the treatment of that pain is an important health concern. CX 388-b.

FN16. Novartis also argues that the evidence shows that consumers did not find the challenged ads interesting or persuasive. RAB 57-59. Even if this were the case, in the context of the materiality inquiry, it is the challenged claim that is at issue and not the ad as a whole.

FN17. Along with its market *performance* arguments, Novartis advances a market *positioning* argument. Novartis contends that any superior efficacy belief that caused consumers to purchase the product was not the result of the misleading claim contained in the advertising, but rather was the result of product usage and Doan's historical market positioning as specifically for treating back pain. RAB 75-76. We reject this argument. The materiality inquiry focuses on the claim and its effect, not on other conceivable sources of consumer beliefs. Respondent's arguments — that if an advertiser is able to point to other possible sources for the misbelief engendered by its misrepresentation, it should be free to continue making its misrepresentation — is untenable.

FN18. Novartis argues that unit sales, and not dollar sales, is the more appropriate measure. Novartis contends that the strength of the dollar sales is misleading because it is attibutable to the introduction of premium priced line extensions, namely Extra Strength Doan's and Doan's PM. These line extensions, however, were supported by the same advertising as regular Doan's and to the extent that the advertising was successful in convincing consumers to buy these premium-priced items, the profits made on these products suggest that the ads were having their desired effect.

FN19. For example, the existence and strength of competitors, the availability of substitute products, the maturity of the market, the state of domestic and foreign economies, general business cycles, distribution issues, and minds in consumer preferences, among other factors, can all affect market performance and do not relate to an unsubstantiated superior efficacy claim made in an advertising campaign.

FN20. In the first place, respondents puffing argument goes to ad interpretation, an issue properly considered in connection with the second prong of the deception analysis, rather than to materiality. *See* Deception Statement, 103 FTC at 18 1 (puffing addressed as part of the discussion of the reasonable consumer's interpretation of the claim). As noted above respondent has expressly waived any challenge to the second prong.

FN21. Two of the six were challenged commercials, "Activity Playtime" and "Muscles." The remaining four were non-challenged controls. RX 5-z-101 n.1 .

FN22. Question 6a asked the main idea of the commercial, and 6b asked about the other ideas the commercial was trying to get across. RX 5-z-96. Question 8a asked whether the commercial said, showed, or suggested that the advertised brand was more effective than other brands, and question 8b asked what the commercial said, showed or suggested that conveyed a superior efficacy claim. *Id.*; RX 5-z-139; RX 5-z-141. The results from these questions reveal a substantial communication rate for the challenged ads — depending on the question, in the 30 to 50% range. Rx 5-z-120-129; 139-148.

FN23. *Warner-Lambert* was a remarkable case. "Comparable proof of deception-perception-memory influence would be virtually impossible in most advertising cases .... corrective advertising must apply to more than the one-in-a-million type of ad campaign present in *Warner-La mbert*." R. Pitofsky, *Beyond Nader: Consumer Protection Regulation of Advertising.* 90 Harv. L. Rev. 661, 698 (1977) (footnote omitted).

FN24. As the Commission stated in *Stouffer* "[p]erfection is not the prevailing standard for determining whether a copy test may be given any weight. The appropriate standard is whether the evidence is reliable and probative." 118 FTC at 807. While a given study may be flawed in some respects, it still can be probative, and any deficiencies simply will affect the weight given to the evidence. *Id.*

FN25. Random digit dialing reaches both listed and unlisted numbers. Whitcup Tr. 2108.

FN26. Mail panel participants may under-represent those with the lowest incomes (who may not have a permanent address or may be illiterate) and those with the highest incomes (who disproportionately decline to participate). Clarke Tr. 13.

FN27. There are other flaws in the Lavidge study which may tend to understate the frequency of superior efficacy beliefs regarding Doan's. Dr. Mazis testified that it was difficult for consumers to answer the questions used in that study, because it required participants to sort through all the brands of which they were aware and then to make judgments about them. Mazis Tr. 1274-76. Moreover, Mr. Lavidge failed to control for usage bias; therefore, the fact that fewer of his participants used Doan's than used other products understated the superiority beliefs regarding Doan's. Mazis Tr. 1271. Mr. Lavidge even acknowledged that personal experience with a product is very important in shaping a consumer's beliefs about the product. Lavidge Tr. 750. The ALJ rejected the Lavidge study. IDF 310.

FN28. Admittedly, the purpose of the Aleve Tracking Study was to track the introduction of Aleve on the OTC market generally, although it did develop some information about Doan's. Dr. Mazis testified that the respondents in the Aleve Tracking Study were not focusing on back pain, so a back pain-specific product would be much less likely to be recalled. Mazis Tr. 2016.

FN29. Indeed, when Ciba itself tested consumer beliefs in the regular course of business, it limited its samples to those who were aware of the product. The A&U Study and the Brand Equity Study were confined to consumers who were aware of Doan's.

FN30. *See* infra n. 13.

FN31. The Jacoby study, as far as it goes, actually corroborates the results of the NFO study. For example, in the Jacoby study, 38% of Doan's users reported Doan's as "more effective" in contrast to 23% of Advil and 17% of Tylenol users who reported their brands as "more effective." RX 5-z-105.

FN32. Indeed, word-of-mouth recommendations largely depend upon prior exposure to advertising and product usage. *American Home Prods.*, 98 FTC at 281.

FN33. Respondent argues, and the ALJ found, that the attribute of "being particularly effective for back pain" does not necessarily imply that a product is "more effective than other OTC pain relievers for back pain relief," and thus that the Brand Equity Study is not probative of superiority beliefs. IDF 246. We disagree. A product that is no more effective than any other would not be "particularly" effective. The word "particularly" is inherently comparative. *See, e.g., Webster's New International Dictionary* 1783 (2d ed. 1938) (defining "particularly" as "[e]specially, unusually").

FN34. Dr. Mazis testified that consumers would not infer that a product had a special ingredient for back pain simply from the fact it is only advertised and marketed for back pain. Mazis Tr. 1621.

FN35. Contemporaneous documents further indicate that Ciba's ad agency, Jordan McGrath, recognized that the challenged advertising was affecting superiority beliefs about Doan's among consumers. One such document from 1994 stated that:

> [t]he 1993 Brand Equity study showed that the specificity of Doan's positioning, as communicated by "The Back Specialist" campaign line has helped differentiate the Brand from other pain relievers. Clearly this unique positioning has contributed to this.

CX 387-y. (Doan's FY '95 Marketing Plan Key Issues, July 25, 1994.)

> Similarly, Jordan McGrath's Vice President Account Supervisor who worked on the Doan's account noted the effectiveness of the challenged claims: "'The Back Specialist' we have kind of engraved that in the consumer's mind ." CX 503 at 97 [Jackson Dep]. Other Ciba documents indicate the significant role that advertising played in driving Doan's sales. CX 404-a-b; CX 499-a.

FN36. Dr. Mazis testified that he did not ask whether people had seen advertising for Doan's because at the time of the NFO study, the ads had not run for six or seven months, and people might not reliably recall ads that they did, in fact, see. Mazis Tr. 1797. He also testified that beliefs from ads may linger even though recall of specific ad claims may not. Mazis Tr. 1798, 1800.

FN37. Respondent also argues that the low share of usage, conversion rates, and advertising penetration data demonstrate that consumers do not believe that Doan's is more effective than other analgesics for the relief of back pain. RRAB 59-60. At best, these factors serve as an inexact proxy for consumer beliefs. The direct evidence shows that consumers believed that Doan's was superior to other OTC analgesic products.

FN38. Respondent's arguments that the NFO study is flawed, RRAB 67-71, are without merit. As noted above, the NFO study used an appropriately restricted universe, and its protocol was proper and provided reliable results. Respondent argues that the absence of follow-up validation procedures renders the data unreliable. But all experts agreed that the purpose of validation is to deter and detect interviewer misconduct, Mazis Tr. 1128; Lavidge Tr. 788; Jacoby Tr. 2950-51. We therefore find that this mail panel study (which did not utilize an interviewer) did not require validation. Respondent's concern that the wrong household members may have completed the survey questionnaires, thereby rendering the results unreliable, is unwarranted. The study employed mechanisms to account for this possibility, Clark Tr. 40-41, and eliminated questionable responses.

> Finally, Novartis questions the significance of the NFO study results. Dr. Mazis analyzed the different sets of ratings for joint users of Doan's and one of the other five brands and found that, on average, 25% more people rated Doan's as superior for back pain relief. IDF 263. The comparative analysis for non-users who were aware of several products revealed that, on average, 20% more people rated Doan's superior. IDF 265. This demonstrates a strong difference in beliefs among these groups. Mazis Tr. 1196-1199.

FN39. Dr. Mazis testified that the belief's are likely to linger in light of the length and effectiveness of the ads, the fact that they stressed the superiority claim repeatedly, and the recall evidence from the copy tests. Mazis Tr. 1255-56.

FN40. In any event, in a mature market, such as OTC analgesics, a central purpose of advertising is to retain current users and a key criterion for an ad campaign's success is whether it is succeeding in maintaining share, particularly in the face of a competitive onslaught. IDF 335; Stewart Tr. 3467. We find that Doan's was able to maintain and even increase its sales in light of the competitive pressures of new entrants in the back pain category and affirm the ALJ's finding on this point. IDF 336.

FN41. *See, supra,* footnote 23.

FN42. Some of the claims in that case were also secondary to the main message of the ads. 98 FTC at 408.

FN43. Complaint Counsel in that case conceded that the frequency of misbeliefs was not altered by the challenged ad campaign, but argued that the misbeliefs "nonetheless became 'sharper"' as a result thereof. 102 FTC at 799.

FN44. The dissent's emphasis upon the duration of the advertising campaign and dollars spent in these cases neglects the absence in those cases of sufficient evidence demonstrating a likelihood of lingering misbeliefs. This analysis cannot be reduced to a rigid algorithmic inquiry.

FN45. The Aleve Tracking Study indicates that Doan's had a 2 to 3% unaided brand awareness in December 1994 and June 1995, respectively. RX 101-t. None of the 423 respondents in the Whitcup belief study reported "top-of-mind" awareness of Doan's advertising RX 2-o.

FN46. For example, the Aleve Tracking Study focused on general analgesics and was not confined to backache sufferers; thus, it is not surprising that consumers did not mention Doan's, which is not marketed as a general analgesic. Moreover, Novartis' own expert, Dr. Jacoby, conceded that penetration studies are of questionable value in measuring consumer beliefs about a product. People can form and retain beliefs based upon an ad without recalling it. Jacoby Tr. 3201.

FN47. The FDA monograph allows pain-specific advertising, and Novartis is free to make claims specifically allowed by FDA.

FN48. Of the respondents, 145 were Doan's users and 225 were non-users who were aware of Doan's. CX 489.

FN49. In response to the question. "What did the ad say or imply about Doan's?" 38% of the participants indicated that Doan's was the same as or was not proven to be better than other medicines. Only 3 to 4% indicated that it was better or worse. CX 489-p. In response to closed-ended questions regarding what the ad said or implied about Doan's effectiveness for back pain in comparison to other medicines, 69% replied that it was the same or not proven to be better. Between 5 and 8.8% reported that it was better or worse. CX 489-x. Finally, in response to closed-ended questions about what was implied or stated, 75% agreed that the ad implied that Doan's is about as effective for back pain as other OTC pain relievers. None said it was less effective and 17% said it was more effective. CX 489-z.

FN50. In response to an opened-ended question asking what the package said, showed or implied about the product 15% responded that they understood that Doan's was not more effective than other pain relievers. RX 110-q. In response to a closed-ended question as to whether the package compared effectiveness of the product to the effectiveness of other pain relievers, 35% said yes, but 6% said the product was better and 4% said it was worse and 24% said it was the same. RX 110-v.

FN51. Indeed, an internal Novartis document suggests that if we order corrective advertising, they could stop advertising for three years. *See* CX 110-c.

FN52. Respondents spent $65.3 million on advertising between 1988 and 1996. JX 2d ¶ 21. The average annual expenditure on advertising is $8 million.

FN53. Dr. Mazis' expert testimony was that the belief that Doan's is more effective than other OTC pain relievers fro back pain will likely linger for a long time after the claim is no longer disseminated. Mazis Tr. 1255-56. Dr . Mazis' expert opinion is supported by three empirical studies that evaluated the effects of Commission corrective advertising orders. IDF 359.

FN54. Although decided before *Central Hudson, Warner-Lambert* addressed the First Amendment issue and concluded that the First Amendment did not bar a corrective advertising order. 562 F.2d 768-71 (supplemental opinion on petition for rehearing).

APPENDIX

I. THE ATTITUDE & USAGE STUDY

After acquiring the Doan's brand, Ciba wanted to gain a better understanding of the backache category and engaged Arbor, Inc. to conduct an Attitude & Usage Study ("A&U"). CX 221. The specific goals of the 1987 A&U study were to determine awareness and use of Doan's user profiles, brand perception, and reactions to a new Doan's concept. [FN1] CX 221-h. A total of 390 telephone interviews were conducted. [FN2] Almost all respondents were aware of Doan's. CX 221-t. Despite Doan's high brand and advertising awareness, Doan's has been tried by less than one third of backache sufferers. CX 221-v.

***717** In the portion of the study relating to brand perception, one question asked the respondents to rate the brands they were aware of on 14 different attributes. One of the attributes listed was: "Is the most effective pain reliever you can buy for backaches." CX 221-x. The results for this question show that on mean values, Doan's was at 4.4, which was third after Extra-Strength Tylenol, 5.1, and Advil, 4.8. Bayer was fourth at 4.2. CX 221-z-72.

A summary memorandum from the Ciba consumer research department regarding the A&U study to Hal Russo, a member of the marketing department, described the results of the study by saying:

> Overall, Doan's competes in a broad arena, dominated by general purpose analgesics. Doan's has a weak image in comparison to the leading brands of analgesics and would benefit from positioning itself as a more effective product that is strong enough for the types of backache sufferers usually get. Care must be taken in positioning the brand as efficacious so that Doan's is not perceived to be only for very bad back pain. Being seen as for only back pain appears to limit usage occasions and may cause the product to be seen as too strong for frequent use. (emphasis in the original) CX 221-c, d.
>
> The study also noted: STRONG ENOUGH FOR ME is the most important dimension tested and was almost twice as important as the next most important dimension GOOD VALUE. MAXIMUM STRENGTH AND SAFE are the next most important. If a brand is perceived as being for BAD PAIN ONLY, it loses on preferences. Being BACKACHE SPECIFIC is not important. (emphasis in the original) CX 221-z-7.

The study also revealed that Doan's users are more likely to claim to use Extra-Strength Tylenol more often than they are to use Doan's. CX 221-z-21.

The results of the A&U study were used to help create new Doan's advertising. The first new Doan's ad that was created and disseminated after this study was the "Graph" ad. Peabody Tr. 146.

II. BRAND EQUITY STUDY

Five years later, in 1993, Ciba conducted the Brand Equity Study. CX 256. The goal of the study was to establish the current equity and brand image of Doan's and its major competitors in the backache category, to explore how the Doan's position might be optimized versus the incumbent competition, and to establish if there were any other categories where there might be an opportunity for Doan's. CX 256-f. The study was conducted via mall intercept in 10 locations. A total of 336 interviews were conducted among males and females ***718** who suffer from back pain and treat their back pain with OTC products in pill form. All of the respondents were aware of Doan's. CX 256-g.

One aspect of the Brand Equity study was to evaluate how Doan's was perceived on a set of attributes compared to other analgesics used to treat back pain. Specifically, one question listed 21 attributes and used a grid of six boxes adjacent to each of the attributes. CX 260-b. The left hand box was labeled "Unacceptable, brand couldn't be worse." The right hand box was labeled "Ideal, nothing could make brand better." In the middle, above the dividing line on the grid, was the label "Good." Respondents were asked to rate each of a group of analgesics products they were aware of for the treatment of back pain on each of the 21 attributes.

Dr. Mazis created a summary of some of the data obtained from this question because the report itself did not contain a detailed discussion of the results. The data for both users and aware non-users are presented both in terms of "top box" - the right hand box rated "ideal" -- and the "top two box" results -- the boxes to the left of "Ideal." For users of the products, about twice as many people put Doan's in the top box of being particularly effective for back pain as compared to the three all-purpose analgesics -- Tylenol, Advil, and Motrin. CX 480-a. For Doan's aware non-users, the results were also higher than for the other brands, albeit at a lower level. CX 480-c. [FN3]

An Executive Summary describing the study to Ciba management highlights one of the key findings as: "The brand is seen as particularly effective for back pain, and as having a special ingredient." CX 256-c.

The FY'95 Marketing Plan suggests continuing to build on Doan's heritage as "The Back Specialist." It noted that the '93 Brand Equity Study that showed the specificity of Dean's positioning as communicated by the "Back Specialist" has helped differentiate the brand from other pain relievers. It went on to note that: "Clearly this unique positioning has contributed to this as the Equity Study showed the top two attribute ratings for Doan's were ingredients especially for back pain (49%) and Effective for back pain (44%)" CX 387-y.

***719** III. NFO STUDY

Dr. Mazis conducted a belief study for this litigation using National Family Opinion, Inc. ("NFO") a marketing research company which provides mail panel research. [FN4] Mail panel research involves mailing research instruments to individuals who have previously agreed to serve as survey respondents. These individuals then complete and return the research instrument to NFO by mail. NFO sent a screener questionnaire to 40,000 households in October 1996 to identify back pain sufferers/treaters who were Doan's users or aware non-users. CX 420-h. In December 1996, NFO conducted a follow-up survey consisting of 400 Doan's users and 400 Doan's aware non-users selected on a random basis from the larger population of both groups identified on the multi-card screening survey. CX 421-h.

Dr. Mazis concluded that users and aware non-users constituted the appropriate universe for testing beliefs because those who had never heard of the product could not have beliefs about the product. Mazis Tr. 1122. The purpose of the study was to assess beliefs on a number of attributes, but in particular, the "more effective for back pain" attribute and to compare the beliefs of users of Doan's to users of other analgesics for back pain relief, and aware non-users of Doan's to aware non-users of other analgesics. [FN5] Mazis Tr. 1129-30. The purpose of comparing users and aware non-users was to take into account and control for usage effect. [FN6] Mazis Tr. 1199-1201.

A total of 549 households returned surveys. CX 421-h. The results of the NFO belief study summarized in CX 482 show that over three-***720** quarters (77%) of the Doan's users believe Doan's is superior. Between 41 and 62% of users of other brands reported superiority beliefs about their brands. Forty-five percent of Doan's aware non-users held a superiority belief about Doan's, whereas only 17 to 35% of aware non-users of the comparison brands believed those products to be superior to other analgesics. Dr. Mazis concluded that the data for both Doan's users and aware non-users compared to users or aware non-users of each of the five other OTC analgesic products [FN7] show that the level of superiority beliefs for Doan's is substantially higher than it is for any of the competing products. Mazis Tr. 1151.

Dr. Mazis also undertook an analysis of joint users and joint aware non-users of the various products in order to compare their

beliefs about Doan's and their beliefs about other products. Mazis Tr. 1159. This analysis shows disproportionate percentages of both Doan's users and aware non-users believing that Doan's is more effective for back pain. For example, Dr. Mazis looked at individuals who used both Advil and Doan's and compared their beliefs about Advil to their beliefs about Doan's. On average, the proportion of joint users agreeing that Doan's is more effective for back pain than other OTC analgesics was 26% higher than those agreeing that the other brands were more effective. IDF 262, 263; Mazis Tr. 1171-74. This analysis was done for each set of products for aware non-users . On average the proportion of joint aware non-users agreeing that Doan's was more effective for back pain than other OTC analgesics is almost 20% higher than the proportion agreeing that the other brands were more effective. IDF 264, 265; Mazis Tr. 1175-76. Using a two-tailed test, Dr. Mazis calculated that all of the observed differences in the user-to-user comparison for the attribute "more effective for back pain" were statistically significant at the .05 level, as were four of the five [FN8] aware non-user to aware non-user comparisons for the same attribute. Mazis Tr. 1187-89. Dr. Mazis also analyzed the NFO data by applying the Bonferroni adjustment to correct for experiment-wise error. Even after making these adjustments, the results remained statistically significant. Mazis Tr. 1190-96.

***721** IV. ALEVE TRACKING STUDY

In 1994, Procter & Gamble introduced Aleve. Weeks after introduction, Aleve became the number 3 brand with a 6.5% share of the $2.6 billion general analgesic category. RX 101-c. The advertising compared Aleve to other brands directly by name. In 1995, Ciba conducted the Aleve Tracking Study with the objective of monitoring the first year's progress of Aleve's national introduction in order to determine the impact on the OTC analgesic category generally, on major brands, and on the backache segment in particular. R.X 101-d. Telephone interviews were conducted in two waves among nationally-projectable samples of those 18 years of age or older who used an analgesic product in the past year. [FN9] RX 101-e.

In connection with the study, Ciba obtained information about Doan's. The results of this study indicate that Doan's had between a 2 and 3% unaided brand awareness among the respondents. RX 101-t. However, on an aided basis, the results were higher at between 71 and 75%. RX 101-u.

V. JACOBY STUDY

Dr. Jacoby's study, conducted in late 1996, for this litigation, sought to measure both the materiality of the challenged claim as well as the beliefs created or reinforced by the Doan's campaign. Specifically, he sought to determine whether consumers exposed to the challenged Doan's advertising extracted a "more effective" claim, the basis for such a claim, and whether any such "more effective" claim was material to consumers. In addition, Dr. Jacoby also sought to determine whether there were any lingering effects of the implied superiority claim RX 5-z-82, 83. The study tested consumer beliefs first, without exposure to the challenged ads.

