IN THE MATTER OF

THOMPSON MEDICAL COMPANY, INC.

FINAL ORDER, OPINION, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket 9149. Complaint, Feb. 5, 1981—Final Order, Nov. 23, 1984

This Final Order requires a New York City pharmaceutical company to cease, in connection with the advertising, sale or distribution of over-the-counter (OTC) health care products, using the brand name "Aspercreme" for any product that does not contain a significant amount of aspirin; or misrepresenting by any other means that aspirin is an active ingredient of such product. TV and radio advertising for "Aspercreme" must include an explicit aspirin disclaimer statement and such disclaimer must also be prominently displayed in print advertising and product labeling. The Order further bars the firm from misrepresenting the contents, validity, results or interpretations of tests or studies; and from representing, without prescribed substantiation, the speed or effectiveness of its products in the relief of minor pain and other symptoms of arthritis, bursitis, rheumatism or other musculoskeletal disorders. Additionally, the Order dismisses Paragraph 12(f) of the Complaint.

Appearances

For the Commission: *Elizabeth T. Guarino, Grace Polk Stern, Melvin H. Orlans, Randell C. Ogg, Nancy W. Warder* and *Teresa A. Hennessy.*

For the respondent: *Stuart L. Friedel, Joseph M. Burke* and *Patricia Hatry, Davis & Gilbert,* New York City; *Stephen Kurzman, Nixon, Hargrave, Devans & Doyle,* Washington, D.C.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Thompson Medical Company, a corporation, (hereinafter "Thompson"), and Ogilvy & Mather, Inc., a corporation, (hereinafter "Ogilvy"), hereinafter sometimes referred to as respondents, have violated the provisions of the Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Thompson 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 919 Third Avenue, New York, New York.

PAR. 2. Ogilvy is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York with its office and principal place of business located at 2 East 48th Street, New York, New York.

PAR. 3. Thompson is now and has been engaged in the business of manufacturing, advertising, offering for sale, sale, and distribution of various over-the-counter health care products, including the products Aspercreme Creme Rub and Aspercreme Lotion Rub (hereinafter "Aspercreme"), products advertised to treat various disorders. In connection with the manufacture and marketing of Aspercreme, Thompson is now and has been engaged in the dissemination, publication, and distribution of advertisements and promotional material for the purpose of promoting the sale of Aspercreme for human use. As advertised, Aspercreme is a "drug" within the meaning of Section 12 of the Federal Trade Commission Act. [2]

PAR. 4. Thompson causes said products when sold to be transported from its places of business in various States to purchasers located in various other States. Thompson maintains, and at all times mentioned herein has maintained, a substantial course of trade in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Ogilvy is now, and for some time past has been, an advertising agency of Thompson. Ogilvy has prepared and placed for publication, advertising material to promote the sale of Aspercreme for human use.

PAR. 6. In the course and conduct of its business, and at all times mentioned herein, Thompson has been and now is in substantial competition in or affecting commerce with corporations, firms, and individuals representing or engaged in the manufacture or marketing of health care products.

PAR. 7. Ogilvy at all times mentioned herein has been and now is, in substantial competition in or affecting commerce with other advertising agencies.

PAR. 8. In the course and conduct of their businesses, respondents have disseminated and caused the dissemination of certain advertisements concerning Aspercreme through the United States mail and by various means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, including the insertion of advertisements in magazines with national circulations and the placement of advertisements with television stations with sufficient power to broadcast across state lines and into the District of Columbia.

PAR. 9. Typical statements and representations in said advertise-

ments, disseminated as previously described, but not necessarily all-inclusive, are the advertisements attached hereto as Exhibits A through H.

PAR. 10. Through the use of the advertisements referred to in Paragraphs Eight and Nine and others not specifically set forth herein, respondents represented and now represent, directly or by implication that:

a. Aspercreme contains aspirin.

b. Aspercreme is a recently discovered or developed drug product.

c. Valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatic conditions, and their symptoms. [3]

PAR. 11. In truth and in fact:

a. Aspercreme does not contain aspirin.

b. Aspercreme is not a recently discovered or developed drug product; it has been available for purchase since at least 1971 and its active ingredient has been in existence since at least 1954.

c. No valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatism, and their symptoms.

Therefore, the representations, set forth in Paragraph Ten were and are false, misleading, or deceptive; and the advertisements referred to in Paragraphs Eight and Nine were and are misleading in material respects, and constituted and now constitute false advertisements.

PAR. 12. Through the use of the advertisements referred to in Paragraph Eight and Nine and others not specifically set forth herein, respondents represented, and now represent, directly or by implication that:

a. Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.

b. Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.

c. Aspercreme is a more effective drug than orally-ingested aspirin for the relief of minor arthritis and its symptoms.

d. Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms.

e. Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.

f. The use of Aspercreme will result in no side effects.

PAR. 13. At the time of the first and subsequent disseminations of the representations contained in Paragraph Twelve respondents did

not possess and rely upon a reasonable basis for making those representations. Therefore, the dissemination of the said representations as alleged constituted, and now constitutes, unfair or deceptive acts or practices in or affecting commerce.

PAR. 14. Through the use of the advertisements referred to in Paragraphs Eight and Nine and others not specifically set forth herein respondents have represented and now represent [4] directly or by implication that they possessed and relied upon a reasonable basis for the representations set forth in Paragraph Twelve at the time such representations were made.

PAR. 15. In truth and in fact, respondents did not possess and rely upon a reasonable basis for the representations set forth in Paragraph Twelve at the time such representations were made. Therefore, the representations set forth in Paragraph Fourteen were and are false, misleading or deceptive.

PAR. 16. Through the use of the trade name "Aspercreme" in advertising, labels and promotional materials, respondents have represented and now represent that the product "Aspercreme" contains aspirin.

PAR. 17. In truth and in fact, "Aspercreme" contains no aspirin. Therefore, the representation in Paragraph Sixteen was and is false, misleading, deceptive or unfair, and the use of the trade name "Aspercreme" to describe a product which contains no aspirin constituted and now constitutes an unfair or deceptive act or practice in or affecting commerce,

PAR. 18. The use by respondents of the aforesaid unfair or deceptive representations and the dissemination of the aforesaid false advertisements has had, and now has, the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said representations were and are true.

PAR. 19. The acts and practices of respondents, as herein alleged, including the dissemination of the aforesaid false advertisements, were and are all to the prejudice and injury of the public and of respondents' competitors and constituted, and now constitute, unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended.

EXHIBIT A

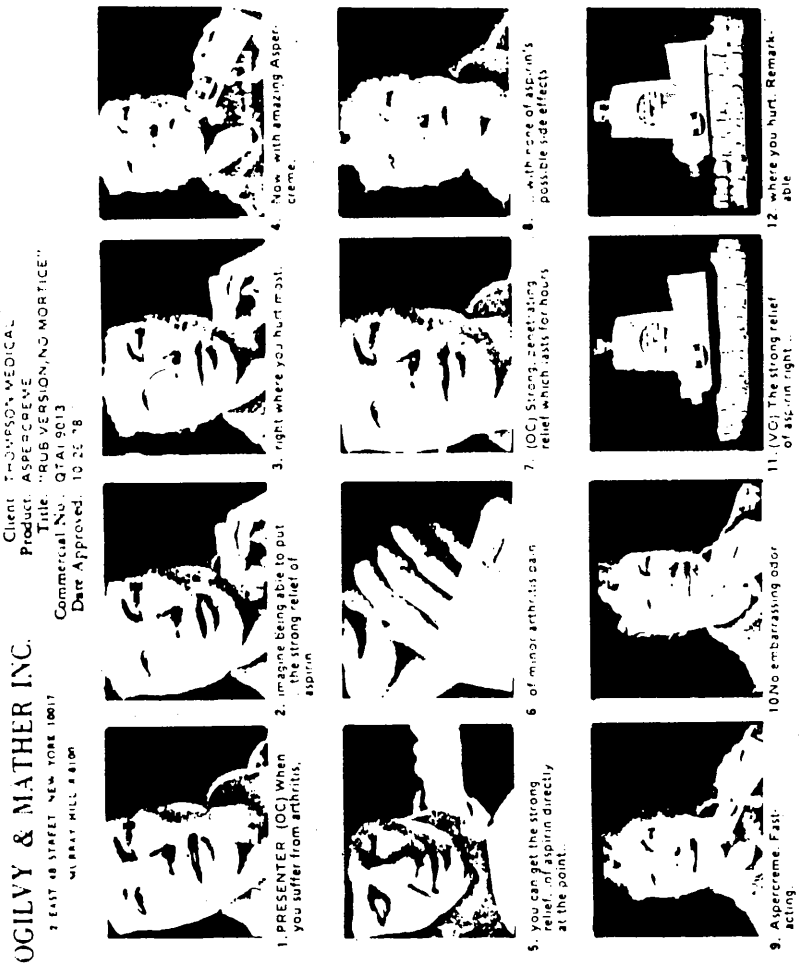

OGILVY & MATHER INC.
Client: THOMPSON MEDICAL
Product: ASPERCREME
Title: "RUB VERSION, NO MORTICE"
Commercial No. QTAI 9013
Date Approved: 10 25 78
1. PRESENTER (OC) When you suffer from arthritis,
2. imagine being able to put the strong relief of aspirin
3. right where you hurt most.
4. Now with amazing Asper-creme.
5. you can get the strong relief of aspirin directly at the point.
6. of minor arthritis pain
7. (OC) Strong, penetrating relief which lasts for hours
8. ... with none of aspirin's possible side effects
9. Aspercreme. Fast-acting.
10 No embarrassing odor
11. (VO) The strong relief of aspirin right
12. where you hurt. Remark-able

EXHIBIT B

OGILVY & MATHER INC.
2 EAST 48 STREET, NEW YORK 10017
MURRAY HILL 8-4100
Client: THOMPSON MEDICAL
Product: ASPERCREME
Title: "VISIBLE MEN"
Commercial No.: QTAJ 9033
Date Approved: 3/30/79
1. PRESENTER: (OC) When you suffer from arthritis,
2. imagine putting the strong relief of aspirin right where you hurt.
3. Aspercreme is an odorless rub
4. which concentrates the relief of aspirin
5. When you take regular aspirin,
6. it goes throughout your body like this.
7. But, in seconds,
8. Aspercreme starts concentrating all the temporary relief of two aspirin
9. directly at the point of minor arthritis pain.
10. Strong, concentrated relief.
11. VO: Aspercreme.
12. The strong relief of aspirin right where you hurt

EXHIBIT C

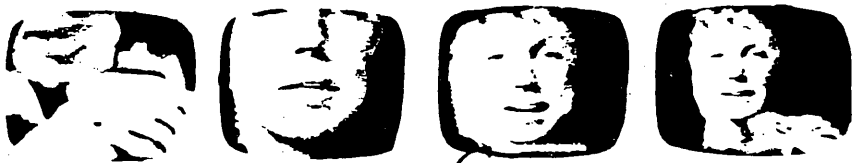
Radio TV Reports

41 East 42nd Street New York, N.Y. 10017
(212) 697-5100

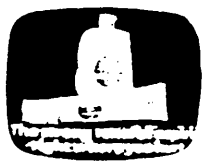
PRODUCT ASPERCREME 80-01116
PROGRAM NEWS 1/23/80 30 SEC.
WNBC-TV (NEW YORK) 7:24PM

REVISION OF COMMERCIAL # 7V9635

1. WOMAN: When you suffer from arthritis.
2. imagine being able to put the strong relief of aspirin right where you hurt most.
3. Now with amazing Aspercreme,
4. you can get the strong relief of aspirin



5. directly at the point of minor arthritis pain.
6. Strong penetrating relief which lasts for hours.
7. With none of aspirin's possible side effects.
8. Aspercreme. Fast acting, no embarrassing odor.



9. The strong relief of aspirin right where you hurt. Remarkable.

ALSO AVAILABLE IN COLOR VIDEO-TAPE CASSETTE

EXHIBIT D

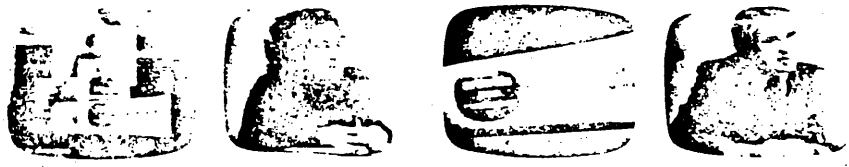
OGILVY & MATHER INC.
2 EAST 48 STREET, NEW YORK 10017
MURRAY HILL 8-4100
Client: THOMPSON MEDICAL
Product: ASPERCREME
Title: "VISIBLE MEN"
Commercial No.: QTAI 9033
Date Approved: 3/30/79
1. PRESENTER: (OC) When you suffer from arthritis,
2. imagine putting the strong relief of aspirin right where you hurt.
3. Aspercreme is an odorless rub
4. which concentrates the relief of aspirin.
5. When you take regular aspirin,
6. it goes throughout your body like this.
7. But, in seconds,
8. Aspercreme starts concentrating all the temporary relief of two aspirin
9. directly at the point of minor arthritis pain.
10. Strong, concentrated relief.
11. VO: Aspercreme.
12. The strong relief of aspirin right where you hurt.

EXHIBIT E

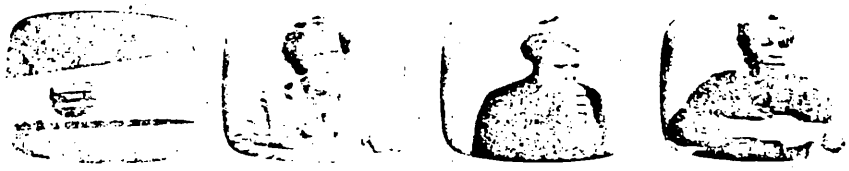
Radio TV Reports

41 East 42nd Street New York N.Y. 10017
(212) 697-5100

PRODUCT ASPERCREME CREME RUB OH80-08742
PROGRAM STATION BREAK 5/14/80 30 SEC.
WYKW-TV (L (CLEVELAND) 10:59 AM



1. ANNCR: Listen to what these people say about Aspercreme for temporary relief of minor arthritis pain.
2. 1ST WOMAN: I really felt like I was rubbing the pain away.
3. ANNCR: Aspercreme.
4. 1ST MAN: The Aspercreme gives me relief without upsetting my stomach.



5. [illegible] free.
6. 2ND WOMAN: It doesn't stain my clothes.
7. 3RD WOMAN: There's no odor.
8. 4TH WOMAN: And look it's greaseless.

9. [illegible] Aspercreme.
10. 2ND MAN: I'm saying that I am really pleased with the relief I got from Aspercreme.
11. 5TH WOMAN: The relief lasts for hours.
12. ANNCR: Aspercreme. Strong, effective relief for arthritis pain. 6TH WOMAN: It really works.

ALSO AVAILABLE IN COLOR VIDEO-TAPE CASSETTE

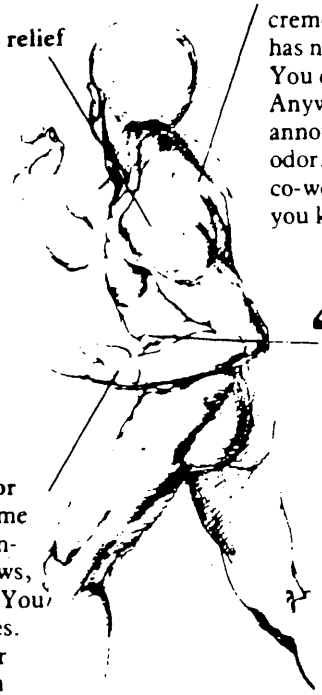
EXHIBIT F

At last! A remarkable breakthrough for arthritis pain: Aspercreme.

Aspercreme is an effective arthritis medicine which concentrates all the strong relief of aspirin directly at the point of pain.

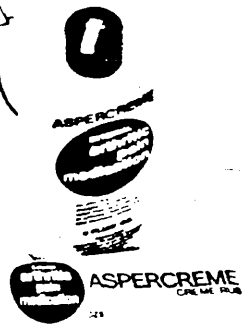
1 Strong concentrated relief Aspercreme™ pinpoints relief where you hurt. Aspirin tablets go throughout your body. But Aspercreme concentrates the relief of an effective aspirin-like analgesic directly at the point of arthritis pain — where you need it the most.

2 Fast relief for minor arthritis pain. Aspercreme penetrates deep into painful areas — fingers, elbows, knees, back, shoulders. You get deep relief in minutes. Aspercreme works faster than aspirin because you rub it in right where you hurt.



3 No embarrassing liniment odor. Aspercreme, like aspirin itself, has no liniment smell. You can use it any time. Anywhere — without any annoying, embarrassing odor. Relatives, friends, co-workers — nobody but you knows you're using it!

4 No side effects. Aspercreme gives you strong, long-lasting relief. It won't upset your stomach. Use it safely as often as you wish.



Available in creme and lotion

EXHIBIT G

At last! A remarkable breakthrough for arthritis pain: Aspercreme.

Aspercreme is an effective arthritis medicine which concentrates all the strong relief of aspirin directly at the point of pain.

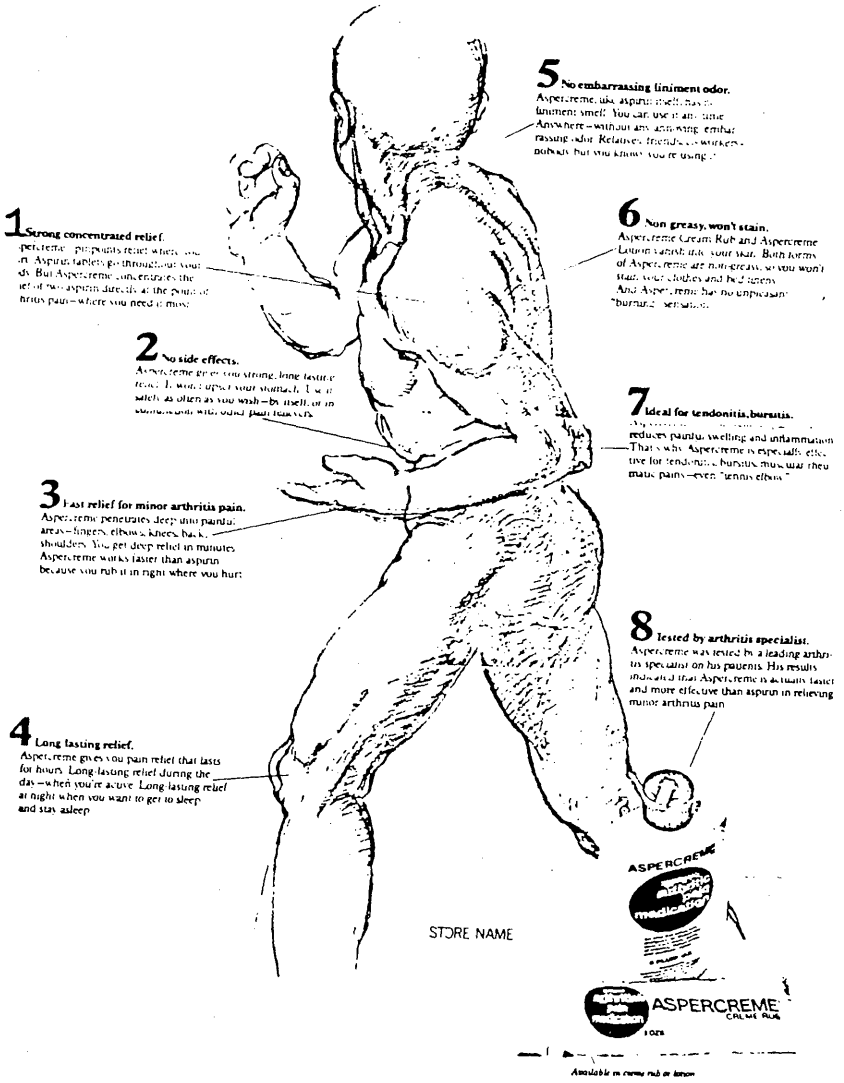
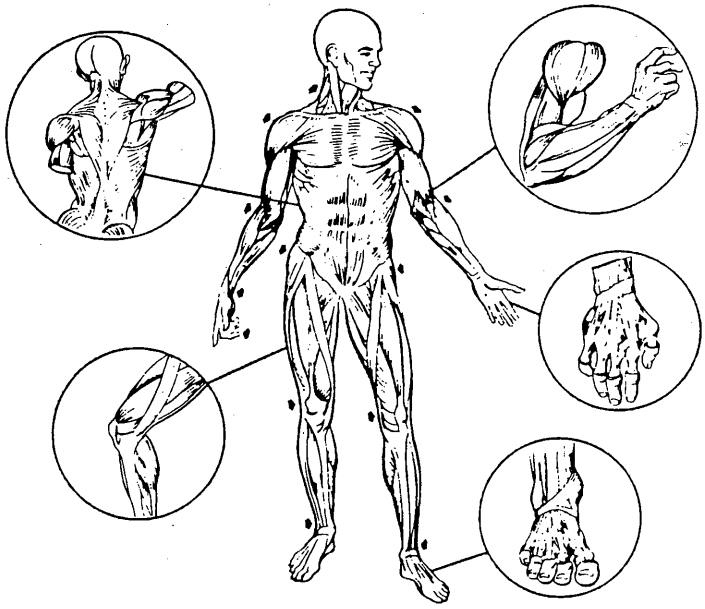


EXHIBIT H

Minor Arthritis Pain?



There's always been aspirin...

Now there's ASPERCREME

Works faster, safer than aspirin—relieves pain in minutes

Aspirin has been helping sufferers of minor arthritis pain for years. Now there's a different way to get relief. ASPERCREME. An analgesic rub that works from the outside in . . . to relieve pain with analgesic power and speed. **No other leading rub works this way.**

RUB ASPERCREME-IN . . . RUB PAIN OUT

Rub ASPERCREME in where you hurt. In just seconds pain starts to fade away. That's because ASPERCREME'S analgesic penetrates, almost instantly, into the area of pain. You get all this relief power without waiting for a tablet to work, and without risk of stomach upset. You just rub ASPERCREME in . . . rub pain out.

ASPERCREME is ideal for Topical Relief of Temporary Minor Pain of Arthritis, Rheumatism & Muscle Aches.

When pain mounts, minutes count. You can't wait for aspirin to work. Maybe aspirin upsets your stomach. Simply rub ASPERCREME in where you hurt . . . fingers, knees, shoulders, back, elbows. In seconds, pain starts to fade away.

Aspercreme penetrates into the painful area relieving that pain with its almost instant-working aspirin-like analgesic. It's true—when you RUB ASPERCREME IN you RUB PAIN OUT.

NO LINIMENT SMELL

ASPERCREME has no liniment smell. This means you can use ASPERCREME anytime and any place you need it, without that annoying and embarrassing liniment smell. And ASPERCREME isn't greasy either. Won't stain clothes or linen. There's never been anything like ASPERCREME before. Try it today.

TESTED BY A LEADING DOCTOR

A leading specialist in arthritis and rheumatism tested Aspercreme on his own patients. Many experienced remarkable relief. Results of his controlled clinical test indicate that Aspercreme actually relieves pain faster, safer, better than aspirin. Aspercreme proved especially effective in the treatment of tendonitis, bursitis, muscular, rheumatic and arthritic pains. No side effects were reported.

SOME report ASPERCREME better than anything tried before for pain relief. . . .

"I am a 100% disabled veteran. I have arthritis and ASPERCREME is without a doubt the very best." C.H.—Petersburg, VA

"ASPERCREME is the only one I have found that has given me great relief from my arthritic pain." J.B.—Boessia City, LA

"ASPERCREME is the only medication I have found anywhere that gives me relief." R.R.—Lowell, MA

"Nothing compares to ASPERCREME." P.K.—Garden Grove, AL

"My husband has been getting wonderful relief from ASPERCREME." Mrs. R.C.—Baton Rouge, LA

"My father says ASPERCREME is better than any other medicine he has tried." M.A.—Reading, O.

Thrifty
DRUG AND DISCOUNT STORES

Available in lotion or creme
Try Aspercreme yourself today, for fast, safe, blessed relief from pain.

INITIAL DECISION BY

MONTGOMERY K. HYUN, ADMINISTRATIVE LAW JUDGE

JUNE 24, 1983

PRELIMINARY STATEMENT

On February 5, 1981, the Federal Trade Commission ("Commission") issued an administrative complaint charging Thompson Medical Company, Inc. ("Thompson") and Ogilvy and Mather, Inc. ("Ogilvy") with violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended (15 U.S.C. 45 and 52), in connection with certain advertisements for Aspercreme. On March 9 and 17, 1981, respondents filed their answers denying that they violated the Federal Trade Commission Act as charged. On January 4, 1983, the Commission issued its Decision and Order settling the complaint charges against Ogilvy and Mather International, Inc. (the successor corporation of Ogilvy and Mather, Inc.) which agreed to the terms of a consent agreement. *In the Matter of Ogilvy & Mather International,* [2] *Inc.,* Docket No. 9149, Decision and Order issued January 4, 1983. [101 F.T.C. 1 (1983)]

The parties were allowed extensive pretrial discovery. Several prehearing conferences were held in order to simplify the issues, to resolve disputes related to discovery and generally to expedite the trial preparation of the parties.

Based on the complaint and answer and prehearing conference orders, the following issues are matters for determination in this proceeding:

1. Whether Thompson represented, directly or by implication, in certain advertisements that:

(a) Aspercreme contains aspirin.

(b) Aspercreme is a recently discovered or developed drug product.

(c) Valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatic conditions and their symptoms.

(d) Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.

(e) Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.

(f) Aspercreme is a more effective drug than orally-ingested aspirin

(g) Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms.

(h) Aspercreme acts by directly penetrating through the skin to the site of the arthritis disorder. [3]

(i) The use of Aspercreme will result in no side effects.

2. Whether, at the time, the above representations were made:

(a) Representations 1 (a) through (c) were false, misleading or deceptive.

(b) Respondent possessed and relied on a reasonable basis for representations 1 (d) through (i) and whether the making of such representations without a reasonable basis was false, misleading or deceptive.

3. Whether, through the use of the brand name "Aspercreme" in advertising, labels and promotional materials, respondent represented that the product "Aspercreme" contains aspirin and whether the use of the brand name "Aspercreme" is false, misleading or deceptive.

4. Whether respondent's use of the aforesaid unfair or deceptive representations and the dissemination of aforesaid false advertisements have the capacity and tendency to mislead consumers into the erroneous belief that these representations are true and into the purchase of substantial quantities of Aspercreme by reason of said erroneous belief and thus constitute unfair methods of competition and unfair or deceptive acts proscribed by Sections 5 and 12 of the Federal Trade Commission Act,

The evidentiary hearings for the presentation of complaint counsel's case-in-chief began on July 5, 1982 and ended on July 23, 1982. Defense hearings began on August 23, 1982 and ended on January 19, 1983, including a recess from September 9 to October 4, 1982. The evidentiary record was closed on [4] March 7, 1983.[1] The parties simultaneously filed their proposed findings of fact, conclusions of law, order and supporting memoranda and replies thereto. Some thirty witnesses, including nineteen expert witnesses, testified. Transcripts of hearings number some 6,500 pages. Some 200 documentary exhibits, including numerous consumer studies and medical-scientific studies, were received into evidence.

The proposed findings and conclusions submitted by the parties and their arguments in support thereof have been given careful consideration by me and to the extent not adopted by this Initial Decision, in the form proposed or in substance, are rejected as not supported by the evidence or as immaterial. Any motion appearing on the record not heretofore or hereby specifically ruled upon either directly or by the necessary effect of the conclusions in this Initial Decision are hereby denied.

[1] By order dated April 5, 1983, the Commission extended the due date of this Initial Decision to June 24, 1983.

Upon consideration of the entire record in this proceeding and having considered the demeanor of the witnesses, I make the following findings of fact and conclusions of law and order based on the record considered as a whole:[2] [5]

FINDINGS OF FACT

I. RESPONDENT, JURISDICTION AND OTHER GENERAL FINDINGS

1. Thompson Medical Company, Inc. ("Thompson") 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 919 Third Avenue, New York, New York (Answer of Thompson, Paragraph 1).

2. Thompson is now and has been engaged in the distribution, advertising, offering for sale, and sale of various over-the-counter drug products, including the products Aspercreme Creme Rub and Aspercreme Lotion Rub ("Aspercreme") (Answer of Thompson, Paragraph 3) and certain appetite control drugs (CX 45F, Admission No. 81). In connection with the marketing of Aspercreme, Thompson is now and has been engaged in the dissemination, publication, and distribution of advertisements and promotional material for the purpose of promoting the sale of Aspercreme for human use. As advertised, Aspercreme is a "drug" within the meaning of Section 12 of the Federal Trade Commission Act (Answer of Thompson, Paragraph 3).

3. In the course and conduct of its business, Thompson causes Aspercreme, when sold, to be transported from its place of business to purchasers located in various other States of the United States and the District of Columbia. Thompson maintains, and at all times relevant to this proceeding has maintained, a substantial course of trade in these products, in or affecting commerce, as "commerce" is defined

[2] For the purposes of this Initial Decision, the following abbreviations were used:

F.	–	Finding of Fact in this Decision
CPF	–	Complaint Counsel's Proposed Findings
CB	–	Complaint Counsel's Memorandum In Support of Proposed Findings
CRB	–	Complaint Counsel's Memorandum In Support of Reply Findings
RPF	–	Respondent's Proposed Findings
RB	–	Respondent's Memorandum In Support of Proposed Findings
RRB	–	Respondent's Reply Memorandum
Tr.	–	Transcript of hearings, sometimes preceded by the name of the witness
CX	–	Complaint Counsel's documentary exhibit
RX	–	Respondent's documentary exhibit
CPX	–	Complaint Counsel's physical exhibit
RPX	–	Respondent's physical exhibit
Comp.	–	Complaint
Ans.	–	Answer

in the Federal Trade Commission Act. The volume of such business has been substantial (Answer of Thompson, Paragraph 4; F. 74–76, *infra*).

4. In the course and conduct of its business, and, at all times relevant to this proceeding, Thompson has been and is now in substantial competition in or affecting commerce with corporations, firms, and individuals representing or engaged in the manufacture or marketing of health care products (Answer of Thompson, Paragraph 6).

5. In the course and conduct of its business, Thompson has disseminated and caused the dissemination of certain advertisements concerning Aspercreme through the United States mail and by various means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, the insertion of advertisements in magazines with national circulations and the placement of advertisements with **[6]** television stations with sufficient power to broadcast across states lines and into the District of Columbia (Answer of Thompson, Paragraph 8; F. 73–75, *infra*).

6. Aspercreme is a topical cream or lotion rub, the active ingredient of which is 10% triethanolamine salicylate ("TEA/S") (*See* RX 276–84; RPX 3–6; CPX 5–7). TEA/S is also known as trolamine salicylate. The package direction for its use advises that the user massage it into painful areas until thoroughly absorbed into skin, three or four times daily (*e.g.,* RX 279).

7. In a report published on December 4, 1979, the Food and Drug Administration's Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products ("FDA OTC External Analgesic Panel") concluded that TEA/S "is safe but that there are insuffficient data available to permit final classification of its effectiveness for use as an OTC external analgesic" for labeling purposes (CX 269, p. 69,856). The Panel placed TEA/S among the Category III ingredients and recommended that during the testing period provided to demonstrate effectiveness, the ingredient TEA/S may bear the labeling provided for topical analgesics (*Id.*).

8. In a notice of proposed rulemaking published on February 8, 1983, the FDA published a tentative final monograph on OTC external analgesic drug products, which in effect adopted the FDA Advisory Panel's conclusions and recommendations regarding TEA/S as a topical analgesic (CX 443).

9. By Citizens Petition dated November 24, 1981 and filed with the FDA (RX 366), Thompson requested the Commission to reopen the administrative record and to receive new data being submitted by Thompson and urged that 10% TEA/S (Aspercreme) be placed by the FDA in Category I as an effective topical analgesic. Although there

has not been a final disposition of Thompson's November 1981 Petition and subsequent correspondence by the FDA, the FDA's proposed rule for OTC external analgesic drug products (CX 443) appears to have considered substantially all of the studies in evidence in this proceeding and to have adopted the OTC External Analgesic Panel's conclusions and recommendations regarding TEA/S. As reflected in this record, it is unlikely that the FDA will reverse its position with respect to topical TEA/S as a result of its review of the pending Thompson submissions (*See* F. 393–400, *infra*). However, respondent states that, under the FDA's monograph procedures for OTC external analgesic drug products, respondent is permitted to continue marketing Aspercreme for an interim period until April 9, 1984, pending development and review of "evidence that will permit final classification of the [7] effectiveness of TEA/S, "presumably including two or more well-controlled clinical trials (RB 18).

II. EXPERT WITNESSES WHO TESTIFIED REGARDING MARKETING AND MEDICAL/SCIENTIFIC ISSUES

10. Complaint counsel called Drs. Joel B. Cohen and Ann Silny on the issues related to advertising, marketing and consumer psychology, and Drs. John Adriani and Sanford H. Roth on the medical/scientific issues in this case.

A. *John Adriani, M.D.*

11. Dr. John Adriani is a Professor of Pharmacology at Louisiana State University Medical School, and Clinical Professor of Oral Surgery (Anesthesiology) at the Louisiana State University School of Dentistry. He is also Director of Research, in the Department of Anesthesiology, Louisiana State University Medical School and at Charity Hospital, in New Orleans, Louisiana (Adriani, Tr. 1128). Dr. Adriani is a respected researcher in the field of analgesics (O'Brien, Tr. 3736–37; Silverman, Tr. 2340). He previously taught physiology and pharmacology as pertains to anesthetic drugs and and did anesthesia research at New York University College of Medicine (Adriani, Tr. 1129). As a practicing physician, Dr. Adriani organized a pain clinic at Charity Hospital in New Orleans. His patients include those suffering from rheumatic and other diseases (Adriani, Tr. 1141). Dr. Adriani is a consultant to the Food and Drug Administration and has served on two advisory panels on OTC drugs, including the OTC External Analgesics Panel which evaluated analgesic, antirheumatic, otic, protectant and sunscreen products, including TEA/S, the active ingredient in Aspercreme (Adriani, Tr. 1130, 1135–36, 1147–48). He is also a consultant to the State of Louisiana Governor's Formulary Committee which admits certain drugs onto a list that the hospitals will stock

and supply to private patients (Adriani, Tr. 1136). Dr. Adriani has served as an advisor and consultant to a number of pharmaceutical companies, including Norwich-Eaton and Cetilyte Laboratories. He also has done consulting work involving the testing of ether and different narcotics and the stability of anesthetics with the presence of soda lime for pharmaceutical firms such as Squibb and Malinckradt (Adriani, Tr. 1138–39). Dr. Adriani has also conducted studies which evaluated certain pain-relieving drugs for pharmaceutical firms, including Darvon and Demerol (Adriani, Tr. 1138–40). Dr. Adriani himself has [8] been personally involved in well over 100 clinical studies (Adriani, Tr. 1144).

12. Dr. Adriani is a Fellow in the American College of Clinical Pharmacology and the American Society for Clinical Pharmacology and Therapeutics (Adriani, Tr. 1131–32). He is a Board-certified member of the American Board of Anesthesiology. For 10 years, he was a member of the Council on Drugs of the American Medical Association, serving as Chairman of the Council for a period of three years (Adriani, Tr. 1133). In addition, Dr. Adriani belongs to numerous research societies, including the Southern Society for Clinical Research and the National Society for Medical Research (Adriani, Tr. 1129–31). He has served in both elected and appointed positions on several scientific and educational committees. He is a member of the Society of Experimental Biology and Medicine, the International Congress of Pharmacology, and served on the Advisory Committee to Commissioner Larrick of the Food and Drug Administration from 1963 to 1965. Dr. Adriani was Chairman of the Advisory Committee of the Food and Drug Administration on Anesthetic and Respiratory Drugs, and a member of the Scientific Review Panel on publication of the Book, *Drug Interactions,* published by the American Pharmaceutical Association (Adriani, Tr. 1130).

13. Dr. Adriani has authored thirteen books covering such areas as drugs used for stimulation, anesthesia, and sedation, pain-relieving drugs, drugs given prophylactically, and muscle relaxants (Adriani, Tr. 1143–44). Of the approximately 600 articles he has published, half are scientific papers relating to research work and approximately 200 of them involved the clinical testing of drugs. A great many of these articles have been published in peer-reviewed scientific journals, including *Anesthesia and Anesthesiology, Clinical Pharmacology and Therapeutics,* the *Journal of Experimental Medicine and Biology,* and the *Journal of the American Medical Association* (Adriani, Tr. 1146). Dr. Adriani has served as editor and reviewer of articles on pain-relieving drugs or anesthetics for numerous scientific magazines and journals, and has edited over thirty textbooks and resource works on anesthesia (Adriani, Tr. 1142; CX 368W–X). He was Editor-in-Chief of

the *1971 AMA Drug Evaluations* and wrote approximately ten chapters of the book, including sections on strong analgesics and mild analgesics (Adriani, Tr. 1132–35). Dr. Adriani has appeared as an expert witness in a number of legal proceedings and before Congressional committees, and has testified in malpractice and product liability cases as well. Most of these cases involved pain-relieving drugs (Adriani, Tr. 1140). He also served as an expert witness in a product liability case concerning Benzocaine (Adriani, Tr. 1138). [9]

14. Dr. Adriani has received numerous awards and honors. Among these are the Distinguished Service Award of the American Society of Anesthesiologists and the Distinguished Service Award of the International Anesthesia Research Society. He received the Gold Medal For Distinguished Achievements in Medicine of an International Scope, from the Columbia University Alumni Association. He also received the Ralph M. Waters Medal, which in anesthesiology is comparable to the Nobel Prize, and was invited to donate his personal papers and letters to the National Library of Medicine, at the National Institutes of Health (CX 368Q). Dr. Adriani received the highest honor awarded to a civilian by the Italian Government, for his activities in medicine. He also received the Gaston Labat award which is given to physicians who contribute to the development of regional anesthesia. Dr. Adriani received this award in connection with his investigative work in local anesthetics and different techniques in nerve blocking (Adriani, Tr. 1137–38).

15. Based on his background, training, experience and familiarity with the literature, Dr. Adriani is eminently qualified as an expert in clinical pharmacology, topical analgesics, and in the evaluation of the safety and efficacy of analgesic drugs.

B. *Dr. Joel B. Cohen*

16. Dr. Joel B. Cohen is Chairman of the Marketing Department and a Professor of Marketing at the University of Florida where he also serves ad Director of the Center of Consumer Research (Cohen, Tr. 82). It conducts theoretical and applied research on consumer behavior, focused primarily on consumer information processing and decisionmaking (Cohen, Tr. 83). Dr. Cohen's teaching responsibilities are almost entirely in the consumer behavior area (Cohen, Tr. 85). Dr. Cohen holds a Ph.D. from U.C.L.A. in Marketing with a minor in Social Psychology. In 1966, he joined the faculty of the University of Illinois where he taught consumer behavior, behavioral science, marketing research and graduate level research design courses (Cohen, Tr. 87). From 1972–1974, Dr. Cohen served as Director of the Social and Behavioral Science Division of National Analysts, a leading marketing research and social science research organization (Cohen, Tr.

93–94). Dr. Cohen has been working in the area of consumer research and information processing for more than seventeen years. His primary areas of expertise are in consumer information processing, the study of consumer attitudes and cognition (what consumers have learned and believe), mass communication, and research design questions and measurement [10] (Cohen, Tr. 92). Over the years, Dr. Cohen has done consulting for both industry and governmental agencies (Cohen, Tr. 93–94). As consultant to the National Academy of Sciences Panel on the Impact of Drug Use and Misuse, he advised the panel regarding research design questions which could be used to evaluate the success of any advertising program which might be developed to combat drug abuse (Cohen, Tr. 95–96). More recently, he did consulting work for R.J. Reynolds relating to the processes through which advertising leads to changed cognitions and attitudes (Cohen, Tr. 96). Dr. Cohen was chief witness on advertising for Senator Packwood's Commerce Committee with respect to how cigarette warning information works. Dr. Cohen has been a consultant to the Federal Trade Commission since 1974.

17. Dr. Cohen is a member of the Association for Consumer Research. He is a member of the American Marketing Association and served as Chairman of their 1975 National Conference. Dr. Cohen is a member of the American Psychological Association and has chaired a number of professional symposia and workshops on consumer information processing (Cohen. Tr. 88–90, 98). While Dr. Cohen's work has concentrated on consumer behavior, he has presented papers at various conferences dealing with advertising, attitude measurement and applied projects in marketing and advertising (Cohen, Tr. 87–88). Dr. Cohen has authored a book, *Behavioral Science Foundations of Consumer Behavior,* and numerous articles and papers in the field of consumer behavior and attitudes (Cohen, Tr. 87–88; CX 36B–F). Dr. Cohen is a permanent member of the editorial boards of the *Journal of Consumer Research* and the *Journal of Marketing.* He is an editorial consultant for other journals in psychology and marketing including the *Journal of Applied Psychology,* the *Journal of Experimental Psychology,* the *Journal of Marketing Research, Economic Development and Cultural Change,* and *Population and Environments: Behavioral and Social Issues.* The types of articles Dr. Cohen reviews for the various journals include those in the areas of consumer information processing, advertising issues, measurement of persuasion, and particularly articles on processes through which advertising is supposed to affect a consumer's preferences and subsequent decisions (Cohen, Tr. 90–91). Dr. Cohen is well qualified as an expert in consumer information processing and analysis of consumer research.

C. *Sanford H. Roth, M.D.*

18. Dr. Sanford H. Roth currently serves as Medical Director of the Arthritis Program at St. Luke's Hospital Medical Center in Phoenix, Arizona, and has extensive experience in the [11] field of rheumatology and has been involved in clinical research relating to analgesic and anti-inflammatory drugs (Roth, Tr. 1488, 1499–1500, 1501–03, 1512). Dr. Roth's experience includes more than seventeen years of clinical practice with patients suffering from rheumatoid diseases, musculoskeletal disorders, and complications of osteoarthritis as well as considerable research in the areas of anti-arthritic, anti-inflammatory, analgesic and immuno modulating drugs (Roth, Tr. 1500–05). Dr. Roth has been involved in multiple research efforts comparing aspirin to nonsteroidal anti-inflammatory drugs (Roth, Tr. 1500). His former association with the Phoenix Arthritis Center focused on the treatment of rheumatic disorders, but also involved clinical investigations (Roth, Tr. 1506–07). He is a well-known and respected rheumatologist (O'Brien, Tr. 3736–37; Ehrlick, Tr. 4038). Dr. Roth has served as a consultant to the FDA and was an expert witness in rheumatology before the Arthritis Advisory Committee (Roth, Tr. 1495). He participated in the development of new FDA guidelines on package inserts, and worked with the National Institute of Health creating the American Rheumatism Association Medical Information System ("ARAMIS") which is now the world's largest repository of rheumatic disease, clinical data. Dr. Roth presently serves as co-director and principal investigator for the Phoenix data bank (Roth, Tr. 1495–97). Dr. Roth has served as a consultant to various pharmaceutical companies including Hoechst-Roussel Company, Pfizer Drug Company, Syntex Drug Company, Perdue Frederick and the MMM RIKER Company (Roth, Tr. 1497–98). This work involved the clinical evaluation of drugs and, in particular, salicylates (including the development of a nonacetylated salicylate for Perdue Frederick), work with teaching programs for the Riker Company in connection with another nonacetylated salicylate, and involvement with Bristol Myers relating to the gastrointestinal safety of a highly buffered aspirin product (Roth, Tr. 1499–1500).

