HEARING REQUESTED

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL INTERNATIONAL CORP.,	)	
companies, and	)	Docket No. 9344
	)	PUBLIC
	)	
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

RESPONDENTS' RENEWED MOTION TO EXCEED THE FIVE (5) EXPERT LIMIT AND MEMORANDUM IN SUPPORT

Pursuant to Rule 3.31A(b) of the Commission's Rules of Practice, Respondents respectfully renew their request that the Court enlarge the number of expert witnesses that Respondents may designate from five to a maximum of eight.[1] Rule 3.31A(b) empowers the Court to grant this relief. Indeed, when it recently adopted the five-per-side default for "the vast majority of cases," the Commission specifically adopted a "safety valve" allowing for more than five experts when "extraordinary circumstances" exist. *See* FTC Interim Final Rules With Request for Comment, 74 F.R. 1804, 1814 (Jan. 13, 2009); Rule 3.31A(b) ("A party may file a motion seeking leave to call additional expert witnesses due to extraordinary circumstances."). The circumstances of this case are, if anything, extraordinary.

Unlike many advertising substantiation cases where there is a single core claim, Complainant challenges here a variety of alleged health claims that touch upon multiple, wholly

[1] In response to the suggestions in the Court's correspondence on February 4, 2011, Respondents withdrew their initial motion on February 9, 2011, indicating their intent to renew the motion in order to provide additional information regarding the expert testimony required.

distinct and independent areas of science. In order to respond meaningfully to the Complainant's varied allegations, Respondents require expert witnesses from each of the fields of science implicated by the Complaint. In addition to scientific testimony, and as is common in advertising substantiation cases, Respondents also will need to designate experts to opine on consumer responses to the advertisements at issue in this case, the meaning of such advertisements, and to opine on any interpretation of the ads proffered by Complainant.

In light of the breadth of the issues framed by the Complaint, extraordinary circumstances warrant Respondents' designation of eight expert witnesses. Permitting Respondents to designate these experts will not result in duplicative expert testimony at the administrative hearing, but, rather, will allow Respondents to address the various and diverse allegations in this case. Accordingly, this motion should be granted.

Background

This advertising substantiation case involves an unusual variety of allegations and a truly unprecedented amount of relevant scientific research regarding a botanical food product.

Scope of Issues Framed by the Complaint

Complainant alleges, among other things, that Respondents made unsubstantiated claims in their advertising and promotional materials regarding the health benefits of their pomegranate products ("Challenged Products"). In particular, the Complaint alleges that Respondents made claims, either expressly or impliedly, regarding the benefits that the Challenged Products have on cardiovascular health and disease, prostate cancer, and erectile dysfunction. With respect to cardiovascular claims, Complainant alleges that Respondents claimed that the Challenged Products would help prevent, treat, or cure heart disease, including blood pressure, blood flow, and could lead to a decrease in arterial plaque. Compl. ¶ 12. Each of these cardiovascular issues

involve distinct and areas of specialization and expertise. The Complaint further alleges that, with regard to prostate cancer, Respondents made claims that the Challenged Products would help prevent, treat, or cure prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"). Compl. ¶¶ 14-15, 19(E)-(F). The Complaint also alleges that Respondents made unsubstantiated claims regarding the Challenged Product's ability to prevent, treat, or cure erectile dysfunction. *Id.* ¶¶ 16-17, 19(E)-(F).

The Complaint also identifies more than twenty (20) advertising or promotional pieces, *see generally* Compl. at Exhibits A-N, and more than eight alleged unsubstantiated claims. Compl. ¶ 13-16; *see also* Complaint Counsel's Response to Respondent POM Wonderful LLC's First Set of Interrogatories at 3-12, attached hereto as Exhibit A. Despite Respondents' attempts to get Complaint Counsel to commit to a specific set of ads and claims, Complaint Counsel continues to introduce additional advertisements during depositions and to expand the potential scope of this case.

Respondents have attempted to try to resolve this issue with Complainant Counsel; however, Complainant has declined to consent to any enlargement in the number of experts. Thus, Respondents bring the instant motion.

Argument

The Court should allow Respondents to designate up to eight expert witnesses because the array of allegations in this case -- which touch on distinct areas of science -- coupled with the number of advertisements referenced in the Complaint involve more than five areas of expertise and, therefore, more than five experts are required for Respondents to cover the waterfront of issues raised by this case. Unlike traditional substantiation cases where there is a

central core claim at issue, here, the Complaint alleges that Respondents' made a variety of distinct claims -- each of which require expert testimony.

Scientific Experts

Expert testimony regarding health claims is typical in advertising substantiation cases. *See, e.g., In re Daniel Chapter One, et. al.*, 2009 WL 5160000 (Dec. 21, 2009) (considering scientific expert testimony (oncology) in evaluating substantiation of cancer treatment claim); *In re Kraft, Inc.*, 114 F.T.C. 40 (1991) (considering scientific expert testimony in evaluating substantiation of ingredient claim); *In re Bristol-Myers Co.*, 102 F.T.C. 21 (1983) (considering clinical and scientific testimony in evaluating substantiation claim for aspirin); *In re Sterling Drug. Inc.*, 102 F.T.C. 395 (1983) (considering scientific expert testimony in ad substantiation case). For example, in *Daniel Chapter One*, a case that concerned whether the respondents' product was an effective therapy for cancer treatment, this Court considered the expert opinion of Dr. Denis Miller, a medical doctor with specialization in oncology to evaluate the substation for the alleged cancer treatment claims. Unlike *Daniel Chapter One*, here, Complainant has not only alleged that Respondents' made cancer treatment claims, but they also contend that Respondents' made unsubstantiated claims regarding cardiovascular issues (including blood pressure, blood flow, and arterial thickness) and regarding the benefits of the Challenged Products in treating erectile dysfunction. Other Commission advertising substantiation cases have also typically involved only a single core claim. *E.g., In re Daniel Chapter One, et al.* 2009 WL 5160000 (alleging unsubstantiated cancer and tumor treatment claims); *In re Novartis Corp., et. al.*, 1998 WL 34060101 (1998) (alleging unsubstantiated efficacy claim relating to back pain); *In re Telebrands Corp., et al.*, 140 F.T.C. 278 (2005) (alleging claim of weight loss and abdominal benefits); *In re Kraft, Inc.*, 114 F.T.C. 40 (1991) (alleging unsubstantiated claims

regarding product ingredient). As noted above, however, the Complaint here contains allegations touching on many distinct and independent areas of science.

Human Nutrition and Health Properties of the Challenged Products

As set forth in Respondents' Answer and as Respondents further noted at the initial Scheduling Conference before the Court, there is a vast array of scientific research demonstrating the healthy properties of the Challenged Products. To demonstrate the healthy properties of the Challenged Products and, specifically, that there was more than adequate scientific substantiation to support Respondents' health claims, Respondents are entitled to offer expert testimony regarding the general nutritional and healthy properties of the Challenged Products, including the benefits of antioxidants present in the Challenged Products. Specifically, such expert testimony will discuss, among other things, the mechanisms of action, bioavailability and metabolism of pomegranate polyphenols in the human body, and the way that such polyphenols relate to antioxidation and inflammation.

It is particularly noteworthy that in their initial designation of experts, Complaint Counsel not only designated experts to address specific issues relating to prostate cancer, erectile dysfunction and cardiovascular disease, but also a Professor of Epidemiology and Nutrition. *See* Complaint Counsel's Expert Witness List, attached as Exhibit B. Respondents agree (without knowing the substance or details of the testimony to be offered by this witness) that such a broad perspective is appropriate when evaluating the health benefits of a natural product such as pomegranate juice. Respondents therefore will require a scientific expert to provide an explanation of the nutritional benefit and role of the Challenged Products and to rebut the testimony of Dr. Stampfer, who has been designated as an expert by Complainant.

Expert Testimony on the Role of the Challenged Products with Regard to Cardiovascular Claims

Complainant has put at issue a myriad of cardiovascular issues in this case, including allegations that Respondents claimed the Challenged Products treat, cure, and prevent cardiovascular disease, including high blood pressure and arterial thickness. In order to meaningfully respond to these allegations, Respondents will need to introduce expert testimony as to the role of the Challenged Products in the separate areas of cardiovascular health implicated by the Complaint. Expert testimony is also required to interpret the vast array of literature involving the cardiovascular benefits of pomegranate on cardiovascular health.

Expert Testimony on the Role of the Challenged Products and Erectile Dysfunction

In addition to the variety of cardiovascular issues that Complainant has put at issue in this case, the Complaint also alleges that Respondents made claims that the Challenged Products treat, cure, or prevent erectile dysfunction. In order to respond to such allegations, Respondents will need to introduce expert testimony regarding the effect of the Challenged Products in these areas.

Expert Testimony on the Complex Chemistry of Nitric Oxide

Expert testimony is also needed in order to explain the role that chemical compounds, specifically nitric oxide (NO), play in erectile dysfunction and with regard to blood flow. The complex science regarding nitric oxide is relevant to both erectile dysfunction issues and cardiovascular issues, including because a lack of nitric oxide affects the level of oxygen that is delivered to blood tissues and can restrict blood flow. Thus, Respondents will also need to introduce expert testimony to elaborate the role that the Challenged Products play in protecting nitric oxide against oxidative destruction and to interpret the scientific literature regarding the effect that pomegranate products have on the availability of nitric oxide in the human body.

Expert Testimony on The Role of The Challenged Products in Prostate Health

Complainant has also alleged that Respondents made claims that the Challenged Products treat, prevent, and cure prostate cancer. Respondents therefore require expert testimony regarding the nutritional and chemical properties of the Challenged Products and their role with regard to prostate health.

Expert Testimony Regarding the Level of Substantiation Required for Health Claims

In addition to introducing expert testimony regarding the properties of the Challenged Products, Respondents will also need to introduce testimony regarding the level of substantiation required for the alleged claims. The Complainant has put at issue how "competent and reliable scientific evidence," the Commission's traditional standard for advertising substation, should be applied to food marketing -- both as to liability and remedy. As only one example, Complainant alleges that Respondents have represented that the Challenged Products treat, prevent, or cure prostate cancer by prolonging prostate-specific antigen doubling time ("PSADT"), but dispute the validity of such claims and critique the criteria by reference to FDA's drug approval standard. Expert testimony regarding the level of substantiation required for these claims, including the appropriateness of PSADT as an endpoint, is required for a meaningful evaluation of these allegations.

As demonstrated in the sections above, the array of allegations in this case coupled with the vast body of scientific literature regarding the healthy properties of the Challenged Products presents the requisite extraordinary circumstances under Rule 3.31A(b), which empowers the Court to extend the number of expert witnesses. The scientific expert testimony proffered by Respondents will not be duplicative; rather, it will address the myriad complex scientific matters at issue in this case. Complainant implicitly acknowledges the need for at least four of these experts, as they, too, have designated experts to opine on the nutritional properties,

cardiovascular properties, erectile dysfunction properties, and prostate properties of the Challenged Products. *See, e.g.,* Ex. B. Respondents are entitled to present their own expert testimony on these areas, and also on the complex nature of nitric oxide and on the general substantiation for health claims, as these issues also involve distinct areas of expertise.