Dr. Jacoby's universe included 684 men and women, at least 18 years old, who in the past year had purchased, or in the past six months had used, a non-prescription medicine to relieve backache or back pain. [FN10] RX 5-z-85, 87. Dr. Jacoby specifically included consumers who were not aware of Doan's as long as they satisfied the other criteria. Jacoby Tr. 2936. The study was conducted via mall ***722** intercept in sixteen geographically dispersed markets, in each U.S. Census Division. RX 5-z-89.

The first three questions asked the respondents which products they had used during the past year. By aggregating the answers to these questions, the data show that 21%, or 123 respondents had used Doan's; 71% had used Tylenol; 58% Advil; 31% Aleve; 28% Motrin; and 21% Bayer. RX 5-z-104. There is no information in the study as to what percent of the respondents were aware of Doan's. Next, respondents were asked whether certain brands were more effective. Seven percent of the 684 respondents rated Doan's as more effective, compared to 13% who reported Advil more effective, and 12% who reported that Tylenol is more effective. RX 5-z-105. When analyzing the data further, 38% of the Doan's users reported Doan's as "more effective" in contrast to 23% of Advil and 17% of Tylenol users who reported their brands as more effective. *Id.* The study also showed that many more respondents attributed their usage of Doan's to personal experience (42%) than to advertising (11%). [FN11] RX 5-z-108-09. Dr. Jacoby also asked whether the respondents recalled any advertising and what it is they recalled from the advertising. The results indicate that for Doan's users, 48% did not recall any ads and that of those who did recall advertising, 44% remember a visual about the ad, 36% mentioned relief of back pain, and 3% mentioned superiority. [FN12] RX 5-z-110.

VI. WHITCUP STUDY

Dr. Whitcup's belief study was conducted, for this litigation, between February and April 1996. RX 2. It attempted to measure consumer awareness of Doan's and of Doan's advertising. Specifically, Dr. Whitcup attempted to access consumer beliefs about Doan's concerning its effectiveness for relief of back pain that may be the results of prior advertising, product usage, word of mouth, and other factors, as well as to ascertain whether or not Doan's is perceived by relevant consumers as containing a special ingredient for back pain that other OTC analgesics do not contain. RX 2-c.

There were a total of 423 respondents who were men and women aged 18 or older, who have used an OTC analgesic in pill form in the ***723** past year, taken an OTC pain reliever in the past year for back pain, and have no one in their household employed in an industry or with atypical knowledge of pain relievers. Interviewing was conducted by telephone using random digit dialing. RX 2-e. The study was administered under "double blind" conditions where neither respondents nor interviewers were aware of the identity of the sponsor nor the true purpose of the study. RX 2-g. Only 35 respondents had used Doan's RX 2-z-49. In contrast, 190 of the respondents had used Tylenol and 121 had used Advil. *Id.* As a result of the small number of Doan's users in this study, Dr. Whitcup added the letter "c" ("caution small base") whenever he presented data based on their responses . *See e.g.* RX 2-q, s.

After screening for qualifications, respondents were asked a series of questions designed to measure their awareness and use of OTC analgesic brands and their advertising. RX 2-e. Specifically, the first question asked what brand of OTC pain relievers first came to mind. In response to this question 1% of the 423 respondents reported awareness of Doan's in comparison to 51 and 18% of the 423 respondents who mentioned Tylenol and Advil. RX 2-n. Other questions asked respondents to recollect which OTC pain relievers they have seen or heard ads for. No respondents reported top-of-mind awareness of Doan's advertising, in comparison to 36% and 20% who reported top-of-mind awareness for Tylenol and Advil respectively. RX 2-o. Other questions asked what brands respondents used in the past year to treat back pain. Eight percent indicated that they used Doan's in comparison to 45% and 29% who indicated that they used Tylenol and Advil respectively. RX 2-p. Finally, in response to a question asking which brands were most effective, 8% believed Doan's was more effective. RX 2-u. Dr. Whitcup acknowledged that the 8% superior efficacy belief measured for Doan's is at about the same level as Tylenol and Advil. Whitcup Tr. 2816.

VII. THE LAVIDGE STUDY

The Lavidge Study was conducted from October 1996 through January 1997. RX 23-a. It was designed for this litigation with the purpose of determining both what claims the "muscles" ads conveyed and whether consumers held a belief that Doan's contains an ingredient the other products do not have. RX 23-e. The universe included people 18 - 34 years of age who had experienced back pain ***724** within the past 2 months and had taken OTC pain relievers for back pain within the past year. RX 23-f. Seventy one percent of the sample were unaware of Doan's. RX 182.

The Lavidge study was divided into three tests with a total of 750 respondents. RX 23-b. This test was also conducted under double blind conditions using a mall intercept approach in ten cities throughout the U.S. RX 23-e. The respondents were shown TV ads for four OTC products marketed for the relief of back pain -- Advil, Bufferin, Doan's and Tylenol. The Doan's ad used in Tests 1 and 3 was the challenged Muscle's ad, and the Doan's ad used in Test 2 was an unchallenged Doan's ad. Immediately after viewing the ads in Test 1 and Test 2, consumers were asked questions to evaluate the impact of the advertising on their beliefs. The Test 3 participants were asked follow-up questions 11 days later.

The study asked respondents questions about their beliefs after exposure to a clutter tape of ads which included both challenged and unchallenged Doan's ads as well as three other 15 second ads for other analgesic products promoted for back pain relief. Immediately after viewing the ads, 57% of the 499 respondents in two of the tests indicated that they did not believe that any OTC analgesic was more effective than others for the relief of back pain RX 23-j; RX 181. After exposure to the challenged Muscles ad, 5.2% of 249 respondents indicated that they believed that Doan's was more effective for relieving back pain. RX

23-j. Six percent of 250 respondents who saw the unchallenged Muscles ad believed that Doan's was more effective. RX 23-j; RX 181. In comparison, 10.6 % of the 499 respondents believed that Tylenol was more effective and 9.6% believed that Advil was more effective. *Id.* Of those who saw the challenged Muscle's ad and were questioned eleven days later, 3.1% believed that Doan's was more effective. *Id.*

FN1. The new concept was an extra strength product.

FN2. Respondents were qualified if they were 18 years or older, suffered from backaches in an average six month period, usually treat backaches with either prescription or non prescription products, and either purchase the products themselves or decide what product is to be bought. An additional 45 consumer who had used Doan's in the past six months were included in the study in order to have 75 users. CX 221-i.

FN3. Twenty percent of aware non-users rated Doan's top box for the attribute particularly effective for back pain, while 7.1% put Extra Strength Tylenol in the Top Box category, 5.3% did for Advil, 6.6% for Motrin IB.

FN4. The mail panel NFO maintains is a bank of over 500,000 households who have agreed, in advance, to participate in research projects. Clarke Tr. 9.

FN5. The questionnaire presented ten attribute statements and asked respondents to rate each statement on a seven-point scale, ranging from strongly agree to strongly disagree. CX 421 z-12. The list of ten belief attributes was chosen to include the belief of primary interest in this case, "Is more effective than other OTC pain relievers for back pain relief," as well as two other belief statements that tracked claims made in Doan's advertising: "Has an ingredient especially for back pain" and "Is Just for back pain." Mazis Tr. 1133. The other attributes were: (1) Is just for headaches. (2) Is safe to use, (3) Has an ingredient especially for headaches, (4) Is gentle on the stomach, (5) Is effective for all kinds of pain, (6) Is more effective than other OTC pain relievers for headache relief, and (7) Is safer to use than other OTC pain relievers. CX 421-z-12. In addition, each questionnaire also asked respondents to write in their age and sex in spaces provided at the end of the questionnaire as a control procedure to guard against the possibility that the wrong member of the household completed the questionnaire. When the questionnaires were returned, NFO cross-checked this age and sex information against their records. Clarke Tr. 40.

FN6. The marketing phenomenon called "usage effect" is the tendency of users of a product to give the product a higher rating than non-users of the product. Mazis Tr. 992.

FN7. Advil, Aleve, Bayer, Motrin, and Tylenol.

FN8. The Motrin non-user comparison was not statistically significant at the .05 level. Mazis Tr. 1189.

FN9. Of the respondents, between 39 and 42% had used an OTC pain reliever in the past year to treat a backache. RX 101-z-33.

FN10. Dr. Jacoby's universe included people who may not have suffered from back pain, but purchased the product. Dr. Jacoby reanalyzed the data after becoming aware of this fact and concluded that 95% of his survey respondents were themselves backache sufferers/treaters. Jacoby Tr. 3140.

FN11. Interestingly, only users of Doan's reported that advertising was the basis for their belief.

FN12. The ALJ stated that it was agreed at trial that the fact that respondents played back a general recall of Doan's ads, does not establish that they did not form a superiority belief from their exposure to Doan's ads. IDF 288.

***725** FINAL ORDER

For purposes of this Order:

1. "*Doan's*" shall mean any over-the-counter analgesic drug, as "drug" is defined in the Federal Trade Commission Act, bearing the Doan's brand name, including, but not limited to, Regular Strength Doan's analgesic, Extra Strength Doan's analgesic, and Extra Strength Doan's P.M. analgesic.
2. "*Competent and reliable scientific evidence*" shall mean 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.
3. "*Advertisement"* shall mean any written, oral or electronic statement, illustration or depiction which is designed to create interest in the purchasing of, impart information about the attitudes of, publicize the availability of, or affect the sale or use of goods or services, whether it appears in a brochure, newspaper, magazine, free standing insert, marketing kit, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point-of purchase display, package insert, package label, product instructions, electronic mail, website, homepage, film, slide, radio, television, cable television, program-length commercial or "infomercial," or in any other medium.

I.

It is ordered, That respondents Novartis Corporation, and Novartis Consumer Health, Inc., corporations, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Doan's or any other over-the-counter analgesic drug, in or affecting commerce, as "drug" and "commerce" are defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that such product is more effective than other over-the-counter analgesic drugs for relieving back pain or any other particular kind of pain, unless, at the time of making such ***726** representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of Part I of this Order, "competent and reliable scientific evidence" shall include at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, each of whom is qualified by training and experience to conduct such studies, independently of each other.

II.

It is further ordered, That respondents Novartis Corporation, and Novartis Consumer Health, Inc., corporations, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sales or distribution of Doan's or any over-the-counter analgesic drugs in or affecting commerce, as "drug" and "commerce" are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication, regarding such product's efficacy, safety, benefits, or performance, unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IV.

It is further ordered, That respondents Novartis Corporation, and Novartis Consumer Health, Inc., corporations, their successors and assigns, and their officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or any device, do forthwith cease and desist from disseminating or causing the dissemination of any advertisement for Doan's in or affecting commerce, as "commerce" is defined, in the Federal Trade ***727** Commission Act, unless the advertising

includes the following corrective notice, clearly and prominently, in the exact language that follows:

"Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain."

Provided, that respondents' obligation to include the corrective notice shall not be required for any television or radio advertisement of 15 seconds or less in duration.

Provided further, that respondents' obligation to include the corrective notice in all advertising shall continue for one year and until respondent has expended on Doan's advertising a sum equal to the average spent annually during the eight years of the challenged campaign.

V.

It is further ordered, That for a period of five (5) years after the last date of dissemination of any representation covered by this Order, respondents or their successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials that were relied upon in disseminating such representation; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

VI.

It is further ordered, That respondents shall:

A. Within thirty (30) days from the date this Order becomes effective, provide a copy of this Order to each of their current principals, officers, directors, and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this Order, and

B. For a period of ten (10) years from the date this Order becomes effective, provide a copy of this Order to each of their future principals, officers, directors, and managers, and to all personnel, ***728** agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this Order who are associated with them or any subsidiary, successor, or assign, within three (3) days after, the person assumes his or her position.

VII.

It is further ordered, That respondents shall notify the Commission at least thirty (30) days prior to any proposed change in their corporate structures, including, but not limited to, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or affiliates, or any other corporate change that may affect compliance obligations arising out of this Order.

VIII.

It is further ordered, That this Order will terminate twenty (20) years from the date this Order becomes effective, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this Order that terminates in less than twenty (20) years;

B. This Order's application to any respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this

paragraph as though the complaint was never filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling, and the date such dismissal or ruling is upheld on appeal.

***729** IX.

It is further ordered, That respondents shall, within sixty (60) days from the date this Order becomes effective, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

STATEMENT OF COMMISSIONER ORSON SWINDLE CONCURRING IN PART AND DISSENTING IN PART

Today, the Commission has decided to order corrective advertising based on a full adjudicative record for the first time in nearly 25 years. I agree with my colleagues that respondents Novartis and Novartis Consumer Health, Inc. (collectively "Novartis" or "respondents") made the unsubstantiated claim that their Doan's analgesic product is superior to other over-the-counter ("OTC") analgesics in treating back pain ("the superior efficacy claim"). I also agree that the traditional cease-and-desist provisions contained in Parts I and II of the Order, which would prohibit Novartis from making the same or similar deceptive claims in the future, are necessary and appropriate. Unlike my colleagues, however, I conclude that the evidence does not support the imposition of the corrective advertising remedy contained in Part IV of the Order.

Corrective advertising is intended to prevent the harm to consumers and competition that is caused when a false belief engendered by prior deceptive advertising lingers. Novartis made an implied superior efficacy claim for Doan's through short television advertisements that have not been disseminated since May 1996. The majority concludes that these advertisements caused a false superior efficacy belief that has lingered and is likely to continue to linger until the corrective advertising provision terminates in July 2000 or beyond. I disagree with this conclusion, because the evidence offered to prove lingering effect is extremely weak, consisting mainly of inconclusive extrinsic evidence, indefinite expert testimony and broad inferences. This evidence is certainly far weaker than the evidence that proved the existence of a lingering effect in *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 762 (D.C. Cir. 1977), *modifying and enforcing* 86 FTC 1398 (1975). I conclude that this weak evidence does not prove by a preponderance of the evidence that the false superior ***730** efficacy belief is likely to linger until July 2000 or beyond. Therefore, the Commission cannot order corrective advertising in this case.

I also conclude that the corrective advertising requirement, which is a form of compelled speech, infringes on Novartis's right to engage in commercial speech under the First Amendment to the United States Constitution. The Commission may compel Novartis to engage in corrective advertising only if the remedy "directly advances a substantial governmental interest" and is "no more extensive than necessary to serve that interest." *Central Hudson Gas & Electric Corp. v. Public Serv. Comm. of N.Y.*, 447 U.S. 557, 566 (1980). Because it has not been proven that the false superior efficacy belief in this case is likely to linger, there is no false belief that needs to be corrected to prevent deception; therefore, corrective advertising cannot directly advance any substantial governmental interest. In addition, because the majority opinion has not given adequate consideration to alternatives to corrective advertising or to less restrictive alternatives to the all-media corrective advertising remedy imposed (such as a corrective statement on the product label or point-of-sale materials), the Commission has not shown that the prescribed corrective advertising requirement here is no more extensive than necessary to prevent deception.

Corrective advertising is an extraordinary remedy that can serve the salutary purpose of preventing harm to consumers and competition. I have supported the imposition of corrective advertising provisions in those rare instances where the legal standard for its imposition has been satisfied and the remedy was otherwise warranted. I will continue to support the use of corrective advertising remedies in appropriate cases. But I am not willing to support a corrective advertising remedy in this case because the adjudicated record does not prove that any false superior efficacy belief is likely to linger and because the imposition of the remedy would be unconstitutional.

I. DECEPTION AND TRADITIONAL RELIEF

Before I turn to the question of corrective advertising, let me make clear that I concur in the majority's conclusions that Novartis's superior efficacy claim was deceptive and that the traditional cease-and-desist relief imposed by the order is necessary and appropriate. Administrative Law Judge Lewis F. Parker ("the ALJ") concluded that Novartis had violated Sections 5 and 12 of the Federal Trade ***731** Commission Act, 15 U.S.C. 45, 52, by making the unsubstantiated claim that Doan's was superior to other OTC analgesics in treating back pain. Initial Decision ("ID") at 63-64. In its appeal from the ALJ's conclusion that the superior efficacy claim was deceptive, Novartis argued only that the claim was not material to consumers. I agree with the majority's conclusion that the superior efficacy claim was material, Majority Op. at 11-20, although not with all of the reasoning that supports this conclusion. [FN1] Accordingly, I agree that Novartis engaged in deception in violation of Sections 5 and 12 of the FTC Act.

The Commission has wide discretion in choosing a remedy to prevent Novartis from engaging in the same or similar deception in the future. The Commission may include provisions in its cease-and-desist orders that go beyond prohibiting the repetition of the deception that has been found, so long as such "fencing-in" relief bears a "reasonable relation" to the unlawful practices found. *FTC v. National Lead Co.*, 352 U.S. 419, 429 (1957); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611-13 (1946). In determining the appropriate extent of fencing-in relief to remedy a law violation, the Commission considers the seriousness and deliberateness of the violations; the ease with which the unlawful conduct could be transferred to other products; and the respondent's history of violations. *See, e.g., Kraft, Inc.*, 114 FTC 40, 139-40 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992); *Thompson Medical Co.*, 104 FTC 648, 833 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).

The Order here includes both core relief prohibiting Novartis from repeating its deceptive superior efficacy claim for Doan's and traditional fencing-in relief preventing similar violations. Part I prohibits Novartis from making any unsubstantiated claim that Doan's or any other OTC analgesic is more efficacious than other OTC analgesics for relieving back pain or any other particular type of pain. Part II also bars Novartis from making any unsubstantiated claim regarding the efficacy, safety, benefits, or performance of Doan's or any other OTC analgesic. Given the seriousness of ***732** deceptive health claims and the ease with which Novartis could make similar unsubstantiated claims for Doan's or other OTC analgesics, both the core relief and the fencing-in relief included in Parts I and II of the Order are necessary and appropriate.

II. CORRECTIVE ADVERTISING

The majority also would require Novartis to undertake corrective advertising. Part IV of the Order mandates that Novartis make a specified corrective statement in all of its "advertising" [FN2] (except television or radio advertisements of 15 seconds or less in duration) for "one year and until the respondents have expended on Doan's advertising a sum equal to the average amount spent annually during the eight years of the challenged campaign." The prescribed corrective statement is: "Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain."

A. Legal Standard

Corrective advertising is a type of fencing-in relief for which the court in *Warner-Lamber t* adopted a higher standard than the "reasonably related" standard applicable to traditional forms of fencing-in relief. *Warner-Lambert*, 562 F. 2d at 762. [FN3] In *WarnerLambert*, the respondent spent "vast sums" on a 51-year advertising campaign making the false claim that Listerine mouthwash was effective in treating colds and sore throats. 86 FTC at 1468, 1502 . In affirming the Commission's imposition of an approximately one-year corrective advertising requirement, the court held the Commission could impose a corrective advertising requirement if it concluded that "Listerine's advertisements play[ed] a substantial role in creating or reinforcing in the public's mind a false belief about the product" and "this belief [would] linger on after the false advertising ceases." 562 F. 2d at 762. The court relied on consumer surveys over many years ***733** and expert testimony in concluding that there was substantial evidence in the record as a whole to support these two factual prerequisites. *Id.* at 762 n.65. The *Warner-Lambert* court also concluded that the approximately one-year time period for the corrective advertising requirement was not "an unreasonably long time in which to correct a hundred years of cold claims." *Id.* at 764.

Since it decided *Warner-Lambert*, the Commission has considered the imposition of corrective advertising in three adjudicated cases, all of them involving claims made for OTC analgesics. *Sterling Drug, Inc.*, 102 FTC 395 (1983), *aff'd*, 741 F.2d 1146 (9th Cir. 1984); *Bristol-Myers* Co., 102 FTC 21 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984); *American Home Products Corp.*, 98 FTC 136 (1 981), *aff'd as modified*, 695 F.2d 681 (3d Cir. 1982). In none of these cases, however, did complaint counsel prove the factual prerequisites for ordering corrective advertising -- that the deceptive advertisements substantially created or reinforced a false belief and that the belief was likely to linger -- and thus the Commission declined in each case to order corrective advertising. Because *Warner-Lamb ert* is the only adjudicated case in more than two decades in which the Commission has ordered corrective advertising, it provides the benchmark [FN4] for determining whether the evidence proves [FN5] the factual prerequisites for corrective advertising. I do not think that the evidence here proves these prerequisites.

B. Lingering Effect

In my view, corrective advertising cannot be ordered in this case because the evidence does not prove that any false superior efficacy ***734** belief substantially caused by the deceptive advertising campaign is likely to linger. [FN6] The majority concludes that the false superior efficacy belief will linger, but fails to address or even identify how long the belief must be likely to linger to support the corrective advertising remedy in this case. A false superior efficacy belief will not support corrective advertising unless it is likely to linger throughout the period during which the corrective advertising provision will be in effect. Without a lingering false belief, there is no more reason to impose a corrective advertising remedy than there is for a doctor to prescribe a remedy for a patient who has already recovered. Specifically, the false superior efficacy belief must exist at the time that the Commission's order becomes final -- that is, the date on which the corrective advertising provision must commence -and must continue, albeit presumably at a decreasing level due to the effects of the provision, at least until the corrective advertising requirement expires. [FN7] Hence, for the Commission to order corrective advertising in this case, the false superior efficacy belief would have to exist when the Order becomes final (in July 1999 [FN8]) and would have to continue to exist until the corrective advertising requirement terminates (in July 2000 or beyond). [FN9]

The ALJ did not order corrective advertising because he was not persuaded that the evidence in the record proved that the false ***735** superior efficacy belief would linger. ID at 63-64. According to the ALJ, the evidence revealed that it is uncertain [FN10] that the false belief is likely to linger, given that the advertisements in *Warner-Lambert* ran for 51 years while the advertisements here ran for only 8 years. *Id.* at 64 . The ALJ also found unpersuasive the testimony of Dr. Michael Mazis, complaint counsel's marketing expert, that the false superior efficacy belief would linger. *Id.* at 63. Finally, the ALJ not only rejected complaint counsel's argument that a lingering effect can be inferred from other facts, but also found "indications in the record that the belief in Doan's superiority may be transitory," *id.*, including evidence that the deceptive advertisements were not memorable and did not cause any increase in product sales. *Id.* at 64-65. A careful review of the evidence persuades me that the ALJ correctly concluded that the requisite lingering effect has not been proven.