19. Dr. Roth has served as Chairman of the Anti-Rheumatic Drug Therapy Study Group of the American Rheumatism Association and is currently a member of other professional associations with particular interest in rheumatology (Roth, Tr. 1493). He is affiliated with the American Society of Clinical Rheumatology, a peer group limited to twenty members, the American College of Clinical Pharmacology and the American Society of Clinical Pharmacology and Therapeutics (Roth, Tr. 1494). Dr. Roth has been involved in clincial testing and has

published many papers on this subject in peer-reviewed journals, including the *Journal of Rheumatology, Excerpta Medica,* and the *Journal of Clinical Pharmacology.* In addition, Dr. Roth has been invited to lecture at many seminars and symposiums (Roth, Tr. 1507–11; CX 369E–O). Dr. Roth has [12] been involved in the editing of various professional journals and books and other resource works on rheumatology (Roth, Tr. 1509–11; CX 369A, P). He is extensively involved in writing and lecturing about clinical evaluations and current work relating to analgesic and anti-inflammatory agents (Roth, Tr. 1513).

20. Dr. Roth's research background and clinical experience, as well as his familiarity with the current literature qualify him well as an expert in rheumatology and in the design, execution and analysis of clinical research regarding analgesic and anti-inflammatory drugs.

D. *Ann Silny, Ph.D.*

21. Dr. Ann Silny is Vice President of Client Services for ASI Market Research, a Los Angeles firm involved in custom research, syndicated copy testing and program testing for networks (Silny, Tr. 684–85). Dr. Silny holds a Ph.D. in experimental psychology from the University of California, Berkeley, with her primary area of graduate study being in the design and conduct of experiments and the analysis of experimental results with a specialization in behavioral endocrinology (Silny, Tr. 691–92). Throughout her studies at Berkeley, she taught such courses as Introductory Psychology, Cognative Psychology, Information Processing, and Comparative Psychology (Silny, Tr. 693). During graduate school, she studied under Dr. Leo Postman, a well-known theoretician and recognized authority in the area of learning and memory (Silny, Tr. 694). After receiving her Ph.D. in 1975, Dr. Silny joined the Roosevelt University in Chicago as Assistant Professor of Psychology teaching basic courses in research and methodology and design and quantitative methods (Silny, Tr. 694).

22. In her present position at ASI, Dr. Silny, after conferring with a client to determine their research objectives, recommends a research design using either a standardized copy testing system or designing custom research. She oversees the implementation of that research and then performs data analysis and presentation recommendation to the client. Most of Dr. Silny's time is devoted to the design of custom research which is research design custom tailored to specific research objectives as opposed to standardized research which is done under the same format with the same set of measures (Silny, Tr. 686–87). Dr. Silny has performed attitudinal tracking studies, media evaluation experiments and syndicated copy testing for many major consumer research clients including Alberto-Culver, Firestone,

Arco, Chevron, Home Box Office, and [13] VISA (Silny, Tr. 688–89). In Dr. Silny's previous position with ASI, she was responsible for decisions as to appropriate statistical tests, conducting those tests and evaluation of the data. In addition, she supervised the maintenance of norm systems which are records of how commercials in given categories have tested over a period of time. This system becomes the evaluative benchmark (Silny, Tr. 689–90).

23. Dr. Silny has published in various textbooks and technical journals (Silny, Tr. 695; CX 31B). She is a member of the Advertising Research Foundation, the American Marketing Association and the Association of Consumer Research (Silny, Tr. 695). Dr. Silny has served as an expert witness in cases involving consumer research, including *Vidal Sassoon v. Bristol Myers* and *U-Haul v. Jartran* (Silny, Tr. 696).

24. Dr. Silny is a qualified expert in the design, execution and interpretation of advertising copy research.

25. Thompson called a large number of expert witnesses. Five expert witnesses testified regarding the marketing, advertising and consumer psychology issues. They are Jacqueline Silver, Dr. Ivan Ross, Dr. Roslyn Freudenthal, Dr. Kenneth M. Warwick and Jay Jasper. Ten expert witnesses testified regarding the medical/scientific issues. They are Drs. H.I. Maibach, R.L. Marlin, A.J. Patel, S.L. Altschuler, J.L. Rabinowitz, G.E. Ehrlich, E.L. Golden, W.M. O'Brien, H.I. Silverman and S.I. Heller.

E. *Howard I. Maibach, M.D.*

26. Dr. Howard I. Maibach's testimony and his qualifications as an expert in dermatology, dermatopharmacology, and the percutaneous absorption of drugs have been stipulated by counsel. Dr. Maibach is a Professor of Dermatology at the University of California Medical School, San Francisco, California. He is a Research Associate at the Cancer Research Institute, is on the active staff of the University of California - H.C. Moffitt Hospitals, and is a Consultant in Dermatology to the Stanford Research Institute and to the State of California Department of Public Health. He is a Diplomate of the American Board of Dermatology (certified in 1961), and is a Fellow of the American College of Physicians. He is a member of the American Academy of Dermatology, the New York Academy of Sciences, the American Federation for Clinical Research, the American Dermatological Association, and the American Society for Clinical Pharmacology and Therapeutics. He is on the Board of Editors of the *International Journal of Dermatology.* He [14] has published over 400 papers on dermatology, including percutaneous absorption or penetration of topical drugs.

F. *Robert L. Marlin, Ph.D.*

27. Dr. Robert L. Marlin has been a consultant in the field of clinical research since 1972. Most of his clients are pharmaceutical companies. Dr. Marlin advises pharmaceutical companies on the design of clinical studies, helps define the scope of the investigations, initiates and monitors the clinical research, and after the investigation is completed, works with the clinician to review the results (Marlin, Tr. 3150–51).

28. Dr. Marlin received a bachelor's degree in psychology from Syracuse University, a master's degree in administration from the Maxwell School in Syracuse, and a doctorate in information science from Rutgers University. His doctoral research investigated the reliability of the adverse reaction reporting system in the FDA hospital reporting programs. Dr. Marlin has also taken post-graduate courses in pharmacology at Rutgers University (Marlin, Tr. 3154–56).

29. Dr. Marlin's first professional position was with the New York State Department of Mental Hygiene as an assistant in the testing of the patient population at a State facility. His next position was with the Sterling-Winthrop Research Institute, where he later became an assistant to the executive vice president of Winthrop Laboratories. His duties included the evaluation of laboratory data, biological data, pharmacological data, and other clinical information on drugs which were being licensed in the United States or other countries in Europe or the Far East. Concurrently, Dr. Marlin worked in the clinical research department of the company, monitoring the clinical trials conducted by Winthrop Laboratories in the southeast part of the United States, including clinical trials of a parenteral analgesic, an anesthetic, and several radioactive-type drugs used as diagnostic tools. Dr. Marlin's next position was coordinator of medical affairs for Knoll Pharmaceutical. In that position, he was responsible for designing the protocols for the clinical investigations, initiating the studies, monitoring the studies, and evaluating the data and oversaw the submission of the drug to the FDA for approval. While at Knoll, Dr. Marlin supervised the research for various drugs in the analgesic and asthmatic areas. Thereafter, Dr. Marlin was employed by Schering Pharmaceutical as an assistant to the vice president of Research of New Product Development and oversaw the research for new products. Dr. Marlin also worked for Sandoz as the senior clinical research associate, where he remained for [**15**] six years until 1975 when he opened a consulting business. Dr. Marlin has been involved in clinical research on both ethical and OTC preparations for some twenty pharmaceutical companies. His work with OTC drugs has

involved mostly analgesics such as aspirin, acetophenetidin, and other salicylates (Marlin, Tr. 3156–63).

30. Dr. Marlin is a member of the Drug Information Association, The American Association for the Advancement of Science, The New Jersey Academy of Science, The American Statistical Association, and The Biometric Society (Marlin, Tr. 3163–66). Dr. Marlin is qualified as an expert in clinical trials for the evaluation of the safety and efficacy of drug substances.

G. *Professor Alain Jacques Patel*

31. Professor Alain Jacques Patel is a French physician and is chief surgeon and head of the orthopedic and traumatologic surgery department at the Raymond Poincare Hospital, Paris, France, a teaching hospital connected with the University of Paris, where he is a professor of medicine. The orthopedic and traumatologic surgery department with 144 beds provides both in-patient and out-patient care. The majority of patients in the department suffer from musculoskeletal problems. Professor Patel treats many patients with rheumatic disease (Patel, Tr. 1805–06, 1812). Dr. Patel divides his time among treating patients, teaching graduate and post-graduate refresher courses in medical treatment and surgery, and doing research. He conducts research at the Institute of Research in Orthopedics, connected with the University of Paris. He has been president of the Institute for approximately ten years (Patel, Tr. 1815–17).

32. About twelve years ago, the French Ministerial of Health designated Professor Patel as a national expert on drugs. In this capacity, Professor Patel conducts tests on the efficacy and safety of new drug products. In order for a drug to be put on the French market and qualify as an approved drug for Social Security purposes, it must first be tested and approved by designated experts of the French Ministerial of Health. He has conducted about twenty-four clinical tests. Because his specialty involves musculoskeletal and bone disease of which pain, swelling, and limitation of movement are the primary symptoms, many of the drugs that Professor Patel has tested have been analgesics (Patel, Tr. 1817–20). Professor Patel is also associated with the French Foreign Office as the medical coordinator for all medical affairs for [16] Southeast Asia. Until he became a designated national expert on drugs, he had published about 175 papers on such topics as orthopedic lesions, congenital or rheumatological lesions, traumatologic cases, research on trauma, and research or drugs (Patel, Tr. 1822–23, 1835–36).

33. Professor Patel has received many honors for his work in orthopedics and traumatology, including the Croix du Merite National from the French Ministerial of Health, which is regarded as the high-

est honor the French government bestows on a civilian of his age (Patel, Tr. 1836–37). Professor Patel is qualified as an expert in osteoarthritis, rheumatoid arthritis, and cases involving bone, muscle, and ligament difficulties.

H. *Stanley L. Altschuler, M.D.*

34. Dr. Stanley L. Altschuler is a physician licensed to practice in New York, New Jersey, and Pennsylvania. He is a board-certified specialist in internal medicine and pulmonary diseases. In addition to a private practice, Dr. Altschuler is on the staff of the Medical College of Pennsylvania, Frankfort Hospital, Nazareth Hospital, and the Albert Einstein Medical Center, all of Philadelphia. He has teaching responsibilities in internal medicine and pulmonary disease at Frankfort Hospital, the Medical College of Pennsylvania, and the Albert Einstein Medical Center. He also makes medical rounds with the hospital staff. Dr. Altschuler is a member of the American College of Physicians, the American Thoracic Society, and the Pennsylvania Lung Association (Altschuler, Tr. 2990–91, 2993–94, 3003).

35. Dr. Altschuler attended medical school at Upstate Medical Center in Syracuse, New York. He interned at Monmouth Medical Center in New Jersey and did his medical residency at the Veterans Administration Hospital at the Medical College of Pennsylvania, which was followed by a two year fellowship in pulmonary disease at Temple University. Thereafter, Dr. Altschuler joined the staff of the Philadelphia VA Hospital, where he remained for approximately eight years and began a private practice. In 1979, he resigned from the staff of the VA Hospital for full-time private practice. Approximately 20% of Dr. Altschuler's patients have rheumatic difficulties (Altschuler, Tr. 2990–92, 2994).

36. Dr. Altschuler has conducted some ten clinical tests on drug products for pharmaceutical companies. Generally, the agents that he has tested have been for use in the field of internal medicine. Dr. Altschuler is also the author of several [17] articles in the fields of his specialties (Altschuler, Tr. 2994, 2995–96; RX 575). Dr. Altschuler is qualified as an expert in internal medicine, pulmonary disease, and the conduct of clinical trials for the testing of drugs.

I. *Joseph L. Rabinowitz, Ph.D.*

37. Dr. Joseph L. Rabinowitz is a biochemist who specializes in the field of lipid isotopes. His work consists of using radioactive isotopes to discover how the body utilizes fat and how it metabolizes nutritional products and drugs. Many of his projects involve and analysis of drug absorption and he has been using radioactive carbon (carbon 14) in his biochemical and pharmacological research for thirty years. He

has conducted research for a number of pharmaceutical companies in the area of radioactive tracers and drug absorption testing (Rabinowitz, Tr. 3481, 3491–92).

38. Dr. Rabinowitz is currently chief of radioisotope research at the VA Hospital in Philadelphia and a professor of biochemistry at the University of Pennsylvania. His responsibilities at the University consist of teaching biochemistry and radioisotope courses to medical and dental students at the graduate level and overseeing the radioisotope research conducted at the University. As chief of radioisotope research at the VA Hospital, he functions as an advisor to investigators on the feasibility and desirability of using isotopes in their research. In addition, Dr. Rabinowitz serves as a reviewer and/or a member of the editorial boards of several professional journals, including the *Journal of Medicinal Chemistry,* the *Journal of Lipid Research,* and the *Journal of Nuclear Medicine* (Rabinowitz, Tr. 3482–83; RX 563).

39. Dr. Rabinowitz received his Master of Science degree in chemistry and his doctorate in organic chemistry from the University of Pennsylvania. He has done postdoctoral work in biochemistry, chemistry, and physiology at the University of Pennsylvania; Carlsberg Laboratory in Copenhagen, Denmark; Milstead Enzyme Laboratory in England; and Orsay Physiology Laboratory in Paris, France. With respect to radioisotope research, Dr. Rabinowitz has taken several physics and radiation safety courses at the University of Pennsylvania, has received on-the-job training in the handling and use of radioisotopes, and has taken courses in isotope technology at the College of Pharmacy at the University of Pennsylvania. He has been licensed for many years by the Atomic Energy Commission to use and possess radionuclides (radioactive atoms) (Rabinowitz, Tr. 3481–82; RX 563). [18]

40. Dr. Rabinowitz is a member of a number of professional societies, including the American Society of Biological Chemistry. Membership in this society is considered difficult to achieve. Dr. Rabinowitz has been honored for his work in radionuclides with many awards, including the Doctor Honoris Causa from the University of Bordeaux, France; the Harrison Award in Chemistry from the University of Pennsylvania; the Fulbright Professor Award in Biochemistry at the Carlsberg Laboratory, Denmark; The Silver Medal of the City of Bordeaux, France; and the Medal of the City of Nancy, France (Rabinowitz, Tr. 3484–85; RX 563). Dr. Rabinowitz has published some 200 books, articles, and abstracts, including many that discuss radioactive materials and their interrelationships with drugs. He has co-authored a book on radioisotope methodology which is used in many universities throughout the world (Rabinowitz, Tr. 3490–92)

Dr. Rabinowitz is well qualified to give testimony as an expert in radioisotope testing.

J. George E. Ehrlich, M.D.

41. Dr. George E. Ehrlich is currently a professor of medicine and director of the Division of Rheumatology of Hahnemann Medical College, Philadelphia, Pennsylvania and specializes in rheumatology. At Hahnemann, he provides a teaching program for medical students, health professionals, and graduate physicians specializing in rheumatology, provides patient care programs in rheumatology and helps guide research in rheumatology (Ehrlich, Tr. 3980–82). He is also on the associate staff of Albert Einstein Medical Center and the Moss Rehabilitation Hospital (Ehrlich, Tr. 3980–82).

42. Dr. Ehrlich received his undergraduate degree from Harvard University and his bachelor of medicine and doctor of medicine degrees from Chicago Medical School. He did his internship at Michael Reese Hospital in Chicago. He followed his internship with several residencies: Francis Delafield Hospital of Columbia Presbyterian Medical Center, New York City (soft tissue pathology and surgery); Beth Israel Hospital, Boston (internal medicine); and Tufts New England Medical Center, Boston (senior residency in medicine). After his residencies, Dr. Ehrlich did two fellowships in rheumatology, the first at the National Institute of Arthritis and Metabolic Diseases of the National Institute of Health, and the second at a hospital for special surgery at the New York Hospital Medical Center Complex of Cornell University. Concurrently with this second fellowship, he held a special fellowship in research at the Sloan-Kettering Institute. Prior to joining the faculty at [19] Hahnemann College, Dr. Ehrlich was a professor of medicine and rehabilitative medicine at Temple University School of Medicine and director of the Section of Rheumatology at the Albert Einstein Medical Center and Moss Rehabilitation Hospital (Ehrlich, Tr. 3980–82).

43. Many awards and honors granted to Dr. Ehrlich for his work in rheumatology include the distinguished alumnus award from Chicago Medical School, the Phillip Hench award of the Association of Military Surgeons, several Distinguished Service Awards from the Arthritis Foundation, two official citations from the City of Philadelphia, The Order of the Star with the rank of Cavaliere from the Italian Solidarity, the Phillip Hench lectureship from the American College of Physicians (twice), and the William K. Ishmael lectureship at the University of Oklahoma (Ehrlich, Tr. 3982–84).

44. Dr. Ehrlich is a former consultant on inflammatory drugs to the FDA Bureau of Drugs. He is currently a consultant to the American Medical Association Directory of Drugs, and serves as a consultant to

pharmaceutical companies on the development of testing for new inflammatory drugs. He is a member of numerous professional organizations and holds fellowships in various organizations including the American College of Clinical Pharmacology, the American Congress of Rehabilitation Medicine, and the American College of Physicians (Ehrlich, Tr. 3985–87; RX 135). Dr. Ehrlich's publications on rheumatology numbering some 150, includes papers concerned with the clinical testing of drugs, as Dr. Ehrlich has participated in more than thirty clinical trials in the past twenty years (Ehrlich, Tr. 3987–88).

45. Dr. Ehrlich has testified at many proceedings as an expert. He was invited by the Food and Drug Administration to give testimony as to the value of studies that were submitted as efficacy evidence for salicylate drugs and related inflammatory drugs. He has also testified at the Department of Health, Education and Welfare regarding the federal licensing program for physical therapists. He has been an expert witness in a variety of litigation involving malpractice cases and compensation cases (Ehrlich, Tr. 3989–90). Dr. Ehrlich is qualified as an expert in the design, execution, and analysis of clinical trials and is well qualified as an expert in rheumatology (Ehrlich, Tr. 3990–91).

K. *Emanuel L. Golden, M.D.*

46. Dr. Emanuel L. Golden is a specialist in internal medicine and rheumatology. He has practiced in internal [20] medicine since 1956 and in rheumatology since 1960. His current practice is approximately 75% rheumatology and 25% internal medicine, and he sees between 100 and 125 patients a week. He is certified as a Diplomate of the American Board of Rheumatology, and as a Fellow of the American College of Physicians. He is affiliated with the North Broward Hospital and the Boca Raton Community Hospital in Florida. Dr. Golden is a member of the American Rheumatism Association, the Arthritis Foundation, the Broward County Arthritis Foundation, and the American Medical Association. He is an accredited lecturer in rheumatology for the Palm Beach Arthritis Foundation and the Broward County Arthritis Foundation, and he lectures at the hospital staff training programs for nurses and therapists at North Broward Hospital and Boca Raton Community Hospital. Dr. Golden is also a visiting physician at the Jackson Memorial Hospital at the University of Miami (Golden, Tr. 2647–49, 2663–68; CX 327).

47. Dr. Golden received his medical training at the Chicago Medical School, interned at Brooklyn Jewish Hospital, and did a three year medical residency at Kingsbridge Veterans Hospital in New York City. Prior to attending medical school, Dr. Golden received one year

of post-graduate training in bio-chemistry and endocrinology. From 1960 to 1963, Dr. Golden trained with Dr. Steinbrocher at the Joint Disease Hospital in New York City, where he received further training in joint diseases from a clinic which was run by the school. After spending three years at the Joint Disease Hospital, Dr. Golden was appointed by the director of medicine at Mt. Sinai Hospital to the position of director of the arthritis clinic at Greenpoint Hospital, a city hospital which was at that time affiliated with Mt. Sinai Hospital. From here, he moved to Elmhurst City Hospital, a teaching hospital affiliated with Mt. Siani, and became an associate professor of medicine at Mt. Sinai Hospital School of Medicine. He stayed at Elmhurt City Hospital for ten years during which time he taught interns and residents in the field of rheumatology, acted as a consultant to the hospital, and directed both the Regular Arthritis Clinic and the Combined Arthritis Rehabilitation Clinic. As director of the Regular Arthritis Clinic, Dr. Golden set up a treatment program for outpatients with arthritis, ran the clinic, and supervised a staff of three rheumatologists. Approximately 100 patients a week were treated on a regular basis at this clinic. The Combined Arthritis Rehabilitation Clinic was created by Dr. Golden in collaboration with a doctor in rehabilitative medicine. The object of this clinic was to tailor a treatment program for chronic arthritics to meet all of their medical needs. This combined treatment clinic was a new concept at this time, but has since been adopted by other hospitals. Dr. Golden [21] served as the director of the Combined Clinic and oversaw the activities of the entire staff of physicians, residents, therapists, and paramedics (Golden, Tr. 2648–61). In 1975, when the American College of Physicians formally recognized rheumatology as a special field of medicine, Dr. Golden took the required examination and became a Diplomate of the American Board of Rheumatology (Golden, Tr. 2649). Dr. Golden is well qualified as an expert in internal medicine and rheumatology.

L. *William M. O'Brien, M.D.*

48. Dr. William M. O'Brien is a physician and a specialist in rheumatic diseases. Dr. O'Brien is an attending physician at the University of Virginia Hospital and Blue Ridge Sanitarium and a professor of internal medicine at the University of Virginia Medical School. In his capacity as a professor, he runs four clinics a week, one for patients with rheumatoid arthritis, two for patients with general rheumatic disease, and one for patients with lupus erythematosus (O'Brien, Tr. 3642–43).

49. After graduating from Yale Medical School, Dr. O'Brien trained in internal medicine at Massachusetts General Hospital and at Harvard. He did a Fellowship at the National Institute of Arthritic and

Metabolic Diseases at the National Institute of Health. At the Manchester Royal Infirmary in England, he served as Senior Registrar in rheumatology. For three years, he was Senior Clinical Investigator at the Arthritis Institute of the National Institute of Health. He was an assistant professor in internal medicine for three years at Yale Medical School. He has held his present position as a professor of medicine at the University of Virginia for eleven years (O'Brien, Tr. 3642).

50. Dr. O'Brien has been accorded many honors for his work. He is a member of the Heberden Society in England, a society limited to 100 experts in rheumatology. He is a member of the Academy of Medicine in Chile, and has received an award from the American Epidemiology Society. As an adviser to the chief of medicine of the Veterans Administration, he served for four years on the committee that designs the long-term clinical trials for the Veterans Administration. The many clinical trials Dr. O'Brien was involved in included the trials to discover the role of aspirin in preventing myocardial infarction. He also served as medical consultant to the Consumers Union of the United States for three years and has assisted for many years in the publishing of a medical letter on clinical trials established by the Consumers Union. Recently, he published two letters criticizing the use of the arthritis prescription drugs Oraflex and Feldine (O'Brien, Tr. 3643–44). [22] The professional societies to which Dr. O'Brien belongs include the American Rheumatism Association and the Anti-Inflammatory Drug Study Group. In his association with the former he designed and directed, for six years, all of the clinical trials run by the association. These trials, through the association's cooperating clinic committee of which Dr. O'Brien was chairman, focused on anti-rheumatic drugs. This year he was made co-president of the Anti-Inflammatory Study Group which provides for discussion among physicians about clinical trials (O'Brien, Tr. 3644–45).

51. Dr. O'Brien has published numerous articles, books, and lectures. Most of these are in the field of rheumatology and most concern the testing of drugs. While he was chairman of the cooperating clinic committee of the American Rheumatism Association, Dr. O'Brien published in the *New England Journal of Medicine* and in *Clinical Pharmacology and Therapeutics* a series of articles on trials which he conducted on aspirin and aspirin-like drugs (O'Brien, Tr. 3645–46). He has appeared before the Federal Trade Commission, the FDA Internal Analgesic Advisory Panel, and the United States Senate. Many drug companies have requested him to render opinions on analgesics and anti-inflammatory drugs (O'Brien, Tr. 3646–48). Dr. O'Brien is well qualifed as an expert in rheumatology; internal medicine; and the design, execution, and analysis of clinical trials.

M. *Harold I. Silverman, Ph.D.*

52. Dr. Harold I. Silverman is a professor of pharmacy and executive director of Pfeiffer Pharmaceutical Sciences Laboratories at the Massachusetts College of Pharmacy and Allied Health Sciences, Boston, Massachusetts. He is also a member of the faculty at Boston University Medical School and the New England College of Optometry. He is a registered pharmacist in Massachusetts, New Jersey, and Pennsylvania. Dr. Silverman has been the executive director of Pfeiffer Pharmaceutical Sciences Laboratories since its inception approximately five years ago. In this role, Dr. Silverman helps plan, design, and execute the research at the laboratory and is responsible for all the reports it issues. The staff also provides teaching for Massachusetts College of Pharmacy and Allied Health Sciences of which the laboratory is a part. Dr. Silverman has taught courses in biopharmaceutics (the development, design, and analysis of a pharmaceutical product), product development, industrial pharmacy, physical pharmacy, and OTC drug products. All of these courses have touched upon FDA rules and regulations and the toxicology, safety, and efficacy of drug substances (Silverman, Tr. 2070–76, 2086–89, 2090–92). [**23**]

53. Dr. Silverman began his education as a pharmacist at the Philadelphia College of Pharmacy and Science, graduating with a baccalaureat degree in 1951, a masters degree in 1952, and a doctorate in 1956. Thereafter, he went to Long Island University as a professor of pharmacy and taught basic pharmaceutics, veterinary pharmacy, physical pharmacy, and dosage form development. During part of this time, he also worked as a senior scientist at Warner Lambert Research Institute. Following his teaching at Long Island University, Dr. Silverman worked for Knoll Pharmaceutical Company for several years, attaining the position of vice president in charge of pharmaceutical research and development. He left Knoll Pharmaceutical to begin work at the Massachusetts College of Pharmacy as a professor of pharmacy and chairman of the Department of Pharmacy. After a time, he became the associate dean and executive director of the Pfeiffer Pharmaceutical Sciences Laboratories. Throughout most of his career, he has remained in touch with the practical side of his field by working part-time as a registered pharmacist (Silverman, Tr. 2076–77, 2079, 2092).

54. In addition to belonging to numerous societies, holding various appointments as a lecturer or visiting scientist, serving as an advisor to the Food and Drug Administration, and having been honored with many awards including the Newcomb Award for original research in pharmacognosy, Dr. Silverman is the author of numerous publications. At the present time, his major areas of interest are the develop-

ment of drugs, the evaluation of the dosage form, and improvement of the bioavailability of drugs. Dr. Silverman has studied topically creams and barriers, and the absorption of chemical substances through the skin (Silverman, Tr. 2099–101; RX 578). Dr. Silverman is qualified as an expert in pharmacy, pharmacokinetics, drug absorption, drug stability, bioavailability, and the safety, efficacy, and mode of action of topical and oral drugs as seen from the perspective of a pharmaceutical expert.

N. *Saul I. Heller, M.D.*

55. Dr. Saul I. Heller is a physician licensed to practice medicine in New York and Connecticut and specializes in psychiatry, neurology, and acupuncture and is certified as a Diplomate of the American Board of Psychiatry and Neurology. Throughout his years of practice, Dr. Heller has been interested in the treatment of pain. He received the first license in New York State for the practice of acupuncture, and was instrumental in developing the legislation which established the [24] acupuncture licensing program. Dr. Heller has been engaged in private practice for fifty years. In his practice, he has treated over 25,000 patients for pain-related problems and disorders. The most common disorder that he sees in his patients is headache pain of various types, but he also sees patients with spinal symptoms, neuralgia, bursitis, and tendonitis. As most of his patients suffer from arthritis from time to time, it is not uncommon for him to treat arthritis-related pain (Heller, Tr. 2565–66, 2571–72, 2579–81).

56. Dr. Heller received his Bachelor of Arts degree from Cornell University and His Doctorate of Medicine from Cornell Medical College. Following his graduation, Dr. Heller interned at Lenox Hill Hospital and did his residency at the New York State Psychiatric Institute, a division of Columbia Presbyterian Medical Center. He thereafter served as a research fellow at Bellevue Hospital in New York. Throughout his practice, Dr. Heller has served on the attending staff of several major New York hospitals, including Bellevue Hospital, New York University College of Medicine, Riverside Hospital, LeRoy Hospital, Gracie Square Hospital, Mid-Island Hospital, and Nassau County Medical Center. For five years, he was a member of the faculty of New York University College of Medicine and taught courses in psychiatry. He served for ten years as the director of the Neurology and Psychiatry Departments at Cabrini Hospital (Heller, Tr. 2566–67).

57. Dr. Heller has held many government appointments, including that of medical advisor to the director of the Selective Service System. He was president of the New York State Board of Medicine and president and founder of the New York Society of Acupuncture for

Physicians and Dentists. He has served on the Insurance Committee of the American Psychiatric Association, the Medical Malpractice Panel of the New York State Supreme Court, and the Medical Grievance Committee of the New York State Board of Regents. Dr. Heller was appointed to the Rockefeller Commission to study the uses, efficacy, and regulations of acupuncture. He has been vice president and trustee of both the American College of Acupuncture and the International College of Acupuncture (Heller, Tr. 2469–70). Dr. Heller is the author of two publications that discuss his studies on the use of Sedac electrical current in acupuncture to relieve pain. He has received many honors for his professional work including a Congressional Medal of Honor (Heller, Tr. 2572–74; 2578–79). Dr. Heller is qualified as a specialist in neurology, psychiatry, and the diagnosis and treatment of pain-related problems. [25]

O. *Roslyn Freudenthal, Ph.D.*

58. Dr. Roslyn Freudenthal is a statistical consultant specializing in biomedical trials and psychological research. She received her bachelor of science degree in chemistry with minors in mathematics and physics from New York University in 1931. In 1933, she obtained a master's degree in microanalysis, and in 1940, a doctorate in organic synthesis with a minor in biochemistry, both from New York University. Her studies were supplemented by a year at Pregl Institute at the University of Graz, Austria where she studied microanalysis, and by a year at Fordham University, where she took a graduate course in statistical applications in experimental science.

59. Dr. Freudenthal began her career as a research chemist in 1937, but taught herself statistics by reading recognized works on the subject. Realizing the extent of the demand for biostatisticians, she decided to go into the field. In 1940, she left the Psychiatric Institute to work at Killian Research Laboratory in New York City. Although hired as a chemist, she continued to do statistical work, analyzing the results of the studies conducted at the laboratory. After three years, she went to the Food Research Laboratory in Long Island City as a biometrist and the director of research and became a full-time statistician. Dr. Freudenthal designed and interpreted bioassays and acted as a statistical consultant for clients. In 1947, Dr. Freudenthal left the Food Research Laboratory and became a private consultant (Freudenthal, Tr. 4869–74; RX 88).

60. Over the years, Dr. Freudenthal has performed consulting work for many physicians in connection with their clinical research. She has also worked for Thompson Medical Company for over twenty years and has been involved with approximately thirty projects. In the past thirty to forty years, Dr. Freudenthal has participated in

approximately 300 research projects and clinical trials and approximately 125 clinical trials. On these 125 trials, roughly twenty have involved analgesic medications such as Aspercreme, aspirin, sodium salicylate, and methyl salicylate (Freudenthal, Tr. 4878–90; RX 88). Dr. Freudenthal has contributed to many published papers, and her name appears on about twenty of them. She is a member of Phi Beta Kappa, the New York Academy of Sciences, the American Statistical Association, Sigma Xi, and the Biometric Association (Freudenthal, Tr. 4891–92; RX 88). Dr. Freudenthal is qualified as an expert in the evaluation of medical research data and the setting up of codes for clinical trials.

61. Respondents called the following advertising and consumer research experts. **[26]**

A. *Jacqueline Silver*

62. Ms. Jacqueline Silver is a senior vice president of Needham Harper & Steers ("NH&S"), a major international advertising agency ranked among the top twenty advertising agencies in the world (Silver, Tr. 5583). Her responsibilities include the Research Department of NH&S's New York office (Silver, Tr. 5584), the chairing of the important Strategy Review Board and the Advertising Review Board of NH&S (Silver, Tr. 5584–85). The Strategy Review Board reviews research strategies developed for its advertising compaigns (Silver, Tr. 5586–87). The Advertising Review Board reviews the advertising plans developed by the account groups and the advertising created in accordance with the strategies approved by the Strategy Review Board (Silver, Tr. 5587–88). Ms. Silver's duties also include the design, implementation and analysis of research programs developed for NH&S clients (Silver, Tr. 5588–89). She is directly responsible for all research, including studying the marketplace, positioning the product within the competition, assessing the attitudes of consumers, establishing the product's primary benefits and profiling the consumer in terms of psychographic dimensions (Silver, Tr. 5588–89). The agency regularly conducts strategic studies, copy tests, tracking studies and product tests which Ms. Silver oversees (Silver, Tr. 5592–93). NH&S also conducts the "Lifestyle Study,, on an ongoing basis as a current source of information with respect to consumer behavior and attitudes (Silver, Tr. 5626–27). Prior to joining NH&S in 1976 as Director of Research, Ms. Silver was vice president-executive research director at Grey Advertising, Inc. where she conducted research for clients, including drug companies such as Sandoz, Bristol-Myers, Richardson, Merrill, A.H. Robbins, Sterling Drug, Whitehall Laboratories, and Merck, Sharpe & Dome (Silver, Tr. 5602). Ms. Silver has also assisted clients in the development of product packaging and

labeling, the creation of brand names and their positioning within the product category (Silver, Tr. 5602–03). She has conducted approximately fifty studies with respect to brand names and approximately 200 studies on product packaging (Silver, Tr. 5603) and has been involved in some ten strategic studies of analgesic products, including a research project for internal analgesics for arthritis (Silver, Tr. 5606–07). Recently, Ms. Silver conducted a study for the USDA on nutrition in which her role included the design, execution and presentation of the research (Silver, Tr. 5608).

63. Ms. Silver has an Associate of Arts Degree from the University of California at Berkley and a Bachelor of Science in [27] Mathematics from New York University. Ms. Silver has since taken courses in experimental design, statistics, computer sciences and psychology at New York University and The New School. After beginning her career as an interviewer at age fifteen, she has been employed by many market research organizations including Opinion Research Corporation, Market Facts, National Analysts, Mervin Fields, Human Factors, Marketing Impact, Oxtoby Smith, and Daniel Starch (Silver, Tr. 5611-12). At Marketing Impact and Oxtoby Smith, (research suppliers), she was a field director (Silver, Tr. 5613), at Data Decision, a computer company, a group head in charge of processing and analyzing copy tests for Colgate-Palmolive, among other client companies (Silver, Tr. 5613–14) and at Market Facts, Inc., senior study director (Silver, Tr. 5614).

64. Ms. Silver regularly reads the important journals which focus on advertising, market research and consumer behavior (Silver, Tr. 5631). Ms. Silver is a member of the American Marketing Association, Advertising Women of New York, the Advertising Research Foundation (being a member of the latter's Copytesting Practices Committee and the Public Opinion Committee), the American Association of Advertising Agencies (Silver, Tr. 5627) and the Association of Advertising Research Directors. Ms. Silver has given courses, seminars and presentations in marketing research, strategy development and techniques (Silver, Tr. 5629). Ms. Silver has a broad range of practical experience in the design, execution and analysis of consumer and market research (Silver, Tr. 5620). Ms. Silver is qualified as an expert in market and consumer research, advertising strategy and evaluation, including packaging and brand names, consumer behavior, and the design, implementation and analysis of market and advertising research.

B. *Ivan Ross, Ph.D.*

65. Dr. Ivan Ross is a Professor of Marketing at the University of Minnesota School of Management and former Chairman of the Mar-

keting Department. He is a member of the Graduate Faculty of the College of Business Administration and the Department of Psychology of the University (RX 570). Dr. Ross has a doctorate in Industrial and Consumer Psychology and teaches courses in Consumer Behavior, Advertising and Sales Promotion, Marketing Research and Marketing Communications (RX 570). Dr. Ross is a licensed Consulting Psychologist. His areas of specialization include consumer behavior, marketing and advertising research, motivation research, and the design and analysis of consumer and marketing surveys and experiments, including the construction of questionnaires (RX 570). [28]

66. Dr. Ross has published many papers on consumer psychology and attitudes, marketing analysis and research and the selection and meaning of brand names (RX 570F–I) and has spoken before professional associations and societies dealing with consumer behavior and decisionmaking (RX 570). Dr. Ross has been a consultant to the United States Public Health Service and to the FDA Bureau of Drugs from 1976 to 1977 with respect to package inserts and consumer information to be placed on OTC and prescription products (Ross, Tr. 5947, 5949–50). He has served as a consultant to advertising agencies with respect to advertising strategy, marketing, advertising and consumer research matters and has conducted many focus group interviews (RX 570).

67. Since 1974, Dr. Ross has been a member of the Minnesota Advertising Review Board, acting as an arbitrator of advertising complaints (Ross, Tr. 5947–48), the American Council for Consumer Interest and the Society of Consumer Affairs Professionals ("SOCAP,,) and a member and former President of the Division of Consumer Psychology of the American Psychological Association (Ross, Tr. 5948–49). He is an advisor to the State of Minnesota Office of Consumer Services with respect to consumer legislation and consumer protection issues (Ross, Tr. 5949) and has served as Vice Chairman of the Minnesota Advertising Review Board.

68. Dr. Ross has appeared in behalf of the Federal Trade Commission in administrative hearings as an expert in consumer psychology, consumer behavior and marketing research and gave testimony regarding various marketing and advertising issues, including the meaning of advertisements, the consumer perceptions of the messages in advertisements and their impact on the consumer (Ross, Tr. 5053–54). Such cases include the Federal Trade Commission's recent internal analgesic cases (*In the Matter of American Home Products Corporation,* Docket No. 8918 [98 F.T.C. 136 (1981)], *aff'd in part and mod. in part,* 695 F. 2d 681 (3rd Cir. 1982 [101 F.T.C. 698 (1983)]; *In the Matter of Bristol-Myers Company,* Docket No. 8917 [102 F.T.C. 21 (1983)]; and *In the Matter of Sterling Drug, Inc.,* Docket No. 8919 [102

F.T.C. 395 (1983)]. He has also testified as an expert in trademark infringement litigations and has served as a consultant in many trademark cases (Ross, Tr. 5962; RX 570). Dr. Ross is qualified as an expert in consumer psychology and consumer behavior, marketing research, and evaluation of advertising and trademarks.

C. *Dr. Kenneth M. Warwick*

69. Dr. Kenneth M. Warwick is the President of Ken Warwick & Associates, Inc. (a marketing research consulting firm) and [29] has been in the marketing research business for over twenty years. He graduated from Queens University in Ireland with a Bachelor of Arts degree in Psychology. In 1963, Dr. Warwick received a Doctorate in Psychology and Statistics from the University of London. He has taught courses in Experimental Psychology, Consumer Psychology, Research Design, Methodology and Analysis, and Statistics at London University, Northwest University, Columbia University and New York University. He has been a reviewer of faculty research proposals for the City University of the City of New York for the past five years. In the United Kingdom, he was a partner in an advertising research firm, DRC, Limited. In this country, Dr. Warwick has served as a consultant in marketing and consumer research to two advertising agencies, Foote, Cone & Belding and Kenyon & Eckhardt. He was employed as Executive Vice President of Grudin, Appel & Haley, a market research company (which performed marketing and advertising research for such companies as Warner-Lambert, ITT, American Cyanamid and the Lorillard Corporation) and supervised the Statistical Analysis Group and the researchers and project directors engaged in the ongoing research projects and assisted in designing the execution and the analysis of market research (Warwick, Tr. 5281–82). Dr. Warwick was also employed at Grey Advertising, Inc. as a Vice President and Associate Research Director in charge of research projects for such clients as Ford Motor Company, United States Steel and General Electric (Warwick, Tr. 5280–81). In his own company, Dr. Warwick provides consulting services with respect to advertising and market research, including the design, execution and evaluation of research projects, His clients include AT&T, RCA, American Cyanamid, Warner-Lambert, and major advertising agencies such as BBD&O, Backer & Spielvogel, Scali, McCabe & Sloves, and McCann Erickson. He also provides consulting advice to law firms and market research companies and suppliers such as Simmons Market Research and Data Developing Corporation. Dr. Warwick has been involved in some 200 copy test and sixty research studies (Warwick, Tr. 5291).

70. Dr. Warwick has testified in trademark litigations and litigations involving deceptive advertising as an expert on advertising and

marketing research (Warwick, Tr. 5279–80). Dr. Warwick has published and presented numerous papers dealing with marketing research and consumer research. Among his publications is the "Statistical Data Processing in Market Research" chapter in the *Standard Handbook in Marketing Research* published by the American Marketing Association (Warwick, Tr. 5288–89; RX 577).

71. Dr. Warwick is a member of the American Psychological Association, American Statistical Association, American [30] Marketing Association, the New York Academy of Science and the Royal Statistical Society (Warwick, Tr. 5291), and is the Computer Science Editor and a member of the editorial review board of the *Journal of Marketing Research* (Warwick, Tr. 5290). Dr. Warwick is qualified as an expert in consumer psychology and the design, implementation, review and evaluation of marketing and advertising research (RX 577).

D. *Jay Jasper*

72. Mr. Jay Jasper is a Senior Vice President and Creative Director of Ogilvy and Mather International, Inc. where he has been employed for fourteen years (Jasper, Tr. 4698). As Creative Director, Mr. Jasper is responsible for supervision of the writers, art directors and producers who create advertising (Jasper, Tr. 4698–700). After graduating magna cum laude from Brandeis University, Mr. Jasper attended Yale University, the College de France and the Sorbonne (on a Fulbright Scholarship) (Jasper, Tr. 4703). He frequently lectures on advertising to advertising and trade groups as well as to management personnel of O&M throughout the world (Jasper, Tr. 4703–04). Mr. Jasper is an expert in the creation and evaluation of advertising and advertising strategy.