Consumer Science and Marketing Expert Testimony

This Court routinely considers the testimony of consumer science and marketing experts to help determine the meaning of advertisements and claims at issue in advertising substantiation cases. Where, as here, the Complaint alleges that certain claims were made implicitly by the advertisements at issue, the Court looks to extrinsic evidence regarding the advertisements' meaning, including "expert opinion as to how an advertisement might reasonably be interpreted, copy tests, generally accepted principles of consumer behavior, surveys, or 'any other reliable evidence of consumer interpretation.'" *In re Telebrands Corp., et. al.*, 140 F.T.C. 278, 290-291 (2005) (citing *Cliffdale Associates*, 103 F.T.C. 110, 166 (1984); *In re Thompson Medical Co.*, 104 F.T.C. 648, 789-90 (1984) (expert testimony; consumer survey), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *In re Novartis*, 127 F.T.C. 580, 611-12, 617-33, 682-84 (expert testimony; copy tests); *In re Kraft*, 114 F.T.C. 40, 121-22 (expert testimony; copy tests); *In re Figgie Internat'l, Inc.*, 107 F.T.C. 313, 337-39, 377 n.10 (1986) (expert testimony), *aff'd*, 994 F.2d 595 (9th Cir. 1993), *cert. denied*, 510 U.S. 1110 (1994)).

In many cases, parties have put forth numerous experts to, among other things, opine on the reasonable consumer interpretation of advertisements, interpret consumer surveys that have conducted to evaluate the message presented by such advertisements, and to evaluate whether the claims at issue were material to customers' purchasing decisions. For example, in *In re Novartis Corp., et. al.*, 1998 WL 34060101 (1998), this Court considered the opinion of seven experts in

determining the meaning of the advertisements at issue -- five of which were designated by respondents.

In this case, which involves more claims and distinct scientific areas of inquiry than in *Novartis*, Respondents will need to introduce expert testimony regarding (1) the advertisements themselves (including linguistic and semiotics analysis) and also (2) regarding the way in which consumers interpret such advertisements, including whether the alleged claims are material to their decisions to purchase the Challenged Products. Respondents believe that they will need at least two experts to present this testimony, as it involves at least two distinct fields of expertise. This is reasonable in light of the fact that in many less complex advertising cases numerous consumer experts have been designated. *E.g.*, *In re Novartis Corp., et. al.*, 1998 WL 34060101 (1998) (designation of five consumer research experts by respondent), *In re Kraft, Inc.*, 114 F.T.C. 40 (1991) (designation of three consumer research experts by complainant).

Equitable Considerations

Granting this motion will not prejudice Complainant, who will have the opportunity through rebuttal to respond to expert testimony offered by Respondents. Moreover, Respondents are willing to consent to the Complainant designating more than five experts if it can demonstrate the need for such witnesses. In contrast to the Complainant, who will not be prejudiced if this motion is granted, Respondents will be highly prejudiced if they are not able to present expert testimony regarding the array of advertisements and claims at issue and the scientific substantiation supporting their claims.

Conclusion

For the foregoing reasons, Respondents' motion should be granted. Respondents respectfully request a hearing on this motion.

Respectfully Submitted,

/s John Graubert

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Counsel for Respondents

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
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POM WONDERFUL LLC and	)	
ROLL INTERNATIONAL CORP.,	)	
companies, and	)	Docket No. 9344
	)	PUBLIC
	)	
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

STATEMENT OF MEET AND CONFER

In accordance with paragraph 4 of the Scheduling Order, Respondents hereby certify that they conferred with opposing counsel on multiple occasions regarding the expert limits in this case, but that opposing counsel refused to consent to any enlargement of the number of experts to be designated by Respondent.

Respectfully Submitted,

/s John Graubert

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Counsel for Respondents

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FEDERAL TRADE COMMISSION

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MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

Draft Proposed Order

On Thursday, February 10, 2011, Respondents filed a Renewed Motion to Exceed The Five Expert Limit. Finding good cause for the motion, Complaint Counsel's Motion is GRANTED and Respondents are permitted to designate the witnesses identified on their Expert Witness List.

ORDERED

_____
Honorable D. Michael Chappell
Administrative Law Judge

Dated:

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

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CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of the PUBLIC and CORRECTED version of Respondents' **RENEWED MOTION TO EXCEED THE FIVE (5) EXPERT LIMIT AND MEMORANDUM IN SUPPORT**, and that on this 15th day of February, 2011, I caused the foregoing to be served by FTC E-File and hand delivery on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-159
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-110
Washington, DC 20580

I hereby certify that this is a true and correct copy of the PUBLIC AND CORRECTED version of Respondents' **RENEWED MOTION TO EXCEED THE FIVE (5) EXPERT LIMIT AND MEMORANDUM IN SUPPORT**, and that on this 15th day of February, 2011, I caused the foregoing to be served by e-mail on the following:

Mary Engle
Associate Director for Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission
601 New Jersey Avenue, NW
Washington, DC 20580

Heather Hippsley
Mary L. Johnson
Tawana Davis
Federal Trade Commission
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Washington, DC 20580

/Skye Perryman

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Counsel for Respondents Stewart Resnick and Lynda Rae Resnick

Dated: February 15, 2011

H

2009 WL 5160000 (F.T.C.)

Federal Trade Commission (F.T.C.)

In the Matter of DANIEL CHAPTER ONE, a corporation, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One

Docket No. 9329

December 24, 2009

COMMISSIONERS:

Jon Leibowitz, Chairman

Pamela Jones Harbour

William E. Kovacic

J. Thomas Rosch

FINAL ORDER

The Commission has heard this matter on the appeal of Respondents from the Initial Decision and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to enter the following order. Accordingly,

I.

IT IS HEREBY ORDERED that for purposes of this Order, the following definitions shall apply:

A. "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.

B. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx.

C. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

D. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect a sale or to create interest in the purchasing of goods or services, whether it appears in a book, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio

program transmitted over a telephone system, infomercial, the Internet, email, or in any other medium.

E. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

F. "Commerce" shall mean "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

G. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

II.

IT IS HEREBY ORDERED that Respondents, 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 BioShark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

1. BioShark inhibits tumor growth;
2. BioShark is effective in the treatment of cancer;
3. 7 Herb Formula is effective in the treatment or cure of cancer;
4. 7 Herb Formula inhibits tumor formation;
5. GDU eliminates tumors;
6. GDU is effective in the treatment of cancer;
7. BioMixx is effective in the treatment of cancer; or
8. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that Respondents, directly or through any person, 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 or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit Respondents 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.

V.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased BioShark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the date of service of this order, Respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part V.A., above. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, Respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Respondent, at any time prior to the issuance of this order, in connection with the purchase of BioShark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however,* that Respondents may disclose such identifying information to the FTC pursuant to Part V.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

VI.

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 shall maintain and upon request 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, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such 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 Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having 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. Respondents 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 Feijo, for a period of ten (10) years after the date of issuance of this or-

der, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a 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 DCO learns less than thirty (30) days prior to the date such action is to take place, Respondent DCO shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after the date of service 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.

XI.

IT IS FURTHER ORDERED that this order will terminate on December 18, 2029, 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 this order, and the dismissal 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.

By the Commission.

Donald S. Clark
Secretary

Seal:

Issued: December 18, 2009

ATTACHMENT A

LETTER TO BE SENT BY FIRST CLASS MAIL

[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought **[names of products]** from our website **[name of website]** or through a call center using our toll-free number. We are writing to tell you that the Federal Trade Commission ("FTC") has found our advertising claims for these products to be deceptive because they were not substantiated by competent and reliable scientific evidence, and the FTC has issued an Order prohibiting us from making these claims in the future.

The Order entered against us by the FTC requires that we send you the following information from the FTC about the scientific evidence on these products:

Competent and reliable scientific evidence does not demonstrate that any of the ingredients in BioShark, 7 Herb Formula, GDU or BioMixx, are effective when used for prevention, treatment or cure of cancer.

It is important that you talk to your doctor or health care provider before using any herbal product in order to ensure that all aspects of your medical treatment work together. Some herbal products may interfere or affect your cancer or other medical treatment, may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines, or in high doses. It is also important that you talk to your doctor or health care provider before you decide to take any herbal product instead of taking cancer treatments that have been scientifically proven to be safe and effective in humans.

Sincerely,

ATTACHMENT B

Daniel Chapter One

1028 East Main Road

Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

In the Matter of Daniel Chapter One and James Feijo

Docket No. 9329

OPINION OF THE COMMISSION

By ROSCH, Commissioner, For A Unanimous Commission:

Upon consideration of the record and the arguments of counsel, the Commission denies the Respondents' appeal and affirms the Initial Decision of the Administrative Law Judge both as a matter of fact and as a matter of law. The Commission finds the order entered below to be proper, but modifies the language in Attachment A of the Order, the prescribed notice that the Respondents are required to send to consumers who purchased the products at issue.

I. Background and Proceedings Below

The Commission issued the Complaint in this matter on September 16, 2008 against Daniel Chapter One ("DCO") and James Feijo (collectively, "Respondents"). The Complaint alleged that Respondents engaged in deceptive acts or practices, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a) and 52. Compl. ¶ 17.

The Complaint alleged that these deceptive acts or practices occurred in connection with the Respondents' advertising, promotion, offering for sale and distribution of four DCO products: BioShark, 7 Herb Formula, GDU and BioMixx (collectively, "the Challenged Products"), which purport to prevent, treat, or cure cancer or tumors and other serious medical illnesses. *Id.* ¶¶ 3-13.

More specifically, the Complaint alleged that advertisements for the Challenged Products represented, expressly or by implication, that:

BioShark inhibits tumor growth and is effective in the treatment of cancer;
7 Herb Formula inhibits tumor growth and is effective in the treatment or cure of cancer;
GDU eliminates tumors and is effective in the treatment of cancer; and
BioMixx heals the destructive effects of radiation and chemotherapy and is effective in the treatment of cancer.

Id. ¶ 14. The Complaint alleged that those representations were deceptive in that Respondents represented, directly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations when in fact Respondents lacked a reasonable basis to substantiate them. *Id.* ¶¶ 15-17.

Respondents filed their Answer on October 11, 2008. The Answer admitted that Respondents made the representations alleged in the Complaint about the efficacy of the Challenged Products. Answer ¶ 14. The Answer also admitted that Respondents operated a website that provided information respecting the Challenged Products in a religious and educational context, but otherwise denied the allegations that they engaged in deceptive acts or practices in connection with the advertising or sale of the Challenged Products. *Id.* ¶¶ 5, 7, 9, 11, 13-15. The Answer affirmatively averred that Respondents possessed and relied upon a reasonable basis that substantiated the representations made about the Challenged Products at the time the representations were made. *Id.* ¶ 16.

Respondents filed two motions to amend their Answer. Chief Administrative Law Judge D. Michael Chappell ("ALJ"), who presided over all pretrial proceedings and the trial, denied those motions on the grounds, *inter alia*, that the proposed amendments, coming after the close of discovery and approximately two months before trial, would have been unduly prejudicial to Complaint Counsel. Respondents also filed two motions to dismiss, and cross-motions for summary judgment were filed by Respondents and Complaint Counsel. Those motions were denied.

An evidentiary hearing on jurisdiction was held on April 21, 2009. Thereafter, the ALJ issued a ruling that Complaint Counsel had demonstrated, by a preponderance of evidence, that jurisdiction existed in the case. Respondents' motion for an interlocutory appeal from that ruling was denied.

The final pre-trial conference was held on April 22, 2009, with trial commencing immediately thereafter. Following trial, Respondents and Complaint Counsel filed concurrent post-trial briefs, proposed findings of fact and conclusions of law, and replies to each other's post trial briefs and proposed findings. Closing argument was held on July 9, 2009. The ALJ

issued his Initial Decision and Proposed Order on August 5, 2009.