1. Direct Evidence of Lingering Effect

The majority first relies on extrinsic evidence for its conclusion that the false superior efficacy belief will linger. In December 1996, National Family Opinion, Inc. ("NFO") conducted a mail panel research study of consumer beliefs (the "1996 NFO Study"). CX-421. The 1996 NFO Study tested the efficacy beliefs of users and aware non-users of six OTC analgesics -- Advil, Aleve, Bayer, Doan's, Motrin, and Tylenol. For each of these OTC analgesics, users and aware non-users were asked whether they strongly agreed, agreed, somewhat agreed, neither agreed nor disagreed, somewhat disagreed, disagreed, or strongly disagreed with the statement that the OTC analgesic was "more effective than other over-the-counter pain relievers for back pain." CX 421-V. For each of these six OTC analgesics, a significant proportion of the users and aware non-users had a false superior efficacy belief, [FN11] even though none of the OTC ***736** analgesics other than Doan's had been advertised specifically as a back pain medication . Even though many users and aware non-users held the false superior efficacy belief for all of the OTC analgesics, Dr. Mazis testified that, following statistical adjustments, on average 20 to 25% more users and aware non-users of Doan's had a false superior efficacy belief than did the users and aware non-users of the other OTC analgesics tested. Mazis Tr. at 1385. Given a statistical confidence level of approximately 5%, Dr. Mazis testified that when a 20% reduction (*i.e.*, only a reduction of one in five of the relevant consumers) occurred, there would no longer be a lingering false superior efficacy belief to be corrected. *Id.* at 1385, 1386-87.

While the 1996 NFO Study shows that 20% more Doan's users and aware non-users have the false superior efficacy belief than the users and aware non-users of other OTC analgesics, it does not prove that this level of beliefs about Doan's is the lingering effect of the deceptive advertising . Study participants were simply never asked whether they had ever seen any Doan's advertising, much less the particular deceptive advertisements at issue here. Mazis Tr. at 1642, 1644, 1786. It is not impossible that study participants saw the deceptive advertising before it was discontinued in May 1996 and formed the false superior efficacy belief as a result of exposure to this advertising, and that this belief lingered until December 1996. However, a variety of influences -- other than any particular advertising campaign -- create, reinforce, and change consumer beliefs about a product. Given that other, entirely plausible influences could well be responsible for the belief reported in the 1996 NFO Study (such as historic positioning and the introduction of new extra strength Doan's products), I am not willing to infer that the belief is the enduring effect of the discontinued deceptive advertising. Jacoby Tr. at 3005-06; Scheffman Tr. at 2618.

Even if the 1996 NFO Study had established that the false superior efficacy belief had lingered, it would prove only that the belief had lingered until December 1996 — not that it was likely to linger until July 2000 or beyond. Persuasive expert testimony is one possible method [FN12] of proving that the false superior efficacy belief ***737** would continue to linger from December 1996 until July 2000 or beyond. Dr. Mazis, complaint counsel's expert, did testify that the heightened false superior efficacy belief is likely to linger, but his testimony on lingering effect is not persuasive. In support of his conclusion, Dr. Mazis briefly mentioned the length and effectiveness of the advertisements, the emphasis in the advertisements on the superior efficacy claim, and the results of copy tests. But he provided no analysis of the reasons that each of these factors demonstrates that a lingering effect is likely under the particular facts of this case. Mazis Tr. at 1255-56. In the absence of a thorough analysis as to why these considerations mean that the false superior efficacy belief is likely to linger, the unsupported conclusion of Dr. Mazis that the false belief will linger is no more persuasive than the conclusions of Novartis' experts that it will not. *See* Whitcup Tr. at 2336; Scheffman Tr. at 2536; Jacoby Tr. at 3201. [FN13]

Moreover, even assuming that Dr. Mazis had testified persuasively that the false superior efficacy belief generally is likely to linger, his testimony is flawed because it is extraordinarily indefinite as to how long the belief is likely to linger. Dr. Mazis variously phrased the length of the likely lingering effect as that it would "last for quite some time," it would "go on for years," it would "not go away quickly," it would linger for a "very, very long time," it would linger a "considerable length of time," and it would be "hard to know" how long it would linger, but "beliefs tend to dissipate slowly." Mazis Tr. at 1254, 1256, 1263, 1798, 1975. Dr. Mazis's testimony thus does ***738** not address with any specificity how long the false superior efficacy belief is likely to linger. [FN14]

Dr. Mazis's expert testimony is far weaker than the expert testimony that has been offered in other Commission corrective advertising cases on the issue of how long the false belief will linger. For example, in *Warner-Lambert*, one marketing expert testified that the levels of false cold and sore throat efficacy beliefs for Listerine "would continue at the 1971 rate (59 percent) for about two years after colds advertising ceased and would remain high even *after* five years," while another marketing expert opined that "in the absence of colds advertising consumer beliefs would decline at *no greater* a rate than 5 percent a year." 86 FTC at 1503-04 (emphasis in original). Similarly, in *American Home Products*, experts testified that after deceptive advertising making a false superior efficacy claim about Anacin ceased, the false belief created would linger among non-users for "approximately one year" and among users for more than one year. 98 FTC at 283-84.

Some quantitative assessment is needed in this case if expert testimony is going to support the imposition of corrective advertising. After all, because the deceptive advertising here ceased three years ago, corrective advertising cannot be ordered as a matter of law if the false superior efficacy belief is likely to linger for three years or less, while it could be ordered if the belief is likely to linger for approximately four years or more. Expert testimony that the false superior efficacy belief is likely to linger for some indeterminate period of time is of little probative value when the Commission must decide whether the belief is likely to linger for a particular period of time. Given Dr. Mazis's lack of analysis in support of his opinion that the false belief is likely to linger and his inability to identify with any specificity how long the false belief will linger, I conclude, like the ALJ, that his testimony is not persuasive.

2. Inference of Lingering Effect

Absent a basis in the direct evidence, the majority turns to inference as an additional ground for its conclusion that the ***739** heightened level of false superior efficacy beliefs among Doan's users and aware non-users will linger. Majority Op. at 30-31. The majority infers a lingering effect from the fact that the deceptive superior efficacy claim was very salient to consumers, *Id.* at 30. The majority also draws such an inference from the fact that the deceptive superior efficacy claim was clearly and consistently conveyed to consumers, as revealed by copy tests. *Id.* at 30-31. Finally, the majority infers lingering effect from the fact that the deceptive advertising campaign was an integral part of an eight-year advertising campaign that cost $65 million. *Id.* at 30.

The Commission has said that inferences drawn from other facts may be used to prove the requisite lingering effect in some circumstances. "[A]bsent probative evidence one way or the other, [the Commission may] infer that a deceptive advertisement will leave a lingering deceptive impression in consumers' minds." *American Home Products Corp.*, 98 FTC at 408 n.93; *see Bristol-Myers*, 102 FTC at 380 n.102 ("survey evidence is only one factor to be considered in determining whether corrective advertising is appropriate in a particular case"); *Statement in Regard to Corrective Advertising*, 6 Trade Reg. Rep. (CCH) ¶ 39,046 at 41,705 (1979) ("In some cases, the [Commission] might conclude that corrective advertising is necessary without formal surveys to show that consumers have lasting wrong impressions about the product."). While an inference from other facts may be employed in appropriate cases, such an inference generally will have less probative value than direct evidence because inference is by nature an indirect and imprecise method of proof. [FN15] Indeed, it is important to emphasize that the only time that the Commission has ordered corrective advertising in an adjudicated case in more than two decades, it relied on direct evidence in the form of persuasive extrinsic evidence and expert testimony, not simply on inferences . *Warner-Lambert*, 86 FTC at 150 1-04.

***740** While inference of lingering effect may be considered in this case, the particular inferences that the majority seeks to draw are not persuasive. The majority first infers a lingering effect from the purported powerful impact of the deceptive advertising on consumers, which, in turn, is based on the majority's conclusions that the superior efficacy claim was "very salient" and was made "clearly and consistently." Consumers may have taken away the implied claim immediately after seeing the deceptive advertisements, but only a minimal proportion (between 1% and 8%) of test participants recalled the claim 24 hours or 72 hours after viewing the advertisements along with programming and other advertisements. [FN16] Similarly, only a minimal proportion (0% top-of-the-mind and 2% total unaided) of consumers recalled any advertising for Doan's, including the deceptive advertisements. RX 2-O. Although consumers could conceivably form a belief about a product based on a deceptive advertisement without being able to recall the claim shortly thereafter or without being able to recall any advertising for the product, the far more plausible conclusion is that the extremely low recall of the deceptive claim and of Doan's advertising means that the deceptive advertisements had no real lasting impact because they were not memorable. Whitcup Tr. at 2123. Indeed, the conclusion that the deceptive advertisements did not have a powerful impact on consumer beliefs is corroborated by the fact that unit sales of Doan's declined during 1988 to 1993, the first five years in which the deceptive advertisements were being disseminated. RX-189-A; Scheffman Tr. at 2550-51; Stewart Tr. at 3487. I am not persuaded that an inference can be drawn that this ineffective advertising campaign caused a false belief that is likely to linger until July 2000 or beyond, more than four years after Novartis ceased disseminating the deceptive advertisements.

The majority, emphasizing that the campaign lasted eight years, cost $65 million, and reached 80 to 90% of the target audience 20 to 27 times per year, also would infer a lingering effect from the purported extensiveness of the advertising campaign. Majority Op. at 30-31. But reaching 80 to 90% of one's target audience 20 to 27 times per year pales in comparison to the level of advertising by Novartis's ***741** competitors, who reach 98 to 99% of their target audience between 32.5 and 121.2 times per year. JX 2-H, ¶ 32; RX 36-M, Z-27. Moreover, Novartis was primarily using short television advertisements (15 seconds in duration), while its competitors generally were using much longer advertisements (30 seconds and 45 seconds in duration). IDF 318; Peabody Tr. at 465. Given that Novartis competes with other OTC analgesic advertisers for the limited attention of OTC analgesic customers, I am not persuaded that the relatively infrequent and short advertisements here captured the limited attention that consumers devote to considering information about OTC analgesics so as to have caused strong beliefs that are likely to linger for years. [FN17]

A comparison to prior Commission cases in which corrective advertising has been considered and rejected also persuades me

that a lingering effect cannot be inferred from the fact that Novartis clearly and consistently made a very salient superior efficacy claim for Doan's during an eight-year, $65 million advertising campaign. The deceptive advertising campaign here pales in comparison with other deceptive advertising campaigns (especially when advertising expenditures are measured in constant dollars) that have not resulted in the Commission imposing corrective advertising. *See* Appendix A. [FN18] For example, in *American Home Products*, the respondent had made, expressly and by clear implication, a false superior efficacy claim for Anacin during a more than 12-year, $204 million advertising campaign. 98 FTC at 151. The Commission did not order a statement to correct any resulting false superior efficacy establishment belief because there was "little likelihood that a false or unsubstantiated image of proven superiority [would] survive" in ***742** light of the traditional relief contained in the Commission's cease-and-desist order. *Id.* at 411.

Similarly, in *Bri stol-Myers*, the respondent had made, expressly and by clear implication, false superior efficacy claims for Bufferin and Excedrin that were important to consumers. These claims were made during a 13-year, $171 million advertising campaign for Bufferin, and a 13-year, $98 million advertising campaign for Excedrin. 102 FTC at 21, 104-06, 254, 250. The Commission did not order a statement to correct any resulting false superior efficacy establishment claims for either Bufferin or Excedrin. The Commission concluded that such a remedy was not warranted because there was "no evidence that consumers will retain an image that this superiority has been established," *id.* at 380, and in the absence of such evidence the Commission was unwilling to infer the existence of such an enduring image from the superior efficacy belief held and the extent and nature of the deceptive advertising campaign. *Id* . at 380 n.102. Accordingly, *Bristol-Myers and American Home Products* [FN19] provide no support for the inference that the majority draws in this case.

In contrast, it might be instructive to consider a recent case in which I drew an inference of lingering effect. *R.J. Reynolds Tobacco Co*, FTC File No. 992-3025 (Mar. 1, 1999). In August 1997, R.J. Reynolds ("Reynolds") commenced a massive [FN20] national advertising campaign running innovative print, billboard, and point-of-sale advertisements for Winston cigarettes that made an express "No Additives" representation. The advertising campaign was so successful that by the end of 1997, Reynolds had already increased its volume of Winston sales by 9%. *1997 RJR Nabisco Annual Report* 24 (1997). In March 1999, when the advertising campaign was ongoing, the Commission accepted for public comment a consent ***743** agreement with Reynolds accompanied by a complaint alleging that the "No Additives" representation made the implied claim that Winston cigarettes are safer to smoke because they contain no additives . The proposed order would require that Reynolds make a corrective statement in its advertising for one year. I was willing to infer that the false belief would linger in the minds of consumers for one year "[b]ased on the extent and magnitude of the ongoing ad campaign and the demonstrated strength of the implied health claim." Inferring a one-year lingering effect from the ongoing, massive, and innovative advertising campaign in *R.J. Reynolds* for purposes of accepting a consent agreement for public comment, however, is a far cry from the present case, in which a more than four-year lingering effect is being inferred from a long-discontinued, limited, and uncreative advertising campaign. [FN21]

In my view, complaint counsel have not met their burden of proving that the false superior efficacy belief concerning Doan's is likely to linger. The direct evidence in the record on the issue of lingering effect -- the 1996 NFO Study and Dr. Mazis's testimony -- is far weaker than the direct evidence of lingering effect that justified corrective advertising in *Warner-Lambert*, and it does not persuade me that the false superior efficacy belief is likely to linger. The inference as to lingering effect that the majority seeks to draw is not persuasive, and the Commission did not draw such an inference from even stronger facts in *American Home Products* and *Bristol-Myers*. Complaint counsel's failure to meet their burden of proof on the issue of lingering effect should not be surprising, given how rarely complaint counsel will be able to prove this effect. *See* R. Pitofsky, *Beyond Nader*, 90 Harv. L. Rev. at 697 (if the burden of proving lingering effect remains with complaint counsel -- so that complaint counsel is not simply entitled to a presumption on this issue -- then corrective advertising will be "imposed rarely"). Without stronger evidence of lingering effect, the Commission cannot order corrective advertising.

***744** III. CONSTITUTIONALITY OF CORRECTIVE ADVERTISING REQUIREMENT

I also believe that the corrective advertising provision is a form of compelled speech that infringes Novartis's constitutional right to engage in commercial speech. The Supreme Court has recognized that advertising is a form of commercial speech entitled to protection under the First Amendment to the United States Constitution. The free flow of commercial information

through advertising is "indispensable to the proper allocation of resources in a free enterprise system" because it informs the numerous private decisions that drive the system. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976). Advertising is critical to consumers because a "particular consumer's interest in the free flow of commercial information … may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id.* at 763. Corrective advertising requirements disrupt the free flow of information from advertisers to consumers because they compel advertisers to make statements that they would not otherwise make, sometimes having adverse incidental consequences for those advertisers. *See Sterling Drug, Inc.*, 102 FTC at 723 (Initial Decision); *see also* R. Pitofsky, *Beyond Nader*, 90 Harv. L. Rev. at 698 ("The purchase of advertising space or time for the corrective message is expensive, and the remedy is unusually embarrassing to the false advertiser."); Note, *Corrective Advertising — The New Response to Consumer Deception*, 72 Colum. L. Rev. 415, 429, 431 (1972)¢ Y (remedy is "severe" and "dramatic").

Notwithstanding the fact that corrective advertising remedies disrupt the free flow of information from advertisers to consumers and may otherwise harm advertisers, the burdens associated with such compelled speech pass constitutional muster if they meet the test first enunciated in *Central Hudson Gas & Electric Corp. v. Public Serv. Comm. of N.Y.*, 447 U.S. 557 (1980). *Central Hudson* set out a framework for determining whether a regulation of commercial speech (or compelled speech in the commercial speech context [FN22]) survives First Amendment scrutiny:

> ***745** For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

447 U.S. at 566.

I agree with my colleagues that the initial portions of the *Central Hudson* test have been satisfied, *see Warner-Lambert*, 562 F. 2d at 771 (corrective advertising is intended to serve the substantial governmental interest of protecting citizens against deception), but I disagree that the corrective advertising provision here "directly advances the governmental interest asserted" and is "not more extensive than is necessary to serve that interest."

A. Direct Advancement of Substantial Governmental Interest

Central Hudson requires that the restriction on commercial speech "directly advance [] the governmental interest asserted." 477 U.S. at 566. [FN23] This "is not satisfied by mere speculation or conjecture; rather [the government] must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." *Edenfield*, 507 U.S . at 770-71; *see also 44 Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1495, 1509 (1996) ("some impact" in redressing harm is not enough; ban on alcohol price advertising must "*significantly* reduce alcohol consumption") (emphasis in original). A restriction thus will not be sustained if "it provides only ineffective or remote support for the government's purpose." *Edenfield*, 507 U.S. at 770, *quoting Central Hudson*, 447 U.S. at 564; *see also City of Cincinnati v. Discovery Network Inc.*, 507 U.S. 410 (1993).

Corrective advertising is intended to prevent deception by curing the lingering false beliefs of consumers that were caused by deceptive advertising. The record before us does not demonstrate that the false superior efficacy belief here is likely to linger through the time that the corrective advertising provision will be in effect. As explained above, the only evidence that a heightened level of false superior efficacy beliefs is likely to linger until July 2000 or beyond is the ***746** inconclusive 1996 NFO Study, the unsupported and indefinite testimony of Dr. Mazis, and the unwarranted broad inferences that the majority draws. This weak evidence of lingering effect does not satisfy the Commission's burden of showing direct advancement of a substantial governmental interest, because a corrective advertising provision cannot prevent deception arising from false superior efficacy beliefs in the absence of proof that such lingering beliefs are likely to exist. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490 (1995) ("anecdotal evidence" and "educated guesses" are not sufficient); *Edenfield*, 507 U.S. at 771 (conclusory testimony is not sufficient). [FN24]

B. No More Extensive Than Necessary

The corrective advertising requirement also violates the last prong of *Central Hudson*, 477 U.S. at 566, which requires that the governmental restriction be no more extensive than necessary to serve the asserted governmental interest. *See also* *Warner-Lambert*, 562 F.2d at 758 (Commission has a "special responsibility to … order corrective advertising only if the restriction inherent in its order is no greater than necessary to serve the interest involved"). This means that there must be a "reasonable fit" between the restriction imposed and the government interest sought to be advanced. *Board of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989). "[I]f there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable." *City of Cincinnati*, 507 U.S. at 417 n.13; *see also* *Rubin*, 514 U.S. at 490-91 (no reasonable fit between restriction and governmental interest existed because less restrictive options were available). In analyzing the fit between the restriction and the governmental interest, the government must carefully calculate the costs and benefits associated with the restriction. *City of Cincinnati*, 507 U.S. at 417-18; *Fox*, 492 U.S. at 480.

The majority addresses in one short paragraph whether the corrective advertising provision here is a reasonable fit with the ***747** asserted governmental interest in preventing deception. The paragraph states that the Commission has balanced the need for correcting lingering false beliefs against Novartis's ability to broadcast effectively, the upshot of which is to exempt short television and radio advertisements from the corrective advertising requirement. Majority Op. at 37. Thus, except for not applying the corrective advertising requirement to short television and radio advertisements, the majority does not consider any less restrictive alternatives. This minimal analysis is not the careful calculation of the costs and benefits associated with alternatives that *Central Hudson* requires.

First, the majority does not analyze whether there are any narrower alternatives to imposing corrective advertising, including considering whether traditional cease-and-desist order provisions (such as those contained in Parts I and II of the Order, or triggered disclosure requirements) could be adequate to address future deception. [FN25] Second, assuming that some corrective advertising provision is warranted, the majority does not address in any detail whether there are narrower alternatives to this particular corrective advertising provision. The corrective advertising requirement in this case apparently is intended to closely track the requirement imposed in *Warner-Lambert.* The respondent in *Warner-Lambert* was required to make a corrective statement in all advertising until it had "expended on Listerine advertising a sum equal to the average annual Listerine advertising budget for the period of April 1962 to March 1972." 86 FTC at 1515. [FN26] Here, Novartis is required to make a corrective statement in all of its "advertising" (except short television and radio advertisements) for "one year and until the respondents have expended on Doan's advertising a sum equal to the average amount spent annually during the eight years of the challenged campaign." The Order defines an "advertisement" broadly to include any intended inducement to sale that appears in:

> ***748** a brochure, newspaper, magazine, free standing insert, marketing kit, leaflet, circular, mailer, book insert, letter, catalog, poster, chart, billboard, public transit card, point-of-purchase display, package insert, package label, product instructions, electronic mail, website, homepage, film, slide, radio, television, cable television, program-length commercial or infomercial, or in any other medium.