III. THE MARKETING AND ADVERTISING OF ASPERCREME

73. Thompson first began to market Aspercreme in 1976 after purchasing it from the Sperti Drug Company (CX 45E (Admission No. 79)). Prior to acquisition of Aspercreme by Thompson, Sperti advertised the product on a live, local television program in Ohio and part of Indiana. Thompson continued this advertising until August of 1979 (RX 285B). Spot market television advertising was first disseminated in October of 1978. Aspercreme advertising was first aired on network television in September of 1979 (RX 285C). Network, spot and syndicated television advertising for the period 1978 through 1981 included the following:

CX 1, disseminated 2,814 times from October 1978 through February 1980.

CX 2, disseminated 1,443 times from April through December 1979.

CX 3, disseminated 1,890 times from January through June 1980. [31]

CX 4, disseminated one time in December of 1979.

CX 5, disseminated 492 times in April to June 1980.

CX 9 and 21, disseminated 130 times from November 1980 through April 1981 on a combined basis.

CX 12 through 20, disseminated 253 times during the 1976 through 1979 time frame on a combined basis (CX 25).

Print advertising for the period 1978 through 1981 including the following:

CX 6 was disseminated twice in the *Readers Digest* in March and April of 1979 and once in the *Saturday Evening Post* in May of 1979 (CX 25).

CX 7, 8, 10 and 11 are co-op advertisements for which there are no specific dissemination data available: however, they were disseminated (Tr. 47–49; Paragraph 9 and Exhibits G and H of the Complaint and Paragraph 9 of the Answer).

74. For the years 1976 through 1981, Thompson's net annual sales, net sales of Aspercreme and Aspercreme advertising expenditures were as follows:

	Annual Sales	Aspercreme Sales	Aspercreme Ad Expenditures
	(000)	(000)	(000)
1976	$18,385	$ 68	$ 1
1977	29,092	289	10
1978	27,243	589	95
1979	45,847	3,188	1,768
1980	92,275	5,860	2,230
1981	N.A.	5,931	1,595
1982 (Thru July)	N.A.	4,452	2,056

(CX 45E–F (Admission No. 80); RX 573) [32]

75. From 1976 through 1981, annual consumer sales of Aspercreme averaged about $2.5 million. In promoting Aspercreme by advertising from 1976 through 1981, Thompson spent at least $5 million. Thus, annual advertising expenditures for Aspercreme from 1976 through 1981 have averaged approximately $950,000. The average advertising-to-sales ratio for Aspercreme for the 1976 through 1981 period was about 36%.

76. For the years 1976 through 1981, the share of the topical analgesic market accounted for by Aspercreme was as follows:

1976	.8%	(CX 45Z–017)
1977	.8%	(CX 45Z–017)
1978	1.4%	(CX 45Z–017)
1979	7.4%	(CX 45Z–017)
1980	16.8%	(RX 286D)

During the same time period, the market share held by Ben-Gay has remained at about 40% and that of Mentholatum, at about 9%. The market share held by Aspercreme has grown steadily from virtually nothing to 7.4% in 1979 and to 16.8% in 1980 (RX 286D).

IV. MEANING OF ASPERCREME ADVERTISEMENTS AND THE BRAND NAME "ASPERCREME"

A. *Standards For The Determination Of The Meaning Of Advertisements*

77. In determining whether an advertisement made a particular representation, the appropriate standard is whether, taking the advertisement as a whole, the representation constitutes a reasonable interpretation of that advertisement. The question is whether the representation at issue is an interpretation of the advertisement to which more than an insubstantial number of consumers would adhere. Since more often than not several reasonable interpretations of a given advertisement are possible (Ross, Tr. 5969–70), it is not necessary that the claim found to have been made be the only or the most reasonable interpretation of the advertisement.

78. The primary evidence with respect to the meaning of the advertisements in the record consists of the advertisements [**33**] themselves. The record also contains extrinsic or secondary evidence regarding the meaning of the advertisements, namely, expert testimony, consumer research, and evidence of how the networks and other expert bodies interpreted the advertisements.

79. In determining the meaning of individual advertisements, I have primarily relied on my knowledge and experience to determine what impression or impressions an advertisement as a whole is reasonably likely to convey to a consumer. When my initial determination is confirmed by the expert testimony of complaint counsel or respondent, I rested. When my initial determination disagreed with that of expert testimony, which was often conflicting, I reexamined the advertisement in question, and further considered other record evidence such as copy tests and other consumer research before reaching a final determination. I have not relied on such extrinsic evidence when, after careful study and reflection, I found it to be unpersuasive and contrary to the weight of evidence.

B. *Respondent Has Made Certain Representations Alleged In The Complaint*

(1) *Complaint Paragraph 10 (a):* The claim that Aspercreme contains aspirin.

80. Thompson has respresented, expressly or impliedly, that Aspercreme contains aspirin. This representation was made in varying degrees in all of the TV and print advertisements in evidence in this proceeding. They include CXs 1–22 and 37.

81. For example, CXs 1 and 2, the earlier TV ads in evidence, unmistakably suggested that Aspercreme is an aspirin rub, which enables a user to put the relief of aspirin directly at the point of pain. CX 1, a TV commercial aired some 2,814 times from October 1978 through February 1980 (CX 25A), states in part:

> When you suffer from arthritis, imagine being able to put the strong relief of aspirin right where you hurt most.
>
> Now with amazing Aspercreme, you can get the strong relief of aspirin directly at the point of minor arthritis pain. [34]
>
> The strong relief of aspirin right where you hurt (both voice and video super).

CX 2, another TV commercial, aired some 1,400 times during 1979 (CX 25A), states in part:

> When you suffer from arthritis, imagine putting the strong relief of aspirin right where you hurt.
>
> Aspercreme is an odorless rub which concentrates the relief of aspirin.
>
> When you take regular aspirin, it goes throughout your body like this. (Video shows how regular aspirin tablets dissolve in the stomach, are absorbed in the blood and circulate throughout the body to reach the pain site in the left shoulder.)
>
> But, in seconds, Aspercreme starts concentrating all the . . . relief of two aspirin directly at the point of minor arthritis pain. (Video shows Aspercreme "concentrating all the temporary relief of two aspirin directly at the point of . . . pain" in the shoulder without going through the stomach and throughout other parts of the same body).

82. CX 9, a TV commercial which was aired in 1980 and 1981 (CX 25A), is an example of Aspercreme ads which do not contain "no-aspirin" video super or other aspirin disclaimer statements but state instead that "Aspercreme contains salycin, a strong non-aspirin pain reliever which penetrates right to the point of pain." CX 9 contains no other references to "aspirin." CX 9 is of some importance for the reason that it was copy tested by the parties separately for use in this litigation (CX 26, the ASI Theatre Test; CX 35/RX 520, the FRC Test; and CX 32/RX 500, the Lieberman Test) and was the subject of exten-

sive discussion by marketing expert witnesses of both parties at the trial.

83. Most of the more recent TV commercials for Aspercreme in evidence contain a short video super "contains no aspirin" (CX 3), or "relief without aspirin" (CX 4), or a phrase " aspirin [35] free" (CX 5). Several others contain, a statement "Aspercreme contains salycin, a strong non-aspirin pain reliever" without a "no-aspirin" video super of any type (CXs 9, 21–22). Still others contain a statement "it delivers an aspirin-like formula right in the lotion" (CX 19).

84. Several Aspercreme advertisements include affirmative statements to the effect that Aspercreme does not contain aspirin (*See* CXs 3–5, 9, 21–22, 37). These disclosure statements were added because the networks required them (Jasper, TR. 4739, 4746), and this fact indicates that the Aspercreme ads were construed as communicating an aspirin content message. Moreover, the disclosures in these particular advertisements were shown to be ineffective. With respect to CX 3 and CX 4, the "video super" is too brief in duration and disclosures obscure when compared to the repeated audio and video phrases such as "the relief of aspirin" (Cohen, Tr. 213–15; Ross, Tr. 6194). This conclusion is confirmed by CBS and the National Association of Broadcasters ("NAB"), both of which advised Thompson that a video super was insufficient to counter the net impression of these ads (See CXs 79–80, 88D). In fact, Thompson's own advertising agency had reached the same conclusion regarding the ineffectiveness of the video super (*See* CX 66B). The disclosure in the other advertisements were shown to be insufficient to overcome the aspirin content message conveyed by the brand name and the comparison to oral aspirin (Cohen, Tr. 218–22, 226–27; *see* CX 27). Moreover, some of these ads (*i.e.*, CXs 9, 21–22, 37) state that Aspercreme "contains salycin, a non-aspirin pain reliever." This phrase is ambiguous because it does not negate the impression that "Aspercreme" may also contain aspirin in addition to "salycin" (Ross, Tr. 6205–06; Silver, Tr. 5715, CX 92A).

85. In addition to the use of brand name "Aspercreme," most of the advertisements contain statements which may lead the consumer to conclude that Aspercreme is an aspirin rub. For example, a majority of the ads compare and contrast Aspercreme with pills (*i.e.*, aspirin tablets) (CXs 1–11, 21–22, 37). This direct comparison tends to lead consumers to conclude that Aspercreme contains aspirin and that Aspercreme is another form in which aspirin can be taken, that is, in cream form as opposed to pill form (Cohen, Tr. 558; Ross, Tr. 5985–87, 5988–89, 5991).

86. Another way in which the ads suggest that Aspercreme contains aspirin is to repeat the words "Aspercreme" and "aspirin" in the same

commercial (Cohen, Tr. 207). *See, e.g.,* CXs 1–4, 6–8). The two things viewers are likely to recall most from such ads are the name Aspercreme and the word "aspirin" (*Id.*). **[36]**

87. Many of the Aspercreme advertisements in evidence state more than once that Aspercreme provides "the strong relief of aspirin" (*See, e.g.,* CXs 1–4, 6–7, 10–11). In the print ads (CXs 6–7, 10–11), this statement appears in the subheadline, which is more prominent than the test (Cohen, Tr. 223; Ross, Tr. 6199). The phrase "relief of aspirin" is, of course, provided by aspirin (Ross, Tr. 6179–80). Indeed, Mr. Jasper indicated that, in creating ad copy, he would consider the phrase "aspirin's relief" to be an excellent way of communicating aspirin content (*See* Jasper, Tr. 4738). Even if "relief of aspirin" is understood to mean the relief of tablets containing aspirin (*See* Ross, Tr. 6181–82), the fact remains that the relief provided by such tablets comes from the aspirin they contain (Ross, Tr. 6182). Consequently, the phrase "relief of aspirin" may be reasonably understood to mean that Aspercreme provides the ingredient aspirin (*i.e.,* that Aspercreme's relief comes from aspirin) (CXs 60B, 79A).

88. Other phrases used in the ads which suggest aspirin as an ingredient include "like aspirin itself" (*See* CXs 6–7) and a comparison between Aspercreme, a topical rub, and "regular" aspirin (CXs 2, 4). These phrases may reasonably be construed to mean that Aspercreme is a form of aspirin rub (Cohen, Tr. 210–12, 223–24).

89. Some Aspercreme ads use visual images to reinforce the aspirin content suggestion. For example, in CXs 1–4, a woman holds two aspirin tablets while saying that Aspercreme enables you to put the "strong relief of aspirin right where you hurt." The aspirin tablets in the woman's hand are then replaced by a tube of Aspercreme. Two images are evoked: a product which places aspirin tablets at the point of the pain, and a product which contains aspirin tablets in a cream form.

90. The determination that the brand name "Aspercreme" is capable of suggesting to a consumer that the product is a form of aspirin rub is reasonable. When an advertisement, obviously addressed to a target audience of arthritics and rheumatics, touts "Aspercreme" as a new rub which enables them to concentrate the "strong relief of two aspirin" right where you hurt most without upsetting your stomach, its clear, dominant message is that "Aspercreme" is, as the name suggests, a form of aspirin rub which relieves minor pains of arthritis and rheumatism without the stomach upset you get from taking aspirin in a tablet form.

91. The determination that the Aspercreme ads discussed above contain express or implied claims that the product is a form of aspirin

rub is supported by the advertisements [37] themselves viewed as a whole and is confirmed by expert testimony (*e.g.,* Cohen, Tr. 206–29, Silny, Tr. 771–72, 814–16; Ross, Tr. 5985–86, 5991, 6197–98), consumer research, other documents showing how self-regulatory bodies (the National Association of Broadcasters and CBS) and Thompson's own advertising agency viewed the ads (CXs 79, 80, 92, 116).

92. The copy tests and other consumer research regarding the ingredient inferences viewers are likely to draw from the brand name "Aspercreme" and some of the Aspercreme commercials is confirmatory of the foregoing determinations. Such consumer research includes:

a. The ASI Interlock Experiment (CX 26)
b. The ASI Theatre Test (CX 27)
c. The Mapes and Ross Test (CX 50)
d. The FRC Test (CX 35/RX 520)
e. The Lieberman Test (CX 32/RX 500)
f. The Video Storyboard Test (CX 51)
g. The Schneider Focus Groups (CX 52)
h. The Nicholas Focus Groups (CX 53)

Of the above, the two ASI Tests (CXs 26 and 27) were conducted for the FTC counsel, and the FRC Test (RX 520/CX 35) and Lieberman Test (RX 500/CX 32), for Thompson. All of these four tests were designed and conducted for use in this litigation. Generally speaking, these copy tests and other research show that a significant number of viewers took the Aspercreme commercials to suggest that Aspercreme contained aspirin.

93. The Mapes and Ross Test (CX 50), is a copy test on CXs 1 and 2 conducted in May 1979 for Ogilvy and Mather, Thompson's advertising agency for Aspercreme, and is the only copy test which predated this litigation and sheds some light on the ingredient issue.

94. Ogilvy and Mather, Thompson's advertising agency, concluded from the Mapes & Ross Test (CX 50) that a substantial number of respondents who viewed CXs 1 and 2 had misinterpreted the commercials to mean that Aspercreme contained aspirin. Specifically, the verbatim comments were reviewed by several Ogilvy and Mather employees who marked the comments as showing "confusion" regarding the ingredients in Aspercreme (*See,* CXs 45B–C, 93, 94, 95, 96, 97, 98 (Admissions No. 24–27)). In September 1979, Barbara Thompson, an employee from Ogilvy's research department, sent a memo (CX 116) to the head of Ogilvy's legal department detailing the percentages of viewers who had "misinterpreted" the ads to mean Asper-

creme contains [38] aspirin. According to CX 116, of those viewers who confirmed they had seen the ads, 30% who saw CX 1 ("Stand-Up Presenter") and 21% who saw CX 2 ("Visible Men") "misinterpreted" the ads to mean Aspercreme contains aspirin (CXs 45B, 116 (Admission No. 15)). *Also see* CPF 112)

95. Thompson's criticisms of the reliability of the Mapes and Ross Test (CX 50) during this trial are somewhat undermined by the fact that representatives of Thompson had discussed the Mapes and Ross Test during a meeting with its advertising agency, Ogilvy and Mather, and based on that discussion, Thompson decided which commercial to air (CX 99A). Thus, Thompson has relied on the Mapes and Ross Test to make an important business decision.

96. The ASI Interlock Experiment (CX 26) was designed specifically to measure consumers' ingredient inferences from the brand names of three products in the topical analgesics product class, Aspercreme, Ben Gay and Mobisyl (a TEA/S cream similar to Aspercreme). The responses to an open-ended question "What ingredient or ingredients, if any, are suggested by the brand name?" are summarized below:

	Ingredient Mentions (in percentage)			
	Aspercreme (N=120)	Mobisyl (N=66)	Ben Gay (N=73)	Total Sample (N=259)
Aspirin	78%	8%	3%	39%
Creme	31	2	10	17
Mobil Oil/Gas/Motor Oil	–	12	–	3
Camphor	–	–	5	2
Heat	–	–	5	2
Penicillin	–	3	–	1
Silicone	–	3	–	1
Pain killer	–	–	4	1
Nengol	–	–	1	0
Benvereen	–	–	1	0
Benzedrine	–	–	1	0
Sedative	–	2	–	0
Benzoyl peroxide	–	–	1	0

(CX 26G, Table II).

97. The following tabulation of the ASI Interlock Experiment data demonstrates the ability of brand names of the [39] test products to suggest specific ingredients and dramatically confirms what common sense and daily experience would tell us about the brand name "Aspercreme":

Ingredient Type Mentions (in percentage)	Aspercreme (N=120)	Mobisyl (N=66)	Ben Gay (N=73)
Aspirin mentioned	78%	8%	3%
Other active ingredients without aspirin mentioned	0	5	19
Cream or other inactive ingredients without aspirin mentioned	5	17	11
No ingredient mentioned (Don't Know, None or Declined to Answer)	17	74	73

(CX 26J, Table IV).

98. Another conclusion suggested by the CX 26 data is that the product category (analgesic rub) alone does not generate an inference that the product contains aspirin or that the pain relieving ingredient in the product is aspirin. These results clearly show that the brand name "Aspercreme" produced a remarkably high level of aspirin mentions, while the names Ben Gay and Mobisyl showed low levels of aspirin mentions and that the name "Aspercreme" is capable of suggesting to many that the product contains aspirin (Cohen, Tr. 161–63; Silny, Tr. 771–72).

99. The purpose of CX 27, the ASI Theatre Test, was to investigate the effects of an Aspercreme commercial which contains an affirmative ingredient disclosure statement on viewers' perception of the products' ingredients, and specifically to determine whether such an advertisement (CX 9) effectively overcame the aspirin-content suggestion conveyed by the brand name "Aspercreme" (Cohen, Tr. 163–64; Silny, Tr. 773; CX 27B–C). In response to an unaided question, 17% of the survey respondents who remembered seeing CX 9 stated that CX 9 represented that Aspercreme contained aspirin. When an aided question was put, the proportion increased to 38% (CX 27F–H). **[40]**

100. The CX 27 data show that, in response to the unaided recall question ("what ingredient or ingredients, if any, did the commercial say Aspercreme [or Mobisyl] contained"), of the people who saw the Mobisyl commercial, only 1% thought Mobisyl contained aspirin, while 17% who saw the Aspercreme commercial containing an ingredient disclosure statement thought Aspercreme contained aspirin. In response to the aided recognition question (which read a list of ingredients to respondents and, as each ingredient was read, asked them whether that particular ingredient is contained in the product) only 5% of those in the Mobisyl group thought the product contained

aspirin, whereas 38% of respondents in the Aspercreme group thought Aspercreme contained aspirin. For every ingredient except aspirin, the recognition levels were statistically the same between the Aspercreme and Mobisyl groups (Cohen, Tr. 188–90; Silny, Tr. 814–15; CX 27G).

101. Thus, the ASI Theatre Test (CX 27) clearly shows that the tested commercial (CX 9) led more viewers to state that Aspercreme contains aspirin, despite the affirmative disclosure to the contrary, than did a competitive product in the same category. Significantly, more people thought Aspercreme contained aspirin (an ingredient the commercial says it does not have) than thought it contained salycin (an ingredient the commercial says it has). This indicates that the brand name Aspercreme creates a strong perception that the product contains aspirin and the affirmative ingredient disclosure statement is not effective in overcoming that perception (Cohen, Tr. 194–95; Silny, Tr. 814–16, 1068–69).

102. Respondents in the ASI Theatre Test (CX 27) were not limited to users of topical rubs or arthritis sufferers because it was a perception test. In such a test, there is no reason to believe that users and non-users of the product class would differ in their perceptions (Silny, Tr. 749, 778). Thompson's chief marketing witness, Dr. Ross, agreed that as a general principle of marketing research, usage or non-usage of the product category has no measurable impact on respondents' perceptions of what is represented in the test ad, and that in this study there were, in any event, no substantial differences between users and non-users in terms of their responses to the perception questions (Ross, Tr. 6234–35, 6240–42).

103. Thompson's other criticisms directed to the design and execution of CX 27 do not diminish the essential import of this ASI copy test (*See* RB 129–36; CPF 92–102).

104. Thompson, through its counsel (Davis and Gilbert), commissioned two copy tests of CX 9 for the purpose of this [41] litigation: The FRC Test (RX 520/CX 35) and the Lieberman Test (RX 500/CX 32). Davis and Gilbert retained Dr. Kenneth Warwick to design and execute the tests (Warwick, Tr. 5296). CX 9 contains an ingredient disclosure statement "Aspercreme contains salycin, a strong non-aspirin pain reliever." Dr. Warwick was aware of the possibility that the tests may be used in litigation and that he might be requested to appear as a witness (Warwick, Tr. 5364–71). Before the design and execution of the studies, counsel for Thompson showed Dr. Warwick a document that outlined the complaint allegations in this proceeding (*i.e.*, that the Aspercreme advertising implies that the product contains aspirin) (Warwick, Tr. 5371–73).

105. In the FRC Test (RX 520), while 2.9% of the respondents an-

swered "aspirin" in response to the unaided Question 1, "What was the name of the ingredient in the product you just saw advertised?", the aspirin ingredient answers increased to 22% in response to the aided Question 2, "Based on the commercial you just saw, does the product in the commercial contain aspirin?".

106. Question 2 is a straightforward and reasonable aided recall question and appropriate in light of the objective of the study. Although it suggests to a respondent that the product may contain aspirin and it can be answered in a yes/no fashion, it is not "leading" in the sense of signalling what the desired answer is.

107. The FRC Test (RX 520) shows that CX 9, an Aspercreme advertisement containing an affirmative ingredient disclosure statement, and shown under fairly optimal conditions for communication (respondents were told to pay attention, the ad was shown twice, and respondents were questioned immediately thereafter) led 3–22% of the respondents to say the product contains aspirin, and left an additional 10% confused as to whether the product contains aspirin (Cohen, Tr. 281–82; Silny, Tr. 841–42).

108. The Lieberman Test (RX 500) is the second copy test on CX 9 designed by Dr. Warwick, who also designed the FRC Test (RX 520). It was administered by Lieberman Research Suburban, Inc. ("Lieberman"). The reasons for conducting two copy tests on CX 9, both designed by Dr. Warwick, are not clear in this record. However, Dr. Warwick had not intended to do two tests in the outset (Warwick, Tr. 5401; CX 45Z–019 (Admission No. 46)). The decision to do the Liberman Test was made after FRC was completed and after Dr. Warwick communicated the FRC results to Davis and Gilbert. The Lieberman Test was then done at the request of Davis and Gilbert (CX 45Z–030 (Admission No. 64); Warwick, Tr. 5403). [42]

109. Dr. Warwick did not include in the Lieberman questinnaire a direct aspirin ingredient question which he had included in the FRC Test. Although Dr. Warwick testified that this was an improvement over the FRC Test design, which he characterized as "flawed," the evidence is also consistent with the conclusion that the direct ingredient question was dropped because it had produced results unfavorable to Thompson in the FRC Test.

110. A major defect in the Lieberman questionnaire is that the open-ended question ("What was the name of the ingredient in the Aspercreme—the product advertised?") was not followed by a probe or any aided question (in contrast to the FRC Test which had the direct, close-ended ingredient question) (CX 34B).

111. Also, as in the FRC Test (RX 520), the question in Lieberman was biased in that it suggested that there was only one ingredient, so

that respondents were permitted to answer with only one ingredient (Cohen, Tr. 263–64; Silny, Tr. 839).

112. Considering the fact that the test audiences had just twice seen CX 9 which states "Aspercreme contains salycin, a strong non-aspirin pain reliever," it is somewhat surprising that only 25% of the respondents named salycin (RX 500E). In any event, a probe would have made it possible for respondents to mention aspirin as well, since a salycin response does not negate the possibility that respondents may have thought the product also contained aspirin (Silny, Tr. 834). It is accepted in marketing research that an open-ended question is not respresentative of everything stored in respondents' minds (Silny, Tr. 835). As Dr. Ross, Thompson's marketing witness, stated, open-ended questions lead most respondents to play back only one theme or point. They do not draw out a complete or exhaustive list of all the things respondents may have on their minds. Rather, respondents will play back the dominant theme or primary impression and, having done that, will probably stop (Ross, Tr. 6260).

113. In the final analysis, there is no way to test whether a consumer does or does not take a certain meaning from an ad other than putting that direct question to the consumer and asking the consumer to affirm or deny that the claim was made (Ross, Tr. 6260–63). In other cases, Dr. Ross has relied on aided, close-ended, ultimate questions, such as the question in a *Sterling Drug* study which read, "Did the advertisement suggest or did it not suggest that Bayer worked better than any other aspirin" (Ross, Tr. 6264). And another Thompson witness agreed **[43]** that a probe following an open-end question is common and accepted in marketing research (Silver, Tr. 5941). The initial reasoning regarding questionnaire design that occurred to Dr. Warwick, a marketing researcher with 20 years' experience, was that since he was interested in aspirin, he should ask a direct question about aspirin (Warwick, Tr. 5457–58, 5470).

114. An aided or close-ended question (as in the FRC Test) may well have cleared up the confusion caused by the wording of Question 1, and would have given respondents a further opportunity to say whether aspirin as well as salycin was an ingredient (Silny, Tr. 834–35). Because no aided or close-ended question was asked, there is no way of knowing how much information respondents had in their minds that was not revealed in response to Question 1 (Cohen, Tr. 276).

115. In any event, the Lieberman Test (CX 32/RX 500) shows that CX 9, an Aspercreme commercial which contains a non-aspirin ingredient disclosure statement led, on the basis of an unaided question, about 3% of the test audience to name Aspirin as an ingredient in Aspercreme (RX 500C). This is substantially lower than the 17% level

produced by an unaided question in the ASI Theatre Test (CX 27), which also tested CX 9.

116. In sum, the three copy tests on CX 9 in evidence (CX 27, RXs 500 and 520), taken together, are generally confirmatory of my view that the non-aspirin ingredient disclosure statement contained in CX 9 is woefully insufficient.

(a) *The Video Storyboard Test (CX 51)*

117. CX 51, the Video Storyboard Test, was a copy test conducted for Thompson to measure the relative persuasiveness of CX 1 and CX 2. The methodology involved a shopping mall intercept approach in Bridgeport, Connecticut. The sample consisted of 100 persons selected from among the shoppers. Respondents were shown one of the test commercials, and the questionnaire was administered immediately thereafter (CX 51N).

118. The Video Storyboard Test does not shed any light on the issue whether there is an aspirin content representation in the tested ads. It was designed specifically to find out what main idea in the ad is of most interest to viewers (Cohen, Tr. 229–30; Ross, Tr. 6310–11). The questionnaire primarily asked respondents how interested the ad made them in trying Aspercreme, and what the main idea in the ad was (CX 51N). The study did not ask whether or not the advertisements suggested [44] that the product contains aspirin. It is obvious that the main idea of the Aspercreme ads is relief of arthritis pain (Cohen, Tr. 231). People might have given that answer on this test and still thought that a secondary idea of the ad was that the product contains aspirin (Cohen, Tr. 229–30).

119. Thompson's marketing witness Dr. Ross asserted that if respondents had perceived aspirin as an ingredient in Aspercreme as a result of seeing CX 1 or CX 2 in this test, the questionnaire afforded them opportunities to express this (Ross, Tr. 6002–03). However, in order to make the statement that Aspercreme contains aspirin, the respondent would have to believe that that was the one main idea the commercial was trying to get across (Cohen, Tr. 231). It cannot be determined from the responses to this test whether the ads led these respondents to the inference that aspirin is an ingredient in Aspercreme. To answer that question, a direct ingredient question must be included as was done in the ASI and FRC tests (Cohen, Tr. 232; CX 27 and RX 520).

(b) *The Schneider Focus Groups (CX 52)*

120. CX 52, entitled "An Analysis of Group Sessions on Aspercreme" (the Schneider focus groups), is a report of two focus group

sessions conducted for Thompson by David L. Schneider, Ph.D. (CX 52).

121. Qualitative research (such as the focus group), while lacking the "respresentativeness" of other types of marketing studies such as surveys, copy tests, and controlled experiments, is a widely used form of marketing research today. Trained moderators probe in very careful ways to elicit answers to the research questions (Cohen, Tr. 106).

122. The respondents in CX 52 had been given Aspercreme for a two week period of trial. All suffered from arthritis or some form of muscular aches or pains on a continuing basis (CX 52B–C). They were not shown any advertisements for Aspercreme, but had the Aspercreme package during the trial period. After the two week trial period, a number of people either thought the product they used contained aspirin or were confused as to the product's aspirin content (Cohen, Tr. 197–99, 552; CX 52K–N).

123. For example, CX 52 noted that respondents had relief expectations based on the idea that the product contained aspirin (CX 52M). Among the quotes cited were the following: "I wondered if it would be able to work since aspirin is [45] something you swallow"; "I figured they'd ground it up and mixed it with cream till it was smooth"; "When I saw it and saw 'Asper', I right away thought it must also have aspirin in it" (CX 52L).

(c) *Nicholas Research Focus Groups (CX 53)*

124. CX 53 is a report by Nicholas Research on three focus group sessions conducted for Thompson involving Aspercreme. No advertisements were shown to respondents, but they had been given Aspercreme packages to use for a ten-day trial period (CX 53F). The objectives of the study were to gain insight regarding respondents' arthritis symptoms, and the products they currently used for arthritis, and to determine their reactions to Aspercreme vis-a-vis other over-the-counter remedies after use (CX 53D).

125. A number of respondents in CX 53 believed that the product contained aspirin (Cohen, Tr. 552). For example, the moderator observed that respondents "were attracted to the name Asper/Aspercreme because it has aspirin in it, or it is full of aspirin" (CXs 53Z, Z–056). The moderator also reported that several respondents felt since Aspercreme contained aspirin they could substitute it for aspirin (CXs 53Y, Z–053). One respondent said, "I didn't take any aspirin [during the trial period]—the name—Aspercreme—I said to myself, 'Maybe it has aspirin in it—I'd be applying the aspirin to the localized area instead of taking it internally.' " And another respondent noted, "Don't need to take aspirin, since this contains aspirin in it" (CX 53Z–053; Cohen, Tr. 200).

(2) *Complaint Paragraph 10 (b):* The claim that Aspercreme is a recently developed drug product.

126. Thompson has represented, directly or by implication, that Aspercreme is a recently discovered or developed drug product. This representation was made in CXs 6–8, 10–11. The fact that Aspercreme advertisements made this representation is evidenced by the advertisements themselves and is corroborated by expert testimony (*See* CXs 6–8, 10–11; Cohen, Tr. 249–50).

127. The representation that Aspercreme is a newly developed product is made through the use of a bold headline which states "At last! A remarkable breakthrough for arthritis [**46**] pain: Aspercreme" (CXs 6–7, 10–11; Cohen, Tr. 250). If Aspercreme is a "remarkable breakthrough" which has "at last" been achieved, then consumers would reasonably conclude that it is newly discovered (Cohen, Tr. 250).

128. In CX 8, the headline states that "There's always been aspirin . . . Now there's Aspercreme." This headline suggests that the product is newly developed, and the message is reinforced in the first paragraph of the test, which reads: "Aspirin has been helping sufferers of minor arthritis pain for years. Now there is a different way to get relief. Aspercreme" (Cohen, Tr. 250).

(3) *Complaint Paragraph 10(c):* The claim that valid scientific studies have proven that Aspercreme is more effective than orally-ingested aspirin for the relief of minor pain of arthritis or rheumatic conditions.

129. Thompson has represented, expressly and by implication, that valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of minor pain of arthritis and rheumatic conditions. This representation was made in CX 7 and CX 8, a fact which is evidenced by the advertisements themselves (*See* CXs 7–8).

130. CX 8, a print ad, explicitly states that Aspercreme was "tested" and "proved" more effective than oral aspirin in treating tendonitis, bursitis, muscular, rheumatic and arthritic pains. CX 8 goes on to discuss a particular test done by "a leading specialist in arthritis and rheumatism," and describes that test as a "controlled clinical test" (*See* CX 8). From these statements, consumers could reasonably understand the "test" to be valid scientific proof of the proposition asserted in the ad—that Aspercreme is faster and better than aspirin. CX 7, another print ad, similarly represents that Aspercreme has been "tested," and that its superiority demonstrated by scientific tests conducted by "a leading arthritis specialist."

(4) *Complaint Paragraph 12(a):* The claim that Aspercreme is an effective drug for the relief of minor pain of arthritis and its symptoms.

131. Thompson has represented, expressly or by implication, that Aspercreme is an effective drug for the relief of minor [47] pain of arthritis and its symptoms such as inflammation. This representation was made in all of the advertisements in evidence, including CXs 1–22 and 37. Respondent does not dispute that it made this claim (*See* RB 142). However, none of the Aspercreme ads in evidence contain a claim that Aspercreme cures arthritis.

(5) *Complaint Paragraph 12(b):* The claim that Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor pain of arthritis and its symptoms.

132. Thompson has represented, expressly or by implication, that Aspercreme is as effective a drug as orally-ingested representation was made in all of the Aspercreme ads in evidence, including CXs 1–22 and 37. Respondent does not dispute that it made this claim (*See* RB 142-43). However, none of the ads in evidence contain a claim that Aspercreme cures arthritis.

(6) *Complaint Paragraph 12(c):* The claim that Aspercreme is a more effective drug than orally-ingested aspirin for the relief of minor pain of arthritis and its symptoms.

133. Thompson has represented, expressly or by implication, that Aspercreme is more effective than aspirin tablets because it works faster than aspirin tablets, or it works without aspirin's side effects such as stomach upsets, or both. Aspercreme ads in evidence which made such a claim include CXs 1–11, 21–22, and 37.

134. Many of the Aspercreme advertisements in evidence represent that Aspercreme provides the same relief as oral aspirin, only faster and/or with fewer side effects (Ross, Tr. 6164. *See* Cohen, Tr. 251, 253, 254; CXs 6–8). Consumers are interested in the end benefit of a product like Aspercreme (Ross, Tr. 6200), and the end benefit of a product which provides faster relief with fewer side effects is that it is more effective (Ross, Tr. 6164–65; Cohen, Tr. 254). Clearly, then, a claim of faster relief or fewer side effects is a claim of greater effectiveness.

135. In CX 8, the subheading states that Aspercreme "Works faster, safer than aspirin." This assertion of superior speed [48] and safety is a representation of superior effectiveness (Cohen, Tr. 254). The text of the ad then goes on to reinforce this message by explicitly stating

that "Aspercreme actually relieves pain, faster, safer, better than aspirin" (CX 8).

136. The claim of superior speed, which would be perceived as superior effectiveness (*See* F. 134, *supra*), is also made in CXs 2, 4, 6–7 (Cohen, Tr. 251, 253–54). CXs 6 and 7 both contain the direct statement that Aspercreme works faster than oral aspirin (Cohen, Tr. 253–54; CXs 6–7). Moreover, CX 7 explicitly states that Aspercreme was found to be "faster and more effective than aspirin" (Cohen, Tr. 254; CX 7). In CXs 2 and 4, Aspercreme's superior speed is demonstrated by the video portion of the commercials. In both instances, the video suggests that Aspercreme reaches the point of pain faster than oral aspirin since it goes directly to the point of pain instead of having to work its way through the body (CXs 2, 4; Cohen, Tr. 251).

137. Another element in Thompson's advertising that communicates superior effectiveness is the claim that Aspercreme, in contrast to oral aspirin, provides "concentrated relief" (Cohen, Tr. 252, 254–55; CXs 78A, 88C. *See* CXs 2, 4, 6–7, 10–11). A number of Thompson's advertisements represent that Aspercreme concentrates the drug directly at the point of pain, as opposed to regular aspirin which diffuses throughout the body (Cohen, Tr. 252, 254–55; CX 78A, 88C). Such a representation could reasonably create the impression that the relief provided at the point of pain by a concentrated product (*i.e.*, Aspercreme) would be superior to that provided by a product which travels throughout the body (*i.e.*, regular aspirin).

138. Confirmatory evidence that CX 2 conveyed a superiority message is found in the Mapes and Ross copy test (Cohen, Tr. 252–53; CX 50). The copy test showed that 44% of the participants who saw "Visible Men" (CX 2) played back a theme relating to the comparative superiority of Aspercreme over tablets (Cohen, Tr. 252–53; CX 50I). Many of these responses went to efficacy, with 27% of the respondents playing back "faster than tablets," 5%, "better than tablets," and 10%, "more effective than tablets" (CXs 50P, V–Z–031).

139. Further confirmation that the challenged superiority claims were made is provided by letters from NBC and the NAB (*See* CXs 78A, 88C). Both of these specialists in the field of communications wrote to Thompson to indicate that a claim of superiority to aspirin was being made (*Id.*).

140. Dr. Ross, Thompson's expert witness, agreed that a claim of faster relief, or relief with fewer side effects, is a [**49**] superiority claim. He stressed, however, that the superiority claim in these Aspercreme ads referred not to the product ingredients or formulation but to the modes of product application—topical versus oral (*See* Ross, Tr. 6165). However, to the consumer, what is important is the end benefit of the product (pain relief), not how that benefit is achieved

(Ross, Tr. 6201), and a superiority claim in these Aspercreme ads will be understood to mean that Aspercreme is a superior pain reliever than aspirin tablets. By the same token, an ad claim which compares Aspercreme with aspirin and says Aspercreme is faster or safer than aspirin tablets is a "comparative claim" in a real sense, although it does not name the aspirin tablets being compared by brand name.

(7) *Complaint Paragraph 12(d):* The claim that Aspercreme is an effective drug for the relief of minor pain of rheumatic conditions.

141. Several Aspercreme advertisements in evidence represented, expressly or by implication, that aspercreme is an effective drug for the relief of minor pain of rheumatic conditions. They include CXs 7–8, 13–14, 16–20. Respondent does not dispute that some Aspercreme ads contain a claim that Aspercreme is effective for the relief of minor pain of rheumatic conditions (RB 142–43). However, none of the Aspercreme ads in evidence suggests that Aspercreme cures rheumatic diseases.

(8) *Complaint Paragraph 12(e):* The claim that Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.

142. Many Aspercreme ads in evidence represented, expressly or by implication, that Aspercreme acts directly by penetrating through the skin to the site of arthritic pain. They include CXs 1–4, 6–11, 21–22, 37. Respondent does not dispute that it has represented that Aspercreme penetrates directly from the skin to the point of arthritic pain (RB 143–44). **[50]**

(9) *Complaint Paragraph 12(f):* The claim that Aspercreme has no side effects.

143. It is true that several Aspercreme advertisements expressly represented that Aspercreme has "no" side effects (CXs 6–8, 10–11). However, when viewed as a whole, each ad was clearly saying no more than Aspercreme does not cause stomach upsets as oral aspirin is known to do. In my view, these ads can be reasonably construed to say (1) that Aspercreme is a topical rub and does not cause stomach upsets and other side effects associated with aspirin tablets, or (2) that Aspercreme is a safe product and does not have any side effects to worry about. In the context of these ads, a claim of "no side effects" will be taken to mean "no *significant* side effects."

(10) *Complaint Paragraph 14:* The claim that Thompson possessed and relied upon a reasonable basis for the efficacy and safety claims contained in Aspercreme advertisements.

144. Thompson has represented, directly or by implication, that it possessed and relied on a reasonable basis for Aspercreme's efficacy and safety claim contained in the advertisements in evidence, including CXs 1–22 and 37. This determination is evidenced by the advertisements themselves and supported by expert testimony (Cohen, Tr. 256–59; Ross, Tr. 6461).

145. Consumers generally believe that there must be a basis for efficacy and safety claims for OTC drugs or advertisers would not be allowed to make them (Cohen, Tr. 256–59; Ross, Tr. 6461). Consumers assume that this basis would be the kind of support or proof that would be acceptable to the medical/scientific community or the FDA (Cohen, Tr. 256–57; Ross, Tr. 6462). Hence, all Thompson's advertisements which made efficacy or safety claims implied that there is an appropriate scientific basis for these claims.

146. Several Aspercreme ads in evidence also reinforce the reasonable basis representation through the use of various trappings of scientific support. These trappings include explicit representations of "controlled clinical test" (CX 8), and other clinical proof (CXs 7, 20, 37), references to support in the medical community (CXs 7–8), and the use of a scientific model (CXs 2, 4). **[51]**

C. *The Use Of The Brand Name "Aspercreme" In Advertisement: Complaint Paragraph 16*

147. It is found that through the use of the brand name "Aspercreme" in advertisements, labels and promotional material, Thompson represented, directly or by implication, that Aspercreme contains aspirin as alleged in Paragraph 16 of the complaint. This determination is based on the advertisements and related consumer research in evidence and expert testimony regarding the use of the "Aspercreme" brand name.

148. The determination that many consumers are likely to take from the brand name "Aspercreme" a meaning that the product contains aspirin is reasonable and conforms to our common sense and daily experience. This view is also confirmed by the record evidence pertaining to this issue.

149. The brand name is the most salient part of a commercial (Cohen, Tr. 549). Consumers are more apt to be aware of and recall brand names than specific copy points made in advertising (Ross, Tr. 6317–19). The brand name is a more powerful stimulus and will be

remembered by consumers far longer than any specific advertising or copy points (Cohen, Tr. 559; Ross, Tr. 6319).

150. Respondent's expert witnesses do not dispute that a brand name is not only capable of communicating information about product ingredients but also capable of playing a role in creating beliefs about a product (Ross, Tr. 6315–17), especially during the product's introductory phase (Ross, Tr. 6341). However, they testified that most consumers will not construe "Aspercreme" to mean that the product contains aspirin (Ross, Tr. 5970, 5983–85; Silver Tr. 5797–99, 5804, 5815).

151. Dr. Ross suggested that a brand name immediately acquires a "secondary meaning" (which he defined as simply identifying or standing for the particular product), and that when it does, any associations the brand name may originally have triggered are immediately lost (*See* Ross, Tr. 5963, 6083).

152. Dr. Ross also took the position that a brand name is not deceptive where the consumer can, through information or experience, determine for him or herself whether or not the association suggested by the name is true (*See* Ross, Tr. 6333). This approach confuses the issue of whether a given advertisement is deceptive with the issue of whether the initial deception can be cured by other information or consumer's use [**52**] experience. In this connection, Dr. Ross agreed that the consumer will not generally search for further ingredient information in order to verify what he or she has been told in advertising (Ross, Tr. 6370. *Also see,* F. 179–86, *infra*).

153. On the other hand, Dr. Ross agreed that the brand name Aspercreme, in the context of an ad for an analgesic product, may convey to some consumers that the product contains aspirin, as distinguished from an ad where the brand name was "X" (Ross, Tr. 6197–98). Dr. Ross also recognized that if a consumer is in an "ingredient" frame of mind and comes upon the brand name Aspercreme in an analgesic context, "Aspercreme" would be associated with aspirin (Ross, Tr. 6231, 6277–78).