As set forth in the Initial Decision, the ALJ found that the record showed that DCO, described by the Respondents as a house ministry, was led by Respondent James Feijo, with his wife Patricia Feijo, and that DCO engaged in business for profit for itself or for its member, James Feijo. The ALJ found that, although DCO's activities included spiritual counseling to individuals, they also included advertising and selling the dietary supplements BioShark, 7 Herb Formula, GDU and BioMixx to the public.

The ALJ also found that Respondents disseminated advertisements for the purpose of inducing, and which did induce, the purchase of a food or drug, in or having an effect on commerce within the meaning of Sections 5(a) and 12 of the FTC Act, and that those advertisements claimed that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. The ALJ also found that Respondents did not have a reasonable basis to substantiate these claims and that the claims made were material to consumers.

The ALJ held that Complaint Counsel had carried its burden of proving that Respondents are liable under Sections 5(a) and 12 of the FTC Act. The ALJ considered the defenses raised by the Respondents and concluded that they were not meritorious. The ALJ imposed a cease and desist order that, *inter alia*, enjoins Respondents from making any representation, expressly or by implication, that any dietary supplement, food, drug, or other health-related product, service, or program, including but not limited to the Challenged Products, prevents, treats, cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The order also enjoins the Respondents from making any representation about the efficacy, performance, or health-related benefits of any dietary supplement, food, drug, or other health-related product, service, or program, including but not limited to the Challenged Products, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The order also requires the Respondents to send a prescribed notice to all consumers who purchased the Challenged Products that informs those consumers that the FTC has found that the advertising claims at issue were false and unsubstantiated, that the FTC has issued an order prohibiting those claims from being made in the future, and that informs those consumers about the scientific evidence on the Challenged Products.

Respondents filed a timely appeal and Complaint Counsel did not cross-appeal. The decision of the ALJ is subject to *de novo* review by the Commission. *See* 16 C.F.R. § 3.54. Accordingly, the Commission on appeal may consider the entire record and determine whether there is a sufficient evidentiary basis for the ALJ's findings of fact.

The Commission has reviewed the ALJ's findings of fact, as well as the record underlying them. The Commission has also reviewed the advertisements at issue to determine the overall net impressions conveyed by them. The Commission sees no reason to disturb the ALJ's findings of fact and adopts them as the Commission's own insofar as they are consistent with those set forth in this Opinion. Otherwise, the findings of fact in this Opinion are those of the Commission.

II. Respondents' Claims on Appeal

Respondents make three fundamental claims in their appeal: (1) Respondents claim that the FTC did not have jurisdiction over them (RAB at 11, 29-40);[FN1] (2) Respondents claim that the ALJ misinterpreted various statutes, including, among others, Section 5 of the FTC Act, as well as the Due Process Clause and the First Amendment of the United States Constitution, by banning truthful statements about dietary supplements, improperly shifting the burden of proof to Re-

spondents, applying an incorrect standard of proof, and permitting "evidence by presumption" (RAB at 11-29, 40-55); and (3) Respondents argue that the ALJ's remedy not only prohibits truthful speech, but also illegally compels Respondents to engage in government-mandated speech. RAB at 12, 55-65.

The Commission considers the Respondents' arguments in Part III in the following order: Section A considers the Respondents' jurisdictional argument; Sections B through E consider Respondents' statutory and constitutional arguments; and Section F considers the Respondents' argument concerning the remedy.

III. Analysis

A. The FTC Has Jurisdiction.

Findings of Fact.
Prior to 2002, DCO was a for-profit corporation organized in 1990 under the laws of Rhode Island. IDF 22. Its Articles of Incorporation stated that its purposes were "to engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values." IDF 23. Subsequent annual reports, which were signed by Respondent James Feijo, described the character of the business in substantially the same way. IDF 24, 25. James Feijo sold BioShark, 7 Herb Formula, GDU and BioMixx while DCO was registered as a for-profit corporation. IDF 27.

DCO is currently a "corporation sole" organized in 2002 under the laws of the State of Washington. IDF 1; RAB at 30, 32. DCO's Articles of Incorporation do not specifically declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes. IDF 30. The Articles do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. *Id.* Nor do its advertising or promotional materials specifically refer to DCO as a nonprofit entity. IDF 32.

Respondent James Feijo is the sole "overseer" and trustee of DCO's assets and all of its funds, and he is DCO's sole "member." IDF 5, 6; RRB at 8. As such, he is responsible for all of its activities and for directing all of its funds. IDF 5, 6. James Feijo and his wife, Patricia, are the only officers of DCO. IDF 7.

DCO has a number of bank accounts, including accounts that are described as "Business Partner" accounts. IDF 42. DCO's revenue is deposited into the Business Partners Checking accounts, and from there the revenue is distributed at James Feijo's discretion to other DCO bank accounts. IDF 42. Patricia Feijo is a signatory to DCO's bank accounts and writes checks from the DCO accounts. IDF 48. The Business Partners Money Market Fund showed a balance during the period from December 19, 2006 to February 20, 2008 in excess of $1 million, but on February 21, 2008, a debit of over $800,000 was posted. IDF 45.

DCO or its affiliate own the Rhode Island and Florida homes in which James and Patricia Feijo live, as well as two Cadillacs that James Feijo uses. ID at 75; IDF 55-57. DCO paid for all of the Feijos' living expenses, including pool and gardening expenses, tennis and golf club expenses, as well as the Feijos' expenditures on retail items and at restaurants. IDF 58, 61-70.

DCO currently sells 150 to 200 products, including BioShark, 7 Herb Formula, GDU and BioMixx. IDF 8. James Feijo has been solely responsible for the development, creation, production, and pricing of the Challenged Products. IDF 37. James and Patricia Feijo have been solely responsible for creating, drafting and approving directions for the usage, and developing recommended dosages, for the Challenged Products. IDF 38, 39.

Sales of the 150 to 200 products sold by DCO, all of which are dietary supplements, have generated approximately $2 million in annual gross sales. IDF 9, 10. DCO's sales of BioShark, 7 Herb Formula, GDU and BioMixx constituted 20 to 30 percent of DCO's sales during the period from 2006 through 2008. IDF 80. The acquisition costs for those products is about 30 percent of the sale price. IDF 83.

Over a thousand people have purchased the Challenged Products, including people who do not belong to any DCO religious community and people who do not believe in God. IDF 81, 82. Respondents sell the four Challenged Products through publications, a call center, a radio program, over the Internet, and through stores and other resellers. IDF 84, 158. Any consumer could be directed to the DCO website by entering the term "cancer" in a Google internet search. IDF 162.

DCO's publications are fourfold. The first is entitled "Bioguide: The BioMolecular Nutrition Guide to Natural Health" ("BioGuide"), which was prepared by James Feijo, describes "two aspects of BioMolecular Nutrition, the spiritual and the physical" and promotes all four Challenged Products. IDF 203-211, 228, 229, 249, 270-274, 287-290. The second publication is the BioMolecular Nutrition Product Catalog ("Product Catalog"), which describes all of DCO's products including the four Challenged Products, but does not mention the existence of a DCO ministry. IDF 91, 233, 234, 256, 257, 279, 280. The third publication is a newsletter entitled "How to Fight Cancer is Your Choice!!!" ("Newsletter"), which promotes all four of the Challenged Products. IDF 94-96, 194-201, 231, 251, 253, 254, 276, 277, 292, 293. The fourth publication is entitled "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide" ("Most Simple Guide"). It also promotes the four Challenged Products. IDF 192. The Most Simple Guide, the BioGuide, and the Newsletter are all available to anyone by download from DCO's website. IDF 163, 169, 172.

Each of these publications promotes DCO's call center and the toll-free number to access it, as well as DCO's principal website address. IDF 90, 91, 94, 167, 174. The Newsletter promotes the BioGuide and the Most Simple Guide. IDF 168, 175. All except the Product Catalog promote the radio program. IDF 177.

As previously mentioned, DCO has a toll-free number and a call center for consumers to buy their products. IDF 99. They were created, managed and maintained by James Feijo, who has supervised the call center and taken consumer orders. IDF 100, 101. DCO also has several websites at which it takes consumers' orders, the principal one of which invites consumers to shop at DCO's "On-Line Store" and to "Buy Now." IDF 103-107. These websites promote all four of the Challenged Products. IDF 179-190, 220-226, 237-244, 246, 247, 262-268, 283-286.

DCO also has a radio program, which is co-hosted by James and Patricia Feijo for two hours a day. IDF 108, 109. On that program, the Feijos have promoted the Challenged Products. IDF 213-217, 260, 261. They have also counseled individuals who have identified themselves as cancer patients, and they (and the website) have provided listeners with the toll-free number they can use to buy DCO's products. IDF 102, 110, 111.

A number of retail stores and chiropractic centers in various states sell DCO products. IDF 116-119. Respondents have prepared a brochure entitled "The Truth Will Set You Free" for retailers of DCO products. Among the benefits listed in that brochure are financial rewards, and the brochure makes the representation that DCO is "the ONLY nutrition company where the owners personally tell thousands of people to visit your office or store." IDF 122. Respondents also promote an "affiliate program" on their principal web page where they offer website owners "a means of profiting from their websites" by "generat[ing] sales for commercial websites" in order to "earn a commission." IDF 123.

To promote its products, DCO offers consumers coupons for their next online order, and discounts when products are purchased in volume. IDF 113-115. Moreover, in addition to the revenue derived from sale of its products, DCO charges shipping and handling fees totaling $20.95. IDF 112.

Legal Analysis.

On appeal, Respondents argue that the ALJ was mistaken and incorrect in concluding that the FTC had jurisdiction over DCO. In support of this contention, Respondents rely on several alleged Due Process errors and misapplications of law by the ALJ. RAB at 31. Specifically, Respondents argue that the ALJ misapplied the applicable law regarding jurisdiction; disregarded DCO's status as a corporation sole, a legitimate entity outside the FTC's jurisdiction of the FTC; failed to require Complaint Counsel to prove that DCO is a corporation "organized to carry on business for its own profit or that of its members;" and failed to prove that DCO or its members "derived a profit from DCO's activities." RAB 31-40. These arguments are each considered below.

As Respondents acknowledge in their appellate briefs, *California Dental Ass'n v. FTC*, 526 U.S. 756 (1999) and *Community Blood Bank v. FTC*, 405 F.2d 1011 (8th Cir. 1969), are controlling authorities respecting their challenge to the FTC's jurisdiction. RAB at 31, 34; RRB at 17. Both cases, following the language of § 4 of the FTC Act, hold that the Commission's jurisdiction extends to a corporation organized to carry on business for its own profit or that of its members. *See California Dental*, 526 U.S. at 766-67 ("The FTC Act is at pains to include not only an entity 'organized to carry on business for its own profit,' ... but also one that carries on business for the profit 'of its members"'); *Community Blood Bank*, 405 F.2d at 1022 (holding the Commission has jurisdiction over nonprofit corporations without shares of capital, which engage in business for their own profit or that of their members); *see also* 15 U.S.C. § 44.

Respondents try to distinguish these cases from the instant case by parsing the definition of "profit" and by arguing that, contrary to the teaching of *California Dental,* DCO did not make a profit and has no for-profit subsidiaries. RAB at 32. Specifically, Respondents quote *California Dental* for the proposition that "according to a generally accepted definition 'profit' means gain from business or investment over and above expenditures, or gain made on business or investment where both receipts or payments are taken into account." RAB at 32 (*quoting California Dental*, 526 U.S. at 768 n.6 (*citing Community Blood Bank*, 405 F.2d at 1017)). However, the ALJ cited to the same *California Dental* language in evaluating the evidence and reaching his conclusion that by engaging in commercial activities, DCO operates a commercial enterprise and thereby is not a business organized or engaged in only charitable purposes. ID at 70-71. In addition, Respondents failed to include the conclusion of the quoted sentence where the Court noted that "the 'term's meaning must be derived from the context in which it is used."' *California Dental*, 526 U.S. at 768 n.6 (*citing Community Blood Bank*, 405 F.2d at 1016).