Part IV thus imposes a corrective advertising requirement that is nearly identical to the one-year, all-media requirement that the Commission imposed in *Warner-Lam bert.*

While applying the corrective requirement to all media may have been a reasonable fit with the objective of correcting false beliefs in *Warner-Lambert*, it is not a reasonable fit in this case. In *WarnerLambert*, the Commission was trying to correct false beliefs among the *general public* concerning Listerine mouthwash, and so an all-media corrective advertising provision was consistent with that objective. *See* *Warner-Lambert*, 86 FTC at 1501, 1503 (false beliefs exist among "Listerine users as well as nonusers"; "long after Listerine cold efficacy advertising ceased, a substantial portion of the *public* would continue to believe") (emphasis added). In contrast, the Commission here is trying to correct false superior efficacy beliefs among *Doan's users and aware non-users.* Mazis Tr. at 1385, 1805 (back pain sufferers who are neither Doan's users nor aware non-users have no need to receive the corrective statement). Therefore, the media chosen for the dissemination of the corrective message here must be targeted to Doan's users and aware non-users if the Commission's remedy is to achieve the reasonable fit that is constitutionally required. *See* *44 Liquormart, Inc.*, 517 U.S. 484, 529 (1996) (O'Connor, J., concurring in judgment) ("The scope of the restriction on speech must be *reasonably*, though it need not be perfectly, *targeted* to address the harm intended to be regulated.") (emphasis added). Significantly, the difference between the general public as a target audience and Doan's users and aware

non-users as a target audience is quite substantial, given that 31% of back pain sufferers (itself a subset of the general public) are neither Doan's users nor aware non-users. Mazis Tr. at 1793.

The corrective advertising requirement here is in no way limited to media that are likely to target Doan's users and aware non-users. One narrower alternative that would more accurately target Doan's users and aware non-users is to require the corrective statement only on product labeling and in packaging. Product labeling and packaging are sources of critical safety and efficacy information for users and ***749** potential users of Doan's, such as indications for use, directions, warnings, drug interactions, active ingredients, and inactive ingredients. *See* Mazis Tr . at 1607-08 (product package can affect beliefs; consumers look at the product package immediately at the point of purchase). Another narrower alternative is brochures with corrective information that would be made available to Doan's users and aware non-users through prominent displays on the drug store shelves and other locations at which Doan's and other OTC analgesics are sold. Indeed, the Commission has used similar media to target a particular group of consumers who have false beliefs to be corrected. [FN27] Although dissemination of a corrective statement through product packaging and point-of-sale displays, either separately or combined, is a less restrictive alternative that may well be adequate to correct the false belief among Doan's users and aware non-users, the majority does not consider the imposition of such alternatives -- much less conduct a careful calculation of their costs and benefits. Therefore, the corrective advertising requirement imposed here has not been demonstrated to be no more extensive than necessary, as *Central Hudson* requires.

IV. CONCLUSION

Because the evidence in the record does not prove that the false superior efficacy belief will linger for the requisite period of time for imposing corrective advertising under the standard set forth in *Warner-Lambert*, and also because the corrective advertising provision is an unconstitutional infringement on Novartis's right to engage in commercial speech under the First Amendment, I dissent from Part IV of the Order.

FN1. The evidence does not prove that Novartis intended to make the claim or that it was able to charge a premium because of the challenged advertisements, Majority Op. at 13-15, and therefore I do not join in the majority's conclusion as to materiality to the extent that it relies on these findings. I agree with the majority that the effectiveness of the deceptive advertising campaign is not relevant to the issue of materiality, *Id.* at 16-17, but I do not join in the majority's additional determination that the campaign was effective.

FN2. "Advertising" is defined in the Order to include claims made in a brochure, newspaper, magazine, free standing insert, marketing kit, leaflet, circular, mailer, book insert, letter, catalog, poster, chart, billboard, public transit card, point-of-purchase display, package insert, package label, product instructions, electronic mail, website, homepage, film, slide, radio, television, cable television, program-length commercial or infomercial, or in any other medium.

FN3. *See California SunCare, Inc.*, 123 FTC 332, 391 (1997) (Statement of Commissioner Roscoe B. Starek, III, concurring in part and dissenting in part) (*Warner-Lambert* imposes a "more demanding standard for corrective advertising" than traditional fencing-in relief, such as affirmative disclosure requirements.).

FN4. The majority states that the Commission "has frequently noted that the amount of evidence in *Warner -Lambert* was unusually strong and far exceeded the threshold needed to impose corrective advertising." Majority Op. at 30. As discussed below in the text, the Commission has simply recognized that inference, not direct evidence, may be used in appropriate cases. The availability of inference does not relieve complaint counsel of the burden or proving lingering effect by a preponderance of the evidence. Moreover, *Warner-Lambe rt* did set the standard for corrective advertising, and the evidence in that case is the only benchmark that we have for assessing the sufficiency of evidence supporting corrective advertising. *See* E. Levi, *An Introduction to Legal Reasoning* 2 (1949) (the extension of a rule of law to new facts "depends upon a determination of what facts will be considered similar to those present when the rule was first announced").

FN5. Complaint counsel has the burden of proving facts in Commission adjudications by a preponderance of the evidence.

Carter Products, Inc. v. FTC, 268 F.2d 461, 487 (9th Cir. 1959); ABA Antitrust Section, *Antitrust Law Developments* 617 (4th ed. 1997) ("The burden of proof in a Commission proceeding is on complaint counsel to establish its case by a preponderance of the evidence.") (footnotes omitted); *see* 5 U.S.C. 556(d) ("[e]xcept as otherwise provided by statute, the proponent of a[n] *** order has the burden of proof.").

FN6. I am assuming for the sake of argument that the majority is correct that the false superior efficacy belief was caused substantially by the deceptive advertising at issue, rather than by some other entirely plausible factor such as the introduction of new, extra strength Doan's products or the nine decades of positioning Doan's product as an effective remedy for back pain. *Compare Sterling Drug Co.*, 102 FTC at 798-99 (concluding that it was not clear that deceptive advertising campaign was a substantial cause of false efficacy belief because "the longer a brand has been in existence, the less its image stems from one particular advertising campaign," since "[f]or a brand like Bayer, which has been on the market for years, familiarity is the primary influence on brand image").

FN7. *See* R. Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 Harv. L. Rev. 661, 697 (1977) (hereinafter "Pitofsky, *Beyond Nader*") (false belief must continue to "influence purchasing decisions up to the date of the entry of a final Commission order, and [be] likely to continue to be influential for a substantial segment of potential purchasers even if the false claims [are] no longer disseminated by the seller").

FN8. Commission cease and desist orders, including their corrective advertising provisions, become final 60 days after service unless the Commission or a court has granted a stay. Section 5(g) of the FTC Act, 15 U.S.C. 45(g).

FN9. The corrective advertising provision could last substantially longer than one year because it is required to continue for "one year and at least until the respondent has expended on Doan's advertising a sum equal to the average amount spent annually during the eight years of the challenged campaign" (emphasis added). For instance, although the corrective advertising provision in *Warner- Lambert* was similarly prescribed to last until the respondent had spent the same amount on advertising as its average recent annual advertising expenditure, the provision was in effect for at least 18 months. Mazis Tr. at 1798.

FN10. The majority takes the ALJ to task for purportedly requiring that the lingering effect must be proven with certainty. Majority Op. at 21. The ALJ stated that "there is no certainty that the belief at issue requires corrective advertising." ID at 64. While the ALJ's language could have been more precise, the more reasonable understanding of his statement is that the evidence presented as to lingering effect was too uncertain, not that complaint counsel have not accomplished the obviously impossible task of proving lingering effect with certainty.

FN11. Among users, 62.3% of Advil users, 51.4% of Aleve users, 41.3% of Bayer users, 78.9% of Doan's users, 61.4% of Motrin users, and 43.8% of Tylenol users stated that their own brand was superior for back pain relief. CX-421-V. Among aware non-users, 31.2% of Advil aware non-users, 19.9% of Aleve aware non-users, 27.1% of Bayer aware non-users, 44.6% of Doan's aware non-users, 35% of Motrin aware non-users, and 22.4% of Tylenol aware non-users stated that the brand that they were aware of (but did not use) was superior for back pain relief. *Id.*

FN12. Another possible method of proving lingering effect would be through a series of comparable consumer surveys conducted over the course of years demonstrating that the belief is durable. In *Warner-Lambert*, for example, the Commission concluded that a false cold and sore throat efficacy belief concerning Listerine would persist based on numerous, identical quarterly market research reports over an eight-year period demonstrating that consumers had consistent levels of the belief and that the belief did not diminish substantially during periodic cessations of the advertising during the summer months. 86 FTC at 1472-76, 1503-04. Other than the 1996 NFO Study, the only other extrinsic evidence that purports to show the false superior efficacy belief is the 1993 Brand Equity Study Like the ALJ, I do not believe that the 1993 Brand Equity Study is probative because the question posed was unclear as to whether participants were being asked if Doan's was very effective in an absolute sense or if Doan's was more effective than other OTC analgesics, FF 246. Consequently, unlike *Warner-Lambert*, there is no series of comparable tests over the course of years in this case that proves the existence of a stable and enduring false superior efficacy belief.

FN13. Dr. Mazis also relied on consumer research studies purportedly showing lingering false beliefs about Listerine mouthwash and Hawaiian Punch fruit drink in the 1970s. He provided no analysis of the reasons why the results of these studies are applicable to the specific facts of this case - false superior efficacy beliefs about an OTC analgesic in the 1990s. Mazis Tr. at 1256-63. Consumers of OTC analgesics may well be subject to significantly different influences than consumers of mouthwash or fruit punch; for example, advertising for OTC analgesics is much more competitive than advertising for mouthwash or fruit punch. Scheffman Tr. at 2603-04, 2626, 2647. Consumers of products in the 1990s also may well be subject to significantly different influences than in the 1970s because of new media, such as cable television, electronic mail, and websites. Without a cogent analysis of why the results of these consumer research studies are applicable to current consumer beliefs about Doan's, I am not persuaded by Dr. Mazis's testimony that these studies prove lingering effect.

FN14. As an example of how indefinite are Dr. Mazis's testimony and the other evidence on the issue of the duration of the false superior efficacy belief, one need look no further than the disagreement between the majority and complaint counsel over the suitable length of the corrective advertising remedy: the majority has concluded that the evidence warrants a one-year period for corrective advertising, while complaint counsel have argued that (if a fixed period is imposed) the evidence warrants an eight-year period for corrective advertising. CCRB at 40 n. 55.

FN15. It is extremely difficult to infer any particular duration of a lingering effect from other facts. For example, in this case, what are the differences in length of lingering effect among a material claim, a salient claim, and a very salient claim? What are the differences in length of lingering effect for an implied claim, a nearly express claim, a clear and consistent claim, and an express claim? What are the differences in length of lingering effect among a ten-year, $45 million advertising campaign; an eight-year, $65 million advertising campaign; and a five-year, $75 million advertising campaign? The indeterminate duration of any inferred lingering effect indicates that the case in which inference will support corrective advertising is likely to be the exception, not the rule.

FN16. FF 141, 148, 157, 164. While these studies may understate the level of advertising claim communication because they are designed primarily to test the memorability of advertisements, not claims in advertisements, *see* *Kraft, Inc.*, 114 FTC at 126 n.13 , they nevertheless raise serious doubt as to whether the deceptive advertisements had the claimed powerful impact on consumer beliefs.

FN17. In determining whether the deceptive advertisements were so extensive that an inference or lingering false belief can be drawn, the majority rejects any consideration of the extent of advertising by other competitors in the marketplace. Majority Op. at 31. However, in assessing the effects of a deceptive advertising campaign, the Commission should not treat deceptive advertising, especially comparative deceptive advertising, as if it takes place in a vacuum. For instance, assume that Company A spent $20 million over five years on advertisements making the deceptive claim that Product A is better than Product B, while Company B spent $500 million over the same five years on advertisements making the claim that Product B is better than Product A. In determining if it can be inferred that Company A's campaign is likely to create the lingering false belief that Product A is superior, the Commission should consider the nature and extent of the advertising campaigns of both Company A and Company B.

FN18. The majority states that I am emphasizing "the duration of the advertising campaign and the dollars spent in these cases." Majority Op. at 32 n.44. I have addressed the length of deceptive advertising campaigns and the amounts spent during these campaigns simply because they are some of the facts from which the majority is drawing an inference of lingering effect.

FN19. In *Sterling Drug*, the Commission did not order corrective advertising because "it ha[d] not been shown that [the deceptive] advertising created or reinforced the public's image of Bayer," 102 FTC at 799, and, therefore, the Commission did not reach the issue of lingering effect.

FN20. *1997 Annual Report: R.J. Reynolds Tobacco Co.* (1997) ("Winston's comprehensive marketing program includes eye-catching billboards and print ads that speak straight to adults with a twist of humor. Point-of-sale displays cut through the

marketplace clutter, and new packaging - with distinctive wraparound graphics - reflects the "No Bull" attitude."); American Lung Association, *American Lung Association News*, "Winston Campaign Attacked by Health Groups" (Aug. 25, 1997) (R.J. Reynolds launched a "massive national advertising campaign to reposition Winston. Ads *** appeared in such widely circulated publications as People, Glamour, and Inside Sports magazines. Billboards, bus shelters, and other outdoor advertising proclaim Winston as the new cigarette with nothing but tobacco.").

FN21. Resort to inference is more likely in the context of consent agreements than in adjudicated cases. Extrinsic evidence and expert testimony often are not available to the Commission when it considers a consent agreement, which makes the use of inference more probable. *See Eggland's Best*, 118 FTC 340, 365 n.3 (1994) (Statement of Commissioner Roscoe B. Starek, III, concurring) ("It is certainly unrealistic to think that we will have [extrinsic evidence of lingering effect] when the respondents enter into a consent agreement before a complaint is filed."). Moreover, because the Commission applies a "reason to believe" standard to consent agreements and a "preponderance of the evidence" standard to adjudicated cases inference is more likely to suffice in connection with consent agreements than adjudicated cases.

FN22. The corrective advertising remedy mandates that Novartis make a statement that it finds objectionable in part because its competitors in the highly competitive OTC analgesic market do not have to make such statements. Therefore, the corrective advertising remedy here is a form of compelled speech that is to be analyzed under the *Central Hudson* test. *See Glickman v. Wileman Bros. & Elliot, Inc.*, 117 S. Ct. 2130, 2139 (1997) (*Central Hudson* test applies to compelled commercial speech that requires advertisers to "repeat an objectional [sic] message out of their own mouths").

FN23. The government has the burden of proving that a corrective advertising requirement meets the *Central Hudson* standard became "[i]t is well-established that '[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Edenfield v. Fane*, 507 U.S. 761, 770 (1993), *quoting Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 71 n. 20 (1983); *see also Ibanez v. Fla. Dept. of Bus. & Pro. Regulation*, 512 U.S. 136, 142 n.7 (1994).

FN24. Similarly, it is unclear that the corrective advertising provision will in fact correct any remaining false superior efficacy beliefs (and thereby prevent deception) to any material degree in the approximately one year that it will be in effect. While testifying that the remedy will correct beliefs much more quickly than if it were not imposed, Dr. Mazis also acknowledged that "[w]e don't know how much faster" and no one "can measure with any precision how long a corrective notice for this particular case should be run." Mazis Tr. at 1975, 1382.

FN25. In other cases, the Commission analyzed whether other cease-and-desist provisions would substantially prevent deception before concluding that corrective advertising was the "least restrictive means of achieving a substantial and important governmental objective." *Warner-Lambert*, 562 F. 2d at 7 70-71; *see also American Home Products Corp.*, 98 FTC at 411 (corrective advertising was not needed in part because a triggered efficacy disclosure would be sufficient to prevent deception).

FN26. When it issued its decision in 1975, the Commission concluded that the false belief about Listerine would linger "well into the 1980's," 86 FTC at 1504, that is, at least five yeas after the Commission's order became final. The Commission imposed an approximately one-year corrective advertising requirement to address this lingering effect. This demonstrates an effort to carefully craft a remedy that was not overbroad.

FN27. *See, e.g., Eggland's Best*, 118 FTC at 366 (Statement of Commisioner Roscoe B. Starck, III, concurring) (corrective statement on egg cartons was "careful[ly] craft[ed]" to "reach consumers likely to have been misled by Eggland's ads (those who are preparing to purchase the product), rather than the population at large"); *Unocal Corp.*, 117 FTC 500, 511 (1994) (corrective brochure required to be mailed to customers who had company credit cards and who lived in one of five specified states in which deceptive claims were disseminated).

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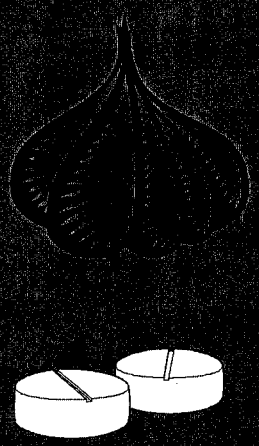
ATTACHMENT H

Dietary Supplements:



An Advertising Guide for Industry

TABLE OF CONTENTS

I

INTRODUCTION

The dietary supplement industry is a dynamic one. Scientific research on the associations between supplements and health is accumulating rapidly. The number of products — and the variety of uses for which they are promoted — have increased significantly in the last few years. The role of the Federal Trade Commission, which enforces laws outlawing "unfair or deceptive acts or practices," is to ensure that consumers get accurate information about dietary supplements so that they can make informed decisions about these products.[1]

The Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) work together under a long-standing liaison agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media. Because of their shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible.

In 1994, the Dietary Supplements Health and Education Act (DSHEA) significantly changed the FDA's role in regulating supplement labeling.[2] These claims are commonly referred to as "structure/function" claims.[3] Although DSHEA does not directly apply to advertising, it has generated many questions about the FTC's approach to dietary supplement advertising. The answer to these questions is that advertising for any product — including dietary supplements — must be truthful, not misleading, and substantiated. Given the dramatic increase in the volume and variety of dietary supplement advertising in recent years, FTC staff is issuing this guide to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising.

The FTC's approach to supplement advertising is best illustrated by its Enforcement Policy Statement on Food Advertising (Food Policy Statement). Although the Food Policy Statement does not specifically refer to supplements, the principles underlying the FTC's regulation of health claims in food advertising are relevant to the agency's approach to health claims in supplement advertising. In general, the FTC gives great deference to an FDA determination of whether there is adequate support for a health claim. Furthermore, the FTC and the FDA will generally arrive at the same conclusion when evaluating unqualified health claims. As the Food Policy Statement notes, however, there may

be certain limited instances when a carefully qualified health claim in advertising may be permissible under FTC law, in circumstances where it has not been authorized for labeling. However, supplement marketers are cautioned that the FTC will require both strong scientific support and careful presentation for such claims.[5]

Supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles. The FTC has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. *Therefore, all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.*

II

APPLICATION OF FTC LAW TO DIETARY SUPPLEMENT ADVERTISING

The FTC's truth-in-advertising law can be boiled down to two common-sense propositions:

1) advertising must be truthful and not misleading; and
2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.[6]

A deceptive ad is one that contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC's substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.

To determine whether an ad complies with FTC law, it is first necessary to identify all express and implied claims that the ad conveys to consumers. Once the claims are identified, the scientific evidence is assessed to determine whether there is adequate support for those claims. The following sections describe this two-step process with examples illustrating how principles of ad interpretation and substantiation apply in the context of dietary supplement advertising. The examples have been simplified to illustrate one or two specific points. Therefore, advertisers should use these examples as general guidance only.[7]

A. Identifying Claims and Interpreting Ad Meaning

1. Identifying Express and Implied Claims

The first step in evaluating the truthfulness and accuracy of advertising is to identify all express and implied claims an ad conveys to consumers. Advertisers must make sure that whatever they say expressly in an ad is accurate. Often, however, an ad conveys other claims beyond those expressly stated. Under FTC law, an advertiser is equally responsible for the accuracy of claims suggested or implied by the ad. Advertisers cannot suggest claims that they could not make directly.

When identifying claims, advertisers should not focus just on individual phrases or statements, but rather should consider the ad as a whole, assessing the "net impression" conveyed by all elements of the ad, including the text, product name, and depictions. When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each

interpretation. Copy tests, or other evidence of how consumers actually interpret an ad, can be valuable. In many cases, however, the implications of the ad are clear enough to determine the existence of the claim by examining the ad alone, without extrinsic evidence.

Example 1

An advertisement claims that "university studies prove" that a mineral supplement can improve athletic performance. The advertiser has expressly stated the level of support for the claimed benefit and is therefore responsible for having "university studies" that document the advertised benefit. Furthermore, the implied reference to scientific evidence likely conveys to consumers the implied claim that the studies are methodologically sound.

Example 2

An advertisement for a vitamin supplement claims that 90% of cardiologists regularly take the product. In addition to the literal claim about the percentage of cardiologists who use the product, the ad likely conveys an implied claim that the product offers some benefit for the heart. Therefore, the advertiser must have adequate support for both representations.

Depending on how it is phrased, or the context in which it is presented, a statement about a product's effect on a normal "structure or function" of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. If elements of the ad imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the ad contains no express reference to disease.

Example 3

An ad for an herbal supplement makes the claim that the product boosts the immune system to help maintain a healthy nose and throat during the winter season. The ad features the product name "Cold Away" and includes images of people sneezing and coughing. The various elements of the ad — the product name, the depictions of cold sufferers, and the reference to nose and throat health during the winter season — likely convey to consumers that the product helps prevent colds. Therefore, the advertiser must be able to substantiate

that claim. Even without the product name and images, the reference to nose and throat health during the winter season may still convey a cold prevention claim.

Example 4

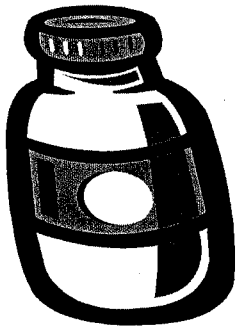
An ad for a dietary supplement called "Arthricure" claims that the product maintains joint health and mobility into old age. The "before" picture shows an elderly women using a walker. The "after" picture shows her dancing with her husband. The images and product name likely convey implied claims that the product is effective in the treatment of the symptoms of arthritis, and may also imply that the product can cure or mitigate the disease. The advertiser must be able to substantiate these implied claims.

2. When to Disclose Qualifying Information

An advertisement can also be deceptive because of what it fails to say. Section 15 of the FTC Act requires advertisers to disclose information if it is material in light of representations made or suggested by the ad, or material considering how consumers would customarily use the product. Thus, if an ad would be misleading without certain qualifying information, that information must be disclosed. For example, advertisers should disclose information relevant to the limited applicability of an advertised benefit. Similarly, advertising that makes either an express or implied safety representation should include information about any significant safety risks. Even in the absence of affirmative safety representations, advertisers may need to inform consumers of significant safety concerns relating to the use of their product.