154. Mr. Jasper of Ogilvy and Mather testified about the creation of advertising for respondent. When asked upon cross-examination what name he would choose to indicate to consumers that a product was an aspirin-containing cream, Mr. Jasper felt that the most effective, straightforward name would be Aspirincreme, or Jay's Aspirincreme (Jasper, Tr. 4838–39). He then conceded that it would be reasonable for an advertiser/marketer to use a phonetic or alphabetic variation of the name Aspirincreme to convey the aspirin content message, and that the name Aspercreme could be viewed as such an alphabetic or phonetic variation (Jasper, Tr. 4839–40). Thompson's witnesses generally agreed that the name Aspercreme might sound

like aspirin to consumers (*See* Jasper, Tr. 4838–40; Ross, Tr. 6350; Silver, Tr. 5689, 5793–95).

155. Complaint counsel's expert witnesses, Drs. Cohen and Silny, both testified that the name Aspercreme strongly implies that the product contains aspirin (Cohen, Tr. 161–62, 549; Silny, Tr. 771–72). These opinions are based on their experience and the consumer research in evidence, including CX 26.

156. In the ASI Interlock experiment (CX 26), a controlled study designed to measure the impact of the brand name, some 78% of the respondents answered an open-ended question about ingredients by stating that the name Aspercreme suggested or implied that aspirin was in the product (CX 26G, F. 96, *supra*). By contrast, when the same generic product description was given to the Ben Gay and Mobisyl groups, only 3% and 8% responded that aspirin was suggested by those names. Thus, the generic product category, which was identified in the experiment by the description "for the relief of arthritis pain," does not generate the inference that aspirin is an ingredient. Although respondent's experts dismissed CX 26 as a word association game, it is reasonable to conclude that it is the name Aspercreme which led to the strong inference of aspirin content (Cohen, Tr. 161–63; Silny, Tr. 771, 1084). **[53]**

157. Two reports of focus group sessions (CXs 52 and 53) also support the proposition that the brand name Aspercreme is capable of leaving some consumers with the impression that the product contains aspirin. CX 52, a report of two focus groups done by David Schneider (*See* F. 120, *supra*), notes that "In a number of instances the *name* made one especially eager to try it, *for the aspirin association was evoked"* (CX 52K (emphasis in original)). The importance of the name's aspirin association is repeatedly emphasized in the report (*See* CXs 52K, M, N). Specific comments made by a number of consumers during the focus group sessions lends support to the conclusion that the brand name Aspercreme suggests aspirin to some consumers (*See* CX 52L). For example, a consumer stated: "When I saw it and saw 'Asper', I right away thought it must also have aspirin in it . . ." (CX 52L). The focus group participants had used Aspercreme for two weeks prior to the focus group sessions.

158. CX 53 is a focus group report by Nicholas Research (*See* F. 124, *supra*) and it provides further support for the conclusion that the name Aspercreme leads to the inference that the product contains aspirin (Cohen, Tr. 199). This focus group study was conducted at a different time and by a different moderator than CX 52, again with people who had used the product. CX 53 concludes that "others [*i.e.,* other respondents] were attracted to the name 'Asper/Aspercreme' because it has 'aspirin' in it" (CX 53Z-Z-056). The report also contains

the comments of several consumers who felt that, since Aspercreme had aspirin it it, they could take it instead of oral aspirin (CX 53Z–053).

159. Further evidence of the brand name's impact is provided by CX 27, the ASI Theatre Test. This study showed that the Aspercreme commercial tested (CX 9) led more viewers to state that Aspercreme contains aspirin than did a commercial for a competitive product, despite the presence of an affirmative ingredient statement "Aspercreme contains salycin, a strong non-aspirin pain reliever" in CX 9. It is also noteworthy that more people thought Aspercreme contained aspirin than thought it contained salycin, the very ingredient named in CX 9 (Cohen, Tr. 194–95).

160. The determination that the name Aspercreme suggests aspirin content is also confirmed by the fact that Thompson's own advertising agency recognized that the name would be so interpreted (*See* CXs 54Z, 55B–E, 60B). For example, in one agency memorandum discussing the aspirin content claim, it was noted that altering the "relief of aspirin" phrase would do nothing about "possible rub-off from the brand name" (CX 60B). Another agency strategy document refers to the "the 'aspirin' component of Aspercreme" (CX 54Z). [54]

161. From all of the foregoing, it is found that the brand name "Aspercreme" for an analgesic product is likely to mislead a significant segment of the target group (consumers of OTC analgesic drugs) into believing that the product contains aspirin.

D. *The Presence Of Aspirin Is A Material Fact In Advertisements Of An OTC Topical Analgesic Product Directed To Consumers Who Suffer From Minor Pains Of Arthritis And Rheumatism*

162. The presence of aspirin in an over-the-counter analgesic product is a material fact to consumers, particularly to arthritics, because aspirin is a commonly known pain reliever and widely associated with the relief of minor pain and other symptoms of arthritis. Many arthritics know that aspirin is a drug of choice for the treatment of minor arthritic pain and also that orally-ingested aspirin can cause stomach discomfort and other side effects. A topical product which provides aspirin relief by the external route without undesirable side effects of orally-taken aspirin would be highly material to those who suffer from minor pain and other symptoms of arthritis and who desire to avoid side effects of aspirin tablets. Essentially, Thompson does not dispute the foregoing proposition (*e.g.*, Ross, Tr. 6370–71, 6373; Silver, Tr. 5694, 5841–42; Warwick, Tr. 5323, 5390–91, 5395; CXs 54D, Z–005, Z–007).

163. The Lieberman Study (RX 500) and the FRC Study (RX 520), both conducted for respondent for use in this litigation, also contain

data which show a significant portion of the test subjects, and a majority of arthritics, preferred an aspirin product over a non-aspirin product for pain relief. In FRC, some 39% said they preferred aspirin products (Warwick, Tr. 5333–34), while in Lieberman, which tested only arthritics, some 53% expressed a preference for an aspirin product (Warwick, Tr. 5333–34; CX 32F). These are substantial magnitudes (Ross, Tr. 6371–72). Other consumer research evidence in the record also confirms the importance of aspirin content in analgesic products to consumers in general and arthritics in particular (CXs 50Z–005, Z–016, 52I–J, 53Z–025–29, 59O).

164. The opinion of Ms. Silver, Thompson's advertising expert, that the materiality of aspirin content is limited to internally-taken products and does not extend to a topical drug such as Aspercreme because consumers generally take topical products less seriously than orally-taken products (Silver, Tr. 5844–45) is contrary to the weight of evidence in this record. **[55]**

E. *Respondent's Argument That The Various Ingredient Statements Printed On Aspercreme Packaging Would Have Effectively Disabused Consumers Of Any Notion They May Have Taken From Aspercreme Advertisements That Aspercreme Is An Aspirin Product Is Contrary To The Evidence And Is Insufficient As A Matter Of Public Policy Against False Or Misleading Advertising*

165. Respondent suggests that since all Aspercreme packages from 1976 to the present, in one form or another, informed the purchaser that Aspercreme does not contain aspirin, consumers were not misled by the advertisements challenged in this proceeding (*See* RPF 304–15).

166. The law is long-settled that when the initial contact between a seller and buyer occurs through a deceptive drug advertisement, Sections 5 and 12 of the Federal Trade Commission Act are violated even if the truth is subsequently made known to the purchaser through information given on the label. *Carter Products, Inc. v. FTC,* 186 F. 2d 821 (7th Cir. 1951). In my view, the proposition that a marketer may mislead consumers in advertising provided the truth is disclosed to the purchaser at the time of purchase is utterly incompatible with any notion of truthful advertising and is unacceptable.

167. In any event, the information printed on Aspercreme packages was at best confusing and did not say unequivocally that Aspercreme does not contain aspirin until December 1982, almost two years after the administrative complaint was issued in this proceeding (*See* F. 169–78, *infra*).

168. Furthermore, the evidence is clear that consumers generally obtain their product information from advertising and that a large

portion of consumers do not read packaging information for ingredient information (*See* F. 180–82, *infra*).

169. RX 276 shows an Aspercreme package used in 1976, when Aspercreme was acquired from Sperti Drug Products, Inc. A two-line statement in small print at the bottom of the front panel states: "Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin" (RX 276A). The ingredient statement on the back panel states: "Active ingredient: 10% Triethanolamine Salicylate." In a large circle just below the ingredient statement, the following statement is printed: **[56]**

Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin. This externally applied analgesic works as effectively in giving temporary relief as many internal pain relievers without stomach upset or other undesirable side effects. Aspercreme produces its amazing results without the unnecessary sensation of heat.

170. RX 277 shows an Aspercreme package used by Thompson after January 1977. A printed statement on the front side (the lower half of RX 277B) and placed below the prominent "ASPERCREME" logo reads "An effective, deep-penetrating aspirin-like analgesic for temporary relief of occasional minor pains of ARTHRITIS, RHEUMATISM, BACK & MUSCULAR ACHES." At the bottom of the same panel, another statement in smaller print states: "Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin."

171. On the top side of the package (the middle segment of RX 277B), a prominent statement covering almost one half of the panel reads:

delivers an aspirin like*
analgesic directly
to the point of pain
*Salicylate

172. The upper 5/6 of RX 277B shows the back of the display panel and package forming a large, single panel. The statement shown on the top side of the package and quoted in the preceding F. 169 is repeated in smaller type. This statement is followed by (in much smaller type):

An effective, deep-penetrating aspirin-like analgesic for temporary relief of occasional minor pains of ARTHRITIS, RHEUMATISM, BACK & MUSCULAR ACHES.

On the bottom side of the package (the middle portion of RX 277B);

a statement appearing above the ingredient statement reads in part: [57]

Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin . . .

173. RX 278 shows an Aspercreme package bearing an expiration date "EXP APR 82" (RX 278B). The phrase "aspirin-like analgesic" appears four times: once prominently on the front display panel (top third of A), once in smaller type on the front side of the package (bottom third of A), and twice on the back panel (upper two-thirds of B). The phrase "an accepted analgesic chemically similar to aspirin" appears twice: once on the top side in small type, and once in much smaller type on the back panel.

174. RX 279 is an Aspercreme package bearing an expiration date "EXP 1/85" and is said to have been created in February 1981 (RPF 307). The front of the display panel ("fifth display panel") states prominently in red:

ARTHRITIS RELIEF
without aspirin

On the front side of the package, "relief without aspirin" is repeated in white print on brown background, to the right of which appears a statement "contains SALICYN, a strong non-aspirin pain reliever."

On the back panel, "RELIEVES PAIN FAST DOES NOT CONTAIN ASPIRIN" appears in white print on brown background in an oval inset, to the right of which appears a statement "Aspercreme delivers an effective non-aspirin analgesic directly to the point of pain." ". . . its strong, effective non-aspirin pain reliever" appears again in a smaller print.

The statement "Arthritis Pain Medication RELIEF WITHOUT ASPIRIN" appears on the bottom panel as well as on both the top and bottom closures of the package. Thus, the phrase "relief without aspirin" appears five times on RX 279.

175. RX 280 is an Aspercreme package for the 1.25 ounce size and was adopted in early 1981. The printed statements are almost identical to those of RX 279 in content and layout.

176. CPXs 5, 6 and 7 are Aspercreme packages which were purchased by complaint counsel in local drug stores during 1982. The printed statements contain such phrases as "Arthritis [58] relief without pills," "contains Salycin, a strong non-aspirin pain reliever," and/or "aspirin-like analgesic." However, none of them contain the phrase "Arthritis relief without aspirin," "Relief without aspirin," or "Does not contain aspirin" which were printed on RXs 279 and 280.

177. RPXs 3 through 6 are current Aspercreme packaging for the full line (the 3 ounce, 1 1/4 ounce and 5 ounce cream and the 6 ounce lotion (RX 286C)). RPX 3 was filed in the Thompson production department in August 1982 and appeared on some retail shelves as early as December 1982. RPXs 3 through 6 are expected to replace Aspercreme packaging on the retail shelves as existing product is exhausted (RX 286C).

178. RPXs 3 through 6 state in bold letters on the front and back of the package, including the fifth display panel: "without aspirin"; "aspirin-free"; "does not contain aspirin"; and "non-aspirin."

179. Respondent's principal advertising and consumer psychology expert witnesses, Dr. Ivan Ross and Ms. Jacqueline Silver, both testified that the package information would be read by those consumers who are interested in ingredients and that those who read it will understand that Aspercreme is not an aspirin product from the clear and prominent disclaimer statements printed on the package (*See* Ross, Tr. 6069–80; Silver, Tr. 5668–69, 5737–60, 5895–96, 5916–20).

180. Dr. Joel Cohen, complaint counsel's principal marketing expert, testified that, as a general principle, product labels are not an important source of product information for consumers and that advertising is a more important and dominant source of such information (Cohen, Tr. 244–45). In support of his expert opinion on the relative roles of advertising and labeling, Dr. Cohen relied on a FDA study entitled "Consumers and Medication." That study, based on a national probability survey, showed that in response to a question asking where people get their information on over-the-counter medicines and remedies, 43% replied advertising, while only 13% said labels (Cohen, Tr. 244–45). The survey also shows that older people are less likely to read labels than younger people (Cohen, Tr. 249). Arthritics are more likely to be older people. Older people are also likely to have a harder time reading labels, and may avoid reading labels in stores (Cohen, Tr. 247–48, 319; Silver, Tr. 5743). There is also a growing trend in the country to sell over-the-counter drugs in supermarkets. When people go to the supermarket they are not likely to spend time reading package labels because they generally would have a large number of items to buy (Cohen, Tr. 247). **[59]**

181. Thompson's witness, Dr. Ross, referred to another FDA study, and discussed the responses to two questions. The first asked "do you read the label for ingredients" and the second asked "whether label reading is necessary or important" (Ross, Tr. 6384, 6386–87). Although people view it as socially desirable to read labels (Ross, Tr. 6384–85), and such questions tend to bias the data by stimulating affirmative responses (Ross, Tr. 6392–93), 38% of the respondents

answered "no" or only "sometimes" to the question on the importance of label reading (Ross, Tr. 6385).

182. In another study referred to by Dr. Ross (the Houston and Rothschild study) label-reading behavior was observed and timed in a store environment (CX 407G). The study concluded that consumers do not read labels, even when advertising encouraged them to do so. The study found that consumers' knowledge about the product was enhanced only when they were provided with information in advertising (Ross, Tr. 6393–94; CX 407N–O). Dr. Ross also agreed that unless consumers have a special interest or concern, they are not apt to attend to what is on a package (Ross, Tr. 6358).

183. Dr. Cohen also testified that if a consumer is convinced by the advertising that the product has a certain ingredient, he or she is less likely to read the label for ingredient information (Cohen, Tr. 419). Since aspirin is among the most familiar OTC drugs, to the extent a consumer is led by advertising to think that a product contains aspirin, he or she is less likely to read the label for ingredient information (Cohen, Tr. 260–61, 326).

184. Dr. Cohen also testified generally that, even to those who do take the time to read the package information, such phrases as "aspirin-like," "similar to aspirin" or "contains Salycin, a strong non-aspirin pain reliever" do not specifically and unequivocally say that Aspercreme does not contain aspirin and merely tend to confuse the consumers (Cohen, Tr. 317–19, 323–24, 5743–44).

185. Ms. Silver, respondent's expert witness, agreed that the phrase "without pills" (CXP 5), is not a statement regarding ingredients (Silver, Tr. 5899) and that those packages which do not contain clear aspirin disclaimers like "without aspirin" or "does not contain aspirin" are less likely to convey a no-aspirin message to a reader (Silver, Tr. 5903–04). And, as Dr. Ross admitted, the phrase "contains Salycin, a strong non-aspirin pain reliever" does not negate the proposition that the product may contain aspirin as well (Silver, Tr. 6205–06). **[60]**

186. Further evidence that Aspercreme packaging information does not overcome impressions that the product contains aspirin is seen in the Schneider (CX 52) and Nicholas (CX 53) focus groups (F. 120–25, *supra*). There, respondents had Aspercreme packages during a trial period of ten days and two weeks. After presumably seeing the package information, a number of them felt that the product contained aspirin (CXs 52, 53; Cohen, Tr. 552; *also see* Cohen, Tr. 552–53; CX 34B).

V. CERTAIN MEDICAL CHARACTERISTICS OF RHEUMATIC DISEASES AND ARTHRITIS AND CONSUMER INJURY WHICH MAY RESULT FROM MISLEADING OR DECEPTIVE ADVERTISEMENTS TARGETED TO ARTHRITICS

A. *Rheumatic Diseases And Arthritis*

187. Rheumatic diseases cause pain and stiffness of the musculoskeletal system (Golden, Tr. 2681–82; CX 268, p. 35,454). The symptoms of the more common rheumatic diseases are joint and muscular aches, pain and stiffness, and joint inflammation (CX 268, p. 35,453).

188. Arthritis is a rheumatic disease which may be defined as inflammation of the joints (Roth, Tr. 1526; Ehrlich, Tr. 3991–92; O'Brien, Tr. 3733; Altschuler, Tr. 3014). The term "arthritis" may be broadly used as an umbrella for more than 100 rheumatic conditions involving discomfort around the joints (O'Brien, Tr. 3929–30; Ehrlich, Tr. 3991; CX 268, p. 35,454). Other types of rheumatic diseases involve muscles, tendons, ligaments, or bursae (a small sac of tissue between muscle and joint (Adriani, Tr. 1281–82)) and are referred to as rheumatism (CX 268, p. 35,454). A non-articular rheumatic condition is one which does not involve the joint, while an arthritic condition is one which involves the joint (CX 45M, No. 240).

189. About 90% of all arthritis is either rheumatoid or osteoarthritis (O'Brien, Tr. 3927–30; CX 268, pp. 35,455–57). Osteoarthritis (degenerative joint disease) is a very common disease, especially among the elderly. Rheumatoid arthritis, which occurs in both adults and juveniles, is a systematic disease, but is characterized by inflammation of the synovial joints (movable joints which have a cavity and are lined by a synovium, or joint lining which is a specialized connective tissue) (Adriani, Tr. 1271–72; Ehrlich, Tr. 3992–93; CX 268, p. 35,457). According to the Arthritis Foundation, osteoarthritis afflicts some sixteen million persons, and rheumatoid arthritis, seven million (O'Brien, Tr. 3930). **[61]**

190. It is a misconception to view arthritis as minor aches and pains, a non-lethal disease of old age for which nothing can be done (O'Brien, Tr. 3928–29; CX 268, p. 35,454). Arthritis is a serious public health problem. Arthritis, particularly rheumatoid arthritis, causes lost work time and money. About twenty-seven million work days are lost annually because of arthritis (Roth, Tr. 1536–37; CX 268, p. 35,455). Osteoarthritis is an aging population like ours is an increasing problem in terms of medical costs (Roth, Tr. 1536–37).

191. Many arthritic diseases interfere with a normal life by changing the quality and productivity of life (Roth, Tr. 1537–38). Arthritis and rheumatism are second only to heart disease as a cause of chronic limitation of major activity. About one in every five chronically housebound invalids has arthritis. Although arthritis cripples a large

number of persons each year, it kills relatively few. There is no other group of diseases which causes so much pain and suffering by so many for so long. Because of the tendency to cripple without killing, arthritis and rheumatism head the list of chronic diseases from the standpoint of social and economic importance (CX 268, p. 35,455).

192. The FDA OTC Internal Analgesic Advisory Panel concluded that accepted OTC antirheumatic agents, such as aspirin and other salicylate products, "should be used in the treatment of rheumatic diseases only under the advice and supervision of a physician" for the reason that "basically, each person with symptoms of the more common rheumatic diseases, *e.g.,* joint and muscular aches, pains and stiffness, and joint swelling should seek the advice of a physician for proper diagnosis of the specific cause of the symptoms and for identification of the exact rheumatic disease involved." The Panel concurred with the National Institute of Arthritis, Metabolism and Digestive Diseases ("NIAMD") which advised "If you have arthritis, do not try to treat yourself. All forms of arthritis must be treated by a qualified physician" (CX 268, p. 35,453).

193. More money is spent on unproven remedies and quackery than on arthritis research in the United States because people with arthritis are desperate and looking for cures (Roth, Tr. 1537).

194. Aspercreme is a topical rub promoted by Thompson for use as an analgesic for relief of various types of musculoskeletal pain. The active ingredient in Aspercreme is 10% triethanolamine salicylate (TEA/S). Aspercreme does not contain aspirin (Ans. at 4). Accordingly, the advertising representations that Aspercreme contains aspirin as alleged in Paragraph 10(a) and Paragraph 16 (the use of the brand name Aspercreme) is false. **[62]**

195. Strictly speaking, Aspercreme is not a recently discovered or developed drug product: Aspercreme has been available since 1971 and TEA/S, its active ingredient, has been in existence since at least 1954 (Ans. at 3). Strictly speaking, therefore, the implied representation that Aspercreme is a recently discovered drug is false. However, common sense argues that a relatively obscure product, such as Aspercreme in the late 1970's, should be allowed some leeway during the initial ad campaign in claiming novelty.

B. *Consumers Are Unable To Evaluate The True Pharmacological Effects Of OTC Analgesic Drugs Such As Aspercreme*

196. There is an important difference between a consumer's ability to perceive his pain relief and his ability to evaluate the true pharmacological efficacy of an OTC analgesic drug (Ross, Tr. 6426–29). *See Warner-Lambert Co.,* 86 F.T.C. 1398, 1495 (1975), *aff'd,* 562 F. 2d 749 (D.C. Cir. 1977), *cert. denied* 435 U.S. 950 (1978).

197. Most arthritis and rheumatism pain is characterized by peaks and valleys and spontaneous remissions and will often subside with the mere passage of time and without treatment (Adriani, Tr. 1271; Altschuler, Tr. 3072–73; Ehrlich, Tr. 4092–93; Golden, Tr. 2905–07; O'Brien, Tr. 3732–33, 3768–69; Silverman, Tr. 2334). Under these circumstances, consumers who use Aspercreme cannot evaluate whether any pain relief they perceived was the result of pharmacologic action of the product or due to mere passage of time (Ross, Tr. 6443–44). Nevertheless, they would attribute the perceived pain relief to Aspercreme (Ross, Tr. 6443–44; *see also,* Ehrlich, Tr. 4225; O'Brien, Tr. 3778).

198. A large number of the users of Aspercreme (and other TEA/S products) use other medications as well (Ehrlich, Tr. 4013, Ross, Tr. 6126; Tr. 2636 (Myoflex recommended for use as an adjuvant). *See* CX 45Z–016–17 (Admission No. 5); Golden, Tr. 2768). These consumers cannot evaluate whether the relief they perceived came from Aspercreme or from the other products they were taking (Ross, Tr. 6442).

199. Consumers are directed to apply Aspercreme by rubbing or massaging it into painful areas until it is well absorbed (*See* RX 282–83; RPX 3–6). Since rubbing alone is well-known to have a soothing effect in treating musculoskeletal pain (Ehrlich, Tr. 4060–61; Golden, Tr. 2768; Heller, Tr. 2622; Roth, Tr. 1630, 1750, 1753–54; CX 269, pp. 69,783–84), consumers are **[63]** unable to evaluate whether any relief they perceived came from the rubbing or from the pharmacological effect of Aspercreme (Ehrlich, Tr. 4088; Golden, Tr. 2768; Ross, Tr. 6442).

200. Placebo response refers to the relief perceived from a pharmacologically inert agent (placebo), and, therefore, not attributable to the agent's pharmacological effect (Altschuler, Tr. 3096; Ehrlich, Tr. 4107; Roth, Tr. 1549; CX 268, p. 35,444). Placebo response is a commonly observed phenomenon, particularly in situations involving analgesia (pain relief) (CX 268, p. 35,444). This is because the subjective nature of pain makes it particularly amenable to suggestion (Ehrlich, Tr. 4092, 4150–51). A drug must provide significantly greater relief than a placebo to be considered effective (Ehrlich, Tr. 4153–54; Roth, Tr. 1629; CX 268, p. 35,444).

201. The placebo response rate averages around 35% (Ehrlich, Tr. 4095–97, 4116–17; O'Brien, Tr. 3790), and may range as high as 60% (O'Brien, Tr. 3773; Roth, Tr. 1550). Placebo response has been extensively investigated by experts in the field of analgesics (O'Brien, Tr. 3790). In a frequently cited 1955 survey article, entitled "The Powerful Placebo," Dr. H. K. Beecher reported that placebos were highly effective, having produced an average response rate of 35.2% in over 1,000 patients in fifteen different clinical studies encompassing a wide

variety of conditions, including post-operative pain, headache pain, angina pain, nausea, cough, anxiety and tension, and the common cold (Ehrlich, Tr. 4095–97, 4116–17; O'Brien, Tr. 3790). The placebo effect is substantial in the case of arthritis (Silverman, Tr. 2337). For example, a published study on rheumatoid arthritis reported a placebo response rate of 50% to placebo pills (Ehrlich, Tr. 4127–29).

202. The placebo response is not just a short-term phenomenon. In the case of arthritis, placebo relief can last for as long as twenty to thirty months (Ehrlich, Tr. 4127–29; O'Brien, Tr. 3774–75). In a study of the placebo response in patients with rheumatoid arthritis, 31% of the patients experienced relief for a period ranging from two to twenty months (Ehrlich, Tr. 4127–29).

203. Consumer expectations also have a significant impact on the perceived performance of a product. Perceptions of performance are heavily influenced by expectations, and these expectations can carry through to consumers' evaluation of the product's performance. In other words, the higher the expectation of performance is, the higher will be the perception of performance (Ross, Tr. 6430–31, 6433). Studies have shown that, despite the fact that one cake was preferred in a blinded test as more moist, labeling the other cake as the preferred brand for moistness can lead consumers to perceive that the **[64]** other brand was more moist (Ross, Tr. 6431). Similarly, in a drug study where a placebo was given to two groups, one of which was told it was an energizer and the other told it was a tranquilizer, both groups responded in accordance with what they were told (Ehrlich, Tr. 4151–52).

204. Advertising can play a major role in creating expectations of relief for an analgesic product (Ross, Tr. 6435). And the impact of advertising is particularly significant on arthritics (Roth, Tr. 1539–40). Aspercreme's advertising created consumer expectations that the product would provide relief (Adriani, Tr. 1238; Ross, Tr. 6435; Roth, Tr. 1615–17). Hence, most Aspercreme purchasers buy the product with the expectation of relief (Ross, Tr. 6435). Thus, Aspercreme advertising may have significantly increased the placebo effect on Aspercreme users (Adriani, Tr. 1238; Roth, Tr. 1615–17).

205. The perception that a treatment is new results in enthusiasm and heightened expectations (Ehrlich, Tr. 4109; O'Brien, Tr. 3770–72, 3775–76; Roth, Tr. 1540). This, in turn, can lead to an exaggerated perception of the treatment's effectiveness (Ehrlich, Tr. 4109; O'Brien, Tr. 3770–72, 3775–76). Hence, the well-known comment that "we must use new drugs quickly before they lose their power to heal" (O'Brien, Tr. 3775–76; *see also,* Ehrlich, Tr. 4109; O'Brien, Tr. 3770–72). To the extent the ads claimed Aspercreme to be a newly developed

drug, consumers' expectations and perceptions of its value may well have been enhanced.

206. The effect of expectations on perceived product performance can be negated if expectations are discomfirmed by experience with the product (Ross, Tr. 6430–31, 6446–47). However, because of the self-limiting nature of rheumatic pain, the placebo response, the effect of concomitant medications, and the rubbing effect, consumers cannot accurately evaluate the true efficacy of Aspercreme (F. 197–99, *supra*). Under these circumstances, there is in fact no opportunity for usage to disconfirm consumer expectations, and each time consumers use Aspercreme they are reinforcing expectations they had when they came to the product in the first place (Ross, Tr. 6446–47).

C. *The Use Of An Unproven OTC Remedy May Cause Significant Physical And Economic Harm To Consumers Who Suffer From Rheumatic Diseases Including Arthritis*

207. The use of an OTC drug product, which is not significantly different from placebo, for self-medication to **[65]** treat rheumatic pain poses a real danger to the consumer (O'Brien, Tr. 3722; Roth, Tr. 1538–39). As indicated by Dr. Altschuler, a physician called as an expert by Thompson, in treating patients with rheumatic pain it is appropriate to address the underlying problem directly, rather than using a placebo for pain relief (Altschuler, Tr. 3043–44; *see* F. 190–92, *supra*). It is not true for patients with rheumatic pain that a placebo is helpful and safe to apply (Altschuler, Tr. 3093). A person with a disease (such as rheumatic disease) should not take an inert substance as therapy (O'Brien, Tr. 3935).

208. The failure to promptly diagnose and treat rheumatic diseases with effective medication can have serious effects upon the individual. Not all musculoskeletal pain is the same (Roth, Tr. 1767; CX 268, p. 35,454). The pain due to overexertion is different from the persistent, although not severe, pain of early rheumatoid arthritis, where the harm of not seeking timely evaluation and treatment is great (*Id.*). In some instances, relatively minor pain can be the first warning of very serious conditions (Roth, Tr. 1636).

209. There is significant harm to consumers when patients in early stages of a rheumatic disease use Aspercreme for minor pain and fail to seek effective therapy (Roth, Tr. 1615–17). Moreover, because of the consumer's inability to evaluate the true efficacy of OTC analgesic drugs, such usage may continue over a long period of time. If not diagnosed and treated properly and at an early stage, rheumatic diseases can lead to progressive degeneration and debilitation (CX 268, pp. 35,454-56). And although the pain associated with rheumatic diseases can sometimes be relieved by antirheumatic OTC analgesics,

the more serious underlying features of the disease, which often lead to progressive degeneration and the prospect of permanent physical disability, may go untreated (*Id.*). Thus, Thompson's own expert, Dr. O'Brien, agreed that it would be inappropriate for an arthritic to self-medicate with a product which in fact is not significantly better than placebo because he or she may thus substitute an ineffective and unproven remedy for a truly effective drug (O'Brien, Tr. 3722).

210. In terms of economic costs, a therapeutically inactive medication, no matter how inexpensive, is a costly drug to the consumer (Silverman, Tr. 2440–41), and to society as well. Not only is the consumer wasting his money (Roth, Tr. 1538–39) by the initial purchase, but because of his inability to evaluate drug efficacy the consumer can also be expected to make repeat purchases of the product. In the aggregate, expenditures for such products represent a waste of societal resources. There is more money spent on unproven remedies and quackery than arthritis research in the United States because people with [**66**] arthritis are desperate and looking for cures (Roth, Tr. 1536–37). Indeed, Ogilvy and Mather International, Inc., Thompson's ad agency which created the challenged Aspercreme advertising, has pointed to a $400 million industry in fraudulent arthritis remedies (CX 54C). The Arthritis Foundation has expressed its concern about ineffective remedies that burden society with their cost (O'Brien, Tr. 3952). The failure to treat rheumatic diseases with effective drugs can lead to lost work time and money by disease victims (Roth, Tr. 1536–37). Additionally, there is the problem of evolving medical costs where the disease progresses unchecked (*Id.*). For these reasons, an unproven remedy such as Aspercreme can cause significant economic harm to the consumer and to society as a whole.

D. *Costs And Benefits Of Requiring Thompson To Have A Reasonable Basis Of Support For Its Advertising Claims For Aspercreme*

211. For the reasons discussed herein above, there are substantial benefits to both individual consumers and society as a whole in requiring Thompson to have a scientifically acceptable and legally sufficient substantiation for its efficacy claims for Aspercreme. Although a pain study is not among the simplest, the costs to Thompson associated with such a requirement are relatively modest. Expert opinion in this case placed the cost of conducting a well-controlled clinical trial to demonstrate analgesic efficacy in the range of $10,000 - $15,000 per test (Adriani, Tr. 1175–76; Roth, Tr. 1562). Because one ideal study that would not require replication might well be more expensive than two acceptable clinical tests, requiring two adequate tests may be

more practical, even viewed from a purely economic standpoint (Roth, Tr. 1562–63).

212. It is apparent that the requirement for clinical trials is not burdensome when one considers the modest cost of conducting clinical testing in light of the costs associated with the marketing and advertising of an unproven drug product. In any event, on the basis of this record, imposition of the relatively modest cost of two clinicals cannot be reasonably expected to have a significant adverse effect on a manufacturer's plans to bring such an OTC analgesic drug product to the market.

213. For all of the foregoing reasons, the benefits of requiring Thompson to possess and rely upon the acceptable level of scientific substantiation for its Aspercreme efficacy claims clearly outweigh the costs involved in meeting that requirement. **[67]**

VI. ADEQUATE SUBSTANTIATION OF OTC ANALGESIC DRUG EFFICACY REQUIRES WELL-CONTROLLED CLINICAL TRIALS

A. *It Is Well Settled That Adequate And Well-Controlled Clinical Trials Are Required To Show The Effectiveness Of Drugs, Including OTC Analgesic Drugs*

214. It is well settled that well-controlled clinical trials are required to establish analgesic efficacy of a drug (Adriani, Tr. 1156; Roth, Tr. 1541–42; 46 FR 47,731 (1979)). *Also see, American Home Product Corp.*, 98 F.T.C. 136, 201, 376–81 (1981), *modified,* 696 F. 2d 681 (3rd Cir. 1983). [101 F.T.C. 698 (1983]

215. The 1962 amendments to the Food, Drug and Cosmetic Act explicitly incorporated the requirement of "adequate and well-controlled" "clinical investigations" for drug efficacy in general. 21 U.S.C. 355(d) (1976). The FDA regulations promulgated to implement the 1962 amendments set forth the essential elements of adequate and well-controlled clinicals. 21 C.F.R. 314.111(a)(5)(ii) (1982). The FDA has also determined that the 1962 Act's requirement for "clinical investigations" means that at least two adequate and well-controlled clinicals are required. 44 FR 51,512, 51,518 (1979).

216. The FDA's 1972 OTC drug review procedure provided by regulation that the same level of clinical evidence to show the effectiveness of a new drug be required to document the efficacy of an OTC drug on the market "unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the value of the investigation." 21 C.F.R. 330.10(a)(4)(ii) (1982). In this connection, the FDA has expressly rejected the contention that the standards for new drug approval are inappropriate for OTC drugs that have been on the market for a substantial period of time and

noted that they represent "what medical scientists today consider to be adequate proof of effectiveness." *See* FDA OTC Drug Review Policy Statement; 46 FR 47,729, 47,731 (1979).

217. The FDA's OTC Internal Analgesic Panel and OTC External Analgesic Panel have adopted similar requirements for adequate and well-controlled clinicals to show efficacy for OTC analgesic drugs (CX 268, pp. 35,444–45, CX 269, pp. 69,857–58).

218. Other corroborative evidence, such as long-term use of a drug in the market and reports of clinical experience with a drug is not an acceptable substitute for well-controlled [**68**] clinicals to show drug efficacy (Adriani, Tr. 1439–40; Roth, Tr. 1765–66; 46 FR 47,731 (1979)).

219. Thompson does not seriously dispute the general requirement that adequate and well-controlled clinicals are needed to establish drug efficacy. However, it has maintained that in the case of a mild and harmless topical analgesic drug (such as Aspercreme) that requirement should be greatly relaxed or dispensed with (Ehrlich, Tr. 4085–86; O'Brien, Tr. 3968–72; Steinberg, Tr. 5205–07, 5218–19). This position is contrary to the prevailing and accepted view of the medical scientific community and has been rejected by the FDA (F. 216, *supra*).

220. There is no adequate substitute for clinical trials to demonstrate the efficacy of a drug for pain relief. The FDA panels on internal and external analgesics both noted that pain is a subjective experience (CX 268, p. 35,444, CX 269, p. 69,857). When a clinical trial involves subjective reports such as pain, the elements of a well-controlled clinical trial are crucial. Hence, the efficacy of an analgesic drug cannot be shown simply by producing a number of positive studies if they are not adequate and well-controlled studies (O'Brien, Tr. 3784–85).

221. The FDA Internal Analgesic Panel and External Analgesic Panel also explicitly rejected animal screening tests, experimental pain, bioavailability studies, and other artificial measures as substitutes for clinical trials to show drug efficacy (CX 268, p. 35,444, CX 269, p. 69,857). Both panels concluded that efficacy of analgesic drugs must be appraised by accepting the subjects' own reports on indices of pain experiences (CX 268, p. 35,444, CX 269, p. 69,857).

222. The medical scientific community requires replication of the results of a clinical test involving an analgesic drug (Adriani, Tr. 1438; O'Brien, Tr. 3796–97; Roth, Tr. 1541). The FDA panels on internal and external analgesics both require a minimum of two positive well-controlled trials by different investigators or laboratories to demonstrate the effectiveness of an analgesic drug (CX 268, p. 35,445, CX 269, 69,858). Replication is necessary because there is a potential for systematic bias and random error in any clinical trial; the methodolo-

gy may be insensitive, or the wrong conclusion may be reached by sheer chance (O'Brien, Tr. 3798). Moreover, even an experienced investigator may use an aberrant methodology, or some unexpected flaw or anomaly in the randomized population may bias the test results (Roth, Tr. 1561). Other possible sources of systematic bias include the geographic location of the trial and idiosyncracies in the way the data are collected (Adriani, Tr. 1174, 1333). **[69]**

B. *Elements Of A Well-Controlled Clinical Trial*

223. Over a period of years, a number of standards for an adequate and well-controlled clinical trial have been developed by the medical scientific community. In regulation promulgated under the 1962 amendments to the Food, Drug and Cosmetic Act, the FDA has codified these standards. 21 C.F.R. 314.111(a)(5)(ii) (1982). The FDA has expressly adopted these same standards for proof of effectiveness of OTC drugs. 21 C.F.R. 330.10(a)(4)(ii) (1982). The record shows that the standards set forth in these FDA regulations are those accepted by the medical/scientific community as a whole (Adriani, Tr. 1158; Ehrlich, Tr. 4066–67; O'Brien, Tr. 3745; Roth, Tr. 1541–42). The reports of the FDA panels on internal (CX 268) and external analgesics (CX 269) also reflect the testing standards the medical/scientific community would apply in the case of analgesic drugs (Adriani, Tr. 1159).

224. The standards commonly used to evaluate the adequacy of a clinical trial for establishing the efficacy of a drug include: (1) a written protocol or plan for the study; (2) a suitable control; (3) adequate blinding of subjects and investigators to minimize bias; (4) randomization of treatments; (5) qualified investigators; (6) an appropriate patient population; and (7) appropriate statistical methods to evaluate the results (*E.g.,* CX 269, pp. 69,857–58).

225. A written protocol which defines the study's objectives and methods is a critical element of a well-controlled trial (Adriani, Tr. 1167; Ehrlich, Tr. 4067–68; O'Brien, Tr. 3754–55; Roth, Tr. 1551). The protocol should be written before the study is conducted (Adriani, Tr. 1167–68; CX 45I (Admission No. 147)). It should describe the essential elements of the study design as well as the analysis plan, including the scoring system to be used in evaluating the results (Adriani, Tr. 1169, 1199–200; Roth, Tr. 1551–52, 1555–56, 1591–92; CX 269, p. 69,-858). Departures from the protocol should be minimized to insure the validity of the ultimate analysis (Ehrlich, Tr. 4067–68; O'Brien, Tr. 3754–55). Any major change or amendment to the protocol should be in writing (Adriani, Tr. 1169; O'Brien, Tr. 3753–55; Roth, Tr. 1551). Data for a subject who breaches the protocol in a meaningful manner, by not taking the drug as directed or by otherwise acting inconsistently with the protocol's directions, should be discarded (Ehrlich, Tr.

4067–68; O'Brien, Tr. 3759–60). Including the analysis plan in the protocol is essential to protect the integrity of the study (Adriani, Tr. 1199–200; Roth, Tr. 1591–92). Selecting the statistical analysis and scoring system in advance guards against conscious or unconscious bias on the part of the investigator. **[70]**

226. In order to minimize bias, a well-controlled clinical trial should incorporate at least one of four types of controls that are generally recognized as providing a comparison of treatments in a way that permits quantitative evaluation of the results. A study may incorporate a placebo control that compares the result of a test drug with an inert substance designed to resemble the test drug. When objective measurements of effectiveness are available and the placebo effect is negligible, comparison of treated and untreated subjects may be appropriate. In circumstances involving diseases with high and predictable mortality and uniform symptoms, an historical control may be used, whereby the results of a new treatment are compared with case histories in similar patient populations. An active treatment control (use of an effective therapy for comparison) may be appropriate in some circumstances, such as a condition where withholding treatment of administering a placebo would be against the interest of the patient. 21 C.F.R. 314.111(a)(5)(ii)(a)(4) (1982).

227. In an analgesic trial, it is not appropriate to use "no treatment" as a control. Pain is a subjective sensation (Adriani, Tr. 1160–61; CX 269, p. 69,857). And the placebo effect is known to be substantial. Also, the use of an historical control is not appropriate because there is no reason not to use a current control (O'Brien, Tr. 3750–51). Moreover, since all pain is subjective and musculoskeletal pain fluctuates, use of an historical control for a drug like TEA/S is inappropriate.

228. A placebo control is commonly required for a clinical trial of an analgesic drug in order to provide a consistent variable to determine whether a drug has a pharmacological effect (Adriani, Tr. 1423–24; Roth, Tr. 1549). A placebo control is particularly important in a study involving a drug for relief of pain because administration of a placebo produces a response that resembles the response to a mild analgesic (Adriani, Tr. 1164–65; Roth Tr. 1550; CX 45J (Admission No. 165), CX 268, p. 35,444). Establishing the sensitivity of the methodology used is important in the case of a clinical trial of a mild analgesic (Adriani, Tr. 1441–44; O'Brien, Tr. 3801–02; CX 268, p. 35,445). Accordingly, a clinical trial comparing a known analgesic to a test drug should incorporate a placebo control if the effectiveness of the test drug has not been established (Adriani, Tr. 1441–44; Roth, Tr. 1563–65). Especially in the case of rheumatoid arthritis and osteoarthritis, an uncontrolled trial is not reliable because the placebo effect may account for the good results (O'Brien, Tr. 3926–27). **[71]**

229. An analgesic trial should be double-blinded (CX 268, p. 35,444, CX 269, p. 69,857). An effective double-blind is critical in analgesic studies because they record patient's subjective responses. Effective blinding requires that neither the bottles, the physical characteristics of the test substance (such as taste and smell), nor the data sheets give any clue as to the identity of the substances used in the trial (Roth, Tr. 1548). Blinding both the subjects and the investigators is required to minimize bias (Adriani, Tr. 1162–63; Golden, Tr. 2959; O'Brien, Tr. 3782–83; Silverman, Tr. 2404). Single-blind studies are not acceptable for mild to moderate analgesics (Adriani, Tr. 1422). 21 C.F.R. 314.111(a)(5)(ii)(c) (1982).