Respondents contend that they are a religious ministry organized and operated for charitable purposes. RAB at 2, 31. Respondents argue that by acknowledging that DCO was a religious ministry, but still concluding that the FTC had jurisdiction over DCO, the ALJ's conclusions are "unprecedented, legally incorrect and unsupported by the facts." RAB at 4, 29-30. But *Community Blood Bank* specifically holds that such a finding does not foreclose the FTC from exercising jurisdiction over a respondent. 405 F.2d at 1017-18; *see also id.* at 1018 ("Congress took pains in drafting § 4 to authorize the Commission to regulate so-called nonprofit corporations, associations and all other entities if they are in fact profit-making enterprises."). Nonprofit status insulates an entity from FTC jurisdiction when the entity is engaged in business for "only charitable purposes." *Id.* at 1022. Whatever else may be said about DCO's religious status and activities, the findings of fact, supported by extensive evidence, establish that DCO conducted business for the purpose and with the effect of selling its products, including the four Challenged Products. IDF 80-84, 91, 94, 96, 98-101, 110-113, 116-119, 123, 158, 174-190, 192, 194-201, 203-211, 213-217, 220-229, 231, 233, 234, 237-244, 246, 247, 249, 253, 254, 256, 257, 260-268, 270-274, 276, 277, 279, 280, 283-290, 292, 293. Thus, the ALJ did nothing to impeach his conclusion that the FTC had jurisdiction over Respondents.

The Respondents also argue that the ALJ failed to require proof that DCO was organized and operated to carry on business for its own profit or that of its members. RAB at 30, 34-35. In support of this contention, Respondents insist that

DCO was not a for-profit corporation because it did not "make a profit" and that "the evidence showed the DCO operates at a breakeven point or less." RAB at 30, 35. Whether or not that is true, it is beside the point. As the ALJ pointed out, it is not necessary to show that the entity was actually successful in running its business or turning a profit. ID at 71 (*citing California Dental*, 526 U.S. at 768 n.6 ("the FTC Act does not require for Commission jurisdiction that members of an entity turn a profit on their membership, but only that the entity be organized to carry on business for members' profit"); *In re Ohio Christian College*, 80 F.T.C. 815, 849-50 (1972) (stating that the fact that respondents "were apparently not very successful in their enterprise" was of "little consequence")). As discussed above, Respondents' activities, as described in the findings of fact, and supported by extensive evidence, establish that DCO conducted business for the purpose and with the effect of selling its products.

Moreover, in *In re College Football Ass'n*, 117 F.T.C. 971, 994 (1994), the Commission stated that *Community Blood Bank* thus established a two-part test looking to "the source of the entity's income, *i.e.*, to whether the corporation is 'organized for and actually engaged in business for only charitable purposes,' and to the destination of the income, *i.e.*, to whether either the corporation or its members derive a profit." Respondents contend that the FTC must also show the "destination" of DCO's income, and argue that the ALJ improperly shifted the burden of proof from the FTC to the Respondents to show that the income did not profit either DCO or Mr. Feijo. RAB at 35-36. However, the ALJ's findings of fact, supported by ample evidence, show that the "destination" of the profits of DCO's for-profit activities was James Feijo. ID at 74-76. As DCO's sole "member," "overseer," and "trustee," James Feijo was responsible for all of DCO's activities, including the distribution of its funds; he distributed those funds to himself and his wife for their benefit. The record also shows that DCO or its affiliate owned the Feijos' Rhode Island and Florida homes and two Cadillacs, and was the source of all of their living expenses, including their tennis, golf and restaurant expenses. IDF 5, 6, 42, 48, 55-58, 61-70. Thus, it cannot be said that the ALJ's conclusion that the FTC had jurisdiction over DCO was "unprecedented." RAB at 11; RRB at 12, 14, 21-22. To the contrary, it was fully supported by *California Dental* and *Community Blood Bank*.

Finally, it cannot be said that the ALJ was "mistaken" in exercising jurisdiction over DCO and Mr. Feijo despite the existence of various statutes and regulations that allow churches to carry on "business activities" for purposes of exemption from federal income taxation or provide "religious workers' special exemptions." RAB at 38-40. Respondents argue that DCO's status as a church and Mr. Feijo's status as a minister entitle Respondents to special tax treatment. RAB at 39. Similarly, Respondents contend that DCO was organized as a "corporation sole" in 2002 under the laws of the State of Washington, and, as such, has been a nonprofit corporation since 2002. RAB at 29-31. As recognized by the ALJ, however, "courts and the Commission look to the substance, rather than the form, of incorporation in determining jurisdiction under the FTC Act." ID at 71 (citations omitted). The Commission agrees with the ALJ's determination, supported by ample evidence in the record, that "DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes." *Id.*

B. Respondents Made the Claims Alleged in the Complaint.

Findings of Fact.

The text of the advertisements at issue here repeatedly links all four products collectively to the prevention, treatment or cure of cancer. IDF 179, 180, 183, 186, 190, 192, 195, 197, 200, 203, 204, 208, 213. Furthermore, the advertisements repeatedly link each product individually to the cure or treatment of cancer, the shrinkage of tumors, or, in the case of BioMixx, to the amelioration of the side effects of radiation and chemotherapy. IDF 182, 198, 199, 204, 206, 221, 222, 223, 225, 226, 228, 231, 233 (respecting BioShark); IDF 237-244, 246, 247, 249, 251-254, 256, 257, 260 (respecting 7 Herb Formula); IDF 262, 264-268, 270-274, 276, 277, 279, 280 (respecting GDU); IDF 283-285, 287-290, 292, 293 (respecting BioMixx). Indeed, in some of these advertisements the linkage between these products and the treatment or

cure of cancer is to a specific type of cancer such as breast cancer (IDF 182, 187, 265, 267, 268, 273); brain cancer (IDF 184, 200, 249, 289); prostate cancer (IDF 187, 206 253, 265, 271, 274, 290); skin cancer (IDF 208, 214); colon cancer (IDF 217, 260); leukemia (IDF 276, 284); bladder cancer (IDF 200); renal cancer (IDF 207); and esophageal cancer (IDF 252). Generally, these links were explicit, but even when they were implicit, the linkage was clear.

The linkage in these advertisements was frequently emphasized by testimonials, generally by consumers. IDF 180, 181, 183, 184, 186, 197-200, 203-210, 231, 242-244, 247, 249, 253, 265, 267, 268, 273, 276, 284, 290, 292. Again, the linkage in the testimonials between the products and the treatment or cure of cancer, the shrinkage of tumors or, in the case of BioMixx, to the healing effects on radiation or chemotherapy was generally explicit, but even where it was implicit, the linkage was clear. That linkage was also frequently stressed either by the use of bold-faced type, the use of italics or the use of capital letters. IDF 180, 182, 186, 187, 190, 192, 204-209, 221, 226, 228, 231, 237, 238, 240-243, 249, 252-254, 266, 271, 274, 276, 283, 285, 289. Additionally, the products or consumers purporting to use them were depicted in the advertisements. IDF 180, 184, 190, 204, 206-208, 210, 221, 237, 238, 240, 241, 251 (logo), 254 (logo), 256, 262, 263, 266, 271, 276, 279, 283-285, 290.

These advertisements did not exist in isolation from each other. As previously described, DCO's publications prominently displayed the existence of DCO's call center and the toll-free number by which the call center could be accessed, as well as DCO's principal website address. IDF 90, 91, 98, 167-169, 174. Also, the Newsletter promoted the BioGuide and The Most Simple Guide, and the call center promoted the DCO email address. IDF 168, 175-177. Thus, the overall net impressions left by these advertisements were mutually reinforcing.

Those overall net impressions were that: (1) BioShark inhibits tumor growth and is effective in the prevention, treatment, or cure of cancer (IDF 224, 227, 230, 232, 235); (2) 7 Herb Formula inhibits tumor formation and is effective in the prevention, treatment, or cure of cancer (IDF 245, 248, 250, 255, 258); (3) GDU eliminates tumors and is an effective treatment for cancer (IDF 269, 275, 278, 281); and (4) BioMixx heals the adverse effects of radiation and chemotherapy and is effective in the prevention, treatment, or cure of cancer. IDF 286, 291, 294.

Respondents' advertisements and materials sometimes included "disclaimers" of these overall net impressions. DCO's websites asserted, *inter alia*, that "[t]he information provided in this site is not intended to diagnose a disease;" that the information "is designed to support, not replace, the relationship that exists between a patient site visitor and his/her health provider;" and that "this product is not intended to diagnose, treat, cure, or prevent disease." IDF 296, 297, 300, 301. The BioGuide and Newsletter stated, *inter alia*, that they were "not intended to diagnose or treat disease." IDF 298, 299. The Most Simple Guide contains no disclaimer language. IDF 302.

For the most part, these disclaimers were made in "mouse print" or type size significantly smaller than the type of the text contributing to those overall net impressions. IDF 296, 298-300, 303. They were often buried in copyright disclosures, and placed well after the conclusion of the advertising claims. IDF 296-300. Moreover, they disclaimed only Respondents' "intentions," not the representations themselves. They did not dispel the overall net impressions left by the advertisements and by the other contributing factors that the Challenged Products prevent, treat, or cure cancer. IDF 306.

Legal Analysis.

Respondents do not take issue with the ALJ's conclusion that the "overall net impression" of the advertising promoting the four Challenged Products determines what impression is conveyed by an advertisement. RAB at 4, 5, 11; RRB at 38. That acknowledgment is not gratuitous. The courts have long held that to be the test applied in determining what impressions are conveyed to consumers. *See, e.g., American Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3rd Cir. 1982); *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963); *FTC v. Bronson Partners LLC*, 564 F. Supp. 2d 119, 125

(D. Conn. 2008); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 920-21, 929, 932 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008). Moreover, Respondents admitted that they made the representations that the ALJ found were conveyed by the advertisements at issue (Answer ¶ 14), although now Respondents shrug off the admissions as "ministerial error" and stress that the ALJ did not consider them. RBB at 35.

However, Respondents repeatedly assert that in assessing those "overall net impressions," the ALJ was obliged by the Due Process Clause and the First Amendment of the Constitution to consider "extrinsic" evidence. RAB at 2, 4, 13, 48-49; RRB at 12-13, 30-31. More specifically, Respondents claim that "Complaint Counsel should have been required to produce evidence that consumers were actually misled by Respondents' promotional efforts and representations," including testimony from the misled consumers themselves. RAB at 14, 23-24; RRB at 33, 34, 37-38, 57. Indeed, Respondents contend that the ALJ's failure to require Complaint Counsel to do so amounted to resorting to "presumptions" instead of evidence or at least "shifting the burden of proof" to Respondents in violation of the Due Process Clause and the First Amendment. RAB at 3, 11, 14, 24.

That is not the law. Federal courts have long held that the Commission has the common sense and expertise to determine "what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear." *Kraft, Inc. v. FTC*, 970 F.2d 311, 319 (7th Cir. 1992); *accord FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965); *Thompson Med. Co. v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1986); *Bronson Partners*, 564 F. Supp. 2d at 126; *FTC v. Nat'l Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *41-43 (N.D. Ga. June 4, 2008) (extrinsic evidence "is only necessary when the asserted claims fall on the 'barely discernable' side of the continuum"); *QT, Inc.*, 448 F. Supp. 2d at 958.