Example 5

An advertisement for a multi-vitamin/mineral supplement claims that the product can eliminate a specific mineral deficiency that results in feelings of fatigue. In fact, less than 2% of the general population to which the ad is targeted suffers from this deficiency. The advertiser should disclose this fact so that consumers will understand that only the small percentage of people who suffer from the actual mineral deficiency are likely to experience any reduction in fatigue from using the product.



Example 6

An advertiser for a weight loss supplement cites a placebo-controlled, double-blind clinical study as demonstrating that the product resulted in an average weight loss of fifteen pounds over an eight-week period. The weight loss for the test group is, in fact, significantly greater than for the control subjects. However, both the control and test subjects engaged in regular exercise and followed a restricted-calorie diet as part of the study regimen. The advertisement should make clear that users of the supplement must follow the same diet and exercise regimen to achieve the claimed weight loss results.

Example 7

An advertiser claims that its herbal product is a natural pain reliever "without the side effects of over-the-counter pain relievers." However, there is substantial evidence that the product can cause nausea in some consumers when taken regularly. Because of the reference to the side effects of other pain relievers, consumers would likely understand this ad to mean that the herbal product posed no significant adverse effects. Therefore, the advertiser should disclose information about the adverse effects of the herbal product.

Example 8

An herbal weight loss product contains an ingredient which, when consumed daily over an extended period, can result in a significant increase in blood pressure. Even in the absence of any representation about the product's safety, the advertiser should disclose this potentially serious risk.

3. Clear and Prominent Disclosure

When the disclosure of qualifying information is necessary to prevent an ad from being deceptive, that information should be presented clearly and prominently so that it is actually noticed and understood by consumers. A fine-print disclosure at the bottom of a print ad, a

disclaimer buried in a body of text, a brief video superscript in a television ad, or a disclaimer that is easily missed on an Internet web site, are not likely to be adequate. To ensure that disclosures are effective, marketers should use clear language, avoid small type, place any qualifying information close to the claim being qualified, and avoid making inconsistent statements or distracting elements that could undercut or contradict the disclosure. Because consumers are likely to be confused by ads that include inconsistent or contradictory information, disclosures need to be both direct and unambiguous to be effective.

Example 9

A marketer promotes a supplement as a weight loss aid. There is adequate substantiation to indicate that the product can contribute to weight loss when used in conjunction with a diet and exercise regimen. The banner headline claims "LOSE 5 POUNDS IN 10 DAYS," the ad copy discusses how easy it is to lose weight by simply taking the product 3 times a day, and the ad includes dramatic before-and-after pictures. A fine print disclosure at the bottom of the ad, "Restricted calorie diet and regular exercise required," would not be sufficiently prominent to qualify the banner headline and the overall impression that the product alone will cause weight loss. The ad should be revised to remove any implication that the weight loss can be achieved by use of the product alone. This revision, combined with a prominent indication of the need for diet and exercise, may be sufficient to qualify the claim. However, if the research does not show that the product contributes anything to the weight loss effect caused by diet and exercise, it would be deceptive, even with a disclosure, to promote the product for weight loss.

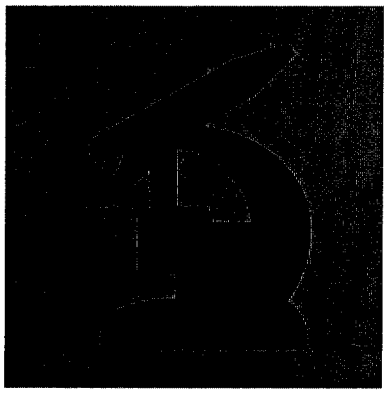
Qualifying information should be sufficiently simple and clear that consumers not only notice it, but also understand its significance. This can be a particular challenge when explaining complicated scientific concepts to a general audience, for example, if an advertiser wants to promote the effect of a supplement where there is an emerging body of science supporting that effect, but the evidence is insufficient to substantiate an unqualified claim. The advertiser should make sure consumers understand both the extent of scientific support and the existence of any significant contrary evidence. Vague qualifying terms — for example, that the product "may" have the claimed benefit or "helps" achieve the claimed benefit — are unlikely to be adequate. Furthermore, advertisers should not make qualified claims where the studies they rely on are contrary to a stronger body of evidence. In such instance, even a qualified claim could mislead consumers.

Example 10

A company has results from two studies suggesting that the main ingredient in its supplement helps to maintain healthy cholesterol levels. There are, however, significant limitations to each of the studies and a better controlled study is necessary to confirm whether the effect is genuine. The company makes a claim in advertising that "scientific studies show that our product may be effective in reducing cholesterol." The use of the word "may" is not likely to be a sufficient disclaimer to convey the limitations of the science. A disclosure that clearly describes the limitations of the research, in language consumers can easily understand, and states directly and unambiguously that additional research is necessary to confirm the preliminary results is more likely to be effective. As discussed in the following section on substantiating claims, the extent to which studies support an unqualified claim will depend largely on what experts in the relevant field would consider to be adequate support.

B. Substantiating Claims

In addition to conveying product claims clearly and accurately, marketers need to verify that there is adequate support for their claims. Under FTC law, before disseminating an ad, advertisers must have a reasonable basis for all express and implied product claims. What constitutes a reasonable basis depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified. The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented in advertising. A number of factors determine the appropriate amount and type of substantiation, including:



- **The Type of Product.** Generally, products related to consumer health or safety require a relatively high level of substantiation.
- **The Type of Claim.** Claims that are difficult for consumers to assess on their own are held to a more exacting standard. Examples include health claims that may be subject to a placebo effect or technical claims that consumers cannot readily verify for themselves.

- **The Benefits of a Truthful Claim** and **The Cost/Feasibility of Developing Substantiation for the Claim.** These factors are often weighed together to ensure that valuable product information is not withheld from consumers because the cost of developing substantiation is prohibitive. This does not mean, however, that an advertiser can make any claim it wishes without substantiation, simply because the cost of research is too high.

- **The Consequences of a False Claim.** This includes physical injury, for example, if a consumer relies on an unsubstantiated claim about the therapeutic benefit of a product and foregoes a proven treatment. Economic injury is also considered.

- **The Amount of Substantiation that Experts in the Field Believe is Reasonable.** In making this determination, the FTC gives great weight to accepted norms in the relevant fields of research and consults with experts from a wide variety of disciplines, including those with experience in botanicals and traditional medicines. Where there is an existing standard for substantiation developed by a government agency or other authoritative body, the FTC accords great deference to that standard.

The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with "competent and reliable scientific evidence," defined in FTC cases as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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." This is the same standard the FTC applies to any industry making health-related claims. There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. There are, however, a number of considerations to guide an advertiser in assessing the adequacy of the scientific support for a specific advertising claim.

1. Ads that Refer to a Specific Level of Support

If an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have.

Example 11

An ad for a supplement includes the statement "Scientists Now Agree!" in discussing the product's benefit. This statement likely conveys to consumers that the state of science supporting the benefit has reached the level of scientific consensus. Unless the advertiser possesses this level of evidence, the claim is not substantiated.

Example 12

An advertiser claims that its product has been "studied for years abroad" and is now the "subject of U.S. government-sponsored research." In addition to the explicit claim that the product has been studied, such phrases likely convey to consumers an implied claim that there exists a substantial body of competently-conducted scientific research supporting the efficacy of the product. The advertiser would be responsible for substantiating both claims.

2. The Amount and Type of Evidence

When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate. The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation. As a general rule, well-controlled human clinical studies are the most reliable form of evidence. Results obtained in animal and *in vitro* studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible. Although there is no requirement that a dietary supplement claim be supported by any specific number of studies, the replication of research results in an independently-conducted study adds to the weight of the evidence. In most situations, the quality of studies will be more important than quantity. When a clinical trial is not possible (e.g., in the case of a relationship between a nutrient and a condition that may take decades to develop), epidemiologic evidence may be an acceptable substitute for clinical data, especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect.

Anecdotal evidence about the individual experience of consumers is not sufficient to substantiate claims about the effects of a supplement. Even if those experiences are genuine, they may be attributable to a placebo effect or other factors unrelated to the supplement. Individual experiences are not a substitute for scientific research.[8]

Example 13

An advertiser relies on animal and *in vitro* studies to support a claim that its vitamin supplement is more easily absorbed into the bloodstream than other forms of the vitamin. However, the animal research uses a species of animal that, unlike humans, is able to synthesize the vitamin, and the *in vitro* study uses a different formulation with a higher concentration of the

compound than the product being marketed. In addition, human research is feasible and relatively inexpensive to conduct in light of the potential sales of the product and is the type of research generally accepted in this particular field of study. The substantiation is likely to be inadequate in this case, both because there are significant methodological problems and because, in this particular instance, human research is both feasible and the accepted approach in the field.

Example 14

A company wants to advertise its supplement as helpful in maintaining good vision into old age. There have been two long-term, large-scale epidemiologic studies showing a strong association between life-long high consumption of the principal ingredient in the supplement and better vision in those over 70. Experts have also discovered a plausible biological mechanism that might explain the effect. A clinical intervention trial would be very difficult and costly to conduct. Assuming that experts in the field generally consider epidemiological evidence to be adequate to support the potential for a protective effect, and assuming the absence of any stronger body of contrary evidence, a claim that is qualified to accurately convey the nature and extent of the evidence would be permitted.

Example 15

An advertisement for a supplement claims that the product will cause dramatic improvements in memory and describes the experiences of 10 people who obtained these results. The descriptions of these anecdotal experiences are truthful, but the advertiser has no scientific substantiation for the effect of its product on memory and cannot explain why the product might produce such results. The individual experiences are not adequate to substantiate the claim without confirming scientific research.

3. The Quality of the Evidence

In addition to the amount and type of evidence, the FTC will also examine the internal validity of each piece of evidence. Where the claim is one that would require scientific support, the research should be conducted in a competent and reliable manner to yield meaningful results. The design, implementation, and results of each piece of research are important to assessing the adequacy of the substantiation.

There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine. There are, however, some principles generally accepted in the scientific community to enhance the validity of test results. For example, a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results. A study of longer duration can provide better evidence that the claimed effect will persist and resolve potential safety questions. Other aspects of the research results — such as evidence of a dose-response relationship (*i.e.*, the larger the dose, the greater the effect) or a recognized biological or chemical mechanism to explain the effect — are examples of factors that add weight to the findings. Statistical significance of findings is also important. A study that fails to show a statistically significant difference between test and control group may indicate that the measured effects are merely the result of placebo effect or chance. The results should also translate into a meaningful benefit for consumers. Some results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health.

The nature and quality of the written report of the research are also important. Research cannot be evaluated accurately on the basis of an abstract or an informal summary. In contrast, although the FTC does not require that studies be published and will consider unpublished, proprietary research, the publication of a peer-reviewed study in a reputable journal indicates that the research has received some measure of scrutiny. At the same time, advertisers should not rely simply on the fact that research is published as proof of the efficacy of a supplement. Research may yield results that are of sufficient interest to the scientific community to warrant publication, but publication does not necessarily mean that such research is conclusive evidence of a substance's effect. The FTC considers studies conducted in foreign countries as long as the design and implementation of the study are scientifically sound.[9]

Example 16

An advertiser conducts a literature search and finds several abstracts summarizing research about the association between a nutrient and the ability to perform better on memory tests. The advertiser relies on these summaries to support a claim that its supplement, which contains the same nutrient, aids memory. However, without looking carefully at the specifics of the study design, implementation, and results, there is

no way for an advertiser to ascertain whether the research substantiates the product claims. (For example, did the research use a comparable formulation of the ingredient? Was the study adequately controlled? Did the study yield results that are statistically significant?) The advertiser should carefully review the underlying science, with the assistance of an expert if necessary, before drafting advertising claims.

Example 17

An advertiser makes an unqualified claim about the anti-clotting effect of a supplement that contains a compound extracted from fruit. There are three studies supporting the effect and no contrary evidence. One study consists of subjects tested over a one-week period, with no control group. The second study is well-controlled, of longer duration, but shows only a slight effect that is not statistically significant. The third study administers the compound through injection and shows a significant anti-clotting effect, but there is some question whether the compound would be absorbed into the bloodstream if administered orally. Because the studies all have significant limitations, it would be difficult to draft even a carefully qualified claim that would adequately convey to consumers the limited nature of the evidence. The advertiser should not base a claim on these studies.

Example 18

The marketer of an herbal supplement claims that its product promotes healthy vision and is approved in Germany for this purpose. The product has been used extensively in Europe for years and has obtained approval by the German governmental authorities, through their monograph process, for use to improve vision in healthy people. The company has two abstracts of German trials that were the basis of the German monograph, showing that the ingredient significantly improved the vision of healthy individuals in the test group over the placebo group. Animal trials done by the company suggest a plausible mechanism to explain the

effect. Although approval of the supplement under the German monograph suggests that the supplement is effective, advertisers should still examine the underlying research to confirm that it is relevant to the advertiser's product (for example, that the dosage and formulation are comparable) and to evaluate whether the studies are scientifically sound. Advertisers should also examine any other research that exists, either supporting or contradicting the monograph, especially if it is not possible to identify and review the research on which the monograph is based.

4. The Totality of the Evidence

Studies cannot be evaluated in isolation. The surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. Ideally, the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence. Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation. Where there are inconsistencies in the evidence, it is important to examine whether there is a plausible explanation for those inconsistencies. In some instances, for example, the differences in results are attributable to differences in dosage, the form of administration (e.g., oral or intravenous), the population tested, or other aspects of study methodology. Advertisers should assess how relevant each piece of research is to the specific claim they wish to make, and also consider the relative strengths and weaknesses of each. If a number of studies of different quality have been conducted on a specific topic, advertisers should look first to the results of the studies with more reliable methodologies.

The surrounding body of evidence will have a significant impact both on what type, amount and quality of evidence is required to substantiate a claim and on how that claim is presented — that is, how carefully the claim is qualified to reflect accurately the strength of the evidence. If a stronger body of surrounding evidence runs contrary to a claimed effect, even a qualified claim is likely to be deceptive.

Example 19

An advertiser wishes to make the claim that a supplement product will substantially reduce body fat. The advertiser has two controlled, double-blind studies showing a modest but statistically significant loss of fat at the end of a six-week period. However, there is an equally well-controlled, blinded 12-week study showing

no statistically significant difference between test and control groups. Assuming other aspects of methodology are similar, the studies taken together suggest that, if the product has any effect on body fat, it would be very small. Given the totality of the evidence on the subject, the claim is likely to be unsubstantiated.

Example 20

Advertisements for a fiber supplement make the claim that the product is "proven" to aid weight loss. Although the company has two published, peer-reviewed studies showing a relationship between fiber and weight loss, neither of these studies used the same proportions of soluble and insoluble fiber or the same total amount of fiber as the supplement product. There are numerous controlled, published human clinical studies, however, using the amount and type of fiber in the supplement product, that provide evidence that the product would not result in measurable weight loss. The totality of the evidence does not support the "proven" claim and, given the stronger body of contrary evidence, even a qualified claim is likely to be deceptive.

Example 21

An advertiser runs an ad in a magazine for retired people, claiming that its supplement product has been found effective in improving joint flexibility. The company sponsored a 6-week study of its supplement, involving 50 subjects over the age of 65, to test the product's effect on improving flexibility. The study was double-blinded and placebo-controlled and has been accepted for publication in a leading medical journal. The study showed dramatic, statistically significant increases in joint flexibility compared to placebo, based on objective measurements. In addition, several large trials have been conducted by European researchers using a similar formulation and dose of the active ingredient in the supplement. These trials also found statistically significant results. The advertiser reviewed the underlying European research and confirmed that it meets accepted research standards. The evidence as a whole likely substantiates the claim.

5. The Relevance of the Evidence to the Specific Claim

A common problem in substantiation of advertising claims is that an advertiser has valid studies, but the studies do not support the claim made in the ad. Advertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised. Therefore, advertisers should ask questions such as: How does the dosage and formulation of the advertised product compare to what was used in the study? Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study? Is the advertised product administered in the same manner as the ingredient used in the study? Does the study population reflect the characteristics and lifestyle of the population targeted by the ad? If there are significant discrepancies between the research conditions and the real life use being promoted, advertisers need to evaluate whether it is appropriate to extrapolate from the research to the claimed effect.

In drafting ad copy, the advertiser should take care to make sure that the claims match the underlying support. Claims that do not match the science, no matter how sound that science is, are likely to be unsubstantiated. Advertising should not exaggerate the extent, nature, or permanence of the effects achieved in a study, and should not suggest greater scientific certainty than actually exists. Although emerging science can sometimes be the basis for a carefully qualified claim, advertisers must make consumers aware of any significant limitations or inconsistencies in the scientific literature.

Example 22

An ad for a supplement claims that a particular nutrient helps maintain healthy cholesterol levels. There is a substantial body of epidemiologic evidence suggesting that foods high in that nutrient are associated with lower cholesterol levels. There is no science, however, demonstrating a relationship between the specific nutrient and cholesterol, although it would be feasible to conduct such a study. If there is a basis for believing that the health effect may be attributable to other components of the food, or to a combination of various components, a claim about the cholesterol maintenance benefits of the supplement product is likely not substantiated by this evidence.

Example 23

A number of well-controlled clinical studies have been conducted to suggest that a mineral supplement can improve mental alertness and memory in subjects with significantly impaired blood circulation to the brain. A claim suggesting that the supplement will improve memory or mental alertness in healthy adults may not be adequately substantiated by this evidence. Advertisers should not rely on research based on a specific test population for claims targeted at the general population without first considering whether it is scientifically sound to make such extrapolations.

Example 24

An advertiser wants to make claims that its combination herbal product helps increase alertness and energy safely and naturally. The product contains two herbs known to have a central nervous system stimulant effect. The advertiser compiles competent and reliable scientific research demonstrating that each of the herbs, individually, is safe and causes no significant side effects in the recommended dose. This evidence may be inadequate to substantiate an unqualified safety claim. Where there is reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the individual ingredients, studies showing the effect of the individual ingredients may be insufficient to substantiate the safety of the multiple ingredient product. In this example, the combination of two herbs with similar stimulant properties could produce a stronger cumulative stimulant effect that might present safety hazards. A better approach would be to investigate the safety of the specific combination of ingredients contained in the product.

Example 25

Several clinical trials have been done on a specific botanical extract showing consistently that the extract is effective for supporting the immune system. The studied extract is a complex combination of many constituents and the active constituents that may produce the benefit are still unknown. An advertiser wishes to cite this research in its advertising, as proof that its product will support the immune system. The advertiser's product is made using a different extraction method of the same botanical. An analysis of the extract reveals that it has a significantly different chemical profile from the studied extract. The advertiser should not rely on these clinical trials alone as substantiation because the difference in extracts may result in significant differences in the two products' efficacy.

C. Other Issues Relating to Dietary Supplement Advertising

In addition to the basic principles of ad meaning and substantiation discussed above, a number of other issues commonly arise in the context of dietary supplement advertising. The following sections provide guidance on some of these issues including: the use of consumer or expert endorsements in ads; advertising claims based on traditional uses of supplements; use of the DSHEA disclaimer in advertising; and the application to advertising of the DSHEA exemption for certain categories of publications, commonly referred to as "third party literature."

1. Claims Based on Consumer Testimonials or Expert Endorsements

An overall principle is that advertisers should not make claims either through consumer or expert endorsements that would be deceptive or could not be substantiated if made directly.[10] It is not enough that a testimonial represents the honest opinion of the endorser. Under FTC law, advertisers must also have appropriate scientific evidence to back up the underlying claim.

Consumer testimonials raise additional concerns about which advertisers need to be aware. Ads that include consumer testimonials about the efficacy or safety of a supplement product should be backed by adequate substantiation that the testimonial experience is representative of what consumers will generally achieve when using the product. As discussed earlier, anecdotal evidence of a product's effect, based solely on the experiences of individual consumers, is generally insufficient to substantiate a claim. Further, if the advertiser's substantiation does not demonstrate that the results are representative, then a clear and

conspicuous disclaimer is necessary. The advertiser should either state what the generally expected results would be or indicate that the consumer should not expect to experience the attested results. Vague disclaimers like "results may vary" are likely to be insufficient.

Example 26

An advertisement for a weight loss supplement features a before-and-after photograph of a woman and quotes her as saying that she lost 20 pounds in 8 weeks while using the supplement. An asterisk next to the quotation references a disclaimer in fine print at the bottom of the ad that reads, "Results may vary." The experience of the woman is accurately represented, but the separate, competent research demonstrating the efficacy of the supplement showed an average weight loss of only 6 pounds in 8 weeks. Therefore, the disclosure does not adequately convey to consumers that they would likely see much less dramatic results. The placement and size of the disclaimer is also insufficiently prominent to qualify the claim effectively. One approach to adequate qualification of this testimonial would be to include a disclaimer immediately adjacent to the quote, in equal print size that says, "These results are not typical. Average weight loss achieved in clinical study was 6 pounds."

When an advertiser uses an expert endorser, it should make sure that the endorser has appropriate qualifications to be represented as an expert and has conducted an examination or testing of the product that would be generally recognized in the field as sufficient to support the endorsement. In addition, whenever an expert or consumer endorser is used, the advertiser should disclose any material connection between the endorser and the advertiser of the product. A material connection is one that would affect the weight or credibility of the endorsement, or put another way, a personal, financial, or similar connection that consumers would not reasonably expect.