230. In a well-controlled clinical trial, test subjects should be assigned to treatment groups in a manner that reduces bias, yet seeks to assure comparability of the test and control groups in terms of relevant variables such as sex, age, severity of condition, and the like. 21 C.F.R. 314.111(a)(5)(ii)(2) (1982). Therefore, an appropriate randomization procedure should be used so that these variables balance out (Adriani, Tr. 1165–66; Roth, Tr. 1543–44; CX 268, p. 35,444, CX 269, p. 69,857).

231. A clinical trial should be conducted by an experienced investigator with an appropriate background in the disease being evaluated (Roth, Tr. 1558; Silverman, Tr. 2311). The personnel who administer the test should also be experienced, as well as properly trained and instructed in using the measures involved in the clinical trial (Adriani, Tr. 1172; Roth, Tr. 1558–59).

232. In an analgesic trial of a drug intended for relief of various types of pain, a sufficient number of subjects with each of the appropriate types of pain should be studied (Silverman, Tr. 2311; CX 269, p. 69,857). The number of subjects should be sufficient to permit statistical analysis of the data, eliminate bias, and take the placebo effect into account. The subjects should be of both sexes and should be within the age range that would use the test drug (CX 269, p. 69,857). For clinical studies of OTC analgesics, each treatment group should contain between thirty and sixty subjects. *See American Home Products Corp.,* 98 F.T.C. at 202–03.

233. For a test of an antirheumatic drug, patients with suitable inflammatory rheumatic diseases should be selected (Adriani, Tr. 1159–60; CX 268, p. 35,468). Subjects should be grouped and studied by disease category (CX 268, p. 35,468).

234. An analysis of the results of a clinical trial is usually reported in terms of statistical significance so that the degree of confidence in the results can be assessed. In biomedical trials, 95% confidence level (or P value not greater [72] than of 0.05) is the accepted standard for statistical significance (Adriani, Tr. 1170; Ehrlich, Tr. 4068–69; Freu-

denthal, Tr. 4983; Roth, Tr. 1556–57; Silverman, Tr. 2317; CX 45Y (Admission No. 148)). In a clinical trial to determine whether treatments are significantly different from each other, a finding of statistical significance at the 95% confidence level means that there is a chance of only one in twenty that the difference observed may be due to chance alone.

235. When the results of a clinical trial have been determined to be statistically significant, the next question is whether the results are also clinically important. Statistically significant results may be clinically so small that the choice between two treatments may lack therapeutic significance (Adriani, Tr. 1171; Roth, Tr. 1557). Accordingly, statistically significant differences can be clinically insignificant.

236. For observed differences between treatments to be clinically significant, the differences must be real. A finding of statistical significance verifies that the observed differences are in fact real (Ehrlich, Tr. 4080–82). Thus, to be clinically significant, the observed differences between two treatments must be statistically significant in order to rule out the possibility that the differences are due to chance alone (Adriani, Tr. 1171–72; Roth, Tr. 1557–58).

237. In a comparative drug trial, the hypothesis being tested is that there is no difference between the two drugs (Freudenthal, Tr. 5007). Since it is not possible to prove a null hypothesis, one can only measure the differences between two treatments and assess whether or not the data are inconsistent with the null hypothesis (Ehrlich, Tr. 4169–70; Freudenthal 5008–09). A danger in evaluating clinical trials is to misinterpret a failure to demonstrate a difference between two treatments as meaning that the treatments are in fact the same. When differences are statistically significant, the results can be said to be due to essential differences in the drugs. When differences are statistically insignificant, however, this does not rule out the possibility that real differences may not exist (Ehrlich, Tr. 4170–72; Freudenthal, Tr. 5009–12; O'Brien, Tr. 3800).

238. Although pain relief cannot be ojbectively measured, there are appropriate objective measures of inflammation that can be used in a trial of an antirheumatic drug. These measures include grip strength, flexion, ring size, and walking time (Adriani, Tr. 1476; Ehrlich, Tr. 4017–18; Roth, Tr. 1545–47). Objective measures are useful in a clinical trial because multiple measurements can corroborate one another (O'Brien, Tr. 3781–82; Roth, Tr. 1553). Moreover, a subject's global [73] evaluation of the level of his pain may be difficult to interpret (Roth, Tr. 1668). Accordingly, a clinical trial incorporating objective measures, where possible, is preferable to a study based exclusively on subjective judgments (Silverman, Tr. 2402, 2411–13;

incorporated objective measures in clinical trials he conducted (Ehrlich, Tr. 4017–18).

239. In a clinical trial, the use of the test drug should conform to reality. The test subjects should use the drug in the same manner as a consumer would in terms of dosage level, method of application, and the like (Adriani, Tr. 1170; Roth, Tr. 1552; Silverman, Tr. 2312). Accordingly, patient subjects should be instructed to use the product correctly. Insuring that the subjects follow instructions is also important (Silverman, Tr. 2312). For example, oral instructions may be reinforced in writing; pill counts may confirm that subjects followed instructions; and urine and blood tests may demonstrate that the subjects actually used the medications (Roth, Tr. 1559–61).

240. The record is clear that the FDA requires, for OTC drug labeling purposes, two or more well-controlled clinical trials to show efficacy. In particular, the FDA OTC External Analgesic Panel and the FDA's Tentative Final Monograph on OTC Analgesic Products have applied the "well-controlled clinicals" rule to TEA/S and concluded that there was insufficient evidence to show TEA/S analgesic efficacy (F. 393–95, *infra*).

241. The obvious need for regulatory harmony and uniform standards governing the issue of OTC drug efficacy dictates that the same level of scientific evidence required by the FDA for OTC drug labeling/marketing be demanded by the FTC for OTC drug advertising with respect to the issue of efficacy.

242. The need to require adequate scientific evidence of efficacy is greater in cases where, as here, a relatively obscure topical product is being touted as a proven effective pain reliever for arthritis sufferers, a group singularly disposed to grasp at new promises of relief (F. 193, *supra*).

VII. THE CLINICAL TRIALS AND OTHER MATERIAL AND INFORMATION IN EVIDENCE FALL SHORT OF AN ADEQUATE SUBSTANTIATION FOR THE EFFICACY CLAIMS CONTAINED IN ASPERCREME ADVERTISEMENTS

243. The clinical trials Thompson relies on in this proceeding as evidence of efficacy are deficient in several important respects and none of them can appropriately be relied [**74**] on as an adequate and well-controlled trial which shows Aspercreme's effectiveness as an analgesic drug.

244. The most that can be said for Aspercreme is that it is being promoted as a topical analgesic for relief of mild pain and, *if shown to be effective,* can offer a topical alternative to OTC internal analgesic products, many of which are known to have significant adverse side effects especially at high arthritic dose levels. The record evidence clearly shows that the analgesic efficacy of Aspercreme remains to be

shown, although there is a modicum of evidence of some skin-penetration of salicylate molecules (bioavailability) (*See* F. 315–25, *infra*). Until the analgesic efficacy of TEA/S is established, however, much more than evidence of *bioavailability* is required. What is required is adequate evidence of *bioactivity*. This was precisely the reason why the FDA's External Analgesics Panel (CX 269) and the FDA's proposed rule governing OTC external analgesic products (CX 443 - Tentative Final Monograph dated February 8, 1982) both concluded that there is yet insufficient evidence to show the analgesic efficacy of TEA/S for labeling purposes under the Food, Drug and Cosmetic Act.

245. The clinical trials relied on by Thompson include the following purportedly well-controlled trials: the Golden study (RX 49/CX 200); the Golden-Altschuler study (RX 50/CX 214); and the so-called French studies by Drs. Patel and Chappelle (RX 34/CX 209; RX 35/CX 208; RX 36/CX 210; RX 37/CX 253 and RX 38/CX 266). *See* RB 39–49.

A. *The Golden Study (RX 49/CX 200)*

246. In 1976, Thompson asked Dr. Robert Marlin, its consultant, to design and set up a clinical study for Aspercreme (Marlin, Tr. 3183–85). Dr. Marlin knew that Dr. Golden was a board-certified rheumatologist and that Dr. Golden possessed the proper credentials to conduct the study (Steinberg, Tr. 5149–50).

247. Dr. Golden first did a pilot study to test the reaction of five patients to this product. He then wrote to Dr. Steinberg of Thompson and reported his preliminary finding that the product worked very well on patients with nonarticular rheumatic problems, that four out of the five patients experienced pain relief, but the fifth, who had severe osteoarthritis of the knee, was not helped (RX 47). Dr. Golden was encouraged by the results of the pilot study and agreed to conduct a full-fledged controlled clinical study (Golden, Tr. 2684–85; Steinberg, Tr. 5150–51). **[75]**

248. Dr. Marlin conferred with Dr. Golden and drafted a protocol for the study, with twenty patients in each group for a total of forty patients. In the opinion of Drs. Marlin and Golden, forty patients was a significant number of subjects from which to derive meaningful data (Golden, Tr. 2687–89; Marlin, Tr. 3183, 3186–87, 3452). Dr. Marlin recommended that Aspercreme be tested against aspirin because aspirin is known as the comparison drug in tests of nonsteroidal inflammatory drugs (Marlin, Tr. 3188, 3452). The study was set up as a double-blind trial with two groups of twenty patients, each group approximately equal in distribution of age, sex, and types of rheumatic pain (Golden, Tr. 2691).

249. In his capacity as coordinator and monitor, Dr. Marlin took

care of getting the test drug, the aspirin, and the placebo products from the manufacturer to Dr. Roslyn Freudenthal, a biostatistician. Dr. Freudenthal packaged the aspirin, placebo, and test medication in boxes that were unmarked except for a code number (Freudenthal, Tr. 4899). When Dr. Freudenthal had completed randomizing the medication to eliminate any possibility of bias, Dr. Marlin arranged for the medication to be sent to Dr. Golden's office (Marlin, Tr. 3209; Steinberg, Tr. 5151–52). The subjects in the study were primarily drawn from a pool of Dr. Golden's regular patients. After Dr. Golden had determined that the subject was acceptable under the study's protocol, the patient was given tablets and cream and instructed in the use of the medication (Golden, Tr. 2693). Dr. Marlin monitored the study by visiting Dr. Golden approximately once every week to ensure that the protocol was being followed. At that time, he also reviewed the case report forms with Dr. Golden (Marlin, Tr. 3124–25). It was Dr. Golden who collected the raw data (Golden, Tr. 2687–88). Dr. Marlin reviewed the data and forwarded the data to the biostatistician, who broke the code and analyzed the results (Golden, Tr. 2696).

250. The Golden study compared the pain relief achieved by the two groups; one group took aspirin tablets and rubbed a placebo cream into the painful area four times a day, the other group ingested a placebo and rubbed Aspercreme into the painful area four times a day (Golden, Tr. 2687–88). Dr. Freudenthal set up the code in such a manner that the study was completely blind. No one except Dr. Freudenthal had access to the code (Freudenthal, Tr. 4899–901). After the study was completed, Dr. Freudenthal conducted her analysis, wrote her report, and sent her report to Thompson (Freudenthal, Tr. 4904–08; RX 83).

251. Dr. Freudenthal's statistical analysis of the data showed that the group receiving the placebo tablets and Aspercreme rub did as well as and sometimes better than the group receiving aspirin tablets and the placebo rub (RX 82). There was a statistically significant greater number of patients **[76]** in the aspirin group that experienced adverse reactions. The report also showed a somewhat faster pain relief for the Aspercreme group (Freudenthal, Tr. 4908–09; Golden, Tr. 2698–700; Marlin, Tr. 3223–24; Steinberg, Tr. 5155–56; RX 49). The Golden Study was the test (or controlled test) referred to in CXs 7 and 8, print ads for Aspercreme. Dr. Marlin analyzed the data and reached conclusions similar to those of Dr. Freudenthal (Marlin, Tr. 3224, 3226).

252. The Golden study, however, failed to show a statistically significant difference between the experience of the aspirin and Aspercreme groups in terms of pain relief (Erhlich, Tr. 4165–66; Freudenthal, Tr. 5015–16; Steinberg, Tr. 5252–53; RX 83F–G). Also,

the Golden study does not show that Aspercreme is *more* effective than aspirin for pain relief (O'Brien, Tr. 3792). Nor did the Golden study measure or show that Aspercreme is effective as an anti-inflammatory drug (Ehrlich, Tr. 4164–65; O'Brien, Tr. 3793–94).

253. A failure to demonstrate statistically significant differences between drugs, however, does not mean that there are no real differences between them (F. 237, *supra*). It is not unusual for a clinical study to fail to distinguish between aspirin, a known active drug, and placebo. Thus, in a single clinical trial, the failure to show a difference between the two tested drugs does not mean that the two drugs are equally effective (O'Brien, Tr. 3798). Errors can occur; the methodology can be insensitive; or the wrong conclusion may be reached by sheer chance (*see* Ehrlich, Tr. 4188–89; Freudenthal, Tr. 4890–91, 4897–98).

254. In clinical trials of mild analgesics, it is important to insure the sensitivity of the test methodology (O'Brien, Tr. 3101–02). A comparison of two drugs, one known to be effective, is termed a positive control (Roth, Tr. 1563–65). If efficacy has not yet been established for the second drug, a placebo must be incorporated into the study design in order to demonstrate the sensitivity of the study's methodology (*Id.*). The Golden study tested Aspercreme against an active control (aspirin), but it did not employ a third group using only placebo pills and placebo cream, and thus was not placebo-controlled (Ehrlich, Tr. 4185; Freudenthal, Tr. 5013–14; Steinberg, Tr. 5252–53; *also see,* F. 228, *supra*). Since there was no placebo control, there is no way to evaluate whether the methodology of this study was sufficiently sensitive to pick up even the known difference between aspirin and a placebo (Ehrlich, Tr. 4187; Freudenthal, Tr. 5014). Accordingly, there is no way to determine whether the study failed to show a difference between aspirin and Aspercreme because no real difference exists or because the methodology used was not sensitive enough to show a difference between the [77] two (Ehrlich, Tr. 4178–79). For this reason, the Golden study's failure to distinguish between Aspercreme and aspirin cannot be considered meaningful in evaluating Aspercreme's analgesic efficacy.

255. Another reason for limiting the import of the Golden study is the truism that a clinical study which fails to show a difference between two drugs does not prove the null hypothesis (*see* F. 234, 237, *supra*). A test of statistical significance at the 95% confidence level enables us to determine whether or not we can reject the null hypothesis (Freudenthal, Tr. 5008). The null hypothesis can be disproven or rejected, but it cannot be proven that the null hypothesis is true (Frudenthal, Tr. 5008–09). Thus, a study which fails to show a statistically significant difference and fails to reject the null

hypothesis does not prove that the two drugs are equal (Freudenthal, Tr. 5012; *see* Freudenthal, Tr. 5009–12). Hence, the Golden study does not show that aspirin and Aspercreme are equally effective.

256. In her addendum to the Golden study (RX 83H), Dr. Freudenthal purported to calculate the type 2 (or beta) error—that is, the likelihood that aspirin is better than Aspercreme—and concluded it was less than .05 (Freudenthal, Tr. 4912–14, 5016–17, 5019–20). However, in calculating the beta error, Dr. Freudenthal did not use the formula that the power of a test is one minus the beta error (Freudenthal, Tr. 5017). Yet, this is the formula set forth by Dr. Mainland, the recognized statistical expert whose word Dr. Freudenthal accepts as authoritative (Freudenthal, Tr. 5008, 5017–19). Dr. Freudenthal's approach to beta error thus differs from Dr. Mainland's (*Id.*). Also, Dr. Freudenthal's results and conclusions are inconsistent with those found in an article by another well-recognized expert, Dr. Freireich (*see* Freudenthal, Tr. 5020–23). In calculating beta error, Dr. Freudenthal did not use any tables referring to the power of a test or to beta error; rather, she referred to tables of confidence intervals (Freudenthal, Tr. 5025–26). Yet, she did not know whether confidence intervals were used to evaluate alpha (type 1) error, rather than beta (type 2) error (Freudenthal, Tr. 5026–27). In later testimony, she defined confidence levels in terms of the likelihood of accepting a chance difference as real (*i.e.,* a type 1, or alpha error) (Freudenthal, Tr. 5033–34). Finally, Dr. Freudenthal did not know whether or not the method she used was the accepted method for calculating beta error (Freudenthal, Tr. 5025). Under these circumstances and for the foregoing reasons, Dr. Freudenthal's calculation of beta error and conclusions based thereon must be rejected as unreliable.

257. The failure of the Golden study to show a difference between aspirin and Aspercreme in terms of pain relief is [78] not surprising in view of its small sample size (twenty in each group). One indication of the consequences of inadequate sample size in the Golden study is that subjects with moderate osteoarthritis who were randomly assigned to the aspirin pills/placebo cream group did not experience pain relief (CX 200D). This result is clearly at variance with other studies of aspirin (Roth, Tr. 1582–83), and would tend to support the conclusion that the Golden study methodology was insensitive. This result may also be attributable in part to the small number of subjects in the study (Roth, Tr. 1767–68).

258. As acknowledged by respondent's own witnesses, and by authorities whose competence and views they acknowledged and respect, the smaller the number of subjects in a study, the more likely it is that the results will show no statistically significant differences between the drugs being tested (Ehrlich, Tr. 4220–22; Freudenthal,

Tr. 5013). As expounded by Dr. Emil Freireich, a recognized authority on the evaluation of clinical trials (Ehrlich, Tr. 4180–81; Marlin, Tr. 3418), comparative studies with small numbers of patients (*i.e.*, twenty-five patients or less in the active treatment group, and the same in the control group) will nearly always produce results showing no significant difference between the two groups (RX 383L). Indeed, Dr. Freireich termed comparative studies using twenty-five subjects or less in each treatment group as "pernicious" (*Id.*). Dr. Marlin conceded that in the Golden study (CX 200), all of the calculations involved sample sizes of twenty or less for each test group (Marlin, Tr. 3419–20).

259. The FDA's Internal Analgesic Panel and External Analgesic Panel recommended sample sizes of at least twenty-five in each group (active treatment and control groups) (Marlin, Tr. 3469–70; CX 268, pp. 35,444–45, CX 269, p. 69,862). In another FTC analgesic proceeding, experts agreed that a sample size of between thirty and sixty in each treatment group was appropriate in analgesic trials (F. 232, *supra*).

260. Dr. Marlin agreed that in analgesic studies (which employ subjective response methodology) one generally needs larger numbers of subjects in order to produce results showing a statistically significant difference between the test group and the control group. The reason is that when one is dealing with subjective responses, the variability is great. In contrast, in studies employing an objective rating methodology, a smaller number of subjects will suffice (Marlin, Tr. 3279–80).

261. The problem of small sample size in the Golden study was exacerbated by the fact that, as reflected in the published report (CX 200), the study data was broken down, after the study was completed, into a large number of smaller subgroups. As [**79**] explained by Dr. Roth, an expert called by complaint counsel, having conducted the study with twenty subjects each in the Aspercreme and aspirin cells, a number well below the recommended sample size, the results were further broken down into subsets that are so small as to make comparisons among them meaningless (Roth, Tr. 1580–81, 1584–85). For example, Table III at CX 200D shows that for patients who were experiencing severe pain at the start of the study, 14% of the subjects in the aspirin pills/placebo cream group subsequently rated their pain relief as "poor," while the same percentage (14%) of the subjects in the TEA/S cream/placebo pills group self-rated their pain relief experience as "excellent." The number of subjects involved in the table is seven in all, five in the TEA/S group and two in the aspirin group (who were experiencing severe pain at the start of the study). Thus, the 14% figures in fact mean *one* subject who experienced

"excellent" pain relief and another subject who experienced "poor" pain relief. Use of percentages based on cells of one or three patients is a breach of the accepted way in which comparisons are made, distorts the degree of difference in the test and control subjects' responses to the test substances and may lead to misleading conclusions (Roth, Tr. 1574–77, 1583). Respondent's own expert, Dr. Ehrlich, conceded that because of the sample sizes, the results do not constitute scientific, statistical proof and are merely suggestive (Ehrlich, Tr. 4164–65).

262. Complaint counsel's experts also criticized the *composition* of the small sample—specifically, that there was an unacceptably wide array of conditions and diseases among the subjects (Adriani, Tr. 1188). The forty subjects were experiencing pain from one or more of the following diverse diseases or conditions: osteoarthritis, rheumatoid arthritis, bursitis, tendinitis, myositis, fibrositis, muscle spasms, myalgias, sprains and strains (CX 213F–Z–057). According to rheumatologist Dr. Roth, it is inappropriate to compare arthritis of the hip to a strain in a non-weightbearing area (Roth, Tr. 1579). If there were subpopulations of significant size in the Golden Study, comparisons could appropriately have been made about the effect of the different treatments on persons suffering the same or similar conditions. As it is, however, the study is "comparing apples, oranges, tomatoes and peanuts" (Roth, Tr. 1579). In order to show a product's efficacy for arthritic pain, the study must have an adequate number of patients of each type of arthritis as subjects in the study (Adriani, Tr. 1189; CX 269, p. 69,862). Because the Golden study did not have sufficient number of subjects in the treatment group and in the control group of each type of syndrome represented among them, the study does not provide a reasonable basis for making analgesic efficacy claims as to particular medical conditions (Adriani, Tr. 1198). [80]

263. There were other flaws in the methodology of the Golden study. One of the more important is the fact that the study did not screen out aspirin non-responders (Golden, Tr. 2805; Roth, Tr. 1581). For this reason alone, the FDA rejected the Golden study, indicating that the inadequate history of aspirin use among the test subjects, and the study's failure to screen out non-responders to aspirin, preclude acceptance of the treatment comparison because of the potential bias against aspirin in treatment responses and adverse reactions (Adriani, Tr. 1191; Roth, Tr. 1582; CX 443; *see* CX 342B).

264. Another significant problem with the Golden study concerns the data forms completed for each of the study subjects: the Background and Clinical Data form and the Patient Reporting Card form. These forms were defective in that, with respect to the substantial number of patients having multiple areas of pain, it was impossible

to determine from their forms where the patients had applied the cream and which area(s) of pain had been relieved (Golden, Tr. 2875–76; Marlin, Tr. 3378). Most of the Golden study subjects had at least two affected areas of pain (Golden, Tr. 2969; CX 213F–Z–057).

265. According to Dr. Marlin, the reason that patients were not asked to identify the specific site(s) of pain relief was that at the time the Golden Study protocol was designed, the focus of the study was on pain relief generally (Marlin, Tr. 3204). The implication of non-specificity in these forms, however, is that since the patient reporting forms used in the Golden study were similar to those subsequently employed in the Golden and Altschuler study (RX 50/CX 214), the inability to determine the *location* of pain relief from the forms detracts from the result claimed from the latter study that Aspercreme achieved statistically significant pain relief in non-weightbearing areas of the body.

266. A further problem that compounded the failure to pinpoint the location of pain relief on the Golden study patient forms is the fact that rheumatic disease, and particularly arthritis, is cyclical in nature. Thus, a study subject could come in with pain in the shoulder, but three days later could experience pain in the back or hip (Golden, Tr. 2880–81). The actual site of cream application thus could be different from the location of pain recorded on the diagnostic portion of the patient forms (*see, e.g.,* CX 213Z–030).

267. Also, as regards to completion of the patient forms, Dr. Golden acknowledged that due to the way the Clinical Data form and Patient Reporting form were designed, if a subject had six affected body areas of pain, the subject would record [**81**] "partial relief" rating regardless of whether he or she experienced pain relief in only one area or five. And there is no way on the face of the form that the person reviewing it could tell exactly in which affected area or areas the pain relief occurred (Golden, Tr. 2887).

268. Another problem with the Golden study is that several test subjects (seven in number, comprising 18% of the sample) were found to have taken one or more concurrent analgesic, antirheumatic, or mood-altering drugs (CX 45Z–022, Admission No. 4 (patients 1, 2, 6, 8, 10, 24, 31); CX 213S (patient 8)). The drugs included Tylenol, Medrol, Valium and Librium. Use of such concomitant medications is unacceptable in a non-crossover study and may have seriously affected the study results (Adriani, Tr. 1192; Roth, Tr. 1577). Moreover, since the subjects were not given a washout period from preexisting aspirin usage, it is unclear what was being measured as far as subjects in the aspirin/placebo cream group were concerned (Adriani, Tr. 1190–91). Thompson's expert, Dr. O'Brien, agreed that subjects using a significant amount of another analgesic or anti-inflammatory drug

should have been dropped from the data base (O'Brien, Tr. 3759–60). However, if you delete the data for these patients in order to eliminate the problem of concurrent medications, you further reduce the sample size of each subset, with the result that the value of the reported results is further diminished (Marlin, Tr. 3415–16).

269. The record also shows instances of significant protocol breach. For example, Dr. Golden included patients with articular (*i.e.*, joint) pain, patients who were outside the age parameters specified in the study protocol, and patients with mild to moderate pain as study subjects. These were not trivial deviations.

270. Departures from a study protocol should be minimized, and any major change or amendment to the protocol should be in writing. Dr. Golden did not make any written changes to the study protocol set forth at CX 213A–C (Golden, Tr. 2785). Although Dr. Golden testified that the protocol was subsequently amended orally, he was unable at his deposition to recall any amendments, either written or oral, to the study protocol indicated at CX 213A–C (CX 45Z–005 (Admission No. 257)). The claimed oral modification of the study protocol is also contrary to respondent's admission that Dr. Golden had "inadvertently" included patients with arthritic conditions as subjects in the CX 213 study (Golden, Tr. 2800; CX 45N (Admission No. 268)).

271. As regards the age range for subjects specified in the study protocol, Dr. Golden acknowledged that at least thirteen of the forty subjects (about 30%) were outside the age parameters specified (Golden, Tr. 2804). And despite the [82] protocol requirement that study subjects have moderate or severe pain, at least six of the forty subjects had only mild to moderate pain symptoms (Golden, Tr. 2831–32, 2834–35).

272. Another problem with the Golden study is the lack of consistency in Dr. Golden's "global evaluations" of his patient's condition following their participation in the study, which reflected his own subjective global opinion and was not based on any numerical scoring system (Golden, Tr. 2850, 2853, 2857–58). As a result, Dr. Golden was less than convincing in explaining some of his "global evaluations" at trial.

273. There are also some questions about the validity of the study's blinding process, based on comments by subjects about headache from the test agent's odor, and bitter taste (Roth, Tr. 1578–79). Finally, there are acknowledged errors in two tables and on three out of the six pages of textual material in the published report (Golden, Tr. 2923; Marlin, Tr. 3239–41, 3246; CX 200, Tables I and III, and pages B, C, and D). Dr. Marlin's explanation of the errors in the two tables was that they stemmed from the fact that data from different sources were

inappropriately combined and patient ratings of degree of pain were confused with the doctor's ratings (Marlin, Tr. 3243, 3246).

274. For all of the foregoing reasons, the Golden study (RX 48/CX 200) is not an adequate and well-controlled study, and its results cannot be relied on to demonstrate the efficacy of Aspercreme for pain and anti-inflammatory relief in this proceeding.

B. *The Golden And Altschuler Studies (RX 50/CX 214)*

275. In 1977, Dr. Steinberg asked Dr. Marlin to design and develop a second study for Aspercreme, a study that would compare Aspercreme to a placebo cream (Marlin, Tr. 3254). Dr. Marlin decided to use two doctors and two sites so that a large patient population could be tested. Dr. Stanley Altschuler, an internist, was chosen as the second investigator and Dr. Golden again served as the rheumatologist (Steinberg, Tr. 5157–58). Dr. Marlin again drafted the protocol and reviewed it with the two investigators. The patients were to be divided into two groups, one which would apply the placebo cream and one which would use Aspercreme (RX 50). Dr. Marlin periodically visited each of the two investigators to monitor the study and to ensure that the protocol was being followed by both investigators (Altschuler, Tr. 3010, 3065; Golden, Tr. 2710; Marlin, Tr. 3257, 3259–61). [83]

276. Drs. Golden and Altschuler each instructed their patients to apply as much of the topical medication to the affected area as was possible and to record the pain relief experienced over a four hour period—at the one-half hour, one hour, two hour, and four hour marks (Altschuler, Tr. 3015–16; Golden, Tr. 2719–21).

277. Prior to the commencement of the studies, it was decided that the protocol should be changed to raise the maximum age allowable in the patient population because Dr. Golden was having difficulty finding patients that fit within the original protocol. The exclusion of patients with rheumatoid arthritis or osteoarthritis was also modified to allow for the use of these patients provided they had non-articular features which could be treated by the cream (Altschuler, Tr. 3085–86; Golden, Tr. 2714–17). These changes in the written protocol are not serious since the purpose of the study was to test the pain relieving properties of the test drug on non-articular involvement (O'Brien, Tr. 3755).

278. Dr. Freudenthal followed the same basic procedures that she had utilized in the Golden study. She prepared the randomization and the code, packaged the medication in unmarked boxes, then opened the code and analyzed the data after the study was completed (Freudenthal, Tr. 4915–16).

279. The Golden and Altschuler studies was thus a double-blind study, using ninety-six patients at two different sites, which tested

Aspercreme against placebo cream for the relief of various types of musculoskeletal pain. The results of the studies, including Dr. Marlin's 1981 analysis (RX 368F–I), fail to show any statistically significant differences overall between Aspercreme and placebo for pain relief (F. 281, *infra.*). This study was rejected by the FDA in the Tentative Final Monograph on OTC Analgesic Products, dated February 8, 1983 (CX 443D). The reason given by the FDA was:

> . . . Of the six results reported, only one was statistically significant. Furthermore, the selective reporting of these six results renders this report uninformative, and no conclusion can be made concerning the effectiveness of trolamine salicylate [TEA/S].

280. According to Thompson's expert witnesses, the results of the study indicated a clear tendency toward greater pain relief with Aspercreme than with the placebo creme at the one-[84]half hour and one hour marks. Twelve patients using Aspercreme, as against ten using the placebo, experienced complete relief at the end of at least two of the four time periods. And 58% of the Aspercreme subjects, as against 30% of the placebo subjects, reported relief for eight or more hours (Freudenthal, Tr. 4924–25; RX 82, 84). In patients who suffered from cervical (neck) pain, significantly more patients obtained relief with Aspercreme than with the placebo. This difference was statistically significant at the 95% confidence level (Freudenthal, Tr. 4925–26; Marlin, Tr. 3272; RX 82, 84). Groups of patients with pain in other areas were not large enough in size to compare, but analysis of the data in terms of weightbearing and non-weightbearing areas revealed that there is statistical significance for the superiority of Aspercreme at the one-half hour mark for non-weightbearing areas and joints, and in the cervical area, there is statistical superiority at one-half hour, one hour, and two hour marks (Freudenthal, Tr. 4925; Marlin, Tr. 3277).

281. The record shows that the overall results of the Golden and Altschuler studies fail to show any statistically significant differences between Aspercreme and placebo for pain relief (Adriani, Tr. 1195–96; Freudenthal, Tr. 4988; O'Brien, Tr. 3834; Roth, Tr. 1585; CX 45Z–021 (Admission No. 1); CX 214L). Three separate analyses of the data, including the initial analysis by Dr. Freudenthal (Freudenthal, Tr. 4988), and the subsequent reanalyses of the data first by Dr. Winick (Marlin, Tr. 3425–26) and later by Dr. Marlin (CX 45Z–021, (Admission No. 1); CX 214L), reached the same conclusion in this respect. Even using the Marlin analysis of 1981, it would be fair to say that none of the overall figures approached statistical significance at the 95% confidence level (Ehrlich, Tr. 4195; CX 214L). Rather, the likelihood that the differences measured were due to chance ranged from

slightly under 20% to over 90%, depending upon which time period is considered (*See* CX 214L).

282. Thompson relies heavily on the Marlin analysis, particularly on the subgroup involving non-weightbearing areas and joints, the only subgroup where statistically significant differences favoring Aspercreme could be shown on some of the time parameters (*See* Marlin, Tr. 3276, 3282; O'Brien, Tr. 3834). However, the Golden and Altschuler studies cannot fairly be interpreted as providing any reliable evidence of Aspercreme's superiority to placebo, even in non-weightbearing areas.

283. The original analysis of the Golden and Altschuler data by Dr. Freudenthal did not conclude that Aspercreme was superior to placebo in the non-weightbearing areas (Steinberg, Tr. 5246–47). In fact, placebo was equal or superior to **[85]** Aspercreme in three out of the five non-weightbearing areas that Dr. Freudenthal analyzed (*i.e.*, hands, shoulders, and arms) (*Id. See* RX 85J–L). Of the two areas where Aspercreme was superior to placebo (*i.e.*, cervical and back), only one (pain relief in the cervical area) was statistically significant. However, there were not enough subjects with cervical *arthritis* in the study for Dr. Freudenthal to reach a conclusion about statistical significance with respect to arthritis in the cervical area (Freudenthal, Tr. 4996). The fact that Dr. Freudenthal did not find that Aspercreme was superior to placebo in non-weightbearing areas is entitled to considerable weight. Not only was Dr. Freudenthal's the first and contemporaneous analysis, but also her analysis employing a non-parametric statistical test (Freudenthal, Tr. 4958–59) was of greater value than Dr. Marlin's later reanalysis employing a parametric test (O'Brien, Tr. 3838–39).

284. It is significant to note that the distinction between weight-bearing and non-weightbearing joints and areas came not from the study protocol or Dr. Freudenthal's biostatistical report, but from a computer analysis done by Dr. Marlin in 1981, three years after the study was conducted (Marlin, Tr. 3423; Steinberg, Tr. 5245). Such *post hoc* analysis of clinical data calls into question the integrity of the result because of the potential bias present in any rearranging or manipulation of data (Roth, Tr. 1591–92).

285. The rating scale to be used in a study should be developed and set forth in the protocol before the study is begun so as to avoid data manipulation (Adriani, Tr. 1199–200; O'Brien, Tr. 3757, 3759; Roth, Tr. 1591–92). The record shows that the scaling system used in the Golden and Altschuler studies (RX 50/CX 214) was developed by Dr. Marlin long after he had broken the code, learned what the raw data showed, and read Dr. Freudenthal's original biostatistical report (Marlin, Tr. 3423, 3427–28). This is an improper procedure and ren-

ders the results questionable (Adriani, Tr. 1199–200; Roth, Tr. 1591–92). Dr. Marlin acknowledged that the results of the Golden and Altschuler study can be significantly affected by the type of scaling system used (Marlin, Tr. 3429). The record demonstrates that Dr. Marlin's scaling system have affected the analysis in favor of Aspercreme (*See* CPF 354).

286. Another problem with the Marlin analysis of non-weightbearing joints and areas is the nature of the underlying data. The patient report forms used in both the Golden and the Golden and Altschuler studies did not require the patients to distinguish between weightbearing and non-weightbearing parts of the body in recording pain relief (Marlin, Tr. 3365). Moreover, for patients having two or more areas of pain, it was impossible in the years following the study to determine from the patients' [**86**] forms exactly the area(s) of the body patients applied the cream to and the areas of the body the pain relief ratings came from (Altschuler, Tr. 3062, 3065, 3066–69; Golden, Tr. 2954–56; Marlin, Tr. 3378). There were also many instances where the data summary sheets (CX 366Z–114–19) and the entries in individual patient forms were not in agreement (*See* Marlin, Tr. 3375–91).

287. It is well-recognized that if a body of data is divided into a large number of small cells, some statistically significant differences will eventually appear among some of them (*See* Marlin, Tr. 3433–34, 3475; O'Brien, Tr. 3841–42; Roth, Tr. 1587; (CX 417 received at 3847, 3848–49; CX 435F–G received at 3853, 3856)). This is called random statistical significance (Marlin, Tr. 3475; Roth, Tr. 1587–88). In the Marlin analysis, the summary table shows no statistically significant differences in the total sample (Roth, Tr. 1586; *See* CX 214L). The fact that after the data is divided into a large number of subsets, a few differences in the non-weightbearing areas can be shown to favor Aspercreme at statistically significant levels is consistent with the concept of random statistical significance (Roth, Tr. 1586–88).

288. Apart from the major problems related to data analysis and interpretation discussed hereinabove, the Golden and Altschuler studies suffer from several significant flaws in its design and execution. As with the earlier Golden study, the patient population included an unacceptably wide array of conditions and diseases (Roth, Tr. 1589–90).

289. There is also some question regarding the propriety of pooling the Golden and Altschuler study data in this case.

290. In the Golden and Altschuler study, the decision to involve a second investigator occurred after Dr. Golden's portion of the test had begun (CX 45Z–003 (Admission No. 213)). The study protocol did not provide for a multi-site clinical trial (CX 214Z–022–024). The study was to consist of 100 subjects to be studied by Dr. Golden. Only when

Dr. Golden expressed his doubts about finding the requisite number of subjects after his study got under way, the study was changed to a multi-site study (Marlin, Tr. 3255–57).

291. It is a requirement of a multi-site study that not only the same protocol be adhered to by all investigators, but also the patient groups be homogeneous in order that the data obtained from the different groups may be combined (Marlin, Tr. 3259–60; O'Brien, Tr. 3831). If the patients in the different groups are dissimilar or if they are being treated for different conditions, pooling the data is inappropriate (O'Brien, Tr. 3831). In the Golden and Altschuler study, [87] Dr.Golden, a rheumatologist, provided mostly rheumatology patients while Dr. Altschuler, an internist, provided general medical patients (CX 45N (Admission No. 253)). There were other significant differences between the patients in the two groups to render pooling of the data questionable (Roth, Tr. 1592–93). For example, in Dr. Altschuler's group, thirty-two of the fifty patients (or 64%) self-rated their baseline pain as severe while only four of Dr. Golden's forty-five patients (or 11%) did so (Altschuler, Tr. 3086–87). Dr. Altschuler attributed this difference to the differences in the underlying conditions of the two patient groups rather than to the differences in their pain perception (Altschuler, Tr. 3087–90).

292. It is also important to determine that the results obtained by the investigators are similar before pooling the data in a multi-site study (O'Brien, Tr. 3815). Thus, the criticism of the FDA's Bureau of Drug directed to the Golden and Altschuler Study and its underlying data submitted by Thompson, included a comment that the study reported the diagnosis and location of the pain on one table for both groups and the statistical analyses treated all ninety-six patients without distinguishing investigators (CX 342B).

293. It is also important in a multi-site study that the different investigators adhere to the same protocol (O'Brien, Tr. 3815). In the Golden and Altschuler study, however, both investigators stated that they knew of no checks to insure that the two physicians conducted the test in the same manner (CX 45I (Admission No. 140); CX 45N (Admission No. 256)). Thus, there is no assurance that the two physicians applied the same criteria in gathering the clinical data and background information on the patients, or that they identified the primary diagnosis or the primary site in the same manner (*Id.*). Thompson has admitted that Drs. Golden and Altschuler never discussed any aspect of the test with each other (CX 45N (Admission No. 255)). As of the time of Dr. Golden's deposition in this case (December 7, 1981), the two physicians had never even spoken to one another (CX 45M (Admission No. 241)). In fact, Dr. Altschuler testified that during his conduct of the study, he was unaware that another investigator

was conducting a trial with a protocol that was identical to his (Altschuler, Tr. 3059).

294. Another problem with the Golden and Altschuler study is the fact that nine subjects (or about 10% of the total sample) at the time of their participation were using anti-inflammatory or mood-altering drugs which may have distorted the study results (Adriani, Tr. 1198; Roth, Tr. 1588–89; CX 45Z–016–17 (Admission No. 5) (patients, 101, 105, 109, 130, 131, 132, 135, 139, 140)). The drugs included tranquilizers such as Valium and Librium, and anti-inflammatory drugs such as [88] Prednisone and Motrin. In view of the fact that the study was not a crossover study, the use of such concomitant medications should have been discontinued (Adriani, Tr. 1198; Roth, Tr. 1588–89).

295. Although the protocol of the Golden and Altschuler studies prohibits concomitant use of "other analgesic medication" during the four-hour test period, neither of the two physicians was instructed about medication usage in the period *prior* to the four-hour test period, nor was either instructed as to specific types of non-analgesic medications which could affect study results if used during the test period (Marlin, Tr. 3396–98). Dr. Altschuler admitted that he did not question study participants after the test about any concomitant pain medications that they might have used either before or during the four-hour test period and that some subjects, especially those who applied the test cream after a lapse of time following their initial visit with him, could have taken analgesic medication *prior to* commencing the four-hour study period (Altschuler, Tr. 3082–83). Such analgesic medication by subjects, Dr. Altschuler agreed, would not have violated his instructions yet could have affected the test results reported by the patient during the four-hour test period. Thus, because of the lack of a washout period for analgesic medications prior to the subjects' participation, and because a number of study subjects took concurrent anti-inflammatory or mood-altering drugs which could have affected study results, concomitant medication usage is a significant problem in the Golden and Altschuler study.

296. In addition, there were several patients in Dr. Altschuler's Aspercreme group who are known to have breached the protocol by applying the cream two times rather than once (patients 11, 30, 32, and 52 (CX 214Z–079, Z–096, Z–098, Z–112)), all of whom recorded that they had experienced pain relief (CX 366Z–114–19). This raises a question of potential bias in favor of the Aspercreme group.

297. Dr. Golden testified at trial that the written protocol, requiring exclusion of patients with diagnosed rheumatoid arthritis or osteoarthritis as well as patients older than fifty-five years, was subsequently modified orally to allow inclusion of arthritis with *non-articular* pain and persons of older age (Golden, Tr. 2714–17). This testimony is

contrary to his deposition testimony where he had recalled no written or oral amendments to the protocol (Golden, Tr. 2937). In any event, the patient's forms for some twenty-five subjects indicated *arthritic pain* and some others only name the affected area or areas of the body. With respect to those subjects, it is not possible to determine from their patient forms whether the pain was of non-articular nature and whether their inclusion [**89**] was proper under the orally-amended protocol (CX 214Z–060, Z–070–72, Z–077, Z–078, Z–081–82, Z–084–92, Z–094–95, Z–097–98, Z–100, Z–102, Z–104, Z–106, Z–108–11, Z–113–16, Z–118–119).

298. For all of the foregoing reasons, the Golden and Altschuler study (RX 50/CX 214) is not an adequate and well-controlled trial and does not constitute a reasonable basis for Aspercreme efficacy claims. This determination is in accord with that of the FDA Final Tentative Monograph for OTC Analgesic Products, published on February 8, 1983 (CX 443D).