Moreover, in *Kraft*, the Seventh Circuit rejected Respondents' First Amendment argument. Like Respondents, Kraft contended that *Peel v. Attorney Registration & Disciplinary Commission*, 496 U.S. 91 (1990), held that the First Amendment required "extrinsic" evidence and prevented the Commission from determining the overall net impression conveyed by advertisements challenged as deceptive under the FTC Act. The Court of Appeals held that the restriction challenged in *Peel* is "a completely different animal than the one challenged here." *Kraft*, 970 F.2d at 317. It explained that in *Peel*, the issue was whether a "regulation applicable to all lawyers, completely prohibiting an entire category of potentially misleading speech, passed constitutional muster" in contrast to "whether an individualized FTC cease and desist order, prohibiting a particular set of deceptive ads, passes constitutional muster." *Id.*

In this case, the ALJ and the Commission itself have determined the "overall net impressions" of the representations made about the Challenged Products, based not only on the text of the advertisements itself, but also on the interaction of other factors that operate to create that impression, such as testimonials, bold type, visual images and mutually reinforcing language. ID at 82-83. Those are factors that the Commission and the courts have recognized are probative in determining what messages advertising is conveying. *In re Kraft*, 114 F.T.C. 40, 121 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992); *see also Bronson Partners*, 564 F. Supp. 2d at 125; *In re Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006). The Commission therefore does not agree with Respondents that "evidence" has been supplanted by "presumptions" or that the ALJ shifted the "burden of proof" to Respondents so as to violate Due Process or the First Amendment of the Constitution in the determination of those overall net impressions.

As discussed below, the alleged "disclaimers" do not dispel these overall net impressions.

C. Respondents' Representations Were Deceptive Unless Properly Substantiated.

After reaching his findings on the overall net impressions of the Respondents's advertising respecting the efficacy of the four Challenged Products, the ALJ next examined whether those representations were deceptive under Commission and

federal case law. He concluded that under that case law, the representations would be deceptive under Sections 5 and 12 of the FTC Act if they were either shown to be false or shown to lack a reasonable basis substantiating the claims made in the advertisement. ID at 99 (*citing FTC v. Pantron I*, 33 F.3d 1088, 1096 (9th Cir. 1994); *In re Thompson Med. Co.*, 104 F.T.C. 648, 818-19 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986)).

The ALJ focused on whether the advertisements at issue were deceptive or misleading under the "reasonable basis" theory because the Complaint only made "reasonable basis" allegations. *Id.* Again, citing Commission and federal case law, the ALJ stated that the "reasonable basis theory holds that claims about a product's attributes, performance, or efficacy ('objective' product claims) carry with them the express or implied representation that the advertiser had a reasonable basis substantiating the claims at the time the claims were made." *Id.* (*citing In re Thompson Med. Co.*, 104 F.T.C. at 813 ; *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 298 (D. Mass. 2008); *In re Kroger Co.*, No. C-9102, 1978 FTC LEXIS 332, at *15 (May 17, 1978)).

Respondents do not (and cannot) dispute that this is a correct reading of the case law. However, Respondents contend that in applying these principles, the ALJ again engaged in "presumptions" and shifted the "burden of proof" in a way that violated the Due Process Clause and the First Amendment of the Constitution. RRB at 34, 51.

First, Respondents contend that the representations made about the efficacy of the four Challenged Products cannot be challenged as deceptive, consistent with the First Amendment. Specifically, Respondents liken those representations to mere "ideas, opinions, beliefs and theories" involved in *In re Rodale Press, Inc.*, 71 F.T.C. 1184 (1967), to a ban on the words "natural," "organic" and "health food" which an FTC Presiding Officer condemned in connection with the Commission's Proposed Trade Regulation Rule on Food Advertising ("Food Rulemaking") (Report of the Presiding Officer, Proposed Trade Regulation Rule: Food Advertising, Pub. Rec. No. 215-40, at 239, Feb. 21, 1978), and with the representations about "matters of opinion" involved in *United States v. Johnson*, 221 U.S. 488 (1911). RAB at 5-11.

Respondents' representations are not matters of opinion, but, as the ALJ put it, "objective product claims ... stated in positive terms and ... not qualified to be statements of opinion." ID at 99. Or, to put the matter more baldly, Respondents' representations were representations of fact, not simply representations about ideas, opinions, beliefs or theories; Respondents made assertions not just about what they believed those products might do, but represented that the four Challenged Products would in fact treat or cure cancer, prevent or shrink tumors, and ameliorate the side effects of radiation and chemotherapy. *See, e.g.*, IDF 179, 180, 183,186, 190, 192, 195, 197, 200, 203, 204, 208, 213 (Challenged Products collectively); IDF 221-223, 225, 226, 228, 231, 233 (BioShark); IDF 182, 198, 199, 204, 206, 237-244, 246, 247, 249, 251-254, 256, 257, 260 (7 Herb Formula); IDF 262, 264-268, 270-274, 276, 277, 279, 280 (GDU); IDF 283-285, 287-290, 292, 293 (BioMixx). Therefore, as a matter of law, there was an implied claim that there was a reasonable basis substantiating those representations. *In re Thompson Med. Co.*, 104 F.T.C. at 813 n.37 (noting that "objective product claims carry with them an express or implied statement that the advertiser has some amount of support for the claim").

Beyond that, *Rodale Press*, the Food Rulemaking, and the *Johnson* case were not decided on constitutional grounds. As Respondents acknowledge, the Commission simply voted to dismiss *Rodale Press*. RAB at 6. Similarly, the Commission abandoned its Proposed Trade Regulation Rule on Food Advertising on the ground that case-by-case scrutiny would be more appropriate. *See* Food Advertising, 45 Fed. Reg. 23705 (Apr. 8, 1980); Termination of Proposed Trade Regulation, 48 Fed. Reg. 23270 (May 24, 1983). In neither instance was the Commission's action compelled by the First Amendment. *See, e.g.*, 45 Fed. Reg. at 23706 (stating that "it is not clear that the claims under scrutiny are readily susceptible to the across-the-board remedies that have been proposed or that this approach represents the ideal solution for remedying deception or unfairness"); *Rodale Press, Inc. v. FTC*, 407 F.2d 1252 (D.C. Cir. 1968) (vacating Commission's order and remanding for further hearing and argument on new theory of violation); *In re Rodale Press, Inc.*, 74 F.T.C. 1429, 1430

(1968) (dismissing complaint because, "[f]urther continuation of these proceedings at this time appearing not to be in the public interest and the possibility appearing remote that the practices challenged in the complaint would be resumed in the future"). Respondents likewise acknowledge that "[t]he *Johnson* case did not reach the constitutional question because the majority disposed of it as a legislative interpretation case." RAB at 11. Indeed, as the ALJ pointed out, Congress effectively overruled *Johnson* by amending the Food and Drug Act to expressly include claims regarding curative effectiveness. ID at 111 (*citing* Act of June 30, 1906, as amended, 37 Stat. 416 (1912)).

Additionally, Respondents' representations are not protected by the First Amendment. It is well established under applicable Supreme Court precedent that commercial speech is accorded less protection than other constitutionally protected forms of speech. ID at 112 (*citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 562-63 (1980); *Va. Pharm. Bd. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 n.24 (1976)). In determining whether speech is commercial, *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626, 637-38 (1985), is instructive. *Zauderer* holds that the determination of whether speech is commercial speech "rests heavily on 'the common sense distinction between speech proposing a commercial transaction ... and other varieties of speech.'" ID at 113 (citations omitted). Thus, as the ALJ pointed out in the Initial Decision, speech that "propose[s] a commercial transaction" necessarily constitutes commercial speech. *Id.* (*citing Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 US. 469, 473-74 (1989)).

As previously discussed in connection with Respondents' jurisdictional challenge, the primary purpose and effect of Respondents' representations concerning the four Challenged Products was to sell those products. Those representations constituted commercial speech, not simply practicing religion or engaging in "charitable solicitations." See RRB at 62. As a matter of law, including religious or political views in the commercial advertising at issue does not convert Respondents' commercial speech to constitutionally protected religious or political speech. ID at 114; *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983) (holding that mailings constituted "commercial speech notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning"); *id.* at 68 (*quoting Central Hudson*, 447 U.S. at 563 n.5 ("[A]dvertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech.")).

Accordingly, the Supreme Court cases concerning *non-commercial* speech upon which Respondents rely - namely, *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 (1980); and *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943) - do not apply at all. *Cf. Church of Scientology v. Richardson*, 437 F. 2d 214, 218 (9th Cir. 1971) (holding there was no First Amendment violation so long as the FDA "could determine the E-meter's [an instrument used in the practice of Scientology] intended use without evaluating the truth or falsity of any related 'religious' claims."). RRB at 56.

The Supreme Court's First Amendment cases involving commercial speech upon which Respondents rely - *Central Hudson,* 447 U.S. 557; *Edenfield v. Fane*, 507 U.S. 761 (1993); *Greater New Orleans Broadcasting Ass'n. v. United States*, 527 U.S. 173 (1999); *Ibanez v. Florida Department of Business & Professional Regulation, Board of Accountancy*, 512 U.S. 136 (1994); *In re R.M.J.*, 455 U.S. 191 (1982); *Peel v. Attorney Registration & Disciplinary Commission*, 496 U.S. 91 (1990); *Rubin v. Coors Brewery Co.*, 514 U.S. 476 (1995); *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); and *Illinois ex rel. Madigan v. Telemarketers Ass'n.*, 538 U.S. 600, 619-20 (2003) - have all affirmed that misleading or deceptive commercial speech is not protected by the First Amendment. Those declarations are often included in the passages cited by Respondents. RAB at 18, 20-21; RRB at 51-52.

Respondents argue that *Central Hudson*, *Peel*, *Ibanez* and *Thompson*, *Madigan* and *Greater New Orleans Broadcasting* teach that under the First Amendment, the government (here the FTC) must identify a "substantial interest" in order to

justify restricting their advertising. RAB at 20-23; RRB at 51-52. Respondents further cite *Edenfield*, 507 U.S. at 770-71, for the proposition that the "substantial interest" cannot be established by mere "speculation and conjecture." RAB at 22. But that gets things backward. In *Central Hudson*, the Supreme Court set forth the four-part analysis for determining whether regulation of commercial speech is constitutional. A first and threshold inquiry is whether the speech in question is false or misleading; for commercial speech to be afforded any First Amendment protection, "it at least must concern lawful activity and not be misleading." 447 U.S. at 566. Non-misleading commercial speech remains subject to reasonable regulation, under the remaining three elements of the *Central Hudson* analysis: whether the regulation is based on a substantial governmental interest; "whether the regulation directly advances the governmental interest asserted;" and "whether it is not more extensive than necessary to serve that interest." *Id.*

The cases cited by Respondents all recognize that the latter three prongs of the test are reached if, and only if, Respondent's advertising is not misleading or deceptive. *See Edenfield*, 507 U.S. at 768 ("[O]ur cases make clear that the State may ban commercial expression that is fraudulent or deceptive without further justification."). The ALJ found Respondents' commercial speech deceptive. The record shows that the ALJ's findings were based on the text of the advertisements at issue, as well as the Respondents' use of testimonials, bold print, pictures and mutually reinforcing advertisements to create the "overall net impressions" conveyed by the advertisements. In reviewing the ALJ's findings, the Commission has also brought its expertise and experience to bear. Once reaching that finding, no further analysis is neces- sary.