Example 27

An infomercial for a dietary supplement features an expert referred to as a "Doctor" and a "leading clinician in joint health" discussing the effect of a supplement product on the maintenance of healthy joints. The expert is not licensed to practice medicine, but has a graduate degree and is a trained physical therapist, running a sports clinic. The expert has not conducted

any review of the scientific literature on the active component of the supplement. In return for appearing in the infomercial, she is given a paid position as an officer the company. The ad is likely to be deceptive for several reasons. First, her qualifications as an expert have been overstated and she has not conducted sufficient examination of the product to support the endorsement. In addition, her connection to the company is one that consumers might not expect and may affect the weight and credibility of her endorsement. Even if she is adequately qualified and has conducted an adequate review of the product, her position as an officer of the company should be clearly disclosed.

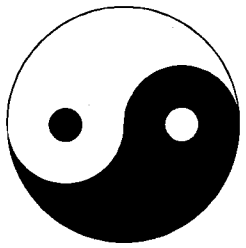
Example 28

A best-selling book about the benefits of a supplement product includes a footnote mentioning the most effective brand of the supplement, by name. The manufacturer of the brand cited in the book has an exclusive promotional agreement with the author and has paid him to reference the product by name. The manufacturer's ad touts the fact that its product is the only brand recommended in this best-selling book. The ad is deceptive since it suggests a neutral endorsement when, in fact, the author has been paid by the manufacturer to promote the product.

2. Claims Based on Traditional Use

Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. A number of supplements, particularly botanical products, have a long history of use as traditional medicines in the United States or in other countries to treat certain conditions or symptoms. Several European countries have a separate regulatory approach to these traditional medicines, allowing manufacturers to make certain limited claims about their traditional use for treating certain health conditions. Some countries also require accompanying disclosures about the fact that the product has not been scientifically established to be effective, as well as disclosures about potential adverse effects. At this time there is no separate regulatory process for approval of claims for these traditional medicine products under DSHEA and FDA labeling rules.

In assessing claims based on traditional use, the FTC will look closely at consumer perceptions and specifically at whether consumers expect such claims to be backed by supporting scientific evidence. Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated for efficacy. The degree of qualification necessary to communicate the absence of scientific substantiation for a traditional use claim will depend in large part on consumer understanding of this category of products. As consumer awareness of and experience with "traditional use" supplements evolve, the extent and type of qualification necessary is also likely to change.



There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support. In determining the level of substantiation necessary to substantiate a claim, the FTC assesses, among other things, the consequences of a false claim. 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. 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.

The advertiser should also make sure that it can document the extent and manner of historical use and be careful not to overstate such use. As part of this inquiry, the advertiser should make sure that the product it is marketing is consistent with the product as traditionally administered. If there are significant differences between the traditional use product and the marketed product, in the form of administration, the formulation of ingredients, or the dose, a "traditional use" claim may not be appropriate.

Example 29

The advertiser of an herbal supplement makes the claim, "Ancient folklore remedy used for centuries by Native Americans to aid digestion." The statement about traditional use is accurate and the supplement product is consistent with the formulation of the product as traditionally used. However, if, in the context of the ad, this statement suggests that there is scientific evidence demonstrating that the product is effective for aiding digestion, the advertiser would need to include a clear and prominent disclaimer about the absence of such evidence.

Example 30

A supplement manufacturer wants to market an herbal product that has been used in the same formulation in China as a tonic for improving mental functions. The manufacturer prepares the product in a manner consistent with Chinese preparation methods. The ad claims, "Traditional Chinese Medicine — Used for Thousands of Years to Bring Mental Clarity and Improve Memory." The ad also contains language that clearly conveys that the efficacy of the product has not been confirmed by research, and that traditional use does not establish that the product will achieve the claimed results. The ad is likely to adequately convey the limited nature of support for the claim.

Example 31

A supplement manufacturer markets a capsule containing a concentrated extract of a botanical product that has been used in its raw form in China to brew teas for increasing energy. The advertisement clearly conveys that the energy benefit is based on traditional use and has not been confirmed by scientific research. The ad may still be deceptive, however, because the concentrated extract is not consistent with the traditional use of the botanical in raw form to brew teas and may produce a significantly different effect.

Example 32

A supplement ad claims that a supplement liquid mineral solution has been a popular American folk remedy since early pioneer days for shrinking tumors. The ad is likely to convey to consumers that the product is an effective treatment for cancer. There is no scientific support for this disease benefit. Because of the potential risks to consumers of taking a product that may or may not be effective to treat such a serious health condition, possibly without medical supervision, the advertiser should not make the claim.

3. Use of the DSHEA Disclaimer in Advertising

Under DSHEA, all statements of nutritional support for dietary supplements must be accompanied by a two-part disclaimer on the product label: that the statement has not been evaluated by FDA and that the product is not intended to "diagnose, treat, cure or prevent any disease." Although DSHEA does not apply to advertising, there are situations where such a disclosure is desirable in advertising as well as in labeling to prevent consumers from being misled about the nature of the product and the extent to which its efficacy and safety have been reviewed by regulatory authorities. For example, a disclosure may be necessary if the text or images in the ad lead consumers to believe that the product has undergone the kind of review for safety and efficacy that the FDA conducts on new drugs and has been found to be beneficial for the treatment of disease. Failure to correct those misperceptions may render the advertising deceptive.

At the same time, the inclusion of a DSHEA disclaimer or similar disclosure will not cure an otherwise deceptive ad, particularly where the deception concerns claims about the disease benefits of a product. In making references to DSHEA and FDA review, advertisers should also be careful not to mischaracterize the extent to which a product or claim has been reviewed or approved by the FDA. Compliance with the notification and disclaimer provisions of DSHEA does not constitute authorization of a claim by FDA and advertisers should not imply that FDA has specifically approved any claim on that basis.

Example 33

A company markets a supplement for "maintaining joint flexibility." The product packaging is similar in color and design to a nonprescription drug used to treat joint pain associated with arthritis and the product name is similar to the drug counterpart. The ad includes statements urging consumers to "ask their pharmacist" and "accept no generic substitute." The various elements of the ad may lead consumers to believe that the supplement is, in fact, an approved drug, or may give consumers more general expectations that the product has been subjected to similar government review for safety and efficacy. A clear and prominent disclaimer may be necessary to indicate that the product has not been evaluated by FDA and is not an approved drug product.

Example 34

An advertisement for an herbal supplement includes strong, unqualified claims that the product will effectively treat or prevent diabetes, heart disease, and various circulatory ailments. The advertiser does not have adequate substantiation for this claim, but includes the DSHEA disclaimer prominently in the ad. In face of the strong contradictory message in the ad, the inclusion of the DSHEA disclaimer is not likely to negate the explicit disease claims made in the ad, and will not cure the fact that the claims are not substantiated.

Example 35

A dietary supplement advertisement makes a number of claims about the benefits of its product for supporting various body functions. The ad also includes the statement, "Complies with FDA notification procedures of the Dietary Supplement Health and Education Act." This statement may suggest to consumers that FDA has authorized the claims made in the ad or that it has reviewed the support for the claims and found the product to be effective. Because there is no review and authorization process for such claims under DSHEA, this would be deceptive.

4. Third Party Literature

Dietary supplement advertisers should be aware that the use of newspaper articles, abstracts of scientific studies, or other "third party literature" to promote a particular brand or product can have an impact on how consumers interpret an advertisement and on what claims the advertiser will be responsible for substantiating. For purposes of dietary supplement labeling, Section 5 of DSHEA provides an exemption from labeling requirements for scientific journal articles, books and other publications used in the sale of dietary supplements, provided these materials are reprinted in their entirety, are not false or misleading, do not promote a specific brand or manufacturer, are presented with other materials to create a balanced view of the scientific information, and are physically separate from the supplements being sold.

The FTC will generally follow an approach consistent with the labeling approach when evaluating the use of such publications in other contexts, such as advertising. Although the FTC does not regulate the content or accuracy of statements made in independently written and published books, articles, or other non-commercial literature, FTC law does prohibit the deceptive use of such materials in marketing products. The determination of whether the

materials will be subject to FTC jurisdiction turns largely on whether the materials have been created or are being used by an advertiser specifically for the purpose of promoting its product. As a practical matter, publications and other materials that comply with the elements of the DSHEA provision, particularly with the requirement that such materials be truthful, not misleading and balanced, are also likely to comply with FTC advertising law.

Example 36

An author publishes a book on the curative properties of an herb. The book title is "The Miracle Cancer Cure." The book does not endorse or otherwise mention any particular supplement brand. The author/publisher does not sell the herbal supplement and does not have any material connection to any marketers of the herb. As non-commercial speech, the book itself would not be subject to the FTC's jurisdiction over advertising. However, if a marketer of the herb referred to the book in advertising materials (for instance, by quoting the title and using excerpts to describe the anti-cancer benefits of its product), such references would likely be considered advertising. The advertiser would be responsible for substantiating any claims about the advertiser's product that are conveyed by these references.

III

CONCLUSION

Marketers of dietary supplements should be familiar with the requirements under both DSHEA and the FTC Act that labeling and advertising claims be truthful, not misleading and substantiated. The FTC approach generally requires that claims be backed by sound, scientific evidence, but also provides flexibility in the precise amount and type of support necessary. This flexibility allows advertisers to provide truthful information to consumers about the benefits of supplement products, and at the same time, preserves consumer confidence by curbing unsubstantiated, false, and misleading claims. To ensure compliance with FTC law, supplement advertisers should follow two important steps: 1) careful drafting of advertising claims with particular attention to how claims are qualified and what express and implied messages are actually conveyed to consumers; and 2) careful review of the support for a claim to make sure it is scientifically sound, adequate in the context of the surrounding body of evidence, and relevant to the specific product and claim advertised.

Endnotes

[1] The FTC's authority derives from Section 5 of the FTC Act. In addition, supplements have traditionally been regulated under Sections 12 and 15, which prohibit false advertisements, defined as those that are "misleading in a material respect," for foods, drugs, devices or cosmetics.

[2] Under DSHEA, supplement marketers are allowed to make two kinds of claims on labeling: 1) health claims specifically authorized by the FDA; and 2) statements of nutritional support. Health claims — representations about the relationship between a nutrient and a disease or health-related condition — are permitted only if they have been authorized by an FDA finding that there is "significant scientific agreement" to support the claim. The Food and Drug Administration Modernization Act of 1997 (FDAMA) also now allows health claims that are based on "authoritative statements" from certain federal scientific bodies, such as NIH and the National Academy of Sciences. Aside from these authorized claims, supplement marketers are prohibited from making any labeling claim about the diagnosis, mitigation, treatment or cure of a disease. In contrast to health claims, "structure/function" claims, within the broader category of "statements of nutritional support," refer to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition.

[3] Structure/function claims are not subject to FDA pre-authorization. A marketer may make these claims in labeling if it notifies FDA and includes a disclaimer that the claim has not been evaluated by FDA and that the product is not intended to diagnose, mitigate, treat, cure, or prevent disease. DSHEA also requires that structure/function claims in labeling be substantiated and be truthful and not misleading. This requirement is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated.

[4] FTC policy statements and other information for businesses and consumers are available on the FTC's Internet home page, **www.ftc.gov**.

[5] As indicated in the Food Policy Statement, the FTC will be "especially vigilant in examining whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community. In the absence of adequate qualification the Commission will find such claims deceptive."

[6] These principles are articulated in the FTC's Deception Policy Statement and Advertising Substantiation Policy Statement, available at **www.ftc.gov**. The FTC also has authority to challenge unfair trade practices. An unfair practice is one that causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition. The majority of advertising cases are brought pursuant to the FTC's deception authority.

[7] Throughout these examples the terms "advertiser," "marketer," "supplement manufacturer" and "company" are used interchangeably.

[8] Additional guidance on the use of consumer testimonials is provided in Part C.1.

[9] Any foreign research submitted to the FTC in the course of an investigation should be presented in English translation and with sufficient detail to allow the agency to evaluate the study.

[10] The FTC has provided detailed guidance on this subject in its Guides Concerning Use of Endorsements and Testimonials in Advertising, available at **www.ftc.gov**.

Federal Trade Commission
Bureau of Consumer Protection
April 2001

FEDERAL TRADE COMMISSION
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FOR THE CONSUMER

ATTACHMENT I

United States Court of Appeals,
Third Circuit.
FEDERAL TRADE COMMISSION, Appellant
v.
LANE LABS-USA, INC; Cartilage Consultants, Inc.; I. William **Lane**; Andrew J. **Lane**.
No. 09-3909.

Argued Sept. 14, 2010.
Filed: Oct. 26, 2010.

Background: Federal Trade Commission (FTC) filed motion to hold manufacturer of calcium supplement and male fertility product in contempt for violation of consent judgments requiring that it refrain from making claims about its products without possessing competent and reliable scientific evidence that substantiated the claims and prohibiting misrepresentations regarding tests, studies or research. The United States District Court for the District of New Jersey, Dennis M. Cavanaugh, J., 2009 WL 2496532, denied motion. FTC appealed.

Holdings: The Court of Appeals, Smith, Circuit Judge, held that:
(1) manufacturer's claim that only its calcium supplement could increase bone density in women was in contempt;
(2) manufacturer's claim that supplement had been shown in clinical tests to increase bone density in the hip was not in contempt;
(3) district court's finding that manufacturer's claim that its product was three to four times more absorbable than other calcium supplements was not in contempt was inadequate;
(4) manufacturer's claim that its product was comparable or superior to prescription osteoporosis drugs was in contempt;
(5) manufacturer's claim that its male fertility product could cause sperm count to "skyrocket" in as little as one month was not in contempt;
(6) district court failed to provide reasoned basis for concluding that manufacturer was not in contempt of prohibition against misrepresentations regarding tests, studies or research;
(7) as matter of first impression, party charged with contempt may avail itself of defense of substantial compliance; but
(8) district court did not make necessary findings for that defense.

Vacated and remanded.

West Headnotes

[1] Contempt 93 66(7)

93 Contempt
93II Power to Punish, and Proceedings Therefor
93k66 Appeal or Error
93k66(7) k. Review. Most Cited Cases
Court of Appeals reviews denial of contempt motion for abuse of discretion, and reversal is appropriate only where the denial is based on error of law or finding of fact that is clearly erroneous.

[2] Federal Courts 170B 844

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)5 Questions of Fact, Verdicts and Findings
170Bk844 k. Credibility of witnesses in general. Most Cited Cases
Where factual findings are based upon testimony of live witnesses, deference due district court is even more considerable.

[3] Federal Courts 170B 844

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)5 Questions of Fact, Verdicts and Findings
170Bk844 k. Credibility of witnesses in general. Most Cited Cases
District court may not insulate its findings from review by denominating them credibility determinations, because factors other than demeanor go into decision whether to believe a witness.

[4] Contempt 93 20

93 Contempt
93I Acts or Conduct Constituting Contempt of Court
93k19 Disobedience to Mandate, Order, or Judgment
93k20 k. In general. Most Cited Cases

Contempt 93 60(3)

93 Contempt
93II Power to Punish, and Proceedings Therefor
93k60 Evidence
93k60(3) k. Weight and sufficiency. Most Cited Cases
Proof of contempt requires movant to demonstrate, by clear and convincing evidence, that valid order of court existed, (2) that defendants had knowledge of order, and (3) that defendants disobeyed order; ambiguities must be resolved in favor of party charged with contempt.

[5] Contempt 93 2

93 Contempt
93I Acts or Conduct Constituting Contempt of Court
93k1 Nature and Elements of Contempt
93k2 k. In general. Most Cited Cases

Contempt 93 28(1)

93 Contempt
93I Acts or Conduct Constituting Contempt of Court
93k28 Defenses
93k28(1) k. In general. Most Cited Cases
Although courts should hesitate to adjudge defendant in contempt when there is ground to doubt wrongfulness of the conduct, alleged contemnor's behavior need not be willful in order to contravene applicable decree; in other words, good faith is not a defense to civil contempt.

[6] Federal Civil Procedure 170A 2397.6

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(A) In General
170Ak2397 On Consent
170Ak2397.6 k. Compliance; enforcement. Most Cited Cases
Calcium supplement manufacturer's claim that only its product could increase bone density in women was in contempt of Federal Trade Commission (FTC) consent judgment requiring that its marketing claims find substantiation in competent or reliable scientific research; government's proffer demonstrated that claims of uniqueness were unsupported by competent and reliable scientific research.

[7] Federal Civil Procedure 170A 2397.6

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(A) In General
170Ak2397 On Consent
170Ak2397.6 k. Compliance; enforcement. Most Cited Cases
Calcium supplement manufacturer did not act in contempt of Federal Trade Commission (FTC) consent judgment requiring that its marketing claims find substantiation in competent or reliable scientific research, by claiming that supplement had been shown in clinical tests to increase bone density in the hip; two clinical studies appearing in peer-reviewed journals showed that calcium increased bone density in human hip.

[8] Federal Courts 170B 947

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(L) Determination and Disposition of Cause
170Bk943 Ordering New Trial or Other Proceeding
170Bk947 k. Further evidence, findings or conclusions. Most Cited Cases
Remand was required of district court's finding that calcium supplement manufacturer's claim that its product was three to four times more absorbable than other calcium supplements was not in contempt of Federal Trade Commission (FTC) consent judgment requiring that its marketing claims find substantiation in competent or reliable scientific research; district court did not address incongruity between manufacturer's argument, that product was marketed to elderly females who might achieve that absorption rate, and actual language of its marketing claims.

[9] Federal Civil Procedure 170A 2397.6

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(A) In General
170Ak2397 On Consent
170Ak2397.6 k. Compliance; enforcement. Most Cited Cases
Calcium supplement manufacturer's claim that its product was comparable or superior to prescription osteoporosis drugs was in contempt of Federal Trade Commission (FTC) consent judgment requiring that its marketing claims find substantiation in competent or reliable scientific research; supplement had never undergone scientific testing for comparison with any prescription drug, and regardless of whether claim was published in private institute's newsletter, manufacturer used this claim to market the product.

[10] Federal Civil Procedure 170A 2397.6

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(A) In General
170Ak2397 On Consent
170Ak2397.6 k. Compliance; enforcement. Most Cited Cases
Calcium supplement manufacturer did not act in contempt of Federal Trade Commission (FTC) consent judgment requiring that its marketing claims find substantiation in competent or reliable scientific research, by claiming that its male fertility product could cause sperm count to "skyrocket" in as little as one month.

[11] Federal Civil Procedure 170A 2397.6

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(A) In General
170Ak2397 On Consent
170Ak2397.6 k. Compliance; enforcement. Most Cited Cases
District court failed to provide reasoned basis for concluding that manufacturer of calcium supplement was not in contempt of Federal Trade Commission (FTC) consent judgments prohibiting misrepresentations regarding tests, studies or research; that supplement was efficacious in delivering calcium to the body did not, ipso facto, preclude manufacturer from misrepresenting scientific research, nor did court's characterization of supplement as good product relieve it of duty to make particularized findings of fact germane to purported misrepresentations challenged by FTC.

[12] Contempt 93 20

93 Contempt
93I Acts or Conduct Constituting Contempt of Court
93k19 Disobedience to Mandate, Order, or Judgment
93k20 k. In general. Most Cited Cases
In order to avail itself of defense of substantial compliance, party charged with contempt must show that it (1) has taken all reasonable steps to comply with valid court order, and (2) has violated order in manner that is merely "technical" or "inadvertent."

[13] Contempt 93 66(7)

93 Contempt
93II Power to Punish, and Proceedings Therefor
93k66 Appeal or Error
93k66(7) k. Review. Most Cited Cases
District Court's application of appropriate test for substantial compliance in contempt case is legal issue to be reviewed de novo.

[14] Contempt 93 66(7)

93 Contempt
93II Power to Punish, and Proceedings Therefor
93k66 Appeal or Error
93k66(7) k. Review. Most Cited Cases
Whether alleged contemnors took all reasonable steps to comply with court order, and extent to which contumacious conduct constitutes "technical" or "inadvertent" violation, supportive of defense of substantial compliance, are factual questions subject to review for clear error.

[15] Federal Courts 170B 947

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(L) Determination and Disposition of Cause
170Bk943 Ordering New Trial or Other Proceeding

170Bk947 k. Further evidence, findings or conclusions. Most Cited Cases
District court's ruling, that supplement manufacturer was entitled to defense of substantial compliance against claim that it was in contempt of Federal Trade Commission (FTC) consent judgments, could not be meaningfully reviewed, and remand was required, due to court's failure to address whether manufacturer's violations were merely "technical" or "inadvertent."
***577** Theodora T. McCormick, Jack Wenik (argued), Sills, Cummis & Gross, Newark, NJ, for Appellee **Lane Labs-USA**, Inc. and Andrew J. **Lane**.

Paul F. Carvelli (argued), McCusker, Anselmi, Rosen & Carvelli, Florham Park, NJ, for Appellee I. William **Lane**.

Michele Arington (argued), John F. Daly, **Federal Trade Commission**, Elsie B. Kappler, Constance M. Vecellio, **Federal Trade Commission**, Amanda C. Basta, Kirkland & Ellis, Washington, DC, Susan J. Steele, Office of United States Attorney, Newark, NJ, for Appellant.

Before: SLOVITER, BARRY, and SMITH, Circuit Judges.

OPINION

SMITH, Circuit Judge.

The **Federal Trade Commission** ("FTC") appeals from an order of the United States District Court for the District of New Jersey denying its motion to hold **Lane Labs-USA**, Inc., I. William **Lane**, and Andrew J. **Lane** in contempt for violation of consent judgments entered by the District Court on July 6, 2000 and September 26, 2000. For the reasons set forth below, we conclude that the District Court committed clear error. Accordingly, we will vacate the order of the District Court and remand for further proceedings.

I.