C. *The French Studies*

299. The French studies relied on by Thompson as substantiation for Aspercreme efficacy claims include the two clinical studies conducted in France for the L'Oreal Corporation by Dr. Alain Patel (RX 34/CX 209) and Dr. Pierre Andre Chappelle (RX 35/CX 208), respectively, and a follow-up study conducted by Dr. Patel (RX 36/CX 120), all during the period 1976 and 1977. A June 4, 1981 statement authored by Dr. Patel (RX 37/CX 253) and a July 6, 1981 letter of Dr. Patel to Dr. Steinberg of Thompson (RX 38/CX 266) also pertain to the Patel studies (RXs 34, 36). Thompson acquired RXs 34 and 35 in early 1977 (Steinberg, Tr. 3139–40) and RXs 36–38 in the summer of 1981. Thompson's Aspercreme advertisement began on a nationwide basis in 1977. These French studies were conducted to meet the French regulatory requirements by government designated investigators. For our purposes, they were uncontrolled and do not permit a proper assessment of their results. *See* the FDA Tentative Final Monograph on OTC External Analgesic Products, dated February 8, 1983 (CX 443D). In any event, they fall far short of adequate and well-controlled clinical trials and cannot be relied on as providing a reasonable basis for making any efficacy claim for Aspercreme.

300. At the time when Thompson purchased the product from the Sperti Drug Company, Inc. in 1976, two studies on the efficacy of Aspercreme were in progress in France. These studies were conducted for the L'Oreal Company ("L'Oreal") which sought to obtain a license to sell Aspercreme in France. Under the French regulatory scheme, a drug must undergo toxicology studies and clinical trials designed to show its safety and efficacy (Patel, Tr. 1817–18, 1825). The clinical

trials must be conducted by two French physicians whose names appear on the French Ministry of Health list of clinicians approved for such trials (Patel, Tr. 1818, 1826–27). The two studies for L'Oreal were conducted by French physicians, Drs. Alain Patel and Pierre Andre Chappelle. However, L'Oreal subsequently decided **[90]** that because of a change in the French Social Security regulations it would not be profitable to market the product in France (Patel, Tr. 1920). Thompson received the results of these studies in the early part of 1977 (Steinberg, Tr. 5137–40).

301. The patient population for these two studies was drawn from the Rehabilitation Center of the hospital in Deauville, France and the Raymond Poincare Hospital in Paris, France. Dr. Chappelle, head of the Rehabilitation Center and a well-known expert in the rehabilitation of rheumatoid and traumatic injuries, supervised the study at the Deauville site. Dr. Patel supervised the Raymond Poincare site. The patients who participated in the study were suffering from pain and swelling either as a result of a rheumatologic disease or a traumatic injury. All of the patients at Dr. Chappelle's site were hospital in-patients, all of those at Dr. Patel's site were out-patients (Patel, Tr. 1868–71, 1875). According to Dr. Patel, in initial meetings with representatives from L'Oreal, Drs. Patel and Chappelle decided that they would observe the effects of the drug over a two-week period and would confine the study to pain caused by trauma and pain in and around the joints. It was decided that fifty patients would be evaluated, twenty-five from Dr. Patel's hospital and twenty-five from Dr. Chappelle's Rehabilitation Center. Drs. Chappelle and Patel worked closely together and conferred on the instructions to be given to the patients and the reporting form which would be used to record the results. According to Dr. Patel, the test was structured in a standard fashion that had been used many times before to test anti-inflammatory and analgesic preparations (Patel, Tr. 1872–76). Also, patients were told to apply the cream to the painful area twice a day, or three times a day if needed. The patients were seen by the doctors three times during the course of the study—at the beginning, after one week, and after two weeks. The total patient population numbered fifty-two (Dr. Patel included two additional subjects), a number considered adequate for drug studies in France (Patel, Tr. 1875–76, 1881–82, 1976).

302. Reports from clinical examinations were compiled on relief of pain, swelling, inflammation, and on improvement in ease of movement (RXs 34, 35). Results of the study were recorded on the patient's medical record and data collection forms. According to Dr. Patel, neither the doctors nor the patients knew the contents of the unmarked tubes of test drug received from the sponsor and sealed en-

velopes contained the identity of the contents of each bottle. According to Dr. Patel, this is standard practice for drug testing in France (Patel, Tr. 1876–77, 1879, 1881, 1962, 1996). Dr. Patel also testified that, in forming their conclusions, the physicians also consulted the medical charts they maintained for each patient as well as the clinical data reported on the data **[91]** collection forms. When the study was completed, they studied the charts and the clinical case forms before writing their recommendations to the Ministry of Health (Patel, Tr. 1962, 1996).

303. Nineteen of the twenty-seven patients at Dr. Patel's site were reported to have shown "good results," and all but one of the twenty-three patients at Dr. Chappelle's site were reported to have "noticed a very clear improvement" (RXs 34A, 35D). According to the investigators, these findings indicate that test medication was very effective in relieving muscle aches, pain from tendonitis, and pain from inflammatory disease. No results were observed where the patient was suffering from serious arthritis affecting large, weightbearing joints (Patel, Tr. 1906–07, 1918–19, 1931; Steinberg, Tr. 5142; RXs 34, 35).

304. Dr. Patel testified that in February or March of 1977, he conducted an informal follow-up study of Aspercreme in order to satisfy himself that the product did work as well as his earlier findings indicated. This time he knew that the cream he was administering was Aspercreme, and he used the product on approximately forty patients and kept records on twenty-five. Dr. Patel testified that the second study results confirmed the findings of the first. Dr. Patel concluded that Aspercreme is effective in providing relief of pain and swelling and in improving facility of movement in cases where there is rheumatic involvement around the joint. He also concluded that Aspercreme is effective in cases that have rheumatic participation inside the joint, that is, in the synovial fluid. Furthermore, patients with arthritis of the small, non-weightbearing joints get good relief of pain when using Aspercreme (Patel, Tr. 1920–25, 1931–32). Dr. Patel testified that he was so impressed with Aspercreme that he has used it since for his hands and has continued to recommend it to patients who are able to purchase Aspercreme in this country (Patel, Tr. 2042, 2045).

305. However, the record shows clearly that neither of Dr. Patel's studies (RXs 34, 36) constitutes a well-controlled, double-blind clinical study. Dr. Patel's studies consist mainly of clinical observations expressing a global evaluation of the product (Roth, Tr. 1604–05). There was no written protocol for either RX 34 or RX 36 (Patel, Tr. 1980), no scoring or scaling system for pain relief, no record of the subjective pain responses obtained from the patients (Patel, Tr. 1983–84), and no

information on concomitant medications (Roth, Tr. 1604–05; Adriani, Tr. 1214). Both investigations also involved self-limiting conditions that were not taken into account in the studies' design (*Id.*). The studies are notable in their lack of adequate data entry and analysis customarily found in [92] other reports of clinical trials. Finally, the Patel studies are seriously flawed by the absence of a placebo or any other control and the unblinded conditions under which his observations were made (CX 342C).

306. The Chappelle study (RX 35/CX 208) shares all the flaws discussed hereinabove with respect to the Patel studies (*See* Adriani, Tr. 1215).

D. *The Batterman And Sanders Myoflex Study (CX 254)*

307. Thompson also relies on a Myoflex study conducted by Drs. Batterman and Sanders (CX 254/CX 344Z–148–56).

308. This was a double-blinded, placeblo-controlled, multi-center study to which Dr. Batterman contributed twenty-eight patients and Dr. Sanders thirty-five. The study employed a cross-over design and compared the efficacy of Myoflex cream (a 10% topically-applied TEA/S ointment like Aspercreme) with that of placebo cream in patients with arthritic involvement of the hands. The nature of a cross-over design is that each subject in the study uses the test and control agents sequentially, and the subject as well as the investigator are blinded (Roth, Tr. 1534).

309. The Batterman and Sanders study employed a total of six measures, or three measures for each of the two groups. There were two objective measures (hand grip strength and finger joint circumference) as well as one subjective measure (global improvement) for each of the two groups. The results showed no difference in patient response between Myoflex and placebo cream in five out of the six measurements taken between the two groups. Neither investigator found any difference between TEA/S and placebo cream in terms of either of the two objective measures of improvement. Also, Dr. Sanders found no difference between TEA/S and placebo in terms of patients' subjective impressions of improvement. But Dr. Batterman reported a significant difference between TEA/S and placebo in terms of patients' subjective impression.

310. For several reasons, the Batterman and Sanders study cannot be regarded as adequate support for Aspercreme efficacy claims. First, as was emphasized in the FDA's Tentative Final Monograph on OTC External Analgesic Products, on five out of the six parameters used to measure drug efficacy, TEA/S was no more effective than placebo (CXs 343B, 443D). In light of these results, the FDA concluded that the study does not indicate any clear superiority of TEA/S over

placebo (CX 443D). Secondly, in [93] terms of the subjective impressions of improvement reported by subjects in Batterman's group, the report lacks any information as to what subjective measure(s) of improvement was employed (Adriani, Tr. 1201–03; Roth, Tr. 1595–96). It may have measured the patient's impression of reduced pain or improved function, and the improvement may or may not have been clinically significant (Adriani, Tr. 1202–03; Roth, Tr. 1594). Without knowing what questions the patients were asked by the doctors, the "subjective improvement" parameter is too vague to be relied on (Roth, Tr. 1597). For this reason, the FDA External Analgesic Panel considered the Batterman and Sanders study to be not adequate and well-controlled. It felt that the report relied heavily on the subjective improvement reported by the Batterman subjects but did not indicate what the subjective improvement consisted of (Adriani, Tr. 1459).

311. There are other important information gaps in the Myoflex study. It lacks information on concomitant medication usage by the subjects, on the frequency and duration of applications, on the type of blinding techniques used, and on how study dropouts were treated (Adriani, Tr. 1204; Roth, Tr. 1598). The inclusion of ten subjects listed as being in a "quiescent phase" also means that those patients had no active disease (Roth, Tr. 1596).

312. In view of the foregoing omissions and problems, the Batterman and Sanders study is not an adequate and well-controlled clinical trial. In any event, this study was not seen by Thompson before it began Aspercreme advertisements, for Thompson acquired it sometime between 1979 and 1981 (Admissions, CX 45D, P).

E. *The Bioavailability Studies*

313. A drug is said to be "bioavailable" when it has been absorbed into the body and is present in the blood, urine, or other body tissue or fluid. A drug is said to be "bioactive" when it also shows a significant therapeutic effect in the human body. For example, if a person with a bacterial infection takes an antibiotic that is generally recognized as being effective, but the strain of bacteria causing the infection is resistant to that antibiotic, the antibiotic will in fact get into the person's system and thus be "bioavailable," but not "bioactive" in that its presence in the body will not show a therapeutic effect (Adriani, Tr. 1178–79).

314. According to the FDA, demonstrating that a drug is bioavailable and demonstrating its efficacy are not the same thing: [94]

> It is not . . . the intent of a bioavailability study to demonstrate effectiveness. The purpose of a bioavailability study is to determine the rate and extent of absorption. If a drug product is not bioavailable, it cannot be regarded as effective. However, a

determination that a drug product is bioavailable is not in itself a determination of effectiveness. The requirement of evidence of bioavailability is intended to supplement, no[t] replace, clinical evidence of effectiveness.

42 FR 1640 (1977).

The record in this proceeding also clearly shows that bioavailability studies are not a substitute for well-controlled clinical trials for the purpose of showing the effectiveness of a drug (Adriani, Tr. 1178; Ehrlich, Tr. 4087; O'Brien, Tr. 3964–66; Rabinowitz, Tr. 3519; Roth, Tr. 1566).

315. As part of its reasonable basis materials, Thompson heavily relies on a radioisotope experiment on dogs and humans conducted by Dr. Joseph L. Rabinowitz and others (RX 70/CX 374). The canine portion of the study involved ten dogs, five of which were given oral aspirin tagged with radioactive carbon-14 and five which were given radioactive TEA/S topically applied at the knee. The human portion involved six subjects who were first given radioactive aspirin orally, and two to six weeks later were given radioactive TEA/S topically applied at the knee. In each case, tissue and fluid samples were analyzed for radioactive material at specific intervals after the drug had been administered. The presence of radioactive materials in tissue samples will show drug penetration of skin and absorption into subcutaneous tissues. However, only clinical studies can demonstrate analgesic efficacy (O'Brien, Tr. 3868–69; Roth, Tr. 1601, 1728). Dr. Rabinowitz agrees that there is nothing in his study to show that TEA/S is an effective analgesic agent (Rabinowitz, Tr. 3518; *accord* Roth, Tr. 1599; Adriani, Tr. 1206–08).

316. In 1978, Thompson issued a grant to the University of Pennsylvania for a study that Dr. Joseph Rabinowitz wanted to conduct. From time to time after the study was underway, Dr. Steinberg of Thompson received from Dr. Rabinowitz preliminary written reports relative to the amount of salicylate available in tissues after the application of TEA/S as compared to the ingestion of aspirin. There were no real differences between the results reported in each of the preliminary reports **[95]** (Steinberg, Tr. 5163–66). Prior to the initiation of the study , three scientific committees at the Veterans Hospital reviewed and approved the proposed investigation. Approval by the committees required a finding by them that the study had scientific merit (Rabinowitz, Tr. 3499). Dr. Rabinowitz maintained full independence in conducting the study. The other participants in the study were physicians of the University of Pennsylvania specializing in arthritis and rheumatology, who had no contact whatever with Thompson (Rabinowitz, Tr. 3495–97).

317. The Rabinowitz study involved "tagging" the TEA/S molecule

with a radioactive isotope. The TEA/S was made radioactive at the New England Nuclear Company by using radioactive carbon dioxide (CO_2) and bubbling it with phenol to yield radioactive salicylic acid. The radioactive salicylic acid was then added to TEA to yield radioactive TEA/S (Rabinowitz, Tr. 3500–01, 3521). The salicylate molecule in the TEA/S compound was tagged with radioactive Carbon 14 (^{14}C). According to Dr. Rabinowitz, it is certain that the salicylate molecule retained the radioactive tag (Rabinowitz, Tr. 3503). There is no difference other than the radioactive carbon between the radioactive TEA/S used in the study and commercially available TEA/S (Rabinowitz, Tr. 3503–04). This fact was proven by use of a nuclear magnetic resonance (Rabinowitz, Tr. 3504).

318. The first stage of the Rabinowitz study was a canine study conducted on beagles. Beagles are considered to be good models to test the absorption of salicylate (O'Brien, Tr. 3890; Rabinowitz, Tr. 3505–06; Silverman, Tr. 2209). The study was conducted by rubbing Aspercreme into the shaved right knee of the dog until all of it was absorbed. After one hour, the area was wiped off with alcohol. The animal was sacrificed and the knee was cut off and sections were taken from the skin. Each section was weighed carefully and the tissue was extracted. Each section was then treated with ether and sulfuric acid to extract the radioactive salicylate. The extract was chromatographed for further purification, and the amount of salicylate present was measured by assessing the amount of radioactivity with a radioactivity counter (Rabinowitz, Tr. 3505, 3507–09). The amount of radioactivity measured represented the amount of concentration of salicylate in the tissue (Rabinowitz, Tr. 3511–12).

319. The results of the canine portion of the study showed that the skin, the muscle, and the fascia absorbed significant quantities of salicylate in all five dogs in the group. The data also revealed that the salicylate level in the blood in the Aspercreme group was 10 to 100 times lower than that of the aspirin group. **[96]**

320. In the canine study conducted by Dr. Rabinowitz, the following salicylate levels were found in body tissues following oral and topical administration:

	Oral	Cream
Muscle	1.76	38.20
Fascia	1.04	16.40
Fat Pad	1.00	5.60
Tendon	.20	3.00
Cartilage	.43	1.62
Synovium	.62	.74

These data reveal that TEA/S topical application resulted in higher

local salicylate concentrations than did ingestion of oral aspirin in dogs and indicate that topical TEA/S was primarily absorbed locally by direct penetration (Rabinowitz, Tr. 3513–14; RX 70C–D).

321. The second stage of the study studied human patients with rheumatoid arthritis. All patients met American Rheumatism Association's criteria for classical or definite rheumatoid arthritis. Dr. Ralph Shumacher, Professor of Medicine at the University of Pennsylvania and a highly regarded rheumatologist, screened the patients for study eligibility. The same patients participated in both the oral aspirin and topical TEA/S parts of the study. Patients abstained from salicylates for six hours prior to each study period. Each patient first received orally 500 milligrams of ^{14}C aspirin. Two to six weeks later, ten gms. of the triethanolamine ^{14}C- salicylate cream was massaged into the skin over one knee. Blood and urine samples were obtained before the administration of either the oral or the topical medication and again at 60 to 120 minutes, at which time a synovial fluid aspiration was performed. The fluid samples were extracted, chromatographed, and measured for radioactivity (Rabinowitz, Tr. 3509–10; RX 70).

322. In the human study conducted by Dr. Rabinowitz, salicylate concentrations in the synovial fluid after the application of TEA/S were found to be approximmately 60% of the concentration found after the oral ingestion of aspirin. However, the concentration in the blood from orally ingested aspirin was four to eight times higher than that resulting from topical application of TEA/S. These data indicate that the TEA/S was absorbed by direct penetration into the joint through the skin since these levels were achieved despite low blood salicylate levels (RX 70). [**97**]

323. The Rabinowitz study shows that salicylate can be and is absorbed through the skin in measurable amounts and that the salicylate component of the TEA/S molecule is capable of penetrating through the skin, muscles, and tendons right down to the joint connecting the bones. Thus, Aspercreme can deliver salicylate to joints and tissues (Adriani, Tr. 1298; Ehrlich, Tr. 4030; O'Brien, Tr. 3675; Rabinowitz, Tr. 3513–14; Roth, Tr. 1728/7–12; Silverman, Tr. 2208; RX 70).

324. Dr. Howard Maibach, professor of dermatology at the University of California Medical School and a recognized expert in the field of percutaneous absorption of drugs, observed that while topical drug absorption was generally believed to be dependent upon being transported through the blood or the general circulatory system (the "microcapillary network") (RX 289), recent studies by Dr. Maibach, Dr. Jean Paul Marty, and others have demonstrated that a drug may be capable of penetrating into the body without being carried by the

blood (RXs 1000–05). These studies also show that subcutaneous drug levels can be achieved following the penetration of a topically applied drug into the layers of the body (RXs 289B–C, 1020). In Dr. Maibach's opinion, topically applied TEA/S is one of those drugs which diffuses into muscles and tissues beneath the skin (RX 289D). Dr. Maibach's paper, accepted for publication in the *Journal of Pharmaceutical Sciences,* reviewed some of the scientific literature in the area of subcutaneous delivery of chemical substances, including the Rabinowitz study (RX 70), the early St. Thomas Institute study (RX 45), and the Golden study (RX 49) and concluded:

> Better (or at least equivalent) therapy is possible, therefore, without systematic distribution of the drug, *i.e.*, significant blood levels, and possible side-effects (RX 102M).

325. Dr. Rabinowitz' bioavailability study is interesting in that it shows that topically applied TEA/S may be capable of delivering salicylate to subcutaneous body tissues by directly penetrating the skin and thus offer an alternative method of administering salicylate for relief of pain. What is needed to verify this potential, however, is an acceptable demonstration of TEA/S' bioactivity.

326. The record also shows some ambiguity as to precisely what chemical was carbon-14 tagged in the experiment itself. TEA/S was obtained by adding radioactive salicylate acid to TEA. Although Dr. Rabinowitz testified that there was no [98] difference between the radioactive TEA/S he used and the commercially available TEA/S and that the TEA molecule in the radioactive TEA/S could not have been tagged in the process, the question as to which of the four different chemical entities (the salicylate ion, salicylic acid, TEA/S or TEA) was measured in the radioisotope experiment remains in the record (Adriani, Tr. 1211 (salicylate ion, salicylic acid, or TEA/S); O'Brien, Tr. 3873 (salicylate ion); Rabinowitz, Tr. 3500–01 (salicylic acid); Roth, Tr. 1599–600 (TEA or salicylate)). There also is some evidence indicating that the sulfuric acid used to extract the tagged material from the samples could have caused the TEA/S to disassociate into TEA and a salicylate moiety (Adriani, Tr. 1209; Rabinowitz, Tr. 3536).

327. Thompson has also admitted that the human portion of the Rabinowitz experiment did not study whether TEA/S broke down into a salicylate ion in the body and that the canine portion did not study whether TEA/S broke down into salicylate in the body (CX 45Q (Admissions Nos. 354–55)).

328. The Rabinowitz data do not show that topically applied TEA/S in the experiment penetrated below the skin in therapeutically significant quantities (Adriani, Tr. 1263; Roth, Tr. 1599–600, 1724). Rather the study shows that most of the tagged material stayed on the skin

(Adriani, Tr. 1263; RX 70C (Table I)) and that the base was actually better absorbed than the tagged material (Rabinowitz, Tr. 3611–12; RX 70C). Dr. Roth, complaint counsel's expert witness, testified that the clinical relevance of the presence of the tagged material in any of the tissue or fluid samples is dubious (Roth, Tr. 1728). Furthermore, the record fails to answer many important questions that would have to be addressed. The Rabinowitz study does not show the rate at which the tagged material penetrated. It has been demonstrated, however, that if an analgesic is slowly absorbed, the minimum effective concentration of the drug at the site of action may never be reached (O'Brien, Tr. 3879–83).

329. Furthermore, there are some significant problems in the experiment's design. The dosage of radioactive aspirin used in the experiment (500 milligrams) is lower than the recommended single dose of aspirin for analgesia (650 milligrams) and is far lower than the recommended dose of aspirin for inflammation (4200 milligrams a day) (O'Brien, Tr. 3868; Rabinowitz, Tr. 3534; Roth, Tr. 1602). In contrast, Dr. Rabinowitz added 20% more radioactive molecules to the TEA/S in order to compensate for the TEA/S that would remain on the glove of the physicians who applied the cream (Rabinowitz, Tr. 3502). Also, although all six human subjects had been on a stable dose of oral aspirin for six months or more, they were instructed not to take aspirin only for six hours before each test period [**99**] (RX 70D). More than six hours, however, would be necessary for the nonradioactive aspirin to be totally cleared from the subjects' systems (Adriani, Tr. 1395; O'Brien, Tr. 3765–67; Roth, Tr. 1600). To the extent the nonradioactive aspirin remained in the body, it may have influenced the test results by diminishing the radioactive aspirin that could have been absorbed.

330. As part of its reasonable basis, Thompson relies on submitted documents (RX 42/CX 202; RX 62/CX 216) pertaining to blood and urine level tests on human volunteers. In both studies, topical TEA/S was applied and blood and urine samples were measured for salicylate at fixed intervals. The only scientific value of these studies is to demonstrate that topically applied TEA/S is absorbed into the blood and excreted in the urine (Adriani, Tr. 1178). Almost any drug applied to the skin will show up in minute traces in the blood. But, the serum levels of salicylate achieved did not reach the minimum levels associated with analgesia (Adriani, Tr. 1390; Roth, Tr. 1760–61). Moreover, in one test (RX 62), the site where the drug was applied was covered with saran wrap overnight. Covering the site of a topical application increases the rate of absorption. Thus, the resulting blood and urine levels of salicylate were substantially higher than they

would have been after normal consumer use (Adriani, Tr. 1229; Silverman, Tr. 2428–29).

331. In addition, Thompson has submitted two rabbit studies (RX 43/CX 215; RX 44/CX 204) measuring salicylate levels in rabbits after application of topical TEA/S. The scientific value of these tests, which involved a total of five rabbits, is questionable. In any event, for the reasons set forth hereinabove, these so-called penetration studies do not provide substantiation for the efficacy of topical TEA/S in humans for relief of musculoskeletal pain.

332. The Myoflex bioavailability studies Thompson refers to (CX 344G; Z–048–49; Z–063–65) simply show that salicylate was present in the blood following a topical application of Myoflex, a topical rub containing 10% TEA/S. The egg membrane experiment (RPF 202) and beef muscule experiment (RPF 203) referred to by Thompson are trivial and of little value to this proceeding.

333. Dr. Steinberg, Thompson's vice president who is responsible for substantiation of advertising claims, testified that Thompson relied on a 1955 article by Howell (Steinberg, Tr. 5175–76; RX 366/CX 366, pp. Z–222–23). Since Thompson acquired the Howell article toward the end of 1981, Thompson could not have relied on it for substantiation of any claims for Aspercreme made before that time. In any event, the Howell [**100**] article, which reports the results of a single-blind English study on diethylamine, cannot be used to substantiate claims for TEA/S, which is an entirely different drug that may not penetrate the skin in the same way.

F. *The Gaudin Patent*

334. Thompson also relies on certain patents as evidence of drug efficacy. A United States patent was issued in 1952 to Dr. Olivier Gaudin for his discovery (No. 2,596,674) of topical absorption of amine salicylates (RX 450/CX 212). It does not refer to TEA/S but to an entirely different compound, diethylamine salicylate (Adriani, Tr. 1288, 1243–44). Other than the patent holder's assertion that dissociation of diethylamine salicylate occurs, there is no other evidence of dissociation in the patent report (CX 212C). In addition, other patents have been issued by the United States Patent Office for different topical salicylate salts (Silverman, Tr. 2227–28; RX 451). These patents reflect a determination that some salicylate salts as described were patentable within the meaning of the patent laws, and the medical scientific community does not use or accept patents as a source of information on drug efficacy (Adriani, Tr. 1227). Patents are merely descriptive claims for compounds, and have no scientific significance for determining drug efficacy for any disease condition (Roth, Tr. 1609).

G. *Clinical Observations And Opinions Of Physicians*

335. It is natural that in the practice of medicine, the determination of what drug is most appropriate for an individual patient rests with the physician's professional judgment based on the patient's history and disease state and the physician's knowledge of and experience with drugs. However, the practice of medicine is not an exact science but an art and a physician's choice of a drug for a particular patient essentially reflects a process of trial and error based on long experience, insight and wisdom. However, it is something else to argue that clinicians' experience with patients with a particular drug should be accepted as scientific proof of efficacy. It is generally recognized by the medical scientific community that physicians' observations and opinions may suggest or lead to controlled clinical trials or be used to augment such trials, but they are not substitutes for well-controlled clinical trials for the purpose of showing drug efficacy (Adriani, Tr. 1436, 1460–61; [**101**] Roth, Tr. 1570). The contrary view expressed by respondent's experts, to the effect that the requirement for well-controlled clinical trials should be substantially relaxed or dispensed with in the case of OTC topical analgesic drugs, such as Aspercreme, do not reflect the prevailing view of the medical scientific community including the FDA. *See* 21 C.F.R. 330.10(a)(4)(ii); FDA OTC Drug Review Policy Statement, 46 FR 47,729, 47,731 (1979).

336. A physician's observation of his patient's response to an analgesic may be affected by bias (Adriani, Tr. 1181), or may be incorrect due to a variety of other factors, such as placebo effect (Ehrlich, Tr. 4155–56). For example, the enthusiasm the physician may consciously or unconsciously communicate to the patient may contribute to a high placebo response rate (Ehrlich, Tr. 4133–36). Moreover, there have been numerous instances where drugs used over a period of years with positive consumer response and physicians' observations were later subjected to clinical tests and found to be ineffective (Adriani, Tr. 1180–83; Ehrlich, Tr. 4117–18; O'Brien, Tr. 3775–76; Roth, Tr. 1571).

337. Physicians' observations and opinions based upon case reports, random experiences, and other reports lacking details necessary for scientific evaluation do not constitute adequate substantiation for Aspercreme's efficacy claims (F. 335–36, *supra*). 21 C.F.R. 330.10(a)(4)(ii). Thus, for example, letters such as RX 47/CX 260 which represent isolated, uncontrolled, and undocumented observations of physicians do not constitute scientific evidence (*Id. See* Adriani, Tr. 1230–32; Golden, Tr. 2763–65, 2767; Roth, Tr. 1609–12). On the other hand, where appropriately documented and systematic, physicians' observations and opinions may constitute reports of significant

human experience during marketing and may thus be viewed as evidence capable of corroborating, but not supplanting, clinical studies (F. 218, *supra*). 21 C.F.R. 330.10(a)(4)ii).

338. In 1982, B.F. Ascher & Co., Inc. ("Ascher"), the marketer of Mobisyl, another 10% TEA/S product, conducted a survey of certain physicians and health practitioners in an effort to determine their opinions of Mobisyl (Borchers, Tr. 5045–56; RX 346A–C). The study was submitted to the FDA in an effort to corroborate the results of clinical tests undertaken by Thompson Medical (Borchers, Tr. 5057–58; RX 346A). The submission to the FDA was made pursuant to 21 C.F.R. 330.10(a)(4)(ii), which provides that proof of effectiveness shall consist of controlled clinical investigations, which may be corroborated, *inter alia,* by reports of significant human experience during marketing (Borchers, Tr. 5058; RX 346A–B). **[102]**

339. Because the Ascher survey was neither possessed nor relied upon by Thompson prior to its dissemination of any of the challenged advertising, it does not aid Thompson in this proceeding (*See* CX 25). In any event, by virtue of the manner in which this survey was conceived and conducted, it is of little value in this proceeding even as corroborative evidence of TEA/S' efficacy (*See* CPF 395–99).

H. *Testimonial Evidence of Users*

340. A significant portion of Thompson's substantiation materials is devoted to testimonial evidence, both by consumers and by persons in health-related occupations. It is well-recognized that such testimonial evidence has no value in determining the issue of drug efficacy (Adriani, Tr. 1180; Roth, Tr. 1567). In FDA regulations and the OTC panel evaluations of analgesic drug efficacy, patient testimonials were not worthy of consideration (Adriani, Tr. 1239; CX 391F, 395B). 21 C.F.R. 330.10(a)(4)(ii). Since consumers are not incapable of evaluating drug efficacy, testimonial evidence is not a reliable source of evidence of drug efficacy (Adriani, Tr. 1239; Roth, Tr. 1617).

341. Thompson's own witnesses acknowledged the inadequacies of testimonial evidence as a basis for demonstrating drug efficacy. For example, Dr. O'Brien admitted that he had criticized pharmaceutical companies for their reliance on testimonials as evidence that Indomethacin (a prescription anti-inflammatory drug) is effective (O'Brien, Tr. 3786). He had also criticized the companies for their reliance on consumers' reports as to the type of pain relief they got from the drug (O'Brien, Tr. 3786–87). Dr. Ehrlich indicated that in dealing with consumers' reports, there is no way to eliminate the possibility that they were due to the placebo effect (Ehrlich, Tr. 4155–56). Consumer letters to companies also suffer from selectivity in that a company only hears from those who want to be heard (*Id.*). Thus, for example

a nurse, who had returned a consumer response card favorable to Aspercreme and subsequently testified at trial, acknowledged that she probably would not have written a negative letter to a company even if she were "downright disappointed" in a product (Walsh, Tr. 4362).

342. The Arthritis Foundation has devoted significant attention to the area of testimonials because it relates to the problem of unproven remedies (Roth, Tr. 1610). Thompson's expert, Dr. O'Brien, acknowledged that the Arthritis Foundation is a reliable source of information about the treatment of arthritis and the scientific issues surrounding the disease, and that the Foundation takes the position that testimonials and [**103**] case histories cannot be relied on to show that a remedy works for the diseases of rheumatoid arthritis and osteoarthritis (O'Brien, Tr. 3919–20, 3925). The reason the Foundation takes this position as regards case histories is because arthritis has peaks and valleys and may go away by itself just when a person tries a new remedy (O'Brien, Tr. 3926). For this reason, the Foundation takes the position that controlled trials of drugs and remedies are employed to determine safety and efficacy while discounting the placebo effect and other sources of bias. Such controlled clinical trials are acceptable as scientific proof (*Id.*).

343. The unreliability of Thompson's testimonial evidence is evident from a sampling of the testimonial letters it received. For example, one letter is from a chiropractor who used Aspercreme on himself and thought it was good. He also indicated that he was using it on his patients in conjunction with ultrasound treatment. Reports such as these do not constitute valid scientific evidence (Adriani, Tr. 1232; Roth, Tr. 1611–12). Another letter stated that Aspercreme was effective in a case of stroke paralysis. There is no topically-applied medication that would be efficacious for stroke victims, and this type of testimonial may be aptly compared to faith healing (Adriani, Tr. 1233; Roth, Tr. 1612). Still another letter submitted by Thompson as substantiation for its claims is a "Dear Doctor" promotional letter sent out by another pharmaceutical company, B.F. Ascher & Co., to physicians introducing a new oral product for arthritis treatment (Adriani, Tr. 1234–35). The letter discusses a topically-applied TEA/S cream as an adjunct to oral therapy for arthritis. This document does not constitute proof of Aspercreme's efficacy (Adriani, Tr. 1235; Roth, Tr. 1612–13).

I. *Drug Compendia And General Scientific Literature As Proof Of Drug Efficacy*

344. Thompson has also relied on the inclusion of TEA/S in certain compendia of drug products as an indication of Aspercreme's drug

efficacy. However, TEA/S is not included in any of the authoritative reference works on drugs. The publications in which TEA/S is listed are listings of marketed drugs. Importantly, there are only a few published reports on TEA/S in the medical or scientific literature.

345. For example, there are no listings for Aspercreme or TEA/S in four of the most authoritative drug compendia: the *U.S. Pharmacopoeia* (O'Brien, Tr. 3716; Silverman, Tr. 2384; Steinberg, Tr. 5229); the *National Formulary* (O'Brien, Tr. 3716; **[104]** Silverman, Tr. 2386); *Remington's;* and Goodman and Gilman's book, *The Pharmacological Basis of Therapeutics* (O'Brien, Tr. 3718; Steinberg, Tr. 5227–29). The omission of TEA/S products from these standard reference works is significant. A drug has to be recognized as efficacious in order to be listed in the *U.S. Pharmacopoeia,* an official standard reference work (Silverman, Tr. 2378–79, 2387). *Remington's* is also considered to be an authoritative treatise on drugs, while Goodman and Gilman's book is widely regarded as a major reference work on drug efficacy and drug action (Steinberg, Tr. 5227). Dr. Steinberg of Thompson was well aware that a number of authoritative United States treatises did not include TEA/S (Steinberg, Tr. 5229). And Dr. Silverman, Thompson's pharmaceutical expert, agreed that in CX 393, the FDA Panel on OTC Skin Protectant Products for Human Use, only drugs that were listed in standard texts were placed in Category 1 absent clinical trials (Silverman, Tr. 2391–94).

346. Aspercreme is listed in the *Handbook of Nonprescription Drugs.* Dr. O'Brien, an expert witness for Thompson, acknowledged that he would not rely on the *Handbook* to determine whether or not an analgesic product is effective (O'Brien, Tr. 3903). Dr. Silverman conceded that the sixth edition of the *Handbook of Nonprescription Drugs* repeats the findings of the FDA Panel on OTC External Analgesic Products about TEA/S (Silverman, Tr. 2420–21).

347. Aspercreme is also listed in the *Physicians' Desk Reference on Nonprescription Drugs.* Dr. O'Brien agreed that the Physicians' Desk Reference ("PDR") is not an authoritative source of drug information. Typically, much of the book consists of excerpts from package inserts and no one would look to it as an academic source of information (O'Brien, Tr. 3905).

348. Three other books in which TEA/S products are listed, namely the *American Drug Index, Facts and Comparisons,* and Perry's *Prescription and Nonprescription Drugs,* are all-inclusive indexes or lists which purport to include all drugs marketed in the United States (Silverman, Tr. 2379, 2384; Steinberg, Tr. 5226). Neither the *American Drug Index* nor *Facts and Comparisons* are compendia in the sense that the *U.S. Pharmacopoeia* is (Silverman, Tr. 2378–79, 2381–

82). Unlike the *U.S. Pharmacopoeia,* they do not constitute official standard reference works on drugs (Silverman, Tr. 2378–79).

349. With respect to published reports about TEA/S in the medical/scientific literature, Thompson's expert witness Dr. Silverman testified that although he conducts a literature search specifically on TEA/S twice a year, he has never seen any articles recommending its use as an analgesic other than those [**105**] written by Drs. Golden (RX 48/CX 200) and Rabinowitz (RX 70/CX 374) (Silverman, Tr. 2347). Dr. Adriani testified that he was not aware of published reports in the literature about TEA/S (Adriani, Tr. 1434). And Dr. Roth indicated that prior to his participation in the instant case, he had never seen anything on TEA/S in the medical literature. Dr. Roth also testified that he had never heard of TEA/S being the subject of a paper at a professional meeting (Roth, Tr. 1761).

J. *The Pharmacology of Triethanolamine Salicylate (TEA/S) And Its Mechanism Of Action*

350. Much of the record information pertaining to the pharmacology and mechanism of action of TEA/S is based on the testimony of Dr. Silverman, Thompson's pharmaceutical expert witness. Respondent's theory, as further elaborated in this case, is essentially that Aspercreme delivers salicylate molecules to the subcutaneous tissues by direct penetration of the skin, and provides pain relief in the site of pain by inhibiting prostaglandin synthesis in the cell (CX 45N (Admission No. 274)). Although Dr. Silverman's testimony in this regard was not directly contradicted or rebutted by other expert testimony, the record is clear that Dr. Silverman's hypothesis is a novel one and was expounded publicly for the first time in this proceeding. The Silverman hypothesis remains to be accepted by the medical scientific community. It also leaves too many important questions unanswered and is inconsistent in some important respects. In any event, theories regarding a drug's mechanism of action are important and useful but they are not substitutes for well-controlled clinicals for the purposes of showing drug efficacy.

351. The active ingredient of Aspercreme is triethanolamine salicylate (TEA/S). TEA//S is manufactured by combining equal amounts of triethanolamine and salicylic acid. The resulting compound has a relatively low molecular weight of 280 (Silverman, Tr. 2113). According to Thompson's pharmaceutical expert, this low molecular weight helps the TEA/S molecule to be absorbed through the skin (Silverman, Tr. 2114). Radioisotope testing and bioavailability studies in this record have suggested that some topically applied drugs can penetrate the skin.

352. The human skin is constructed of several layers of cells. There

are five layers on the stratum corneum and two on the diadermis. Even though the cellular layers are differentiated in function, they have one common characteristic: [**106**] they consist of cells which have a cell membrane on the outside and protoplasm on the inside. The cell membrane consists of both lipid (fat) and water, *i.e.*, the cell is phospholipid (Silverman, Tr. 2140–41). Thus, for a drug to pass through the cell membrane, it needs to have both water solubility and lipid solubility (Silverman, Tr. 2117, 2141). According to Dr. Silverman, TEA/S has very good water solubility and some lipid solubility (Silverman, Tr. 2115). Molecules which have a solubility ratio of one to one, *i.e.*, 50% in water and 50% in lipid, have the best ability to penetrate the biological cell membrane. According to Dr. Silverman, TEA/S has 60/40 solubility ratio (60% in water and 40% in lipid) and penetrates the cell membrane well (Silverman, Tr. 2118).

353. The outer layer of the skin consists of a dead layer of dry cells. According to Dr. Silverman, when Aspercreme is applied, these dry cells are hydrated by the oil in the product, and penetration is facilitated. According to respondent's experts, the TEA/S molecule dissociates into a triethanolamine ("TEA") molecule and a salicylate ("SA") molecule in the presence of water (O'Brien, Tr. 3938; Silverman, Tr. 2125; RX 1013). This fact can be demonstrated by either of two tests: a Beckman thermometer test (which measures temperature differences between a freezing point of the molecule and a freezing point of the dissociated mix) or an osmometer test (which measures the rapidity and depth of electrical signals to determine how many particles are in solution (Silverman, Tr. 2125–26). Dr. Silverman hypothesized as follows: when Aspercreme is placed on the skin, the waxes in the product's vehicle (triethanolamine) soften the dry outer layers of the skin creating an occlusive effect which hampers the evaporation of water from the skin (Silverman, Tr. 2146), the TEA/S molecule starts to dissociate or ionize into its components, a TEA ion and a SA ion, and TEA and SA ions are very water soluble and will pass through the skin slowly (Silverman, Tr. 2127–28, 2146–47). According to the Silverman hypothesis, in addition to ionization, another chemical process, hydrolysis, is taking place. As the TEA ion comes in contact with water in the skin, the TEA ion reacts with the hydroxyl ion of water (*i.e.*, $-OH$) and reverts back to the TEA molecule. The TEA molecule, which has biphasic solubility (solubility in both water and lipid), penetrates the skin (Silverman, Tr. 2128–29). As the SA ion comes in contact with the water in skin, the SA ion reacts with the hydrogen ion of water (*i.e.*, $H+$) to form salicylic acid. According to Dr. Silverman, the salicylic acid molecule has good lipid solubility with some degree of water solubility and penetrates through the skin. [illegible] TEA/S molecule is applied to the skin, chemical

reactions called ionization and hydrolysis occur so that the TEA/S molecule dissociates and recombines as needed to pass through the membranes. These [**107**] reactions establish a constant topical reservoir in equilibrium that provides TEA molecules and SA molecules which penetrate the skin and gradually migrate through the epidermis and diadermis to the underlying tissues of the body (Silverman, Tr. 2132–34, 2136–37, 2146–47). Migration is possible because the outer membrane of the cell wall is phospholipid, (*i.e.,* both lipid and water in nature), while the interior of the cell is largely protoplasm with inorganic salts (and hence largely water in nature). Penetration of a cell by the molecule involves movement through the lipid barrier of the cell membrane and movement through the water barrier inside the cell (Silverman, Tr. 2150). According to Dr. Silverman, because the TEA/S molecule has both water and lipid solubility, it will "percolate" its way through the various layers of the skin, connective tissues, and muscles to the bone (Silverman, Tr. 2152–54, 2165).

354. Penetration of a drug through the skin is enhanced if a drug is soluble in both water and lipid and if it has a molecular weight of less than 1,000 (Adriani, Tr. 1294; CX 269, p. 69,774). Penetration through the skin is also enhanced if the skin is damaged (Adriani, Tr. 1291–92; CX 269, p. 69,774). Damaged skin is skin in which the stratum corneum remains intact, but there is edema (fluid retention), inflammation, or other pathological processes present in the lower layers of the skin as a result of an injury or a disease (Adriani, Tr. 1293; CX 269, p. 69,773). According to Dr. Silverman, where there is inflammation present, as there is in arthritis or rheumatism, penetration is increased (Silverman, Tr. 2167, 2169). And drug absorption is further facilitated if the substance is rubbed or massaged into the affected area (Adriani, Tr. 1295; Silverman, Tr. 2169, 2176).