Respondents also emphasize that *Thompson v. Western States Medical Center* held that under the First Amendment, even if the government has an interest in preventing misleading advertisements, it could not enjoin the compounding of drugs if disclaimers would be a less restrictive alternative. RAB at 60. In their Reply Brief, Respondents argue that *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), said the same thing about the use of disclaimers. RRB at 27-30. That case does not help Respondents either. Both in *Thompson* and in the portion of *Pearson* on which Respondents rely, the issue was not the condemnation of particular commercial speech found to have been actually misleading, but rather the regulation of broad categories of speech, subject to the latter three prongs of the *Central Hudson* analysis. *See Thompson*, 535 U.S. at 368; *Pearson*, 164 F.3d at 655-56. It was in the context of that analysis - assessing the "fit" between government regulation of non-misleading commercial speech and the interests sought to be served - that each court focused on the use of disclaimers as a substantially less restrictive alternative to outright bans. *See Central Hudson*, 535 U.S. at 376; *Pearson*, 164 F.3d at 657-58. Respondents offer no support for their assertion that the *Central Hudson* "fit" analysis should be imported into cases like the present one, in which an administrative agency is adjudicating the deceptive nature of particular advertisements.[FN2]

Even if we were to adopt Respondents' unprecedented approach to this issue, their arguments fail on the record before us. Respondents' "disclaimers" here were ineffective, given the multiple techniques Respondents used to reinforce their overall advertising messages, the comparatively small print in which most of their "disclaimers" were printed (IDF 296, 298, 299, 300, 303), their ambiguity and lack of conspicuousness (IDF 305), and the fact that even those "disclaimers" only disclaimed Respondents' "intentions," not the messages themselves. Any one of these factors would blunt the effectiveness of the disclaimers. *See, e.g., Removatron Int'l v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) (holding that disclaimer that was not clear and conspicuous was ineffective). Considering these factors in combination, Respondents' "disclaimers" did not dispel the overall net impressions that the four Challenged Products would treat or cure the diseases and conditions that Respondents' representations conveyed.

Second, Respondents argue that none of this First Amendment jurisprudence applies to herbal supplements like the four Challenged Products because they are not "drugs" within the meaning of the Food and Drug Act. RAB at 8. As Respondents acknowledge, the Food and Drug Act "differs from" the FTC Act. RRB at 41 (*quoting FTC v. QT, Inc.*, 512 F.3d

858, 861 (7th Cir. 2008)). Respondents do not explain why or how the Food and Drug Act can be considered binding on the Commission in enforcing the Sections 5 and 12 of the FTC Act. Under the FTC Act, these products are embraced within Section 5, and, as the ALJ observed, the FTC Act defines the words "food" and "drug" broadly for purposes of Section 12. ID at 80. Accordingly, the courts have repeatedly held that that definition covers dietary supplements. *See, e.g., FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007); *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303; *see also* ID at 80-81, 103. Moreover, those same courts have specifically held that such products can be deceptive if they lack a reasonable basis substantiating the claims made for them. *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *9-10; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *76-79; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 298.

Third, Respondents repeatedly assert that the Commission cannot challenge their efficacy representations for the four Challenged Products because those representations were simply "structure/function" claims that are permitted under the Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 ("DSHEA"), which amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a ("FDCA"). RAB at 3, 4, 12, 45, 46, 51, 52; RRB at 33, 40, 41, 45. Respondents' representations, however, are not "structure/function" claims under the DSHEA. Under the FDCA, such a claim is defined simply as one that describes "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 C.F.R. § 101.93(f) (2009). The Respondents' representations that the four Challenged Products would treat or cure cancer, prevent or shrink tumors, and ameliorate the side effects of radiation and chemotherapy do not simply describe the "role" that those four products will play in affecting the structure or function in humans. *See United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 568 (D.N.J. 2004); *see also Pearson*, 164 F.3d at 652. Moreover, DSHEA expressly provides that even compliant "structure/function" claims are permitted only if they are "truthful and not misleading" and the manufacturer "has substantiation" that such claims are true. 21 U.S.C. § 343 (r)(6)(B) (2009). Thus, the DSHEA amendment to the FDCA is not inconsistent with the FTC case law as applied by the ALJ. Indeed, even if the FDCA departed from the FTC Act and its relevant case law, Respondents offer no authority that it would be binding on the Commission.

Fourth, Respondents argue that the ALJ failed to adopt a "flexible standard of substantiation" for their representations and ignored numerous studies supporting those representations, contrary to the FTC's guidelines entitled, *Dietary Supplements: An Advertising Guide for Industry* ("Guide"). RAB at 47-48. The Commission does not agree. The Guide advises the Commission's standard of substantiation for dietary supplements is "flexible," because the standard depends upon the claims made for those products. Guide at 8. The Guide warns that the "FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with 'competent and reliable scientific evidence.'" Guide at 9. Thus, where, as here, Respondents represented that the four Challenged Products would treat or cure cancer, prevent or shrink tumors, and/or ameliorate the destructive side effects of radiation or chemotherapy, the competent and reliable scientific standard applies under the Guide.

Fifth, Respondents maintain that they only intended to convey the impression that their "Biblical approach to health care - including use of the Challenged Products - could reinforce the naturally healing capability of the body, including the immune system, and thereby provide adjunct support for whatever path - drugs, surgery or other - an individual freely chose to take for their cancer care regimen." RAB at 44. That stated intent is at odds with almost all of the advertisements themselves, which generally did not mention the "naturally healing ability of the body" or that the four Challenged Products could be only an "adjunct" to traditional cancer treatments. But in any event, the courts have long held that "the subjective good faith of the advertiser is not a valid defense." *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998); *see also FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988).

Finally, Respondents contend that they cannot be held liable for deception because all of the elements of Section 5(n) of

the FTC Act have not been proved. That is, Respondents argue Complaint Counsel failed to prove their acts were both unfair and deceptive. That argument is without merit. No case has ever held that deception claims are subject to Section 5(n).

D. Due Process Was Not Violated.

Despite Respondents' claims to the contrary, it cannot be said that the ALJ violated Due Process in reaching his findings of fact under a "preponderance of evidence" standard instead of a "clear and convincing evidence" standard. RAB at 11, 27-29. As the ALJ states in his Initial Decision, under both the Administrative Procedure Act and the Commission's rules, the proper standard to be applied in FTC Act cases challenging deceptive practices is the "preponderance of evidence" standard. ID at 66-67. Federal court and Commission decisions respecting those challenges have repeatedly so held. *In re Telebrands Corp.*, 140 F.T.C. 278, 426 (2004), *aff'd*, 140 F.T.C. 278 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Auto. Breakthrough Sciences, Inc.*, No. 9275, 1998 FTC LEXIS 112, at *37 n.45 (Sept. 9, 1998); *In re Adventist Health System/West*, 117 F.T.C. 224, 297 (1994); *In re Bristol-Myers Co. v. FTC*, 102 F.T.C. 21, 275 (1983), *aff'd* , 738 F.2d 554 (2d Cir. 1984). Moreover, contrary to Respondents' assertion in their Reply Brief (RRB at 47), those decisions do not simply concern the standard applicable to litigating over whether the FTC has jurisdiction. *Telebrands*, for example, concerned whether certain representations were conveyed in the advertising, and whether they were deceptive. 140 F.T.C. at 427, 449.

Other cases upon which the Respondents rely, *Addington v. Texas*, 441 U.S. 418 (1979); *Stanley v. Illinois*, 405 U.S. 645 (1972); and *Mathews v. Eldridge*, 424 U.S. 319 (1976) (RAB at 26-28), do not hold otherwise. Those cases did not consider the standard of proof applicable under the FTC Act or the standard of proof applicable when the FTC challenges deceptive acts or practices. Indeed, they are entirely inapposite. *Stanley* simply held that a State may not deprive an unwed father of custody of his children, on the basis of a statutory presumption of unfitness, but must afford an individualized fitness hearing. In the present case, Respondents have been afforded an extensive hearing on the specific charges against them. *Mathews* set forth general standards for due process procedures, but emphasized the flexibility of the constitutional standard. 424 U.S. at 334-35. The Court there upheld an administrative scheme for the termination of disability benefits without any pre-termination evidentiary hearing - a holding that offers the present Respondents no support. *Id.* at 339-40. In *Addington* - the only case cited that addresses a constitutional requirement regarding the standard of proof - the Supreme Court held that due process requires "clear and convincing" evidence to support the indefinite, involuntary commitment of an individual to a mental institution. 441 U.S. at 431-32. The holding in *Addington*, respecting an extreme form of deprivation of personal liberty, has no bearing on the present case. Here, Respondents were afforded ample procedural protections, including adjudication under the established preponderance of evidence standard typical of civil litigation. Their assertions that due process required more than this are without merit.

E. There is No Reasonable Basis Substantiating the Representations.

Findings of Fact.

Respondents alleged in their Answer that they possessed and relied upon a reasonable basis that substantiated the representations they made for the four products at issue at the time those representations were made. Answer ¶ 16; RAB at 2. However, Respondents did not conduct or direct others to conduct any scientific testing of the effects of the four Challenged Products. IDF 308, 309, 311, 313, 315. The manufacturers of BioShark and BioMixx likewise did not conduct any testing on those products. IDF 310, 314. Respondents have not produced anything to show that they possessed and relied on any competent and reliable scientific evidence to support the overall net impressions conveyed by the advertisements at issue.

The ALJ considered the evidence presented by Complaint Counsel's expert, Dennis Miller, M.D. and Respondents' five

experts, James Duke, Ph.D., Sally LaMont, N.D., Rustum Roy, James Dews and Jay Lehr, Ph.D. IDF 329-425. The only proffered expert who was a medical doctor, had specialized training or experience regarding cancer or cancer treatment, or had conducted clinical studies regarding cancer treatments was Dr. Miller. IDF 329-337. Dr. Miller is a board-certified pediatric hematologist/oncologist who, *inter alia*, has directed clinical care, education, laboratory and clinical research, and administration heading divisions or departments for over forty years at the University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan-Kettering Cancer Center and Northwestern University Medical School. IDF 320-326.

Dr. Miller testified that "competent and reliable scientific evidence" is required to conclude that a cancer treatment is effective. IDF 343. Dr. Miller explained that in order to constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the products' efficacy and safety must be demonstrated through controlled clinical studies (tests on humans). IDF 344, 345. He further testified that studies performed in test tubes or in animals, testimonials and other anecdotal reports are not substitutes. IDF 345, 351-353. He testified that harm potentially may occur from remedies that are alternatives to those that have undergone clinical studies on humans. IDF 356-361. And, he testified that for these reasons, the need to substantiate a claim by clinical studies (*i.e.*, on humans) was the same whether the purported agent was a herbal medicine or a more conventional pharmaceutical agent. IDF 354.

Dr. Miller was asked to determine whether there was competent and reliable scientific evidence to substantiate each of the overall net impressions conveyed by the advertisements at issue about the Challenged Products, and he did so. IDF 327, 344, 345, 351-354. Dr. Miller concluded that the reference materials relied on by Respondents did not constitute competent and reliable scientific evidence that any of the Challenged Products prevent, treat or cure cancer; that most of those materials were not peer-reviewed papers but instead consisted of author opinions and literature reviews; that many of the studies involved *in vitro* or animal studies, not studies on humans; that others relied on the efficacy or safety of ingredients of the Challenged Products rather than the products themselves and that, absent, evidence that DCO's four products at issue here contained exactly those ingredients in the proportion tested, those studies were not probative; and that there is no competent and reliable scientific evidence that the Challenged Products are effective, either alone or in combination with other DCO products, in the prevention, treatment or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy. IDF 362-367. The reference materials on which Respondents relied were of the sort that Dr. Miller testified were not reliable. IDF 368-386.