Lane Labs-USA, Inc. ("Lane Labs") is a manufacturing distributor of specialty dietary***578** supplements and cosmetic products.[FN1] The company was founded in 1994 by its current president and sole shareholder, Andrew J. Lane ("Lane"). Lane's father, I. William Lane, is not an employee of Lane Labs, but has served as a consultant to the company since its founding.[FN2]

FN1. Although Lane Labs is considered a "products manufacturer" under the Standard Industrial Classification Code, it outsources all manufacturing work for offsite production. The company's in-house staff is primarily concerned with distributing and marketing its products.

FN2. For ease of reference, we collectively refer to **Lane Labs**, Andrew J. **Lane**, and I. William **Lane** as "the **Lane** defendants."

In June of 2000, the FTC charged the **Lane** defendants with deceptive acts in violation of § 5 of the **Federal Trade Commission** Act ("FTC Act").[FN3] The FTC's complaint focused upon unsubstantiated representations pertaining to two products: BeneFin, a dietary supplement, and SkinAnswer, a cosmetic cream.[FN4] Shortly after the litigation was commenced, however, each of the **Lane** defendants reached a settlement with the FTC and agreed to the terms of a consent decree. The District Court entered the decree as a stipulated final order for permanent injunction (hereinafter, the "Final Order"),[FN5] and adjudged **Lane Labs** liable for the sum of $1 million.

FN3. Section 5 of the FTC Act prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1).

FN4. In a related action, the Food and Drug Administration ("FDA") filed a complaint against Lane Labs and Lane on December 10, 1999, alleging violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* Specifically, the government accused both defendants of misbranding and falsely advertising three products: BeneFin, SkinAnswer, and MGN-3. The United States District Court for the District of New Jersey agreed with the FDA, permanently enjoined the offensive conduct, and ordered payment of restitution to consumers who purchased these products. *United States v. **Lane Labs-USA**, Inc.*, 324 F.Supp.2d 547 (D.N.J.2004). We affirmed

the District Court's decision the following year. *United States v. **Lane Labs-USA**, Inc.*, 427 F.3d 219 (3d Cir.2005).

FN5. The District Court actually entered two stipulated final orders for permanent injunction, one against William **Lane** on July 6, 2000, and the other against **Lane Labs** and **Lane** on September 26, 2000. Both orders are identical in all material respects, except that monetary penalties were imposed against **Lane Labs**.

Two provisions of the Final Order are pertinent to this appeal. In Section III, the **Lane** defendants agreed that "in connection with the manufacturing, labeling, advertising, promotion, offering for sale, or distribution of any food, dietary supplement, or drug," they would refrain from

> mak[ing] any representation, in any manner, ... expressly or by implication, about the effect of [a] product on any disease or disorder, or the effect of such product on the structure or function of the human body, or about any other health benefits of such product, unless, at the time the representation is made, [they] possess[ed] and rel[ied] upon competent and reliable scientific evidence that substantiates the representation.

"Competent and reliable scientific evidence" was defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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." Section IV of the Final Order forbade express or implied misrepresentations regarding "the existence, contents, validity, results, ***579** conclusions, or interpretations of any test, study or research" in connection with "the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug." Two other provisos, Sections IX and XIV, imposed record keeping and periodic reporting requirements, respectively.

Two products are at issue: AdvaCal, a calcium supplement, and Fertil Male, which, as the name suggests, purports to improve male fertility. We shall briefly consider the development and marketing of both products before turning to the proceedings that occasioned the instant appeal.

A. AdvaCal

AdvaCal was developed by a renowned Japanese scientist named Takuo Fujita. The product primarily consists of calcium hydroxide derived from oyster shells smelted at extremely high temperatures. Once the smelting process is complete, the calcium component is combined with a heated algae ingredient ("HAI") extracted from Hijiki seaweed. This combination of active ingredients purportedly yields a calcium hydroxide product that is significantly more absorbable by the human body than competing calcium supplements.

Lane Labs began marketing AdvaCal in 2000 as a means to increase bone strength and combat osteoporosis. Over the next several years, the company utilized an array of print, television, and online media to promote its product. Each of these advertisements contained numerous representations regarding AdvaCal's efficacy, and many compared AdvaCal to competing calcium supplements. Typical among the claims appearing in AdvaCal marketing materials were assertions that the supplement (1) was unique in its ability to increase bone mineral density, (2) was clinically proven to be more absorbable than other calcium supplements, and (3) was clinically shown to increase bone density in the hip. In addition, Lane Labs distributed literature promoting AdvaCal as comparable or superior to prescription osteoporosis medicine, and Lane told at least one prospective retail purchaser that the calcium supplement was "on par with" prescription pharmaceuticals.

Consistent with its obligations under the Final Order, Lane Labs provided the FTC with compliance reports pertaining to AdvaCal in 2001, 2004, and 2006. Each report attached print copies of AdvaCal-specific advertisements, as well as the scientific research upon which Lane Labs relied for its representations. The parties do not dispute that many of the marketing claims at issue in this matter were disclosed to the FTC in the 2001 compliance report.

B. Fertil Male

Fertil Male is derived from a Peruvian plant known as "maca." After it is gelatinised and heated, the plant is

combined with HAI. This combination allegedly enhances the human body's capacity to absorb maca, which purportedly improves male fertility parameters such as sperm production and sperm motility. [FN6] In October 2003, Lane Labs began marketing Fertil Male. One advertisement featured a customer who proclaimed that Fertil Male caused his sperm count to "skyrocket" within one month. Just as it had with AdvaCal, Lane Labs submitted an FTC compliance report disclosing its Fertil Male advertisements in 2006.

> FN6. The FTC's expert, Dr. Craig Niederberger, described sperm motility as "the wiggling of the sperm as if they were ... going towards an egg."

***580 C. The Contempt Proceeding**

On July 12, 2006, the FTC notified Lane Labs that certain Fertil Male advertisements contained misrepresentations which amounted to violations of the Final Order. One month later, the FTC provided Lane Labs with a similar notice concerning the marketing of AdvaCal. Both notices threatened litigation absent the negotiation of an appropriate settlement agreement. The parties did not reach a settlement. Thus, on January 12, 2007, the FTC filed a motion with the District Court to hold the Lane defendants in contempt for violating Sections III and IV of the Final Order. To remedy these purported violations, the FTC requested $24 million in monetary damages.

The District Court held a five-day evidentiary hearing on the motion beginning on April 20, 2009. Two expert witnesses testified on behalf of the FTC: Robert Heaney, a physician and researcher at Creighton University, offered testimony concerning AdvaCal, while Craig Niederberger, a urologist at the University of Illinois at Chicago, addressed matters pertaining to Fertil Male. The Lane defendants presented the testimony of two opposing experts. Boston University physician Michael Holick discussed Lane Labs' marketing of AdvaCal, and University of Massachusetts professor Machelle Seibel testified as an expert in reproductive medicine. Each of these witnesses discussed scientific studies relied upon by Lane Labs to support its marketing claims. The FTC experts generally opined that the claims in question were not substantiated by competent or reliable scientific research; not surprisingly, experts for the Lane defendants contradicted this viewpoint.

In addition to these dueling experts, the Court heard testimony from, among others, Lane and Jennifer Morganti, a naturopathic doctor employed by Lane Labs from 2001 to 2004. Lane testified that he took the Final Order "extremely serious[ly]," and he spoke at length about the measures the company pursued to comply with the decree. Lane explained that: the Final Order was distributed to all senior management personnel; copies were sent to Lane Labs' customers; an outside company was retained to compile existing research and to monitor research updates; and Lane hired Morganti to serve as manager of nutritional research. Morganti testified that her primary responsibility was to scrutinize Lane Labs' marketing claims to ensure that each representation was supported by scientific research.[FN7] In all circumstances, however, the ultimate decision to utilize a particular claim was Lane's alone.

> FN7. Lane also testified that marketing claims were vetted by Lane Labs' marketing department and its outside counsel.

By order dated August 10, 2009, the District Court denied the FTC's motion for contempt. The Court explained that it reached its decision after "carefully considering the complete record" and weighing the testimony of each party's witnesses. In the Court's view, "[a]ll four expert witnesses were credible and knowledgeable in their respective fields of expertise," but those testifying on behalf of the Lane defendants were more impressive "because their testimony and approach to the subject matter seemed more reasonable and in accordance with the [Final] Order[ ]." The Court also characterized Lane's testimony in a favorable fashion, stating that it "found Mr. Lane to be forthcoming and credible, and consider[ed] his testimony to be evidence of the efforts undertaken by ***581** Defendants to comply with the [Final Order]."

Against this backdrop, the Court ultimately found that the Lane defendants' marketing claims were supported by competent and reliable scientific evidence. Absent from the decision, however, was any detailed examination of the particular representations challenged by the FTC. Rather, the Court simply set forth, in a series of bullet points, a "representative selection" of the challenged assertions,[FN8] eschewing an analysis of whether each claim found support in the record. It

emphasized that AdvaCal was generally recognized as "a good source of calcium," and that there was little to no evidence that either AdvaCal or Fertil Male was ineffective or potentially dangerous. The Court went on to summarize the evidence as follows: "Lane Labs found a product and obtained scientific evidence that the product is efficacious. Lane Labs then consulted experts who opined that the research supporting the product and the product itself were good. Lane Labs acted in accordance with the spirit of the [the Final] Order[ ]." For the District Court, then, this matter was no more than a dispute over "good" products about which there was a "difference of opinion." The Court found the opinions proffered by the Lane defendants more persuasive and, consequently, determined that they had not disobeyed the Final Order.

> FN8. According to the District Court, the following claims comprised a "representative selection" of the AdvaCal-specific claims challenged by the FTC: (1) AdvaCal has been "clinically shown to be three times more absorbable than other calciums"; (2) AdvaCal is "absorbed three times better than typical calcium carbonate/coral calcium supplements"; (3) AdvaCal is the "only" calcium that can increase bone mineral density; (4) AdvaCal produced a 3 percent per year increase in bone density "over a period of years"; (5) results from a "group" study demonstrate that AdvaCal caused a 13.5% increase in bone density over two years; (6) AdvaCal has been shown in clinical tests to increase bone density in the hip; and (7) a testimonial from a twenty-five-year-old woman who claimed that after taking AdvaCal, her bone density increased by 50% in six months. With respect to Fertil Male, the Court simply stated that "the FTC challenges Defendants' general claim that Fertil Male has been 'clinically-shown' to increase sperm production, sperm motility, and semen production."

The Court further concluded that even if the Lane defendants violated the Final Order, they were entitled to a defense of substantial compliance. According to the Court, the Lane defendants undertook "considerable effort[s] to comply with the [Final] Order[ ]," even if "the materials relied upon by Defendants are in hindsight not perfect." These efforts were frustrated by the FTC, which failed for several years to notify Lane Labs of potential Final Order violations. The Court explained that such governmental foot dragging "raise[s] a significant issue of fundamental fairness." In other words, the Lane defendants attempted to comply with the Final Order, believed in good faith that they were successful in doing so, and received no indication from the government that their efforts were misguided. Under these circumstances, the Court found that "Defendants took all reasonable steps to substantially comply with the [Final] Order[ ]." The motion for contempt was accordingly denied.

The FTC timely appealed.[FN9]

> FN9. The District Court had subject matter jurisdiction pursuant to 15 U.S.C. § 45 and 28 U.S.C. § 1331. We have appellate jurisdiction under 28 U.S.C. § 1291.

II.

[1][2][3] We review the denial of a contempt motion for abuse of discretion. *See* ***582** *Marshak v. Treadwell*, 595 F.3d 478, 485 (3d Cir.2009). "Reversal is appropriate 'only where the denial is based on an error of law or a finding of fact that is clearly erroneous.' " *Roe v. Operation Rescue*, 54 F.3d 133, 137 (3d Cir.1995) (quoting *Harley-Davidson, Inc. v. Morris*, 19 F.3d 142, 145 (3d Cir.1994)). A factual finding is clearly erroneous if it is "completely devoid of a credible evidentiary basis or bears no rational relationship to the supporting data." *Interfaith Cmty. Org. v. Honeywell Int'l, Inc.*, 399 F.3d 248, 254 (3d Cir.2005) (internal quotations omitted); *see also Giles v. Kearney*, 571 F.3d 318, 322 (3d Cir.2009) (explaining that "[c]lear error review is deferential" and that the district court's factual findings should be upheld when they are "plausible in light of the record viewed in its entirety" (internal quotations omitted)). Where factual findings are based upon the testimony of live witnesses, the deference due the district court is even more considerable. *See Anderson v. Bessemer City*, 470 U.S. 564, 575, 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985); *United States v. Igbonwa*, 120 F.3d 437, 441 (3d Cir.1997) (stating that "when the district court's decision is based on testimony that is coherent and plausible, not internally inconsistent and not contradicted by external evidence, there can almost never be a finding of clear error"). However, "a court may not insulate its findings from review by 'denominating

them credibility determinations, [because] factors other than demeanor ... go into the decision whether or not to believe a witness.' " *Giles*, 571 F.3d at 322 (alteration in original) (quoting *Anderson*, 470 U.S. at 575, 105 S.Ct. 1504). With these principles in mind, we turn our attention to the contempt proceedings conducted by the District Court.

III.

[4][5] Proof of contempt requires a movant to demonstrate "(1) that a valid order of the court existed; (2) that the defendants had knowledge of the order; and (3) that the defendants disobeyed the order." *Marshak*, 595 F.3d at 485 (internal quotations omitted); *Roe*, 919 F.2d at 871. These elements "must be proven by 'clear and convincing' evidence, and ambiguities must be resolved in favor of the party charged with contempt." *John T. v. Del. Cnty. Intermediate Unit*, 318 F.3d 545, 552 (3d Cir.2003). Although courts should hesitate to adjudge a defendant in contempt when " 'there is ground to doubt the wrongfulness of the conduct,' " *Robin Woods Inc. v. Woods*, 28 F.3d 396, 399 (3d Cir.1994) (quoting *Quinter v. Volkswagen of Am.*, 676 F.2d 969, 974 (3d Cir.1982)), an alleged contemnor's behavior need not be willful in order to contravene the applicable decree, *John T.*, 318 F.3d at 552; *Harley-Davidson*, 19 F.3d at 148-49. In other words, "good faith is not a defense to civil contempt." *Robin Woods*, 28 F.3d at 399.

The first two elements of contempt are not in dispute. Both parties agree that the Final Order constitutes a valid court order and that the Lane defendants were well aware of its existence and prohibitions. Thus, it is only the final element of contempt-disobedience of a valid court order-about which the parties quarrel. The FTC argues that the Lane defendants disobeyed Sections III and IV of the Final Order, and that the District Court erred in holding otherwise. Section III requires that each of Lane Labs' marketing claims find substantiation in competent or reliable scientific research. According to the FTC, the District Court failed to consider the specific marketing claims challenged during the contempt proceeding. The FTC challenges four claims pertaining to AdvaCal:

> A. Only AdvaCal can increase bone density.
>
> ***583** B. AdvaCal has been shown in clinical tests to increase bone density in the hip.
>
> C. AdvaCal is three to four times more absorbable than other calcium supplements.
>
> D. AdvaCal is comparable or superior to prescription osteoporosis drugs.

The FTC also challenges the assertion that Fertil Male can cause sperm count to "skyrocket" in as little as one month. Finally, the government argues that it proved Lane Labs violated Section IV of the Final Order by distorting research regarding AdvaCal and other forms of calcium. We will address each of these contentions in turn.

A. Only AdvaCal Can Increase Bone Density

[6] In various marketing fora, the Lane defendants claimed that AdvaCal was unique in its ability to increase bone density. One full-page print advertisement proclaimed, "Clinical studies show that AdvaCal does what no other calcium does: actually increases bone density in women." A direct mail circular asserted, "Other calcium supplements cannot increase bone mass. AdvaCal can." Yet another print publication explains,

> When LaneLabs introduced AdvaCal and AdvaCal Ultra in the mid 1990s, the scientific view of calcium changed forever. Up until then, calcium supplements, at best, could only PREVENT bone loss. AdvaCal was different. AdvaCal demonstrated in multiple clinical studies that it could actually BUILD bone density quickly, naturally and safely.

In a 2003 infomercial, William Lane described AdvaCal as "the only calcium that I know of where you can actually increase bone density." Finally, on two occasions in 2005, Lane wrote to a book publisher to promote AdvaCal. In a February 9, 2005 email, Lane portrayed AdvaCal as "the one calcium clinically shown to build bone density in multiple human clinical studies. No other calcium can make that claim." Lane followed this electronic correspondence with a March 2005 letter stating, "AdvaCal offers the following benefits versus other calciums: Actually builds bone density. That's something no calcium has demonstrated consistently in clinical research." Although each of these marketing claims were admitted into the record, none was substantively discussed in the Dis-

trict Court's order.

The FTC presented evidence demonstrating that these claims of uniqueness were unsupported by competent and reliable scientific research. According to its expert, Dr. Heaney, nearly all calcium supplements "produce a measurable increase in bone density." He characterized this effect of calcium intake as "common," and reinforced his opinion by pointing to his own research and the results of at least two other peer-reviewed calcium studies. Both studies showed increases in bone density when human subjects were provided with calcium supplements other than AdvaCal. Dr. Morganti, Lane Labs' former manager of nutritional research, bolstered Dr. Heaney's opinion, explaining that "there's a general consensus that calcium can build bone density." She also remarked, "[t]o say that no other calciums can build bone is probably not true."

The record is devoid of credible evidence to contradict the government's proffer. Dr. Holick did not even address AdvaCal's purported uniqueness, much less dispute Dr. Heaney's interpretation of research indicating that most calcium supplements increase bone density. In fact, Lane was the sole witness who testified in defense of this claim, but his effort was without scientific support. Lane stated that clinical research on other forms of calcium had not produced results demonstrating an increase in bone density above baseline value; the peer-reviewed studies discussed ***584** and introduced into evidence by Dr. Heaney show otherwise. While Lane disputed the findings of these studies, his lay speculation does not constitute credible evidence sufficient to refute the expert testimony and evidence entered into the record through Dr. Heaney.[FN10]

> FN10. Lane questioned the results of one study after "reading the abstract very quickly" on the stand. As a witness with no medical or scientific expertise, Lane was unequipped to credibly refute the government's expert after "quickly" skimming a research abstract during cross examination. What is more, the Lane defendants' own expert, Dr. Holick, undermined Lane's lay opinion, explaining that the analysis appearing in an abstract does not typically represent competent or reliable scientific evidence sufficient to support a given proposition.

On the basis of Lane's lay speculation, and in spite of expert testimony to the contrary, the District Court ruled that the Lane defendants "offered support and substantiation" for the claim that AdvaCal was unique in its ability to increase human bone density. The Court's finding is not plausible in view of the entire record. The Lane defendants were not merely asserting that AdvaCal produced beneficial bone-building results or outcomes that were superior to other calcium supplements; rather, the claims indicated that other supplements did not build bone at all. Dr. Heaney showed that such an assertion was untrue, and Dr. Holick offered no testimony to contradict him. We are thus left with the definite conviction that the District Court's finding is clearly erroneous and must be reversed.

B. AdvaCal Has Been Shown in Clinical Tests to Increase Bone Density in the Hip

[7] The FTC moved into evidence two print documents-one a direct mailing, the other a two-page advertisement-in which Lane Labs touts clinical research exhibiting AdvaCal's ability to increase bone density in the hip. It is undisputed that no such clinical research exists,[FN11] a fact that the District Court did not address in its memorandum. In spite of this omission, our review of the record leaves us satisfied that the Court did not clearly err by finding that these representations were in accord with Section III of the Final Order.

> FN11. A clinical study is one performed upon human subjects. The studies relied upon by the Lane defendants, however, were animal studies.

Dr. Holick pointed to two clinical studies supportive of Lane Labs' claims. Both appeared in peer-reviewed journals, and both showed that calcium increased bone density in the human hip. Although neither study administered AdvaCal to its subjects, Dr. Holick explained that the results were applicable to AdvaCal because "[o]nce the calcium is in your bloodstream, it doesn't make any difference what it was associated with before." [FN12] Thus, one could "extrapolate" the data generated in these generic calcium trials and apply the conclusions drawn therefrom to the likely effect of taking AdvaCal. In Dr. Holick's opinion, competent and reliable clinical research therefore

showed that AdvaCal increases bone density in the human hip.[FN13] The District Court was entitled to rely upon this testimony, to credit Dr. Holick's reliance on data "extrapolated" from generic***585** calcium studies, and to find that the Lane defendants did not violate the Final Order by making the claims in question. Accordingly, we will affirm the District Court's finding.

> FN12. We note that the logic of Dr. Holick's opinion serves to undermine Lane Labs' uniqueness claim, addressed *supra.*
>
> FN13. Although Dr. Heaney disagreed with Dr. Holick's ultimate opinion concerning these particular marketing claims, he did not dispute Dr. Holick's statement concerning the extent to which one could "extrapolate" data from one clinical trial and apply it to a similar product. For example, when Dr. Heaney was presented with one of the two reports cited by Dr. Holick in support of Lane Labs' claims, he testified as follows:
>
> > Q: My question, Doctor, was, could one rely on this study for the proposition that AdvaCal reduces the risk of fracture in the hip?
> >
> > A: One can-one can rely upon it for a statement that calcium reduces the risk of fracture at the hip.
> >
> > Q: And therefore, AdvaCal does.
> >
> > A: And therefore, presumably, AdvaCal does.

C. AdvaCal is Three to Four Times More Absorbable Than Other Calcium Supplements

[8] In direct mailers, print advertisements, and in an infomercial, the Lane defendants represented that AdvaCal was three to four times more absorbable than other calcium supplements. One assertion characteristic of these claims appeared in a direct mail article distributed to Lane Labs' customers. In it, AdvaCal was described as "an extremely high-potency calcium supplement that is absorbed *four times better* than typical calcium-carbonate supplements." Dr. Heaney characterized such a contention as "not physically possible." He explained that the typical calcium carbonate supplement is absorbed at a rate of 30-35%; were AdvaCal capable of performing at the advertised rate, its absorption value would rise to 120%. Dr. Heaney testified that this is physiologically-and mathematically-unattainable. In fact, Dr. Heaney stated, "No adult that I've ever measured under any circumstance would ever have an absorption value above, say, 60 percent, and that's highly unusual."