355. Inflammation is characterized by heat, redness, swelling, and tenderness in the affected tissues (CX 269, pp. 69,777–78). The salicylate ion exerts an anti-inflammatory effect (Roth, Tr. 1658; Silverman, Tr. 2486–87; CX 269, p. 69,778). It has generally been hypothesized of late that the salicylate ion achieves this anti-inflammatory effect by interfering with the biosynthesis of prostaglandins (PGs) at the cellular level. Prostaglandins are complex, hormone-like molecules which are synthesized from arachidonic acid which is present in the body. Prostaglandins E_1 and F_2 have been shown to be capable of producing local inflammation. Trauma to the body causes the cells to produce PGs. PGs E_1 and F_2 cause pain and inflammation by intensifying the pain producing properties of certain compounds within the body (Stipulated testimony of Dr. Ehrlich with respect to medical literature, Tr. 4006; RXs 1014–15). Thus, in theory aspirin and other salicylates can be useful in interfering with the develop-

ment of [108] prostaglandins from arachidonic acid (Ehrlich, Tr. 4005; CX 269, pp. 69,777–78; RX 1015).

356. Respondent's medical experts testified that Aspercreme, through its TEA/S component, achieves its analgesic and anti-inflammatory action by penetrating through the skin to the underlying tissues and working at a cellular level, through its salicylate ion, to inhibit the formation of PGs (Ehrlich, Tr. 4008–09; Heller, Tr. 2612–13).

357. It is difficult if not impossible to determine at what blood (serum) level the salicylate ion becomes an effective analgesic agent. The amount of salicylate in the blood does not correlate to clinical analgesia (Adriani, Tr. 1290; CX 268, p. 35,382).

358. Therapeutic serum levels of salicylate differ from the levels of salicylate at the local site (Roth, Tr. 1688). Therefore, the pain-relieving effectiveness of an analgesic agent cannot be measured by analysis of the salicylate serum level (Roth, Tr. 1688). According to Dr. Silverman, because aspirin is ingested orally and must first circulate through the blood stream before reaching the affected site, the action of oral aspirin in relieving pain is slower than the action of topically applied salicylate (Silverman, Tr. 2174; RX 49).

359. Theories regarding a drug's mechanism of action are not a substitute for clinical testing for purposes of demonstrating drug efficacy. Thus, attempts to evaluate a drug's mechanism of action are generally made after the drug's efficacy has been established clinically (Ehrlich, Tr. 4008–10; Roth, Tr. 1613–15). In any event, even on a purely theoretical basis Thompson's theories of Aspercreme's action leave too many questions unanswered. The record also shows many inconsistencies with respect to the assumptions about salicylates, TEA/S, and prostaglandins upon which the theories essentially rest.

360. As to salicylates, the Thompson's theory apparently is founded on the tenet that topical TEA/S arrives in the muscle or other point of pain as salicylate and that the salicylate in TEA/S is the same as the salicylate in aspirin and will therefore provide relief in the same way as oral aspirin does (Steinberg, Tr. 5131). Aspirin and TEA/S are not the same drug: aspirin is a salicylate to which an acetyl group has been added; TEA/S is a milder nonacetylated salicylate (O'Brien, Tr. 3729, 3877–78; Roth, Tr. 1516–17). The assumption that all salicylates are the same is untenable given that no one really knows how analgesics work and that the metabolism of aspirin in the body is highly complex (Ehrlich, Tr. 4047–48; O'Brien, [109] Tr. 3877). Currently, there are at least two schools of thought on aspirin's action. One is that the salicylate molecule itself is anti-inflammatory, and that the acetyl moiety is merely a means of delivering the salicylate. The other is that the acetylation irreversibly acetylates the platelets that are

part of the inflammatory process and this is essential for full relief (O'Brien, Tr. 3879; Roth, Tr. 1658–59). Moreover, there is a body of opinion to the effect that nonacetylated salicylates do not inhibit prostaglandin synthetase (Roth, Tr. 1675). Regardless of how either aspirin or TEA/S may work, there is also support for the proposition that aspirin and salicylates other than methyl salicylate are not effective as *topical* analgesics (Adriani, Tr. 1480).

361. Disregarding the chemical differences between TEA/S and aspirin, there are still unanswered questions surrounding the "site of action" component of Thompson's theory. Although theories as to how aspirin works are continuously evolving, the prevailing view is that in producing an analgesic effect, aspirin acts peripherally, or locally, as well as centrally on the central nervous system (Ehrlich, Tr. 4057–58; Roth, Tr. 1655–56; CX 268, pp. 35,351, 35,381). When Thompson acquired Aspercreme from Sperti in 1976, there were two theories about Aspercreme's mechanism of action. One was that topical TEA/S exerted an analgesic effect by achieving therapeutic levels in the bloodstream. The other was that TEA/S worked by penetrating directly to the point of pain (Steinberg, Tr. 5261–62; RX 41/CX 251Z–058). For purposes of this proceeding, Thompson has adopted the position that topically applied TEA/S acts locally "at the point of pain" (CX 45N (Admission No. 274)). Topical TEA/S, unlike aspirin, is not a systemic drug and thus would not provide whatever relief is produced by the central nervous system ("CNS") effect of aspirin. In addition, TEA/S could do little to modify a systemic process like inflammation, which is a major factor in many arthritic conditions (Roth, Tr. 1536, 1757).

362. In addition, TEA/S is a relatively obscure drug. There is little medical literature on TEA/S, and it is not included in any authoritative drug treatise (O'Brien, Tr. 3716–18; Roth, Tr. 1761; Silverman, Tr. 2347, 2385–86). An expert advisory panel to the FDA has approved TEA/S, in concentrations of 5% to 12%, as an OTC drug for only one use, as a mild sunscreen (Roth, Tr. 1684; CX 394B, H). It is the salicylate, not the TEA, in TEA/S that acts as a sunscreen (Roth, Tr. 1684; CX 394B (triethanolamine salicylate listed as an active sunscreen ingredient, triethanolamine listed as inactive)). This would suggest that most of the salicylate in TEA/S remains in the dermis, rather than penetrating into the deeper tissues, [**110**] since all sunscreens work in this fashion (Adriani, Tr. 1458; Roth, Tr. 1684).

363. Another problem in Thompson's theory of Aspercreme's efficacy is the assumption that TEA/S works by inhibiting prostaglandin synthetase. Prostaglandins are enzymes found throughout the body, some of which are now thought to be implicated in the inflammatory process (Adriani, Tr. 1286–87; Roth, Tr. 1651–52). However, there is

no evidence in this proceeding showing that TEA/S blocks prostaglandin synthetase. Moreover, blocking prostaglandin formation is not the only way of curbing the inflammatory process, since several mechanisms are known to be involved in inflammation (Ehrlich, Tr. 4049–51; Roth, Tr. 1745–46). Furthermore, prostaglandin theory is an evolving theory and not all prostaglandins have been discovered. Some known prostaglandins, which were initially thought to play a central role in the inflammatory process, are now considered to be less important as new prostaglandins are discovered (Ehrlich, Tr. 4049–50; Roth, Tr. 1755–57). In addition, no one knows which prostaglandins are involved in arthritis (Adriani, Tr. 1445; Ehrlich, Tr. 3996–97). Finally, prostaglandins are only one of a series of inflammatory mechanisms studied over the years (Roth, Tr. 1613–15). In any event, the requirement for well-controlled clinical trials remain unaffected by any theory of the inflammatory process (Adriani, Tr. 1446; Ehrlich, Tr. 4008–10; Roth, Tr. 1624).

364. From all of the foregoing, it is found that Thompson's clinical trials, bioavailability studies, and theories about TEA/S' mechanism of action fail to provide an acceptable level of scientific support for the claim that Aspercreme acts by penetrating through the skin to the site of arthritic disorders. On the contrary, the failure to show significant bioactivity in controlled clinicals suggests that TEA/S in Aspercreme is not absorbed in amounts necessary to demonstrate its analgesic efficacy (Roth, Tr. 1574).

K. *Marketing Data Related To Aspercreme*

365. In support of its claims of Aspercreme's efficacy, Thompson relies on various marketing-related data, including Aspercreme package insert cards mailed in by purchasers of the product, a survey of pharmacists, information on repeat purchases, and unsolicited consumer letters received over the years. According to the FDA Panel Report on External Analgesic Products, as well as expert opinion in this case, marketing experience related to an OTC analgesic product is at best a corroborative or confirmatory type of evidence, and under the [111] prevailing, scientifically accepted principles, it does not constitute the direct evidence or primary evidence needed to prove drug efficacy in the first instance (Adriani, Tr. 1433–34; Ehrlich, Tr. 4155–56; Roth, Tr. 1764; CX 269, p. 69,780). The FDA regulations governing the advisory panel OTC drug review process specifically provides that reports of significant marketing experience are appropriate only as a source of corroboration for proof of effectiveness, and that isolated case reports, random experiences, and reports of product efficacy lacking the details which permit scientific evaluation are not to be relied on in determining product effectiveness. 21 C.F.R.

330.10(a)(4)(ii). Therefore, marketing experience by itself cannot be regarded as constituting adequate proof of drug efficacy (CX 395B).

366. Marketing data includes information on the number of units of the product sold to consumers and the number of consumer complaints received by the manufacturer (Adriani, Tr. 1346–47). Marketing data can indicate wide consumer acceptance of a drug (Adriani, Tr. 1345). And while not a primary source of information on a drug's efficacy (Roth, Tr. 1704), postmarketing data can provide a level of important information related to product safety—primarily long-term toxicity and idiosyncratic reactions resulting from product usage (Roth, Tr. 1709–10).

1. Consumer Response Cards And Consumer Letters

367. Evidence relied on by Thompson includes various data showing consumer satisfaction with the product, such as the following:

(i) Consumer response cards (package insert cards): Beginning in 1978, Thompson Medical included response cards in Aspercreme packages which were to be filled out and returned by the user. While there have been various forms of response cards which asked somewhat different questions, consumers were generally asked their general opinion of Aspercreme, particularly whether it worked better than aspirin. By 1982, some 30,000 response cards had been returned to Thompson. Two different tabulations of various groups of response cards were prepared. The results generally indicated that the consumers who returned the response cards had a favorable opinion towards Aspercreme (RXs 292, 521, 711). [112]

(ii) Consumer letters: When Thompson acquired Aspercreme from the Sperti Drug Company in 1976, all consumer letters which had been received by Sperti were turned over to Thompson (Siegal, Tr. 4599). Since then, Thompson has continued to receive consumer letters regarding Aspercreme (Siegal, Tr. 4598–99). Currently, Thompson's file of consumer letters contains almost 800 letters, most of which comment favorably on Aspercreme's efficacy (Siegal, Tr. 4603–04).

(iii) Thompson Medical has received approximately 3,400 requests for refunds since 1978 (RX 94).

368. The consumer response cards and letters represent only a small fraction (about 2%) of the Aspercreme purchases (Siegal, Tr. 4666; Silver, Tr. 5884, 5886). Such a low response rate is considered unacceptable for a survey because the respondents could not be considered representative in any meaningful sense (*See* Silver, Tr. 5883–84). This is particularly true with respect to the response cards and letters because, unlike a survey, these consumers were completely

self-selected. It is also clear that those who sent in the response cards and letters differ substantially from those who did not in that the former feel much more strongly about Aspercreme than the latter (Ross, Tr. 6449–50).

2. *Pharmacy Times* Survey (RX 143)

369. RX 143, "OTC Products The Pharmacist Recommends And Why," is a 1981 survey of pharmacists by *The Pharmacy Times,* offered to support Aspercreme's efficacy claims. *The Pharmacy Times* is a marketing publication for the pharmacy trade and is distributed free of charge to pharmacists and pharmaceutical houses. Its costs are borne by its advertisers. *The Pharmacy Times* purports to provide marketing information in the field of pharmacy (Reis, Tr. 5488). *The Pharmacy Times* survey of OTC drug products is conducted on an alternate year basis (Reis, Tr. 5492). RX 143, the report of the results of the survey, was first published in *The Pharmacy Times* in approximately late spring of 1981 (Reis, Tr. 5493). The survey was conducted by mailing questionnaires to a selected group from among the retail trade portion of *The Pharmacy Times'* mailing list (Reis, Tr. 5493–94). The survey questionnaires were mailed concurrently with a request for verification of address, as part [113] of *The Pharmacy Times'* audit of circulation conducted once every three years (Reis, Tr. 5495, 5498–99). A total of 3,000 questionnaires were mailed out, and there were some 807 completed returns at the time the report was prepared (RX 143C). The survey questionnaire first asked respondents to estimate the number of recommendations they or their employees make for all brand name products in each category of OTC products each month. Secondly, the questionnaire asked which single product within each category the respondent would recommend by brand name (Reis, Tr. 5511–12; RX 143).

370. *The Pharmacy Times* survey is thus essentially a marketing survey. The results show that only 11.5% of the respondents recommended Aspercreme, and about 70% of the respondents made no recommendations for topical analgesics or did not recommend a TEA/S-based product (RX 143). In any event, pharmacists' recommendations are substantially influenced by advertising and other promotional activities (Ross, Tr. 5541, 6404–05). Studies in the literature have demonstrated the influence of advertising on physicians and dentists (Ross, Tr. 6405). The effect of advertising on consumer experience has been noted by FDA expert advisory panels (*See, e.g.,* CX 396B). In the present case, Thompson's trade ads, such as RX 166E (a trade ad to druggists), made strong express claims that Aspercreme's effectiveness was clinically proven, and proven better than aspirin in clinical studies (Ross, Tr. 6406–07). Dr. Roth testified that a survey of

pharmacist recommendations of pain relief products is not reliable evidence that the product in fact relieves pain (Roth, Tr. 1706–07). Dr. O'Brien testified that he does not rely on retail pharmacists as a source of information on the efficacy of OTC drug products (O'Brien, Tr. 3906–07). Since pharmacists' recommendations are based on a number of factors other than product efficacy, they do not provide reliable evidence of the efficacy of Aspercreme. The survey (RX 143) also suffers from a number of methodological problems (*See* CPF 435–38). It is of little value in this proceeding.

371. In any event, the 1981 *Pharmacy Times* survey (RX 143) was not published until late spring of 1981 (Reis, Tr. 5493). Thompson did not possess and rely on RX 143 when those advertising claims were made (*See* CX 25), nor did it cite or rely on this survey as part of its reasonable basis materials (*See* CX 44A).

L. *The Significance of Other Clinical Trials Showing Negative Results For 10% TEA/S Topical Products*

372. Just as the clinical trials which failed to show significant differences between TEA/S and aspirin do not prove **[114]** that the two are equally effective (F. 237, *supra*), the five other clinical studies in evidence which compared TEA/S and placebo with negative results do not prove that there is no difference between the two. These negative studies simply show that the analgesic efficacy of TEA/S remains to be established. The five studies are the Roth study (CX 344Z–195); Ehrlich study (CX 344Z–157); Charles study (CX 344Z–168); Brown study (CX 344Z–182); and Algozzine study (CX 255). All of the five tested a 10% TEA/S creme as an adjunctive drug to be used in conjunction with other therapy (Adriani, Tr. 1454).

373. The first four studies (CX 344 series) had been submitted by Warren-Teed Pharmaceuticals Corporation, the marketer of Myoflex (a 10% TEA/S rub), to the FDA in connection with the FDA's monograph proceeding involving OTC external analgesic drug products (CX 344A). In its Tentative Final Monograph on OTC External Analgesic Products, published February 8, 1983, the FDA referred to the four studies and stated that none of them reported any significant differences between TEA/S and placebo for any of the measurements recorded (CX 443D).

374. While some of these negative studies have been criticized as not being well-controlled in several respects, these studies, together with the other studies discussed earlier (*i.e.*, the Golden study, the Golden and Altschuler study, the French studies and the Batterman and Sanders study) show the many opportunities that TEA/S has had—with different methodologies, by different investigators, and under

various conditions—to show that it is significantly better than placebo (Roth, Tr. 1622–23).

375. The five negative studies discussed here which tested TEA/S as an adjunctive drug also show that Aspercreme's efficacy when used to relieve the so-called breakthrough pain (*See* RPFs 138 and 140) remains to be demonstrated (Adriani, Tr. 1454–55). In any event, the evidence regarding the five so-called negative clinicals is summarized below.

1. The Roth Study (CX 344Z–195)

376. The first study, entitled *Myoflex Arthritis Study* (CX 344Z–195), by Dr. Sanford Roth, was a double-blind, two-way crossover study which compared the effects of Myoflex cream and a placebo cream in arthritis patients. One hundred and two patients were enrolled in the study, which took from July 1976 to November 1978 to complete (Roth, Tr. 1521). Efficacy measures in the study included the average daily duration of morning stiffness; average joint size in both hands; grip strength in both hands; an articular index with categories for **[115]** pain, swelling, and limitation of movement; a nine-point scale showing the patient's overall assessment of pain; and a composite articular index. Observations on each of these variables were taken at baseline and at the end of the first and fourth weeks of each treatment sequence. In addition, a treatment preference rating was obtained from the subjects at the end of the second treatment sequence. The study results shows that in comparing the two creams on ten objective efficacy parameters and on the subjective parameter of patient treatment preference, there were no statistically significant differences between Myoflex cream and placebo cream (Roth, Tr. 1518–21, 1524–25; CX 344Z–200–04).

377. The subjects in the Roth study were patients with diagnosed chronic rheumatoid arthritis. The study design provided that the subjects could continue to use, as concomitant medications on an as needed basis, those oral anti-inflammatory and/or analgesic agents that they had been using prior to their participation in the study (CX 344Z–197–98). The reason for this was that rheumatoid arthritis is a systemic disease and since there was no evidence that the topically applied agent had any systemic effect, the existing forms of systemic therapy were continued to provide a baseline. The topically applied creams were being added on to the patients' regimens as a layer of further treatment to see if the test ingredient made an extra difference in controlling the pain symptom (Roth, Tr. 1752). By crossover of the test and control substances in a double-blind manner, each of the patients acted as his own control (Roth, Tr. 1552). There were no major changes in the subjects' regimens during the study period

(Roth, Tr. 1523). An additional reason for the subjects' continuing their systemic medications during the study period was that the TEA/S product tested in the Roth study, Myoflex, was intended for use as an adjunct to other treatment and was in fact marketed as an adjunctive product. Where the tested product is so marketed, it would be inappropriate to take study subjects off their concomitant medications (Roth, Tr. 1524).

378. In the Roth study, many subjects suffering from moderate to severe osteoarthritis did not get any relief from aspirin despite the fact that therapeutic doses of aspirin have been proven effective in treating moderate osteoarthritis (Roth, Tr. 1714–15). Dr. Adriani also noted that the use of oral anti-inflammatory or analgesic drugs and the use of physical therapy during the test period made the results unreliable as evidence of Myoflex's analgesic efficacy.

379. The Roth study finding that TEA/S is indistinguishable from placebo was one of those cited in the Tentative Final Monograph on OTC External Analgesic Drug Products as a basis for the FDA's conclusion that the evidence does not support Category I status for TEA/S as an OTC external analgesic [**116**] (CX 443D). In a letter to the manufacturer of Myoflex (CX 343C), the FDA's Bureau of Drugs likewise referred to the Roth study in reaching a similar conclusion.

2. The Ehrlich Study (CX 344Z–157)

380. The second clinical study, entitled *Myoflex Creme in Patients With Chronic Musculoskeletal Complaints* (CX 344Z–157), by Dr. George Ehrlich (one of Thompson's expert witnesses in this case), was a double-blind, placebo-controlled, crossover evaluation of a TEA/S cream and a placebo cream. The fifteen study subjects applied the TEA/S cream or placebo cream to the affected area three times daily for two two-week test periods. The objective of the study was to evaluate the analgesic effectiveness of Myoflex cream in the treatment of prolonged or chronic disability of musculoskeletal origin. Patients with arthritic symptoms, with sporadic musculoskeletal complaints, or with histories of spontaneous remission were excluded from participation in the study (CX 344Z–158).

381. The Ehrlich study was originally scheduled to have thirty subjects, but the investigator was unable to secure sufficient patients with the specified qualifications within a reasonable period of time and a decision was made to terminate the study at fifteen patients. This number is obviously inadequate (F. 232, *supra*). Of the fifteen patients, two did not complete both study periods and thus their results were excluded from the final evaluations. Physical therapy programs and oral anti-inflammatory drugs used by the subjects prior to entering the study were normally maintained. Ten of the subjects

were using a concomitant medication during the study period. This was in keeping with the usage and marketing of Myoflex creme as an adjunct analgesic product. No oral or other typical salicylates were permitted during the study (CX 344–158–59).

382. The study results showed that Myoflex provided some pain relief to six of the thirteen patients completing the study, while four of the thirteen patients reported some relief from use of the placebo cream. The degree of pain relief provided by Myoflex did not appear to be significantly greater than the degree of relief provided by the placebo. For the parameters of onset of pain relief and duration of relief, the differences between Myoflex and placebo were small and probably not significant. In terms of increased strength in the affected area, the improvement with Myoflex was not significantly different from that of placebo. In all, there were no statistically significant differences between active drug and placebo for any of the measurements recorded. [**117**]

3. The Charles Study (CX 344Z–168)

383. The third study by Dr. Alix A. Charles, entitled *Myoflex Creme in the Treatment of Chronic Musculoskeletal Complaints,* had the same basic design as the Ehrlich study. Like the Ehrlich study, it was criticized for inadequate sample size, use of concomitant physical therapy and the maintenance of drug therapy in many of the subjects (Adriani, Tr. 1411–14; Roth, Tr. 1621).

384. Out of a total of thirty subjects planned for inclusion in the Charles study, twenty-six patients entered the study, but final data is available for only twenty who completed the full study regimen. Of these, twelve continued their prior use of physical therapy and/or concomitant medication during the study period, again reflecting the intended use of Myoflex cream as an adjunctive product. The study showed that Myoflex provided some pain relief in fifteen of the twenty patients who completed the study. However, an equal number of patients reported relief from the placebo agent. Relief, as measured by improvement from the initial pain, was statistically significant for both treatments, but there were no significant differences between Myoflex and placebo for any of the parameters studied. The study write-up noted that the high placebo response rate observed in the study was not unusual for analgesic type studies. Both treatments required the topical cream to be rubbed into the affected area, it noted, and this massage action itself may be beneficial to patients with musculoskeletal complaints.

4. The Brown Study (CX 344Z–182)

385. The fourth clinical trial is entitled *Myoflex/Chronic Musculoskeletal Complaints* (CX 344Z–182). It was conducted by Dr. Burnell Brown for Adria Laboratories, manufacturer of Myoflex. The objective of the Brown study was to evaluate the efficacy of Myoflex in the adjunctive relief of pain associated with chronic musculoskeletal complaints. The study included fifty-two patients (of whom forty-two completed the full study regimen) in a double-blind, matched placebo controlled, crossover evaluation. The subjects were assigned to the test groups randomly, with half the subjects starting with Myoflex and half with placebo the first week, before being switched to the crossover medication for an additional one week. After the two one-week periods with TEA/S and placebo (without washout between periods), all patients were treated for a final one-week period with methyl salicylate. Statistical analysis of the data for the forty-two evaluable patients in the Brown study revealed [118] no statistically significant differences between the Myoflex, placebo, or methyl salicylate treatments based on any of the four study parameters analyzed: reduction of pain; increase in mobility; reduction in muscle tenderness; and overall musculoskeletal complaint improvement (CX 344Z–187). The Brown results are questionable because of the use of oral anti-inflammatory agents and failure to distinguish different clinical entities and diseases (Adriani, Tr. 1414–15; CX 344Z–182). Dr. Roth testified that the Brown study's methodology was flawed and that it did not measure up to the criteria for a valid study (Roth, Tr. 1719).

5. The Algozzine Study (CX 255)

386. The most recent of the five clinical studies in which TEA/S was reported to be no more effective than placebo is the study entitled *Trolamine Salicylate Cream in Osteoarthritis of the Knee* (CX 255), by Dr. Gary Algozzine, *et al.*, reported in the March 5, 1982 issue of the *Journal of the American Medical Association.* The study involved twenty-five patients, drawn from a Veteran's Administration hospital in Florida, who had symptomatic osteoarthritis of the knee. Study subjects were asked to designate their most painful knee and to apply either 10% TEA/S or placebo cream four times daily for two one-week periods in a randomized double-blind crossover study. Drug efficacy was measured along both subjective and objective parameters.

387. Patients were prohibited from using any concomitant oral or topical salicylates or any other analgesic drug during the study period and for the two days preceding the test period. However, because TEA/S was considered adjunctive treatment, patients currently re-

ceiving other forms of drug treatment for osteoarthritis (*e.g.,* non-steroidal anti-inflammatory agents) were eligible for inclusion in the study provided that their condition had been stabilized on a stated dose of the drug for the preceding one-month period. There were no changes in drug or dosage permitted during the study period. No patient received an intra-articular injection of a corticosteroid within the preceding six weeks, and no other form of treatment, such as external heat, exercise, or massage was used during the study period. Thirteen patients received concomitant non-steroidal anti-inflammatory medication during the study period.

388. The study results showed no statistically significant difference either in subjective or objective measures of relief between the treatment and control groups. Eight patients preferred the "active" test cream, while six preferred placebo, and eleven had no preference (CX 255B). The investigator **[119]** concluded that the clinical data show the total effect of 10% TEA/S cream to be no better than that of placebo (CX 255C). In any event, this study suffers from a few defects. More than half of the test subjects received concomitant non-steroidal anti-inflammatory agents (Adriani, Tr. 1419), and they were virtually all bedridden males in a VA hospital, a group not well suited for the trial of a topical drug intended for minor pain of arthritis.

389. The presence of conflicting evidence with respect to a drug's efficacy leaves the scientific community in doubt about the drug's efficacy, as respondent's own expert acknowledged (O'Brien, Tr. 3738). Dr. Steinberg, an officer and employee of Thompson, testified that in and around 1980, he became aware of the four TEA/S studies conducted by Drs. Roth, Ehrlich, Charles and Brown (Steinberg, Tr. 5255). He became aware of the Algozzine study when it was published in the *Journal of the American Medical Association* in 1982 (*Id.*). Despite this information, the company continued to make its unqualified efficacy claims for Aspercreme.

M. *The Argument That The Evidence Of Perceived Benefits Constitutes Adequate Substantiation For Aspercreme Efficacy Claims*

390. Respondent vigorously contends that Aspercreme has been shown to be a safe topical drug capable of providing perceptible pain relief to a significant segment of the consuming public and that this evidence alone is sufficient to satisfy the Commission's reasonable basis requirement. In this connection, respondent points to the fact that a number of FDA OTC drug panels, including the OTC External Analgesic Products Panel, have determined a number of ingredients to be effective on the basis of uncontrolled studies, long-term clinical use and marketing experience. Respondent urges that Aspercreme

should be found effective on the same basis (*See* RPF 123, 206–28; RB 49–59). These arguments, however, cannot be reconciled with the consistent refusal of both the FDA and its External Analgesic Panel to find TEA/S to be effective for labeling/marketing purposes (F. 393–95, *infra*).

391. The FDA OTC drug panels which based a finding of drug efficacy on evidence short of two well-controlled clinical trials include the OTC Internal Analgesics Panel:

(a) The Panel found, without well-controlled studies, the ingredient choline salicylate to be an effective analgesic. The Panel based its findings [**120**] solely on a survey of physicians who had given the ingredient to their patients. In some cases, the physician compared the effects of choline salicylate in some patients with the known effects of aspirin in his patient population at large (CX 268, p. 35,418).

(b) The Panel found the ingredient magnesium salicylate to be an effective analgesic. The Panel relied upon a clinical study with only twenty-two patients which compared magnesium salicylate with aspirin and found no statistically significant differences in the levels of analgesia. Because magnesium salicylate produced less gastrointestinal irritation than aspirin, the authors of the study concluded, and the Panel agreed, that magnesium salicylate was not only an effective analgesic, but preferable to aspirin for conditions requiring long-term therapy (CX 268, p. 35,419).

(c) The Panel found calcium carbaspirin to be an effective antipyretic, not based on controlled clinical studies, but on the fact that the absorbed moiety is aspirin and its established adequate bioavailability demonstrated an effect similar to aspirin (CX 268, p. 35,448).

392. In reaching its conclusion of efficacy of a wide variety of externally applied ingredients, the OTC External Analgesic Panel considered data from both controlled and uncontrolled subjective studies (CX 269, p. 69,778). The Panel also gave consideration to reports of long-term, widespread satisfactory clinical use and marketing experience in evaluation of ingredients. For example, the Panel based its determination that:

(a) the ingredient Stronger Ammonia Water was an effective external analgesic on the ingredient's wide use, its clinical acceptance, and on published reports in the literature (CX 269, p. 69,793);

(b) the ingredient Juniper Tar was an effective external analgesic based on the ingredient's wide use, clinical acceptance, [**121**] and on published reports in the literature (CX 269, p. 69,824);

(c) the ingredient Turpentine Oil was an effective external analgesic based on the ingredient's wide use, clinical acceptance, and on published reports in the literature. No scientifically controlled

studies concerning the use of turpentine oil alone for the treatment of rheumatism, arthritis, or muscular aches and pains were submitted (CX 269, p. 69,840).

VIII. FDA DETERMINATIONS ABOUT TEA/S' ANALGESIC EFFICACY

393. The most authoritative record evidence that topical TEA/S' analgesic efficacy remains to be demonstrated is the consistent refusal of both the FDA and its External Analgesics Panel to find TEA/S to be effective for labeling purposes under the Food, Drug and Cosmetics Act. The first decision on TEA/S' lack of efficacy was that of the FDA's Advisory Review Panel in December of 1979 (CX 269). The Panel was unimpressed by the evidence of TEA/S' efficacy.

> The Panel does not give serious consideration to the claim that the drug penetrates the skin and passes directly into the affected deeper structures in sufficient concentrations to be effective because there is no data available to substantiate this claim (CX 269, p. 69,856).

394. In response to the Panel's rejection of TEA/S as a topical analgesic, both Thompson and Warren-Teed Pharmaceuticals, Inc., the maker of another topical TEA/S product, submitted additional material in 1980 to the FDA's Bureau of Drugs in an effort to reverse the Panel's decision (CXs 342–43). The material submitted by the companies included the Golden study (RX 49, discussed in F. 246–74, *supra*), the Golden and Altschuler study (RX 50, discussed in F. 275–98, *supra*), the Batterman and Sanders study (CX 254, discussed in F. 307–12, *supra*), the Patel and Chappelle materials (RX 35–37, discussed in F. 299–306, *supra*), the canine portion of the Rabinowitz study (RX 70, discussed in F. 315–20, *supra*), the Roth study (CX 344Z–195 discussed in F. 376–79, *supra*), the Ehrlich study (CX 344Z–157 discussed in F. 380–82, *supra*), the Charles study (CX 344Z–168 discussed in F. 383–85, *supra*), and [**122**] the Brown study (CX 344Z–182 discussed in F. 385, *supra*). As a result, the FDA's Bureau of Drugs had before it most of the clinical studies in evidence on this proceeding. The Bureau of Drugs reiterated the Advisory Panel's decision with respect to TEA/S, that there were not sufficient data to support the drug's efficacy as a topical analgesic (CXs 342C, 343D).

395. The current position of the FDA with respect to TEA/S' analgesic efficacy was formally announced upon publication of the tenative final monograph for external analgesics (CX 443) in which the FDA adopted the Panel's determination and affirmed the Bureau's position. The pertinent portion of the FDA's tentative final monograph (proposed rule) on external OTC analgesic drug products, announced February 8, 1983, is as follows:

Two comments submitted data on the effectiveness of trolamine salicylate [TEA/S] as a topical analgesic. Based on these data, one of the comments suggested that the monograph include a class of external analgesics that "act upon painful structures below the skin by absorption of the active ingredient directly into subcutaneous structures" and that trolamine salicylate (TEA/S] be placed in this class. The comment also suggested the following indications for this class: "For the temporary relief of minor aches and pains of muscles and joints. Also as a topical adjunct for pain due to arthritis and rheumatism." Both comments suggested that trolamine salicylate [TEA/S] be placed in Category I based on the data submitted.

* * * * * * *

Because the submitted information fails to demonstrate that this ingredient would be effective for application at the site of pain or for any use as an external analgesic, the agency does not agree with the comments that trolamine salicylate [TEA/S] should be placed in a new class of external analgesic drug product. Trolamine salicylate [TEA/S] remains in Category III as an anesthetic, analgesic, and antipuritic in this tentative final monograph (CX 443, p. 5855). **[123]**

The FDA's proposed rule also specifically rejected as inadequate all of the material referred to in F. 394, *supra* (*Id.*).

396. Concomitantly, Dr. William E. Gilbertson, the Director of the Division of OTC Drug Evaluation, advised Thompson by letter dated February 9, 1983:

All of the data and information in your Citizen petition and subsequent correspondence, as identified above, have been included in the Administrative Record. When the review of the data and information is completed, you will be notified of the Agency's findings pursuant to the Agency's feedback procedures (RX 296).

397. Included in the data submitted by Thompson to the FDA but not specifically considered by the FDA in its tentative final monograph (CX 443) are:

(i) Citizen Petition dated November 24, 1981 (RX 366), containing *inter alia,* the published report of Dr. Rabinowitz (RX 70 discussed in F. 315–29, *supra*); the pilot investigation of TEA/S's ability to influence prostaglandins synthesis (RPF 146 discussed in F. 355–63, *supra*); backup data from the Golden and Altschuler study (RX 50 discussed in F. 275–98, *supra*); written report and patient report forms on the French Clinical Trials conducted by Drs. Alain Patel and Pierre Andre Chappelle in 1976 and 1977 (RXs 35–37 discussed in F. 299–306, *supra*); as well as considerable marketing and consumer-generated information.

(ii) B.F. Ascher Company, Inc. survey of physicians (RX 346 discussed in F. 338–39, *supra*).

(iii) "Drug Delivery to Local Subcutaneous Structures Following Topical Administration" a review article by Drs. Guy and Maibach

accepted [124] for publication in *The Journal of Pharmaceutical Sciences* (RX 1020).

(iv) Double-blind clinical study conducted at the Baltimore Center for Clinical Studies entitled "Double-Blind Clinical Evaluation of Aspercreme Plus Two Placebo Tablets Versus Aspirin Plus a Placebo Creme For Relief of Pain Associated with Arthritis," purporting to show that Aspercreme is as effective as aspirin.

See RB 17.

398. Of the pending FDA submissions by Thompson, referred to as "Your Citizen Petition and subsequent correspondence" in Dr. Gilbertson's letter of February 9, 1983 (RX 296). the only biomedical studies not specifically commented on and rejected as insufficient by the FDA to date are: the Rabinowitz study (RX 70 dicussed in F. 315–29, *supra*); the Guy and Maibach article (RX 1020 discussed in F. 324, *supra* and a clinical study conducted for Thompson by the Baltimore Center for Clinical Studies ("Baltimore study"). The last two evidently postdate Thompson's November 1981 FDA petition and thus could not have been possessed or relied on by Thompson as substantiation for the various advertising claims challenged in this proceeding.

399. In any event, the Rabinowitz study and the Guy-Maibach article are penetration studies and do not purport to show TEA/S' bioactivity. The Baltimore study compared Aspercreme plus placebo tablets and aspirin plus placebo creme, as did the Golden study (CX 200), and thus lacked placebo-control. The lack of placebo control is a basic methodological flaw in a pain study (*See* F. 228, *supra*). Furthermore, its failure to show significant difference between the two treatment groups ("Aspercreme was as effective as, if not better than, aspirin") does not demonstrate that Aspercreme and aspirin are equally effective (*See* F. 237, *supra*).

400. Therefore, it is highly unlikely that the FDA, as a result of its review and feedback procedures referred to in the Gilbertson letter (F. 396, *supra*), will reverse its position with respect to TEA/S' topical analgesic efficacy. Against this background, for the FTC to hold, on the basis of essentially the same evidence considered by the FDA, that Thompson's efficacy claims for Aspercreme are based on adequate medical/scientific substantiation for advertising purposes would not only be contrary to the prevailing view of the medical scientific community but also be tantamount to establishing a different and [125] lower standard of efficacy for OTC drug advertising than that applicable to OTC drug marketing.

401. In sum, the clinical trials on which Thompson relies are inadequate to demonstrate the effectiveness of TEA/S as an external

analgesic. The bioavailability studies are not a substitute for well-controlled clinical trials, but also on the whole they show that TEA/S is poorly absorbed and thus probably not bioactive. The physicians' observation and consumer testimonials upon which Thompson relies are corroborative evidence at best. And the general scientific literature and the various theories of TEA/S' mechanism of action are not a substitute for clinical demonstration of TEA/S efficacy.

402. From all the foregoing, it is found that at the time respondent made the advertising claims alleged in Paragraphs 12(a) and 14 of the complaint, it did not possess and rely on a reasonable basis for its claims that Aspercreme is an effective topical pain reliever, including arthritic pain.

IX. THOMPSON DID NOT HAVE A REASONABLE BASIS FOR COMPARATIVE EFFICACY CLAIMS

403. The record shows, and Thompson admits, that in order to show the comparative efficacy of two drugs, clinical trials directly comparing the two drugs are required (Adriani, Tr. 1177; Byers, Tr. 4384, CX 45Q (Admission No. 339); *see also, American Home Products Corp.*, 98 F.T.C. 136, 304–15 (1981), *modified,* 396 F.2d 681 (3rd Cir. 1982) [101 F.T.C. 698 (1983)]. The only clinical trial in evidence comparing the results of using oral aspirin and topical TEA/S is the Golden study (RX 48/CX 200) (Altschuler, Tr. 3060; CX 45I (Admission No. 142). The Golden study is not a well-controlled clinical study for the purpose of showing topical TEA/S' analgesic efficacy (*See* F. 246–74, *supra*). Accordingly, there is no reasonable basis for any claim about either TEA/S' parity with or superiority to oral aspirin. Moreover, since Thompson's substantiation materials as a whole fail to provide the required level of scientific proof of Aspercreme's basic analagesic efficacy, there is clearly no substantiation for claims regarding the comparative efficacy of TEA/S. Thus at the time of the representations alleged in Paragraphs 12(b), 12(c) and 14 of the complaint, Thompson did not have a reasonable basis for the claims that Aspercreme is either as effective as or more effective than oral aspirin for the relief of minor pain associated with arthritis and rheumatism, as alleged in Paragraphs 12(b), 12(c) and 14 of the complaint.

404. Accordingly, the claim that valid studies have scientifically proven that Aspercreme is more effective than **[126]** orally-ingested aspirin, as alleged in Paragraph 10(c) of the complaint, was, and is, false.

X. THOMPSON DID NOT HAVE A REASONABLE BASIS FOR EFFICACY CLAIMS ABOUT RHEUMATIC PAIN

405. Thompson has advertised Aspercreme as being effective for the relief of pain associated with rheumatic as well as arthritic conditions. With the exception of only one document (RX 63/CX 265), Thompson relies on the same materials to justify its claims for rheumatic conditions that it relied on for claims about arthritic conditions (CX 44A-B). For the reasons discussed in Section VII, these materials fail to demonstrate that topical TEA/S is an effective drug for pain relief. Since rheumatism is musculoskeletal pain by definition, the materials Thompson used for arthritic conditions do not constitute a reasonable basis for any claims about Aspercreme's efficacy for relief of rheumatic conditions and symptoms.

406. RX 63/CX 265 is a letter from an employee of Warren-Teed Pharmaceuticals which markets Myoflex (a 10% TEA/S rub), to Dr. Saul Heller, a psychiatrist who specializes in acupuncture and has been a consultant to Thompson for more than twenty years (Heller, Tr. 2566, 2604). Without disclosing his affiliation to Thompson, Dr. Heller wrote to Warren-Teed for information about its topical TEA/S product (Heller, Tr. 2629). Warren-Teed's reply (RX 63) briefly describes some bioavailability and clinical studies conducted by Warren-Teed on Myoflex. Dr. Heller never saw any of the studies mentioned in the letter, and the letter only suggests that Warren-Teed's product may be used as "an adjunctive therapeutic agent" (Heller, Tr. 2625–28; RX 63B). This letter adds nothing as a practical matter to the reasonable basis materials discussed in Section VII above. Accordingly, when Thompson made the representation alleged in Paragraphs 12(d) and 14 of the Commission's complaint there was no acceptable scientific support and no reasonable basis for the claim that Aspercreme is effective for the relief of rheumatic pain (Adriani, Tr. 1185; Roth, Tr. 1573–74).

XI. THOMPSON DID NOT HAVE A REASONABLE BASIS FOR CLAIMS ABOUT DRUG ACTION BY DIRECT PENETRATION

407. For the same reasons underlying the foregoing findings that there is no reasonable basis for Aspercreme's efficacy claims, it is found that there is no reasonable basis for the claim, alleged in Paragraphs 12(e) and 14 of the complaint, that Aspercreme provides pain relief by direct penetration to the site of arthritic pain. Moreover, the mechanism of pain or its [127] relief has not been definitively understood, and the bioavailability or penetration studies in evidence fall short of showing TEA/S' bioactivity or analgesic efficacy.

408. From all of the foregoing, it is found that:

(a) the advertising claims alleged in complaint paragraphs 10(a), 10(b) and 10(c) were false, misleading or deceptive;

(b) the advertising claims alleged in complaint paragraphs 12(a), 12(b), 12(c) and 12(d) lacked a reasonable basis and they were false as alleged in complaint paragraph 14; and

(c) the use of the brand name "Aspercreme" in advertising, labels and promotional materials is false, misleading or deceptive.

XII. RELIEF

409. With respect to certain Aspercreme advertising claims which were false or for which Thompson did not have a reasonable basis, the customary remedy is an order to cease and desist. It is necessary and appropriate in this case to require Thompson to refrain from making false and unsubstantiated claims in the future. Such false or unsubstantiated claims include:

(a) False claims:

(1) Aspercreme contains aspirin (Comp. ¶ 10(a)).

(2) Aspercreme is a newly discovered drug product (Comp. ¶ 10(b)).

(3) Valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of minor pain [128] associated with arthritis and other rheumatic conditions (Comp. ¶ 10(c)).

(b) Unsubstantiated claims:

(1) Aspercreme is an effective drug for the relief of minor pain associated with arthritis or rheumatic conditions (Comp. ¶ 12(a) and (d)).

(2) Aspercreme is as effective as, or more effective than, orally-ingested aspirin for the relief of minor pain associated with arthritis (Comp. ¶ 12(b) and (c)).

(3) Aspercreme acts by directly penetrating through the skin to the site of arthritic pain (Comp. ¶ 12(e)).