Respondents did not ask any of their proffered experts to render an opinion as to whether Respondent's purported substantiation materials constituted competent and reliable scientific evidence substantiating any of the overall net impressions conveyed by the advertisements at issue about the Challenged Products. IDF 339. Neither did Respondents ask any of their proffered experts to render an opinion as to whether there existed any such substantiating evidence. IDF 340. Respondents' expert, Dr. Duke, made no effort to determine whether there were any studies of any sort regarding the Challenged Products; he did not analyze any of those products; and he did not know the ingredients of those products. IDF 392-394. Dr. LaMont likewise did not analyze any of the Challenged Products themselves, but only the ingredients in those products, and she did not know the concentration of those ingredients in those products. IDF 401-403. Mr. Roy did not review or obtain any of the Challenged Products or their labels, and he had no idea what ingredients those products contain. IDF 412, 413. None of the experts proffered by Respondents expressed any opinion about whether there was any competent and reliable scientific evidence to support the overall net impressions respecting the efficacy of the four products at issue created by the challenged advertisements. IDF 341, 389, 390, 398, 399, 408, 409, 419, 420, 423, 424.

Legal Analysis.

Respondents have repeatedly accused the ALJ of improperly engaging in "presumptions," "shifting the burden of proof" away from Complaint Counsel, as well as violating the Due Process Clause and the First Amendment of the Constitution.

Thus, in reviewing the ALJ's conclusion that Respondents lacked a reasonable basis substantiating their representations concerning the efficacy of the Challenged Products, it is appropriate to analyze what the ALJ did not do, in addition to what he did do.

First, the ALJ did not treat Respondents' advertising as making "establishment" claims - that is to say, advertising that represents the amount and type of evidence substantiating the product claims made. ID at 100-101. Although the ALJ pointed out that a few of the advertisements did represent that the claims had been proven by scientific testing (ID at 101 (citing IDF 225, 231, 247)), he concluded, "Complaint Counsel has not alleged or argued that Respondents' advertisements constitute establishment claims. Accordingly, the claims at issue are deemed non-establishment claims, and will be evaluated as such." ID at 101.

The result of that conclusion, however, is that in determining the level of substantiation required, the ALJ did not "presume" the truth of Respondents' representations that their claims were supported a study conducted by "two researchers at the Massachusetts Institute of Technology" or "used by patients involved in clinical studies in cancer clinics." IDF 225 (CX 13); IDF 231 (CX 23 & 24); IDF 247 (CX 18). Instead, the ALJ found the claims to be "health-related efficacy claims," and as a result, under well-established precedent, such claims must be substantiated by "competent and reliable scientific evidence." ID at 101. In addition, to the extent that further analysis for determining the substantiation standard was necessary, the ALJ also analyzed them under the *Pfizer* factors: the type of claim involved, the benefits of a truthful claim, the consequences of a false claim, and the amount of substantiation experts in the field consider reasonable. ID at 102-104; *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972); *QT, Inc.*, 448 F. Supp. 2d at 959; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44, 77-79; *In re Removatron*, 111 F.T.C. 206, 306 n.20 (1988); *In re Thompson Med. Co.*, 104 F.T.C. at 821.

Based upon his findings respecting the "overall net impressions" conveyed by Respondents' representations, the ALJ concluded that: (1) the representations made about the four Challenged Products were "health-related efficacy claims" in that they represented that the products would "treat or cure" cancer, eliminate or shrink tumors, and/or ameliorate the adverse effects of radiation and chemotherapy (ID at 101-102); (2) the benefits of truthful claims were substantial because cancer patients would benefit from truthful representations about effective treatment of, or cure for, the disease (ID at 103); (3) the consequences of a deceptive claim were substantial not only because a patient might forego using products or therapies that were effective in treating or curing the relevant diseases, but also (as Respondents acknowledged in their "disclaimers"), because their products could be harmful if used with the other products or therapies (ID at 103); and (4) clinical studies respecting human beings were required because the representations Respondents made concerned the efficacy of the Challenged Products in treating or curing human beings, not animals, or their efficacy in vitro. ID at 103-104.

Taking those considerations into account, the ALJ concluded that Respondents' representations needed to be substantiated by "competent and reliable scientific evidence," including "controlled clinical studies" - *i.e.*, human studies. ID at 104. That conclusion is supported by numerous decisions describing the standard that should be applied when supplements like the Respondents' four products are represented to be effective to treat diseases or medical conditions. *See, e.g., Natural Solution*, 2007 U.S. Dist LEXIS 60783, at *11-12; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303.

Second, the ALJ did not hold Respondents to the representation they made in their Answer that they had a reasonable basis substantiating their representations at the time the representations were made. The only explanation that the ALJ articulated for not requiring Respondents to tether their proof to "the time the representations were made" was that Complaint Counsel, rather than Respondents, had the burden of proof on all elements of their claim, including whether Re-

spondents had a reasonable basis to substantiate their representations. ID at 67. The Commission considers that conclusion debatable. Respondents specifically averred that they had substantiation at the time their representations were made, and they were in the best position to support their averment. Again, the Commission is not prepared to second-guess the decision by the ALJ. The consequence of that conclusion, however, was that the ALJ considered abundant *ex post* expert testimony on the issue whether there was *ever* a reasonable basis substantiating the representations.

Respondents repeatedly assert that in assessing the expert testimony the ALJ did not just embrace the substantiation standard he had held was applicable - namely "competent and reliable scientific evidence," including "controlled clinical studies" - but instead required that those studies be "double-blind" and "placebo controlled." RAB at 4, 8, 11-12, 15, 25, 43, 45; RRB at 12, 40-41, 53-54, 57, 59, 65. According to Respondents, that substantiation requirement, combined with the lack of a requirement that "extrinsic evidence" be produced, had the effect of creating a "presumption" that their representations were not adequately substantiated and, indeed, of turning the proceeding into "rulemaking by adjudication" in violation of *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the Due Process Clause, and the First Amendment of the Constitution. RAB at 4, 11-12, 15-17, 25-26, 43-44, 54-55; RRB at 40, 54-55.

Respondents' claims are without merit. As previously discussed, "extrinsic" evidence to interpret the advertising is not required, as a matter of law. Respondents' reliance on *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), does not assist their argument either. As the ALJ explained in the Initial Decision, although the Seventh Circuit stated that nothing in the FTC Act required a placebo-controlled, double-blind study, it went on to affirm the district court's holding that substantiation for health-related efficacy claims must be based on competent and reliable scientific evidence. ID at 109. Because the ALJ in this case found the Respondents had not possessed or relied upon *any* adequate substantiation for their claims, the ALJ found their argument that *QT* does not require a placebo-controlled, double-blind study to be irrelevant. ID at 109. The Commission agrees.

The same thing is true of Respondents' assertion that this case involves "rulemaking by adjudication" of the sort condemned in the *Pearson* case. RAB at 15-16, 25-26; RRB at 27, 31-33, 44 n.24, 53-54. *Pearson* bears no resemblance to this case. Not only were the agency (the FDA) and the statute (the Food, Drug, and Cosmetic Act) different than the ones involved here, but the case involved formal rulemaking procedures by the FDA. In *Pearson*, the FDA proposed a rule that would ban all health claims by dietary supplements unless there was "significant scientific agreement" about those claims, regardless of whether or not the claims were deceptive. RAB at 14-16. This case does not involve rule-making or even "amending or bypassing a pending rulemaking proceeding." RAB at 40. This case involves a purely adjudicatory challenge to specific deceptive representations made in advertisements that four specific products would "treat" or "cure" cancer, prevent or shrink tumors, and ameliorate the destructive side effects of radiation or chemotherapy. Most significantly, the substantiation standard used by the ALJ in this case, requiring competent and reliable scientific evidence, including studies on humans is neither "unconstitutionally vague" nor "impossibly high," as Respondents describe the "significant scientific agreement" standard in the FDA's proposed rule. RRB at 27, 31-32, 44 n.24. To borrow the language in *Kraft*, *Pearson* involved "a completely different animal" than the one involved here. *Kraft*, 970 F.2d at 317.

Nor did the ALJ otherwise use any "assumptions" or "shift the burden of proof" away from Complaint Counsel in his assessment of the expert testimony. RAB at 3, 11, 54-55. To the contrary, he found, *inter alia*, that Complaint Counsel's witness, Dr. Miller, a board-certified oncologist who had practiced for over forty years at some of the country's most eminent institutions, was the "only witness in this case qualified as an expert in cancer research and cancer treatment" (ID at 103), and that he was the only expert witness who offered an opinion as to whether there was competent and reliable scientific evidence to support Respondents' representations. ID at 103-106. By contrast, the ALJ found that Respondents and their experts had relied, *inter alia*, on in vitro and animal (not human) clinical reports, searches of literature, testimonials without confirmation that the speakers' treatments were not attributable to other clinical modalities or indeed that

the speakers had cancer, and tests on the ingredients of the four Challenged Products without confirmation that the ingredients were present in those products in the same proportion to the ingredients tested. ID at 104-105.

Respondents do not contend that these findings lacked substantial supporting evidence in the record. As a result, as the ALJ put it, "none of Respondents' experts offered any opinions on any material, contested issue in the case, and the opinions that Respondents' proffered experts did offer are entitled to little, if any, weight." ID at 106. Put differently, the ALJ simply weighed the evidence proffered by the experts. The way he weighed the evidence, moreover, was consistent with his earlier opinion that although Respondents might have the burden of production of some evidence to substantiate their representations, Complaint Counsel bore the burden of proving that the substantiation was inadequate. ID at 67. The ALJ concluded that Complaint Counsel had borne the burden of proving that Respondents' representations were not substantiated. There was no violation of either the Due Process Clause or the First Amendment involved.

F. The Remedy is Proper.

Respondents advance several arguments that the remedy is illegal. RAB at 55-65. The Commission has considered each of these arguments, has reviewed the applicable case law and the language of the proposed Order, and has concluded that these claims are without merit. The Commission considers each of these arguments in turn.

Respondents first argue that the recent unpublished decision in *FTC v. Lane Labs-USA, Inc.*, No. 00-CV-3174 (DMC) (D.N.J. Aug. 10, 2009) (appeal pending),[FN3] "should be instructive and considered here," (RAB at 56-57; *see also* RRB at 59-60), and that they are "identically situated" to the respondents in *Lane Labs*. RRB at 34. In doing so, Respondents focus on three statements made by the district court, which were based upon the specific facts and evidence presented in that case: 1) the district court considered the substantiation proffered by Lane Labs and noted, "[t]his is not a case of a company making claims out of thin air;" 2) the district court found that Lane Labs provided credible medical testimony that the products in question are good products and could have the results advertised; and 3) the district court noted that "there has been no physical harm to the public."

Contrary to Respondents' assertion, they are not "identically situated" to the respondents in *Lane Labs*. *Lane Labs* was a civil contempt proceeding in which the FTC sought a $24 million compensatory contempt award from the defendants for violating a negotiated consent order. According to the district court, in order to establish contempt, the movant bears the burden of proving by clear and convincing evidence that the respondent violated a court order. *Lane Labs*, No. 00-CV-3174 (DMC), slip op. at 11. The district court declined to find contempt because he found that the FTC failed to show by clear and convincing evidence that the defendants had not substantially complied with the Orders. Accordingly, the standard of proof, as well as the proof required, differentiates the DCO Respondents from the Lane Lab respondents.