The Lane defendants argue that AdvaCal was not marketed to the average individual, but rather to elderly females, a substantial number of whom suffer from conditions of achlorhydria and osteoporosis. Achlorhydric individuals cannot produce stomach acid and, as a result, absorb calcium at a rate significantly below average. In some patients, this rate is as low as 4%. Dr. Holick explained that it would not be unusual for an achlorhydric individual, whose calcium absorption rate is far below 30-35%, to absorb AdvaCal three to four times more effectively than calcium carbonate. In such circumstances, Dr. Heaney's criticism is inapplicable, for an achlorhydric patient may absorb AdvaCal three to four times more effectively and still not attain the average absorption rate of 30-35%.

The problem with this argument is its failure to account for the actual language of the challenged representations. Lane Labs' marketing did not include phraseology limiting its claims to elderly females suffering conditions of achlorhydria. A 2003 infomercial was typical: "Osteoporosis now strikes women and men of all ages, races and nationalities. But osteoporosis can be prevented. A key is taking the right calcium and the right calcium supplement is AdvaCal.... AdvaCal has been clinically shown to be three times more absorbable than other calciums." [FN14] Thus, ***586** although AdvaCal may in fact have been targeted at a particular population segment, the challenged representations do not, on their face, limit their claims to any particular target group.

> FN14. The record contains several additional advertisements whose focus is not limited to elderly females suffering conditions of achlorhydria. For example, the Lane defendants' AdvaCal infomercial warned that an individual's long-term health would be impacted

> by "decisions that you make as early as your thirties." Another promotional document states in bold letters, "It's never too early to act," and describes AdvaCal as "an excellent supplement for women of all ages [and] ... an excellent supplement for men." Yet another advertisement notes that "while most of us still think of osteoporosis as something that strikes women aged 60-plus, its precursor, osteopenia, is beginning to appear in women of 30 or even younger. And increasing numbers of men are also being diagnosed with this potentially debilitating condition.... [T]he good news is that there is a calcium supplement [AdvaCal] available right now that is clinically proven to fight osteoporosis."

The District Court did not address the incongruity between the Lane defendants' argument and the actual language of the marketing claims identified by the FTC. We consider this omission problematic, for the record contains some evidence that AdvaCal was, as a matter of fact, marketed toward individuals at risk of, or suffering from, achlorhydria. Lane testified that the company targeted "[o]lder women, [or] postmenopausal women," and much of its advertising generally appears to focus upon this segment of the population. In addition, Dr. Holick's testimony indicates that among this population segment, AdvaCal *could* be three to four times more absorbable than calcium carbonate. The District Court credited the testimony of both Lane and Dr. Holick, but it did not indicate whether AdvaCal was, as a matter of fact, marketed to elderly females at risk of, or suffering from, achlorhyrdria.

Clearly, AdvaCal does not produce ideal outcomes in every patient, but the question is whether Lane Labs' claims promised results that were unattainable for large segments of its audience. The District Court implicitly found that they did not. Were we sitting as the finder of fact, we likely would reach the opposite result. We are not, of course, sitting as a court of first impression; rather, our role is to review the District Court's factual findings. Unfortunately, our attempt to do so is frustrated by the absence of a detailed discussion of whether Lane Labs over-promised on results that could not be attained. In fact, we are unable to say with certainty that the District Court implicitly addressed these claims because the opinion fails to discuss the AdvaCal target market, and gives no indication that the Court considered-and disposed of-this factual dispute. We therefore consider it appropriate to remand so that the District Court may address these particular claims more exhaustively.

D. AdvaCal is Comparable or Superior to Prescription Osteoporosis Medicine

[9] In 1999, Lane sent a "pitch letter" to Monica Reinagel, who was then the editor of the Health Sciences Institute ("HSI") newsletter. In this correspondence, Lane lauded AdvaCal's potential, describing it as "a revolutionary calcium supplement ... that has been clinically shown to actually build postmenopausal bone density, without the side effects of hormonal drugs or supplements." HSI published an article praising AdvaCal shortly thereafter. The article proclaimed, *inter alia*, that AdvaCal "works as well or better than [leading prescription drugs], and without the substantial side effects and risks."

AdvaCal has never undergone scientific testing for comparison with any prescription drug, and Dr. Heaney opined that the above-described claim of comparability/superiority was without competent or reliable substantiation. Notably, the Lane defendants made no attempt to dispute Dr. Heaney's opinion, and our review of the record has revealed no evidence supportive of this particular marketing claim. However, the Lane defendants argued before the District Court that the representation was not their own, and that they had no control over the content appearing in ***587** HSI's newsletter. This assertion was, quite simply, more than a stretch. And, surprisingly, the Lane defendants persist in pressing the argument on appeal. Lane himself acknowledged that Lane Labs paid for the right to distribute the article, and then did so "extensively." It was distributed to past and current customers in direct mailing packets and featured in retail store displays. In short, the Lane defendants adopted HSI's characterization by aggressively promoting the newsletter's content.[FN15] They cannot run from the representation now that its veracity has been subjected to the spotlight.

> FN15. The Final Order requires that the use of third party publications in advertising and promotion not be "false, deceptive, or misleading" under § 5 of the FTC Act, and precludes the Lane defendants from disse-

> minating to "any distributor any material containing any representation prohibited by [the Final] Order." During cross examination, Lane acknowledged that the HSI article constituted a third party publication.

The District Court did not address Lane Labs' comparability/superiority claim or its use of the HSI article to promote AdvaCal. It is therefore unclear whether the Court found substantiation for the claim or whether it accepted Lane Labs' attempt to absolve itself from propagating the representation. In either event, the District Court's finding was clearly erroneous; there is no dispute that the comparability/superiority claim was unsupported by competent or reliable scientific evidence and, by their own admission, the Lane defendants used this claim to market AdvaCal. Thus, this claim violates Section III of the Final Order and the District Court's holding to the contrary is clear error.

E. Fertil Male Can Cause Sperm Count to "Skyrocket" in as Little as One Month

[10] Lane Labs published an advertisement for Fertil Male which claims, *inter alia*, that the supplement caused a male customer's sperm count to "skyrocket" after one month's use. This is the sole Fertil Male representation challenged by the FTC on appeal. Although the District Court did not discuss this specific representation, it expressly credited the testimony of Dr. Seibel, who stated that there was competent or reliable scientific evidence suggesting that Fertil Male improves male fertility parameters such as sperm count, sperm motility, and sperm production.

The FTC attempts to overcome Dr. Seibel's testimony by focusing on the one-month time span identified in Lane Labs' advertisement. According to the FTC, it is impossible for a fertility supplement to increase sperm count in such a short time. The government did not challenge this specific aspect of the Fertil Male claim during the contempt hearing, however, and thus there is little testimony which addresses the contention directly. Dr. Seibel explained that the process of spermatogenesis requires at least three months,[FN16] but he did not explicate the precise manner in which spermatogenesis is related to changes in sperm count. Moreover, when the FTC confronted Dr. Seibel with the print advertisement in question, the following exchange transpired:

> FN16. Dr. Seibel defined spermatogenesis as "the evolution of the sperm into a mature sperm."

Q: Let's look at the next paragraph: "The results were dramatic. In the first month Joe's sperm count skyrocketed."

> Now, Doctor, in a month, Fertil Male could not have caused the sperm count to skyrocket because the sperm wouldn't have been created yet[?] ...

***588** A: Well, the entire impact would require a longer time.

Q: But particularly, sperm count, you told us that sperm takes three months to go from inception to emission; correct?

A: To see an absolute effect, yes.

The Court then attempted to clarify whether it was possible for male sperm count to increase over the course of one month's time.
THE COURT: Could a male's sperm count increase in the first month, or is that something that just couldn't happen?

THE WITNESS: It could have happened as part of the regression to the mean. It could have happened because the sperm-the maca had some effect inside the testes in a way I don't understand.

> But in general, it's a-it's a three-month window.

Neither party pursued this line of questioning any further after this exchange.

Dr. Seibel testified unequivocally that there was competent or reliable scientific research to substantiate the claim that Fertil Male increased sperm count. In the excerpt above, he indicates that the "absolute effect" of an increase requires a period of three months, but appears to imply that some positive change also occurs within the first month. The FTC declined to delve further into this inquiry when it had the opportunity, but now asks that we set aside the District Court's factual findings on the basis of testimony that is ambiguous at best. We decline this invi-

tation. The finding of the District Court with respect to this marketing claim will stand.

F. Distortion of Research

[11] According to the FTC, the District Court committed error by finding that Lane Labs did not violate Section IV of the Final Order. Section IV forbids express or implied misrepresentations regarding "the existence, contents, validity, results, conclusions, or interpretations of any test, study or research" pertaining to "the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug." The District Court's Section IV analysis is brief. It began by acknowledging that "some of the statements contained in the advertising claims made by [the Lane defendants] were incorrect," and that "errors were made over a number of years." These misstatements and errors are nowhere identified. Instead, the Court focused upon AdvaCal's general efficacy, noting that the supplement was considered to be "a good source of calcium" and "will most likely help the people who take [it]." The Court then concluded that the evidence was insufficient to show that the representations in question created a "false impression" in violation of Section IV.

The District Court's analysis is problematic. Section IV of the Final Order prohibits the Lane defendants from misrepresenting the results of research and data; it is simply unconcerned with a product's overall salutary effects. That AdvaCal is efficacious in delivering calcium to the body does not, *ipso facto*, preclude the Lane defendants from misrepresenting scientific research. Nor did the District Court's characterization of AdvaCal as a "good product [ ]" relieve it of the duty to make particularized findings of fact germane to the purported misrepresentations challenged by the FTC. Rather, it was incumbent upon the Court to examine the alleged misrepresentations in detail and to explicitly find whether each transgressed the proscriptions of Section IV.

***589** The District Court's failure to provide us with a reasoned basis for concluding that Lane Labs did not violate Section IV prevents us from exercising meaningful review. Many of the challenged representations appear misleading on their face, and the District Court provides no rationale for its conclusion that they are not. For example, a direct mailing advertisement asserted, "In clinical tests [AdvaCal] has been shown to actually increase bone density-even in the critical hip bones...." It was not disputed, however, that the Lane defendants lacked such clinical research. Even Lane conceded, "There are no clinical studies on AdvaCal in the hip.... [W]e can't verify that statement." Without any explanation from the District Court, we are unable to determine if this claim was even considered in its Section IV analysis. And, if it was, it is difficult to comprehend how the representation did not "create[ ] a false impression in violation of Section IV."

Other challenged representations appear equally misleading. Rather than speculate as to the factual basis underlying the District Court's ultimate conclusions, we will return this matter to the District Court so that it may make findings that are more specific than those presently before us. Some of the representations are unlikely to survive careful factual scrutiny, but we leave the initial resolution of each issue to the District Court. The findings pertaining to the Lane defendants' alleged violation of Section IV will therefore be vacated.

IV.

The District Court held that even if the Lane defendants violated Sections III and IV of the Final Order, they were entitled to a defense of substantial compliance. We have never explicitly recognized the validity of the substantial compliance defense, *see* *Robin Woods*, 28 F.3d at 399, but we note that several of our sister circuits have done so, *see* *Morales-Feliciano v. Parole Bd. of P.R.*, 887 F.2d 1, 4-5 (1st Cir.1989); *Gen. Signal Corp. v. Donallco, Inc.*, 787 F.2d 1376, 1379 (9th Cir.1986); *see also* *Food Lion, Inc. v. United Food & Commercial Workers Int'l Union, AFL-CIO-CLC*, 103 F.3d 1007, 1017 (D.C.Cir.1997) (assuming substantial compliance defense "survives" in the D.C. Circuit). Neither party has objected to the District Court's application of the defense, and, in fact, both appear to proceed under the assumption that the defense is cognizable under this Court's jurisprudence.

In *Robin Woods*, we favorably referenced a decision of the Court of Appeals for the Ninth Circuit and set forth the two-part substantial compliance defense adopted therein. The rule permits a party cited for contempt to assert the defense if it (1) has taken all reasonable steps to comply with the court order at

issue, and (2) has violated the order in a manner that is merely " 'technical' " or " 'inadvertent.' " *See* 28 F.3d at 399 (quoting *Gen. Signal Corp.*, 787 F.2d at 1379). Other courts apply a variation on this rule. The District of Columbia Circuit has stated the defense this way: "In order to prove good faith substantial compliance, a party must demonstrate that it 'took all reasonable steps within [its] power to comply with the court's order.' " *Food Lion*, 103 F.3d at 1017 (quoting *Glover v. Johnson*, 934 F.2d 703, 708 (6th Cir.1991)); *see also Salazar v. District of Columbia*, 602 F.3d 431, 441 (D.C.Cir.2010) (same). In the First Circuit, the rule is even less definitive: "substantiality," like reasonableness, "depend[s] on the circumstances of each case, including the nature of the interest at stake and the degree to which noncompliance affects that interest." ***590***Fortin v. Comm'r of Mass. Dep't of Pub. Welfare*, 692 F.2d 790, 795 (1st Cir.1982).

The Lane defendants cite to our decision in *Harris v. City of Philadelphia*, 47 F.3d 1311 (3d Cir.1995), and urge us to adopt a substantial compliance test akin to that which is applied in the District of Columbia Circuit. In other words, they argue that " 'a defendant may not be held in contempt as long as it took all reasonable steps to comply.' " Appellee's Br. at 42 (quoting *Harris*, 47 F.3d at 1324). In *Harris*, we were concerned not with substantial compliance, but the defense of impossibility. The City of Philadelphia was under court order to improve conditions in its prisons; it failed to fulfill the terms of the order and contempt sanctions were pursued. On appeal, we recognized that "the City would have a valid defense were it able to show physical impossibility" to comply with the court order. *Id.* at 1324. We then cited authority recognizing the impossibility defense and holding that such a position is available only to those defendants that show they have made "in good faith all reasonable efforts to comply." *Id.* (internal quotations omitted).

The impossibility defense necessarily requires the defending party to assert a present inability to comply with the relevant court order. *See Hicks v. Feiock*, 485 U.S. 624, 638 n. 9, 108 S.Ct. 1423, 99 L.Ed.2d 721 (1988); *United States v. Rylander*, 460 U.S. 752, 757, 103 S.Ct. 1548, 75 L.Ed.2d 521 (1983). It "refers to physical impossibility beyond the control of the alleged contemnor." [FN17] *Inmates of Allegheny County v. Wecht*, 874 F.2d 147, 152 (3d Cir.1989) (citing *United States v. Bryan*, 339 U.S. 323, 330-31, 70 S.Ct. 724, 94 L.Ed. 884 (1950)), *vacated on other grounds*, 493 U.S. 948, 110 S.Ct. 355, 107 L.Ed.2d 343 (1989). Such an assertion will naturally precipitate judicial inquiry into the feasibility of the defendant's compliance. *See, e.g., Spallone v. United States*, 487 U.S. 1251, 1256, 1258, 109 S.Ct. 14, 101 L.Ed.2d 964 (1988) (rejecting impossibility defense when city had not attempted certain extreme measures to obtain city council compliance with court order); *Harris*, 47 F.3d at 1330-32 (rejecting impossibility defense when city underfunded and understaffed court-ordered rehabilitation center, thereby leading to its failure to comport with required standards); *Wecht*, 874 F.2d at 152 (rejecting impossibility defense when government officials took insufficient steps to enable prison warden to comply with court order). Thus, a tribunal that concludes that contempt is excused on grounds of impossibility is essentially declaring that the defendant was incapable of compliance in spite of his or her best efforts. Substantial compliance evokes a standard somewhat less demanding. A party substantially complies when it takes all reasonable steps to do so, but nonetheless contravenes the court order by good faith mistake or excusable oversight. [FN18] ***591** The distinction is important, for a party that substantially complies is physically capable of doing so; it has simply erred in a manner for which it would be inequitable to impose contempt sanctions.

FN17. An alleged contemnor may also argue that a change in the law has rendered compliance illegal, even if it is physically possible. *See, e.g., Halderman v. Pennhurst State Sch. & Hosp.*, 673 F.2d 628, 638-39 (3d Cir.1981). This defense is not implicated in the present matter.

FN18. According to the FTC, the Lane defendants' good faith efforts to comply with the Final Order are irrelevant and should have no bearing on the substantial compliance inquiry. This argument is based upon a misreading of our jurisprudence. As we explained in *Robin Woods*, an alleged contemnor may not invoke its good faith efforts as a *defense on the elements* of civil contempt. *See Robin Woods*, 28 F.3d at 399 (stating that "willfulness is not a necessary element of civil contempt," and that "good faith does not bar the conclusion ... that [the defendant] acted in contempt" (alterations in original) (internal quotations omitted)).

> When assessing the *affirmative defense* of substantial compliance, however, good faith efforts inherently factor into the inquiry. *See id.* (considering contemnor's good faith efforts but nevertheless concluding that violations were neither technical nor inadvertent); *see also Food Lion*, 103 F.3d at 1017 (explaining that good faith is relevant when assessing substantial compliance). Indeed, an "inadvertent" error is one that is, by its very nature, made in good faith. This is not to say that a party's good faith efforts necessarily convert its contumacious conduct into inadvertent violations; rather, good faith is relevant to the substantial compliance inquiry, no more, no less.

[12][13][14] Recognizing that we did not formally adopt the defense of substantial compliance in *Robin Woods*, we do so here. In order to avail oneself of the defense, a party must show that it (1) has taken all reasonable steps to comply with the valid court order, and (2) has violated the order in a manner that is merely "technical" or "inadvertent." The District Court's application of the appropriate test for substantial compliance is a legal issue to be reviewed de novo. *See Anderson v. City of Phila.*, 845 F.2d 1216, 1220 (3d Cir.1988). Whether the alleged contemnors took all reasonable steps to comply with the court order, and the extent to which contumacious conduct constitutes a "technical" or "inadvertent" violation, are factual questions subject to review for clear error. Resolution of these questions will naturally depend upon the unique facts of each case, the nature of the conduct precluded, and the capabilities of the parties subject to the order.

[15] In the instant matter, the District Court set forth the correct standard for substantial compliance, explaining that "[i]f a respondent has made in good faith all reasonable efforts to comply with a court order, technical or inadvertent violations of the order will not support a finding of contempt." The Court then applied this rule to the facts, emphasizing the Lane defendants' considerable efforts to comply with the Final Order. In particular, the Lane defendants submitted timely compliance reports disclosing the representations in question; the FTC did not respond to these disclosures and, as the Court explained, "to tell Defendants that their efforts were not good enough years after not advising them of any compliance issues is disingenuous and is highly relevant to the inquiry into whether Defendants should have done something different in the first instance." The Court concluded by recognizing "that the materials relied upon by Defendants are in hindsight not perfect," but that "Defendants took all reasonable steps to substantially comply with the [Final Order]." It did not explicitly address the extent to which violations of the Final Order were "technical" or "inadvertent."

The FTC assails this omission, arguing that the District Court's opinion contains no findings addressing the second step of the substantial compliance inquiry. We are hard-pressed to disagree. The entirety of the Court's substantial compliance analysis is focused upon the reasonableness of the Lane defendants' actions. The Court underscores Lane Labs' submission of compliance reports; its retention of additional compliance personnel; and the government's delay in commencing an enforcement proceeding.[FN19] Each of these ***592** considerations inherently impacts the reasonableness inquiry, but does little to illuminate the justification for violating the Final Order. Moreover, although the Court implicitly recognized that some violations occurred, it neither identified this misconduct nor explained why the conduct qualified as a "technical" or "inadvertent" violation of the Final Order. Absent specific findings addressing this second step of the substantial compliance test, we are reduced to guesswork: speculating at that which the District Court considered contumacious conduct; speculating whether it found that such conduct technically violated the court order, or did so inadvertently; and speculating whether the District Court overlooked this necessary second step and neglected to consider the nature of the violations at all. In short, we are unable to conduct meaningful appellate review.

> FN19. The FTC mistakenly accuses the District Court of applying a laches defense in favor of the Lane defendants. Although the laches defense was briefed by the parties before the District Court, that Court correctly characterized it as a "mis-conceptualiz[ation]" of the issue. We are satisfied that the Court considered the FTC's prolonged delay in initiating contempt proceedings only insofar as it reflected upon the reasonableness of the Lane defendants' conduct. Such consideration is eminently appropriate. In fact, we share the District

> Court's concerns. In 2007, the FTC accused the Lane defendants of numerous misrepresentations, many of which were disclosed in compliance reports as early as 2001. After providing the government with its advertising and the research relevant thereto, the Lane defendants heard nothing for a period of years. To construe the FTC's silence as approval was technically mistaken, but it was not unreasonable. We are, of course, sympathetic to the FTC's significant regulatory and enforcement responsibilities, but delays of this extraordinary length are inordinate. In sum, it was proper for the District Court to consider these facts in its reasonableness assessment.

Accordingly, we will vacate the District Court's finding that the Lane defendants substantially complied with the Final Order, and will remand for reconsideration consistent with the discussion set forth above.

V.

The District Court examined the record in its entirety and concluded that the Lane defendants complied with "the spirit" of the Final Order. This was insufficient. The District Court was not petitioned for an assessment of the general efficacy of AdvaCal and Fertil Male. Rather, the FTC contended that specific marketing claims were violations of two previously-entered consent decrees. Unfortunately, the able District Judge did not provide sufficiently detailed findings or sufficient rationale to allow us to perform effective appellate review. For the reasons set forth above, we will remand this matter to the District Court for further proceedings consistent with this opinion.

C.A.3 (N.J.),2010.
F.T.C. v. Lane Labs-USA, Inc.
624 F.3d 575, 2010-2 Trade Cases P 77,204

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