And, to the extent that *Lane Labs* - as an unpublished decision that is being appealed - can be considered "instructive," it does not help Respondents. As in the instant case, the *Lane Lab* Orders required defendants to possess "competent and reliable scientific evidence" (as defined in the DCO remedy) to substantiate any claims made about the health benefits of a product.[FN4] The *Lane Labs* court specifically found the Orders to be valid and controlling. *Id.* at 12. However, in contrast to the case before us, the medical experts proffered in *Lane Labs* were medical doctors that the district court qualified and found "credible and knowledgeable in their respective fields of expertise." *Id.* at 8-10. The DCO respondents' experts were not medical doctors and the ALJ found that none of these proffered experts had "specialized training or experience regarding cancer or cancer treatment." IDF 335, 336. Indeed, in contrast to *Lane Labs*, in preparing their opinions, none of Respondents' experts here had reviewed the advertising claims at issue. IDF at 338. Furthermore, Respondents did not ask their experts to render an opinion as to whether their purported substantiation materials constituted competent and reliable scientific evidence that would substantiate a claim that any of the Challenged Products prevent, cure or treat, cancer (IDF 339), or whether any such evidence existed. IDF 340.

Second, Respondents argue that the remedy is an arbitrary, capricious and retaliatory attack on their constitutional rights. Respondents make many general allegations regarding this claim, but do not cite any case law or other precedent in support of it. Respondents assert that the ALJ used "Respondents' political and religious speech as a weapon against them when he turned to issuing the Remedy." RRB at 36; *see also* RAB at 57. Respondents also claim that the ALJ took the Respondents' political and religious speech and activities into consideration when crafting the remedy, but not when "portraying Respondents as being engaged purely in commerce." RAB at 57.

As a preliminary matter, the Commission notes that the ALJ did not "portray[] Respondents as being engaged purely in commerce." As the Commission has stated already, this misstates the law and the legal conclusions of the Initial Decision; the ALJ found that Respondents were not a business organized for or engaged in "only" charitable purposes. These two conclusions are not the same. In addition, as discussed earlier in this Opinion, the Commission has already found that the ALJ performed the proper legal analysis in determining the FTC's jurisdiction, *see* section III.A, and Respondents' liability, *see* sections III.C and E. The Commission likewise finds that the ALJ applied the proper standard in drafting the proposed order.[FN5] Accordingly, the Commission declines to characterize the remedy as "arbitrary, capricious and retaliatory."

Third, Respondents claim that the proposed remedy would violate the Religious Freedom Restoration Act of 1993 (P.L. 10-141) ("RFRA"). RAB at 57-60. The Commission disagrees. As Respondents concede, the RFRA only applies to government statutes that "substantially burden a person's exercise of religion." RAB at 58; RRB at 15, 60-61. The Order imposes no burden on Respondents' exercise of religion; it only applies to their commercial advertising. Although Respondents argue the remedy imposes an unconstitutional prior restraint on "truthful speech," (RAB at 61; RRB at 60-63), the speech at issue here was found to be deceptive. As noted in *Central Hudson*, "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." 447 U.S. at 563.

Far from prohibiting truthful speech, Paragraphs II and III of the Order permit Respondents to make any efficacy claims for those products so long as the representations are "true, non-misleading, and, at the time [they are] made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation." In other words, Respondents are only obliged to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception. To be sure, that requirement embraces not just the four Challenged Products, but other dietary supplements, foods, drugs or other health and related programs, services or products. However, the case law holds that this is appropriate "fencing in," given the kinds of representations Respondents made and the frequency with which they made those representations. *Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006); *Kraft*, 970 F.2d at 326.[FN6] The proposed order limits what Respondents may say without substantiation relating to the sale of certain products, but it does not otherwise reach into the Respondents' religious speech or practices.

Finally, Respondents claim that the requirement that they send a letter to their customers - even as modified by the ALJ - would unconstitutionally encroach on their rights under the religious guarantees of the First Amendment and the RFRA. RAB at 61-65; RRB at 63. Specifically, Respondents claim that the proposed remedy "prohibits truthful speech," is "contrary to Mr. Feijo's right to refrain from speaking at all," forces Respondents "to repudiate publicly their faith in God's revealed truth and be forced to embrace and proclaim as their own the FTC's faith in so-called 'science'," and "compels Respondents to conduct government-mandated speech as a condition precedent to continuing their religious ministry." RAB at 12, 57-64; RRB at 58, 64.

Paragraph V of the Order requires Respondents to send to all consumers who have bought the four Challenged Products since the beginning of 2005 an exact copy of the letter appended to the Order as Attachment A. The ALJ modified the proposed letter attached to the Complaint "to make it clear that the information contained in the letter is information that

the FTC has required Respondents to transmit to consumers." ID at 121. Neither the letter nor anything else in the Order compels Respondents to do anything "as a condition precedent to continuing their religious ministry," or forces Respondents to "repudiate publicly 'their faith' in God's revealed truth and be forced to endorse and proclaim as their own the FTC's faith in so-called 'science.'" RRB at 58. Neither does the Commission see any evidence that the ALJ punished Respondents for their political or religious beliefs in his proposed order.

However, in the Order the Commission issues here today, in the interest of brevity, the Commission has further modified the first and second paragraphs of the letter required by Paragraph V (appended to the Order as Attachment A).

IV. Conclusion

The Commission, for the reasons stated in this opinion, has determined to deny the appeal of Respondents and to make final the attached Order, which is identical to the order entered by the ALJ, except as to the modifications made to Attachment A, the letter required to be sent to consumers by Respondents.

FN1. References to the record are abbreviated as follows:

IDF	Initial Decision Finding
ID	Initial Decision
RAB	Respondents' Appellate Brief
CAB	Complaint Counsel's Answering Brief
RRB	Respondents' Reply Brief
Tr.	Transcript of Trial Testimony
CX	Complaint Counsel's Exhibit
RX	Respondents' Exhibit

FN2. Respondents further attempt to bootstrap from *Pearson*'s holding by equating the "potentially misleading" speech subjected to prescriptive regulation there with the implied claims that have been specifically adjudicated in the present case to be actually misleading. RRB at 28. As explained above, however, the two are "completely different animal[s]." *Kraft*, 970 F.2d at 317.

FN3. The Commission is appealing this decision. *FTC v. Lane-Labs-USA, Inc.*, No. 00-CV-3174 (DMC) (D. N.J. Aug. 10, 2009), *appeal docketed*, No. 09-3909 (3rd Cir. Oct. 13, 2009).

FN4. "Competent and 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 results." *Lane Labs*, slip op. at 12. This is the same definition the ALJ uses in the proposed Order.

FN5. Once the determination is made that Respondents violated Section 5 of the FTC Act, the Commission has the authority to issue an order requiring respondents to cease and desist from such acts and or practices. *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). The Commission has considerable discretion in fashioning the remedial order, so long as the order bears a reasonable relationship to the unlawful acts or practices. *See, e.g., FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946).

FN6. The Commission generally considers three factors in determining whether an order bears a reasonable relationship

to a particular violation: (1) the seriousness and deliberateness of the violation; (2) the ease with which the violation may be transferred to other products; and (3) whether the respondent has a history of prior violations. *See In re Stouffer Foods Corp.*, 118 F.T.C. 746, 811 (1994). All three elements need not be present to warrant fencing-in. *See Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982). The ALJ considered these factors and found the relief ordered was reasonably related to the Respondents' violations of the FTC Act. Respondents do not seem to challenge the ALJ's analysis of these elements. ID at 120-21.

FTC

2009 WL 5160000 (F.T.C.)

END OF DOCUMENT

H
1998 WL 34060101 (F.T.C.)

FEDERAL TRADE COMMISSION (F.T.C.)

In the Matter of NOVARTIS CORPORATION, and NOVARTIS CONSUMER HEALTH, INC., corporations.

Docket No. 9279

March 9, 1998

INITIAL DECISION

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ORDER 67

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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.

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 07901. 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 07901. Novartis Consumer Health, Inc., is a subsidiary of Novartis Corporation. (See Ans ¶ 1; JX 2 ¶ 11.) FN;B1[FN1]FN;F1

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. (Ciba-Geigy 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 Doan'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 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; JX 2 ¶ 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 dose 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 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 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 Doan'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 in-

dications 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 (RX 60-A-Z). Doan'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 Doan'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.)

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.)

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 sta-

tions 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).

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).

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).

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).

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).

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 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 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).

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 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).

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 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 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 "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:

> 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 to do" (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). Doan's 1989 Marketing Plan repeated the product superiority playback 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).

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."

(CX 169-B, D; CX 504 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 Doan'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 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 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 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 F.T.C. 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 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 (id. 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).

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-I). Clutter refers to the other commercials that were shown respondents in this copy test (CX 236-E, I; 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).

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 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).

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 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%+ 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).

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 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; 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	40.1%

(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?")

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%

(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).

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-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 (RX 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 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 so-called "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).

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 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).

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 and 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).

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," "Activity-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).

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).

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 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 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.

b. The NFO Belief Study

247. NFO is a marketing research company which provides mail panel research. Mail panel research involves mailing re-

search 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 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).

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 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 comparison brand but who use neither	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	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%

(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).

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 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-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 If was an openended 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 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 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.). 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 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 unaware 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 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 pro-

cessing 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 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.]; Lavidge 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).

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).

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 advert-

ising; 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: "Doan's support continues to drive strong volume and share performance despite competitive activity." This document also states 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; 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 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 users and aware non-users is evidence that Doan's advertising played a role in creating and re-

inforcing 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).

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 re-

sponsible 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).

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 F.T.C. 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 F.T.C. at 293 (IDF 592) (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 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 F.T.C. 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 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 F.T.C. 110, 164-65 (1984). Appeal dismissed sub nom. Koven v. FTC No. 84-5337 (11th Cir. Oct. 10, 1984) ("Deception State- ment").

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 F.T.C. 40, 120 n.9 (1991), aff'd, 970 F.2d 311 (7th Cir. 1992), cert. denied, 507 U.S. 909 (1993); Thompson Medical, 104 F.T.C. 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 (1977), and intent to convey a claim need not be established, Kraft, Inc., 114 F.T.C. 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 F.T.C. 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 F.T.C. at 121; Thompson Medical, 104 F.T.C. 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).

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 F.T.C. 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 F.T.C. at 797, 805-06 (22% of those viewing the ad believed Aspercreme contained aspirin). See also Warner-Lambert, 86 F.T.C. 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 F.T.C. at 791. (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 F.T.C. 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 F.T.C. 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).

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 F.T.C. at 182, because they involve an important health claim, Kraft, Inc., 114 F.T.C. 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 F.T.C. 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 F.T.C. 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 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 FN;B2[FN2]FN;F2 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 F.T.C. at 21 (1983), aff'd, 738 F.2d 554 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985); Sterling Drug, Inc., 102 F.T.C. 395 (1983), aff'd, 741 F.2d 1146 (9th Cir. 1984), cert. denied, 470 U.S. 1084 (1985); American Home Prods. Corp., 98 F.T.C. 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 F.T.C. 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).

The challenged claims were health related and consumers suffered economic injury because Doan'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 F.T.C. 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 F.T.C. 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.

IV. SUMMARY
A. The Federal Trade Commission has jurisdiction over the advertising of Doan'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.

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, 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, 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 of ten (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.

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.

Lewis F. Parker
Administrative Law Judge

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.

FTC

1998 WL 34060101 (F.T.C.)

END OF DOCUMENT

EXHIBIT A

REDACTED

EXHIBIT B

REDACTED