410. With respect to an advertising claim for Aspercreme's efficacy, either in simple or comparative terms, the required reasonable basis comprises two or more adequate and well-controlled clinical trials which demonstrate Aspercreme's simple or comparative efficacy as an analgesic drug for the relief of minor pain associated with arthritis or other rheumatic conditions. This is what the prevailing view of the medical/scientific community requires, as does the FDA for OTC topical analgesic products for labeling purposes. Acceptance by the Federal Trade Commission of a lower level of scientific evidence of drug efficacy would not only be contrary to the prevailing and established view of the medical scientific community but also be tantamount to

establishing a different and lower standard of efficacy for OTC drug advertising under Section 5 of the FTC Act than that applicable to OTC drug marketing under the Food, Drug and Cosmetic Act.

411. The need for adequate substantiation is greater where, as here, a relatively obscure topical drug is being touted as proven effective pain reliever to the long-suffering arthritics, a group known to be singularly disposed to grasp at new promises of relief.

412. Thompson has been aware for some time that its advertising and the product's brand name may imply that [**129**] Aspercreme contains aspirin. For example, the networks and the NAB Code Authority challenged Aspercreme commercials with respect to the aspirin content suggestion, as well as challenging Thompson's substantiation for its efficacy claims (*See, e.g.,* CX 88D, 92). Thompson also was aware of the results of the Mapes & Ross copy test (which showed that an aspirin content message was being communicated) at least as early as June 14, 1979, at which time the test was discussed in a meeting between Ogilvy & Mather and Thompson (*See,* CX 99A: F. 95, *supra*). In a document setting out the strategy for Aspercreme advertising, Thompson's advertising agency stressed the importance of the aspirin communication (CX 54Z ("the 'aspirin' component of Aspercreme is uniquely relevant for arthritis"), Z–002 (discussion of "aspirin in a rub" as the ad strategy), Z–005 (creative strategy: "Aspercreme contains the pain relieving ingredient of aspirin"), Z–007 ("it is the *local aspirin relief* that is important"), Z–012 (with respect to an Aspercreme print ad: "the client has grown to believe it doesn't communicate arthritis or aspirin very well, and we are in the process of developing a new one")). Since representatives of the ad agency communicated regularly with Thompson in the creation of ad strategy and had to get direct approval from Thompson for the strategy (Jasper, Tr. 4815–16), it is reasonable to infer that the ad agency's expressions in CX 54 were known to Thompson. CX 66 is a conference report summarizing a meeting between Thompson and Ogilvy & Mather, at which Thompson gave approval for certain Aspercreme ads to be run (Jasper, Tr. 4794–97). Among those ads were CX 3 and CX 4, television commercials including the network-mandated "contains no aspirin" disclosures. The report states, "the client [Thompson] agreed and will pursue approval of the *aspirin equivalency* claim. In the meantime, the agency will pursue using the 'strong relief of aspirin' claim *to offset the contains no aspirin super"*(CX 66B, emphasis added). CX 66 was sent to Thompson's president, as well as to other Thompson representatives (CX 66A).

413. The record also clearly shows that a significant segment of consumers are likely to get the impression that Aspercreme contains aspirin, either from the brand name "Aspercreme" alone or from

other language in the ads or both, and that ingredient disclosure statements (such as "Aspercreme contains salicyn, a strong non-aspirin pain reliever") or aspirin disclaimers in the ads (such as "does not contain aspirin" super) are ineffective in preventing the consumer perception that Aspercreme is an aspirin product (Cohen, Tr. 287–88, 549–50, 558–60). Therefore, stronger measures are required in Aspercreme advertising in the future in order to insure that the viewer of such advertisements are not misled thereby (*See* F. 84, 101, 116). **[130]**

414. It is the determination of the administrative law judge that, based on the record as a whole an effective aspirin disclaimer should be explicit and unequivocal and should include both audio and video messages which are prominent enough and conspicuous enough to assure that the intended objective will be achieved. In television commercials, a prominent and conspicuous video aspirin disclaimer (such as "Aspirin Free" super) should be displayed throughout the commercial as well as a vocal aspirin disclaimer statement (such as "Aspercreme does not contain aspirin") made at the end of each commercial. In print or radio advertising, the printed or vocal aspirin disclaimers should be explicit and unequivocal and be prominent and conspicuous in relation to each advertisement as a whole. It is the opinion of the adminstrative law judge that without an effective disclaimer measure as described above, a continued use of the brand name "Aspercreme" in advertising will be clearly misleading and deceptive.

415. The brand name Aspercreme was registered in the United States Patent Office under Registration No. 933,107 issued in 1972 (RX 921). It also has been registered in many foreign countries (RX 601A). Furthermore, the perception that Aspercreme contains aspirin is not a result of the natural and literal meaning of the trade name itself but a result of the confusion created by its proximity to "aspirin." The trade name excision complaint counsel advocate is not justified under the circumstances of this case. On the basis of this record, I am unable to conclude that the brand name excision is the only adequate remedy or that a less restrictive remedy (such as effective disclaimers) cannot be devised that will prevent the impression on the part of the viewer that Aspercreme ads represent that the product contains aspirin. *See Beneficial Corp. v. FTC*, 542 F.2d 611, 619 (3rd Cir. 1976).

416. It is found that the cease and desist order provisions should be limited to OTC analgesic products. The record evidence does not justify an "all drug products" provision sought by complaint counsel. **[131]**

DISCUSSION

The record shows that the capacity of the challenged Aspercreme advertisements to mislead a significant segment of reasonable consumers is palpably real, that the deception is material and substantial in health, economic and societal terms, that the information regarding the availability of a topical OTC drug alternative to oral medication can easily and effectively be communicated in advertisements without implying false, deceptive or misleading claims, and that the benefits of requiring adequate substantiation of Aspercreme efficacy claims clearly outweigh potential costs of such requirement. The record also shows that the brand name "Aspercreme" is misleading and that the kind of fleeting aspirin disclaimers (such as "Does not contain aspirin" super displayed for a few seconds) or equivocal ingredient statements (such as "contains salicyn, a strong non-aspirin pain reliever") in Aspercreme ads are not sufficient and more effective, straight-forward aspirin disclaimers are needed. The basic findings with respect to the various disputed issues of law and fact and the reasons for the conclusions reached are set forth in the preceding sections. However, a brief discussion of some key issues may be in order.

1. *The Meaning Of Aspercreme Advertisements And The Materiality Of Aspirin Content*

Thompson argues that its Aspercreme ads sought merely to inform arthritis sufferers that there is an alternative topical OTC remedy which provides as much pain relief as do aspirin tablets without stomach upsets often caused by aspirin tablets. A careful examination of the individual advertisements in evidence, however, has convinced me that, whatever Thompson's intent, these ads *also* made, sometimes directly but mostly by implication, the various representations alleged in the complaint, except for paragraph 12(f). Empirical data, including the four copy tests conducted in connection with this litigation (CXs 26 and 27; RXs 500 and 520), generally confirm what common sense and experience would tell us, namely that the Aspercreme ads, including the use of the brand name "Aspercreme," can reasonably be expected to mislead a significant number of consumers in the manner alleged in the complaint.

The record also amply demonstrates that the presence or absence of aspirin in an OTC analgesic product clearly is a material fact within the meaning of Section 12 of the FTC Act (*See* F. 162–63, *supra*). **[132]**

2. *The Requirement For Well-Controlled Clinical Studies As A Reasonable Basis For Aspercreme Efficacy Claims*

The thrust of Thompson's argument regarding the reasonable basis issue is essentially that, on the basis of the totality of evidence of TEA/S, including clinical trials, drug penetration studies, physician's opinions and clinical experience, marketing experience, user testimonials and consumer reactions regarding Aspercreme over the years, it was reasonable for Thompson to make those advertising claims challenged in this proceeding (RB 59–72). Thompson argues that Aspercreme is a mild and harmless topical product which demonstrably provides tangible benefits to a significant segment of the target population and that, therefore, it should be permitted to make efficacy claims in advertising without the kind and level of medical scientific substantiation required for more potent, potentially harmful drugs (RB 61–62). However, the Commission has determined that with respect to the issue of *efficacy* of an OTC analgesic drug, two or more well-controlled clinical trials are required to prove simple or comparative efficacy. *American Home Products Corp.,* 98 F.T.C. at 376. Therefore, an argument that a level of substantiation less than two well-controlled clinicals constitutes a reasonable basis for the simple and comparative *efficacy* claims made for Aspercreme, a topical OTC analgesic drug, is not acceptable.[3]

Thompson also argues that the FDA does not require two well-controlled studies in the case of the so-called "old" OTC drugs **[133]** (RPF 64–66). Thompson further argues that, in any event, the FDA relies on uncontrolled clinical trials, clinical observations of physicians and marketing experience related to the product in determining the issue of efficacy of OTC drugs (*See* RPF 123–25).[4] Thompson also urges that "under the principles of *res judicata* and collateral estoppel" the FTC should apply to drug efficacy issues in FTC proceedings the same standard the FDA employs in determining drug efficacy. Indeed Thompson points out that "the Commission has itself used the finding of the FDA to reach its own finding that advertising was

[3] In this connection, the record shows that TEA/S is not an effective systemic or internal analgesic (*See* CX 268) but is an effective topical sunscreen agent (F. 362, *supra;* CX 270, pp. 38,251–53). An important property of 5–12% TEA/S as a sunscreen product is its ability to remain on the skin long enough to form an effective surface barrier against ultraviolet rays of the sun. Yet, Thompson's hypothesis regarding Aspercreme's (10% TEA/S) analgesic action is that it penetrates the skin and delivers a therapeutic level of salicylate to the site of pain in the underlying deep tissues of the musculoskeletal system in humans. The records also shows that the use of an unproven OTC drug for self-medication to treat rheumatic pain poses a real danger to the consumer and may result in significant losses of individual and societal resources (F. 207–10, *supra*). In these circumstances, common sense dictates that Aspercreme's analgesic efficacy be subjected to as rigorous a test as, if not more rigorous than, that required of OTC internal analgesic products. *Also see,* F. 242, *supra.*

[4] These arguments ignore Thompson's own statement that "the FDA [OTC monograph] procedures now provides a period until April 9, 1984 for the development and review of evidence that will permit final classification of the effectiveness of TEA/S" and that "during this period the marketing of TEA/S products is, of course, permitted" (RB 18). The "evidence that will permit final classification of the effectiveness of TEA/S" in this context, of course, includes two or more adequate and well-controlled clinical trials.

deceptive," citing *Simeon Mgt. Corp. v. FTC,* 579 F.2d 1137, 1145 n. 10 (9th Cir. 1978) (*See* RB 99–100). According to this argument, the FTC should accept, as the FDA allegedly would, evidence less than two or more well-controlled clinicals as proof of analgesic efficacy of Aspercreme. In my view, these arguments are unpersuasive. As the Commission has explicitly recognized in *American Home Products,* the FDA requires under the Food, Drug and Cosmetic Act two or more well-controlled clinical studies as proof of efficacy with respect to all drugs, including OTC analgesic drug products. 98 F.T.C. at 378–81.

The most authoritative record evidence that topical TEA/S' analgesic efficacy remains to be demonstrated is the consistent refusal of both the FDA and its OTC External Analgesic Panel to find topical TEA/S to be effective under the Food, Drug and Cosmetic Act (*See* F. 393–95, *supra*). Having reviewed substantially all of the material and information presented in this proceeding, the FDA has announced, in the February 8, 1983 Tentative Final Monograph [proposed rule] on OTC External Analgesic Drug Products, its determination that there was insufficient evidence to conclude that TEA/S is an effective topical analgesic agent. Against this background, the need for regulatory harmony and uniform standards among federal agencies with respect to the issue of drug efficacy dictates that the FTC require in this proceeding the same level of medical scientific [134] evidence the FDA requires under the Food, Drug and Cosmetic Act.[5] Thompson has urged as much (RB 99–100).

In light of the foregoing discussion, Thompson's argument that the requirement for well-controlled clinicals in this case is somehow "excessive" and that it is likely to result in limiting the amount of "useful information" made available to consumers is inapposite (*See* RB 59–61). The record clearly shows the substantial harm that misin-

[5] Under the FDA's monograph procedures for OTC external analgesic drug products, the marketing of TEA/S products, including Aspercreme, will be permitted for an interim period until April 9, 1984, pending development and review of "evidence that will permit final classification of the effectiveness of TEA/S," presumably including two or more well-controlled clinical trials (F. 9, *supra*).

In this connection, Thompson obliquely suggests that the FDA might change its position regarding TEA/S when the FDA completes a review of Thompson's "pending" submissions (RB 16–18). However, on the basis of the record, the outcome Thompson suggests is highly unlikely (*See* F. 396–400, *supra*). In any event, the Order makes provision for the contingency that the FDA might, on the basis of new evidence, determine TEA/S to be an effective external analgesic agent. Should that contingency occur, the Order would allow respondent to rely on the same evidence the FDA relied on in the monograph proceeding. That provision will also cover other OTC analgesic drug products that may be marketed by respondent in the future. In this connection, it should be noted that the FDA, in the OTC monograph proceeding, determines the conditions under which OTC analgesic drug products are "generally recognized as safe and effective and not misbranded" and does not deal with the issue of *comparative* efficacy as such (*See* CX 443, pp. 5852–53).

In sum, should the FTC Order herein become effective before April 9, 1984, it would have the practical effect of barring Thompson from advertising Aspercreme as a topical analgesic while Thompson is being permitted by the FDA to continue marketing Aspercreme during the interim period. It may well be that the time required for the final determination of this proceeding may moot the issue. However, in the interest of comity and regulatory harmony, the Order should provide for a grace period similar to the FDA's (namely a period until April 9, 1984) during which simple, non-comparative efficacy claims for Aspercreme may be allowed in advertising. It is the law judge's view, however, that all ad claims of *comparative* or superior efficacy for Aspercreme should cease forthwith and not be allowed until such claims can be adequately substantiated.

formation regarding OTC [**135**] analgesic drugs may cause to the long suffering arthritics as well as to the society as a whole (F. 207–10, *supra*). The record also shows that the message Thompson claims to have sought to convey to the consumer, namely that Aspercreme is an effective topical alternative to oral aspirin, can easily and clearly be conveyed without implying unproven claims of comparative efficacy. In these circumstances, a ban against unproven claims of simple and comparative efficacy for Aspercreme is imperative. Thus, the determination that a reasonable basis for Aspercreme efficacy claims should include well-controlled clinical studies reflects a careful weighing of the possible benefits to consumers if Thompson's efficacy claims are true and the possible costs to consumers if the claims are false. *See* The FTC Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction, 43 Trade Reg. Rep., 570 (1982).

In any event, as the Commission has recognized, the Supreme Court has indicated that the First Amendment does not shield deceptive advertising against appropriate prior restraints needed to prevent its recurrence. *See American Home Products Corp.*, 98 F.T.C. at 403–04, and the cases cited therein.

In this connection, a proposed restriction on commercial speech (including the brand name) designed to prevent recurrence of deception should be viewed in the information cost perspective so as not to inhibit dissemination of economically efficient information.[6] However, it should also be borne in mind that information in this context means accurate, truthful information.[7] False, misleading or deceptive advertising or brand name is not economically efficient. On the contrary, it increases the costs of information about the qualities of products and is economically inefficient. This is such a case.

3. *The Advertising Claims That Aspercreme Is A Newly Developed Drug And That It Has No Side Effects*

It is true that certain early Aspercreme advertisements contain an express or implied claim that Aspercreme is a new drug, as alleged in paragraph 10(b) of the complaint. However, [**136**] the history of Aspercreme advertising supports the view that Thompson was attempting to bring Aspercreme to the consumer's attention during the period when Aspercreme was being nationally advertised for the first time. In my view, Section 5 gives an advertiser some leeway in making a "new drug" claim during the introductory phase even though the same or similar products may have been available on the market. In

[6] *See* Coase, R.H., *The Problem of Social Cost*, 3 J. of Law & Econ., 1, 15 (1960); Alchian, A. & Allen, W.R., EXCHANGE AND PRODUCTION: COMPETITION, COORDINATION AND CONTROL, 110–11, 124, 294–95 (2d ed. 1977).

[7] Alchian & Allen, *supra*, at 124.

any event, Thompson should not make "new drug" claims for Aspercreme in the future.

It is also true that some of Thompson's advertisements contain an express "no side effects" claim, as alleged in paragraph 12(f) (CXs 7, 8, 10, 11). The record also shows that Aspercreme in fact can irritate the skin in some users (Golden, Tr. 2700–01; RX 35Z002). However, when each advertisement (CXs 7, 8, 10, 11) is viewed separately, I am unable to conclude that any of these advertisements can be reasonably understood by viewers as saying that Aspercreme has literally no side effects. It is common knowledge that any topical drug may irritate the skin in some persons. In may view, these ads were saying either that Aspercreme does not cause stomach discomforts as aspirin tablets often do or that Aspercreme has no serious side effects to worry about. To impute any more to the "no side effects" claim in these ads would be unreasonable. Therefore, complaint allegations in paragraph 12(f) will be dismissed.

4. *The Trade Name Excision Issue*

Complaint counsel vigorously argue that the record evidence demonstrating the misleading effect of the brand name "Aspercreme" clearly justifies its excision (CB 109–16). They urge essentially that the brand name "Aspercreme" is so close to "aspirin cream" that any qualification of the name will necessarily involve a contradiction in terms, adding to confusion rather than removing it. Complaint counsel further assert that, when the names of drugs or other medical products are at issue, courts readily have found confusion from less proof of confusing similarity because of the risk of physical harm to the consumer (CB 111). However, trade name excision is an extreme and harsh remedy and should not be employed except in cases where there is no meaningful alternative.

Although the evidence does not show that the brand name "Aspercreme" has acquired a secondary meaning associating it with some standard or price, "Aspercreme" has been in use as a registered brand name since 1972 and extensively advertised on a national scale as an OTC topical analgesic since 1979. As such, "Aspercreme" is a valuable business asset to respondent. *Cf., Friedman v. Rogers,* 440 U.S. 1, n. 11 at 12 (1978). Furthermore, in my view, there is a reasonable, common sense distinction to be made between "aspirin cream" or "Jay's [**137**] aspirincreme" on the one hand and "Aspercreme" on the other. In the former, the natural and literal meaning of the names would be "a creme made of aspirin." These names do not involve any ambiguity. In the latter, the construction that the product contains aspirin is due to the name's ambiguity, or proximity to "aspirin," and the confusion is not attributable to the natural and literal meaning of the name

itself. In these circumstances, applicable precedents require that the Commission fully examine less restrictive measures including the feasibility of requiring rewriting of advertising copy in lieu of total excision. *Beneficial Corp. v. FTC,* 542 F.2d 611, 619 (3rd Cir. 1976); *Continental Wax Corp. v. FTC,* 330 F.2d 475, 479–80 (2d Cir. 1964).

The evidence shows that the direct or indirect aspirin disclaimers used heretofore in Aspercreme ads are ineffective and that, therefore, stronger, more conspicuous aspirin disclaimers are required (F. 84, 101, 116, 413–14, *supra*). Thus, simple, unequivocal aspirin disclaimer statements must be prominently and conspicuously made both in audio and video form in all Aspercreme ads in order to insure that the ambiguity and confusion resulting from the brand name "Aspercreme" are effectively removed. Therefore, the order will include appropriate provisions which will require, in television advertisements, "Aspirin- free" video super throughout the entire commercial *in addition to* a vocal disclaimer "Aspercreme does not contain aspirin" at the end of each Aspercreme commercial. In radio ads, one clear aspirin disclaimer statement at the end of the commercial will be sufficient. In print ads, a simple and unequivocal aspirin disclaimer statement, such as "ASPERCREME DOES NOT CONTAIN ASPIRIN," should be prominently and conspicuously placed in relation to each advertising copy as a whole (F. 415, *supra*).

Conclusions of Law

1. The Federal Trade Commission has jurisdiction over the advertising of Aspercreme under Section 5 of the Federal Trade Commission Act.

2. Respondent's use of false, misleading and deceptive advertising representations (including the brand name "Aspercreme") as herein found has had and now has the capacity and tendency to mislead members of the purchasing public into the erroneous and mistaken belief that said statements and representations were and are true and into the purchase of substantial quantities of Aspercreme by reason of said erroneous and mistaken belief. In the absence of an appropriate order, such members of the purchasing public are likely to continue to purchase substantial quantities of Aspercreme in the mistaken [138] belief that respondent's past advertising representations regarding the aspirin content of Aspercreme, Aspercreme's novelty, and the efficacy and comparative efficacy of Aspercreme (including the existence of valid studies proving Aspercreme to be more effective than aspirin), were true or were supported by a reasonable basis.

3. The acts and practices of respondent as herein found were and are all to the prejudice and injury of the public and of respondent's

competitors and constituted and now constitute unfair methods of competition and unfair and deceptive acts and practices in commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

4. The accompanying order is necessary and appropriate for the purpose of prohibiting the continuation of the proscribed acts.

ORDER

I

It is ordered, That respondent, Thompson Medical Company, Inc., a corporation, its successors and assigns, and respondent's officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of any over-the-counter analgesic "drug" as that term is defined in the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Employing the brand name "Aspercreme" for such products or otherwise representing directly or by implication that an active ingredient of such product is aspirin, unless such product contains aspirin in therapeutically significant quantities or unless the advertising and labeling for such product clearly and prominently discloses that the product does not contain aspirin.

(1) In television advertisements, an explicit and simple aspirin disclaimer statement (such as [**139**] "ASPIRIN-FREE") shall be superimposed and prominently displayed throughout the length of each advertisement as well as a vocal aspirin disclaimer statement (such as "Aspercreme does not contain aspirin") at the end of each advertisement.

(2) In radio advertisements, an explicit aspirin disclaimer statement (such as "Aspercreme does not contain aspirin") shall be made at the end of each advertisement.

(3) In print advertisements, an explicit aspirin disclaimer statement (such as "ASPERCREME DOES NOT CONTAIN ASPIRIN") shall be displayed prominently and conspicuously in relation to each such advertisement as a whole.

(4) In labeling, an explicit aspirin disclaimer statement (such as "DOES NOT CONTAIN ASPIRIN") shall be prominently and conspicuously printed in the front package panel (or in the front of the container if no package is used).

B. Representing, directly or by implication, that such product is

new, or involves a new mechanical or scientific principle except during the product's introductory period, when such product or one involving such principle has been generally available for purchase in the United States for more than one year.

C. Misrepresenting the contents, validity, results, conclusions, or interpretations of any test or study.

II

It is further ordered, That Thompson Medical Company, Inc., a corporation, its successors and assigns, and respondent's officers, representatives, agents and employees, directly or [**140**] through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of any OTC analgesic "drug," as that term is defined in the Federal Trade Commssion Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desit from:

A. Representing, after April 9, 1984, that such product is effective for the relief of minor pain and other symptoms of any musculoskeletal disorder (such as arthritis, tendinitis, bursitis, or rheumatic disorders);

B. Representing that such product is as fast as or faster than, or is as effective as, or more effective than any other drug or device in the relief of minor pain and other symptoms of any musculoskeletal disorder (such as arthritis, tendinitis, bursitis, or rheumatic disorders);

unless at the time of the dissemination of any such representation, respondent possesses and relies upon a reasonable basis for such representation consisting of competent and reliable scientific or medical evidence. For analgesic drug products competent and reliable scientific or medical 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, independently of each other. Such persons shall be qualified by training and experience to conduct such studies. *Provided however,* with respect to any representation covered by this part other than claims of superior or comparative effectiveness or safety, if the Food and Drug Administration promulgates any final standard which establishes conditions under which such product is safe and effective under the Food, Drug and Cosmetic Act, then in lieu of the above, respondent may rely upon scientific evidence which fully conforms to such final standards as a reasonable basis for said representation.

III

It is further ordered, That so much of the complaint as relates t o Paragraph 12(f) be, and the same hereby is, dismissed.

OPINION OF THE COMMISSION

BY DOUGLAS, *Commissioner:*

I. INTRODUCTION

Thompson Medical Company, Inc. ("Thompson") is a pharmaceutical company that sells several different over-the-counter ("OTC") drugs. One such drug is Aspercreme, a topical cream rub or lotion whose active ingredient is 10% triethanolamine salicylate ("TEA/S"). Thompson has marketed Aspercreme as a remedy for relief of minor arthritis pain since 1976, after purchasing it from the Sperti Drug Company. At first, Thompson followed Sperti's practice of marketing the product locally in Ohio. Starting in 1978, however, Thompson began a successful national advertising campaign for Aspercreme which saw sales of the product increase from $589,000 in 1978 to $5.9 million in 1981 (IDF 74.)[1] [2]

On February 5, 1981, the Commission issued a complaint against Thompson and its advertising agency, Ogilvy and Mather, Inc. The complaint charges that Thompson's marketing campaign for Aspercreme involved the following deceptive representations:

Complaint Paragraph Number	Alleged Representation
10(a), 16	Aspercreme contains aspirin.[2]
10(b)	Aspercreme is a recently discovered or developed drug product.

[1] The following abbreviations are used in this opinion:

ID	–	initial decision page number
IDF	–	initial decision finding number
Tr.	–	transcript of testimony page number
CX	–	complaint counsel's exhibit number
CPF	–	complaint counsel's proposed findings of fact and conclusions of law finding number
CMF	–	complaint counsel's memorandum supporting proposed findings of fact and conclusions of law page number
CAP	–	complaint counsel's appeal brief page number
CAB	–	complaint counsel's answering brief page number
RX	–	respondent's exhibit number
RPF	–	respondent's proposed finding of fact and conclusions of law finding number
RMF	–	respondent's memorandum supporting proposed findings of fact and conclusions of law page number
RAP	–	respondent's appeal brief page number
RRB	–	respondent's reply brief page number

[2] Complaint Paragraph 10(a) charges Thompson generally with representing that Aspercreme contains aspirin. Complaint Paragraph 16 specifically charges that use of the trademark "Aspercreme" constitutes such a representation.

10(c)	Valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatic conditions, and their symptoms.
12(a)	Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.
12(b)	Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.
12(c)	Aspercreme is a more effective drug than orally-ingested aspirin for the relief of minor arthritis and its symptoms. **[3]**
12(d)	Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms.
12(e)	Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.
12(f)	The use of Aspercreme will result in no side effects.
14	Thompson had a reasonable basis for representations listed in Complaint Paragraphs 12(a)-(f) at the time they were made.

The complaint alleges that representations listed in Complaint Paragraphs 10, 14, and 16 are false, misleading, and deceptive. It further alleges that Thompson lacked a reasonable basis for the representations listed in Complaint Paragraph 12.

The case was assigned to Administrative Law Judge Montgomery K. Hyun for hearing. On July 7, 1983, Judge Hyun entered his initial decision, which found against Thompson on all charges except those relating to claims that Aspercreme had no side effects (Comp. ¶12(f)).[3] The order he adopted requires Thompson to have a reasonable basis for claims that any OTC analgesic drug is effective for the relief of symptoms of musculoskeletal disorder, and for comparative efficacy claims made for such a [4] drug. The order further prohibits Thompson from: (1) using the brand name "Aspercreme" unless it is accompanied by a disclosure that the product does not contain aspirin; (2) representing that a product is new if it has been generally available for purchase in the United States for more than one year; and (3) misrepresenting any test or study.

Thompson appeals from the ALJ's findings as to liability. Thompson's principal arguments on appeal are: (1) the ALJ erred in finding that Thompson lacked reliable and credible information constituting a reasonable basis for the efficacy claims it made for Aspercreme; (2) the ALJ erred in finding Aspercreme not to be an effective drug for the relief of minor arthritis or rheumatism pains; and (3) the ALJ erred in finding that either the trademark "Aspercreme" or the product 's advertising deceptively represent that the product contains aspirin. Complaint counsel appeal from the ALJ's decision not to prohibit Thompson from using the "Aspercreme" brand name. Com-

[3] Prior to Judge Hyun's decision, the Commission adopted a Decision and Order settling the charges against Ogilvy & Mather. *In the Matter of Oglivy & Mather International, Inc.*, Docket No. 9149, Decision and Order issued January 4, 1983. [101 F.T.C. 1 (1983)]

plaint counsel also appeal the ALJ's decision to limit Part I of the order to OTC analgesic drugs, rather than all OTC drugs, and not to have Part I prohibit false ingredient representations involving any brand name and any active ingredient.

We generally agree with the ALJ's findings and conclusion and, except as noted in this opinion, adopt them as our own. Our analysis of the issues presented here is in four parts. First, we determine whether or not Thompson made the representations alleged in the complaint. Second, we evaluate whether or not the representations were material. Third, we examine whether or not **[5]** the claims were likely to mislead consumers acting reasonably under the circumstances.[4] Finally, in light of our determinations as to the extent and severity of Thompson's deceptive advertising, we consider the appropriate scope of an order prohibiting such conduct in the future.

II. DID THOMPSON MAKE THE REPRESENTATIONS ALLEGED IN THE COMPLAINT?

1. *Legal Framework*

In this part of the opinion, we examine whether Thompson's advertising expressly or impliedly conveyed to consumers the representations listed in the complaint. As our discussion below will show, we conclude that it generally did. Before analyzing the advertising itself, however, we will set out the standards by which we do so. **[6]**

As we noted in *Cliffdale Associates*,[5] we will deem an advertisement to convey a claim if consumers acting reasonably under the circumstances would interpret the advertisement to contain that message. The purpose of such a requirement is to ensure that the flow of useful, accurate information to consumers will not be deterred by advertisers' fears that they could be held responsible for claims that they could not reasonably have known consumers were going to receive from the ads in question.

In evaluating what message an ad could reasonably be interpreted as containing, the Commission has traditionally distinguished between express and implied claims. Express claims are ones that directly state the representation at issue. Because the message is stated unequivocally, it is reasonable to interpret the ads as intending to make the claim.[6] Implied claims are any claims that are not express.

---

[4] As Commissioner Bailey noted in her Concurring and Dissenting Statement in *Cliffdale Associates, Inc.*, Docket No. 9156 (March 23, 1984), she believes the elements of deception are that an act or practice have the tendency or capacity to mislead a substantial number of consumers in a material way. She did not endorse the Commission's *Cliffdale* description (slip op. at 7) of the elements of deception nor does she endorse it in this opinion. However, Commissioner, Bailey agrees that respondent's practices in this case were deceptive under either description of the term. [103 F.T.C. 110 (1984)]

[5] *Id.*

[6] This is the only issue we look at. We do not additionally consider whether the advertiser intended to deceive consumers with the claim or whether an objective product claim (*i.e.*, one not involving puffery or subjective value

They range from claims that would be virtually synonymous with an express claim [7] through language that literally says one thing but strongly suggests another to language which relatively few consumers would interpret as making a particular representation.[7]

Because of this wide range, the Commission employs two different techniques in evaluating whether an advertisement contains implied claims. One is to look at evidence from the advertisement itself. We often conclude that an advertisement contains an implied claim by evaluating the contents of the advertisement and the circumstances surrounding it. This technique is primarily useful in evaluating advertisements whose language or depictions are clear enough, though not express, for us to conclude with confidence after examining the interaction of all the different elements in them that they contain a particular implied claim.

If our initial review of evidence from the advertisement itself does not allow us to conclude with confidence that it is reasonable to read an advertisement as containing a particular implied message, we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a [8] reading of the ad is reasonable.[8] For example, in this case the conflicting messages in some elements of Aspercreme's ads caused us to examine extrinsic evidence to determine what net impression(s) the entire ad could reasonably be interpreted as giving to consumers.[9]

The extrinsic evidence we prefer to use and to which we give great weight is direct evidence of what consumers actually thought upon reading the advertisement in question. Such evidence will be in the form of consumer survey research for widely distributed ads, such as those involved in this proceeding. Ads of that sort are directed at so large an audience that it is too costly to obtain the statements of enough individual consumers in another manner (*e.g.*, by way of af-

judgments) is so far-fetched that reasonable consumers would not believe it. Thus, if an ad expressly claims that a shampoo will cure baldness, we presume that reasonable consumers would be deceived by the ad. We presume this even though we might think few people are unaware of the fact that there is no cure for common baldness. *See, e.g., Keele Hair & Scalp Specialists, Inc.* 55 F.T.C. 1840 (1959), *aff'd*, 275 F.2d 18 (5th Cir. 1960).

[7] Advertisements do not necessarily convey one message to all persons. One subset of consumers reading an ad may interpret it to contain one message, while another subset may interpret it to contain a different message. Each interpretation is reasonable as long as the subset making it is representative of the group of persons to whom the ad is addressed. *See, e.g., Heinz W. Kirchner*, 62 F.T.C. 1282, 1290 (1963).

[8] This longstanding principle of Commission case law was most recently reiterated by us in *Bristol-Myers Co.*, 102 F.T.C. 21, 319 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984) *petition for cert. filed* (No. 84-650) (Oct. 23, 1984), a case involving deceptive advertisements for OTC internal analgesic products: "There also may be instances where claims cannot be inferred from a facial examination of the advertisements and resort to extrinsic evidence is necessary. *See, e.g., Leonard F. Porter, Inc.*, 88 F.T.C. 546, 626 (1976)."

[9] Similarly, past Commission cases recognize that affirmative disclosures can be an effective method for preventing consumer misunderstanding of ads. However, Commission cases also recognize that such disclosures need to be made clearly and prominently to be effective. Whether or not a particular disclosure was clear and prominent is a question for whose answer we often would seek information in addition to that from the ad itself. However, where a simple inspection of the ad leaves us confident that the disclosure was ineffective for ordinary consumers, we will not require extrinsic information. *See, e.g., Litton Industries, Inc.*, 97 F.T.C. 1, 71, n.6 (1981), *aff'd as modified*, 676 F.2d 364 (9th Cir. 1982).

fidavits) to be reasonably confident that the consumers' views on the record of the proceeding were representative of the entire [9] group to which the ad was addressed. Where we use surveys in lieu of individual testimony, the surveys are methodologically sound; they draw valid samples from the appropriate population, ask appropriate questions in ways that minimize bias, and analyze results correctly.[10]

Another type of evidence we will look at is evidence not specifically showing how consumers understood the advertisements at issue before us, but showing how consumers might ordinarily be expected to perceive or understand representations like those contained in the ads we are reviewing. For example, we might look at the dictionary definition of a word to identify the word's common usages. Or we might look at principles derived from market research, as expressed by marketing experts, which show that consumers generally respond in a certain manner to ads that are presented in a particular way, and presume that consumer reactions to a particular ad before us would be consistent with the general response pattern. Where we apply such marketing principles, we will derive them from research presented in references generally accepted as reliable in the field of marketing. Such references may be cited by marketing experts called to testify in the proceeding. Alternatively, we may take official notice of the references and cite to them directly in our opinion. [10]

A third type of evidence we will consider if offered is the opinion of expert witnesses in the proceeding as to how an advertisement might reasonably be interpreted. For example, we might consider the opinion of a marketing expert who stated his or her view that consumers would interpret an ad in a particular manner. However, where the opinions voiced by experts are not adequately supported we ordinarily give them little weight.[11]

Whether we are looking at evidence from the ad itself, extrinsic evidence, or both, we look at the overall, net impression made by an ad to determine what messages it reasonably can be interpreted as conveying to consumers.[12] For example, we would look here at whether or not consumers thought, after viewing Thompson's television ads, that Aspercreme contains aspirin. We would not look at how consumers reacted to a particular element from the ad in a different context than the ad itself.

In this case, Thompson has acknowledged making several of

[10] *See, e.g.*, our discussion of survey methodology in *Bristol-Myers Co.*, 85 F.T.C. 688, 744 n.14 (1975).

[11] We consider to be adequately supported opinions that describe empirical research or analyses based on generally recognized marketing principles or other objective manifestations of professional expertise. Opinions not so supported may easily be contradicted by the contrary opinions of opposing experts and thus may be of little value in resolving the issue.

[12] *See, e.g., Bristol-Myers, supra* note 8, at 320; *Horizon Corp.*, 97 F.T.C. 464, 810 (1981).

the represenations listed in the complaint (RMF 142–43). These are: [11]

Complaint Paragraph Number	Alleged Representation
12(a)	Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.[13]
12(b)	Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.
12(d)	Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms
12(e)	Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.[14]

Because Thompson has acknowledged making the above-listed representations, we may state without reviewing the ads that Thompson intended to make these claims. Therefore, it is reasonable to interpret the ads as making them. [12]

Thompson has not acknowledged making any of the other representations listed in the complaint. We therefore examine each of these alleged representations in turn to determine whether or not consumers acting reasonably under the circumstances would interpret Thompson's advertisements as making them.

2. *Aspirin Content—Paragraphs 10(a), 16.*

Of all the disputed representations, the one that received the most attention at trial was the issue of whether or not Thompson's advertising, and specifically the trade name "Aspercreme" represented that the product contains aspirin. Complaint counsel argued that it did, *i.e.*, that it represented Aspercreme to contain a cream form of acetylated salicylate, as aspirin is defined in the United States Pharmacopoeia. Thompson argued that the ads merely suggest Aspercreme is a drug which works like the more familiar aspirin, not that it actually contains aspirin (RAB 41). Thompson also argued that consumers understand the word "aspirin" as a generic reference to the class of drugs that are pain killers, not to the particular salicylate contained in aspirin tablets (RAB 35–36). Thus, the issues presented for our consideration here are, first, whether one net impression it is reasonable to interpret Thompson's ads as conveying to consumers is that Aspercreme contains aspirin and, second, what consumers would

[13] In acknowledging that it made this claim for relief of arthritis, Thompson denied representing that Aspercreme will cure the disease. Thompson similarly denied representing that Aspercreme will cure rheumatism. The ALJ found that Thompson had not made such representations (IDFs 131–32, 141–42).

[14] We note that the complaint included another allegedly deceptive representation. Complaint Paragraph 12(f) charged Thompson with representing that Aspercreme does not result in the adverse reactions associated with aspirin. The ALJ concluded (IDF 143) that in the context of Thompson's advertisements, the statements about "no" side effects would be taken to mean "no *significant*" side effects, for which representation Thompson had a reasonable basis. Accordingly, the ALJ dismissed so much of the complaint as relates to Paragraph 12(f). We agree with the ALJ's disposition of this part of the complaint.

interpret the word "aspirin" to mean in the context of the Aspercreme ads. [13]

We note to begin that none of the Aspercreme ads includes an express representation that Aspercreme contains aspirin. On the contrary, like much advertising we find deceptive, the ads are drafted with an artful choice of words to make what Thompson thought were literally correct statements (for example, that Aspercreme's pain relieving properties are equivalent to aspirin's). However, in considering the net impression of an advertisement, we do not require that all consumers reading or viewing it be sophisticated experts in interpreting the nuances of the English language. Absent reason to conclude differently, we presume that advertisements are directed at ordinary members of the adult population who, as such, have a range of abilities.[15] We look at how such [14] individuals actually interpret advertisements in real-life situation, not at how they would if they had sufficient time and incentives attentively to review the ads so as to come up with the most semantically correct interpretation of them. We therefore consider here whether one message impliedly conveyed to reasonable consumers by the ads is that Aspercreme contains aspirin. To do this, we need to evaluate the ads' net impression on consumers. The ads are not all alike; rather they fall into several different groups. We describe each group below and consider whether it gives a net impression of aspirin content.[16]

(1) The TV Ads With No Disclosures—CXs 1 and 2

Thompson's earliest television ad for Aspercreme, CX 1, shows a woman talking. As the ad begins, she is shown holding two aspirin tablets and saying ". . . imagine being able to put the strong relief of aspirin right where you hurt most." At this point, the two aspirin tablets in her hand disappear and are replaced by a tube of Aspercreme, while she says: "Now, with amazing Aspercreme, you can get

[15] If advertisements are targeted at special audiences who as a group have a greater or lesser capability to recognize deceptive advertising than ordinary members of the adult population or a distinctive reaction to particular advertising claims, a reasonable consumer is an ordinary members of that target audience. *See, e.g., Travel King,* 80 F.T.C. 715 (1975). However, almost all advertising is targeted at some demographic group, such as farmers, housewives, or residents of a particular area. This alone does not mean that we apply a standard different from our customary one.

Previous Commission cases have recognized that persons with health-related problems can be a target audience. *See, e.g., Travel King, id.; Porter & Dietsch,* 90 F.T.C. 770, 864–65 (1977), *aff'd,* 605 F.2d 294 (7th Cir. 1979), *cert. denied,* 445 U.S. 950 (1980). In this case, Thompson's ads were directed at arthritics. The ALJ's opinion (IDF 90) suggests that he considered arthritics to be a target audience. Though his finding was stated in conclusory fashion, other available evidence and findings (such as the fact that arthritis is a chronic disease (IDF 191) and that consumers spend significant amounts of money on quack remedies (IDF 193) suggests that arthritics may be more susceptible to deceptive analgesic claims than ordinary members of the adult population and therefore are a target audience. Ultimately we find it unnecessary to resolve the question because the evidence in this proceeding shows that Thompson's ads were deceptive whether or not arthritics are considered a target audience.

[16] Our discussion here focuses solely on the advertisements Thompson used in the national consumer advertising campaign for Aspercreme (CXs 1–11, 21–22, and 37). We do not evaluate the Aspercreme ads in the local Ohio market (CXs 12–20) because our conclusions about the national ads makes it unnecessary to do so.

the strong relief of aspirin directly at the point of minor arthritis pain." She continues comparing Aspercreme to aspirin, noting (among other things) that Aspercreme contains none of aspirin's side effects. As the ad ends, she leaves the screen and is replaced by a still life [**15**] showing a tube and bottle of Aspercreme, along with a video super stating: "The strong relief of aspirin right where you hurt." The audio portion of the ad concludes with a voice over stating the same phrase as the video super.

The second early Aspercreme ad, CX 2, is similar to CX 1 at its beginning and end. To begin, it shows a woman holding two aspirin tablets. As she holds the tablets, she tells listeners to "imagine putting the strong relief of aspirin right where you hurt." Next an Aspercreme tube replaces the two tablets, whereupon she states: "Aspercreme is an odorless rub which concentrates the relief of aspirin." At this point, CX 2 diverges from CX 1. In its middle portion, CX 2's visual part uses the transparent outline of a man's body and rays streaming outward from both an aspirin tablet in the stomach and a point on the shoulder where Aspercreme was rubbed. There are fewer rays from the stomach than from the shoulder. As the rays are shown visually, the woman states that "regular aspirin . . . goes through your body like this [through the stomach]. But, in seconds, Aspercreme starts concentrating all the temporary relief of two aspirin directly at the point of minor arthritis pain." The ad concludes with the same still life and audio as does CX 1. [**16**]

The ALJ concluded that a variety of different elements in these ads were representations that Aspercreme contains aspirin.[17] Among the elements were use of the brand name "Aspercreme," repetition of the words "Aspercreme" and "aspirin" in the same commercial, use of the statement that Aspercreme provides "the strong relief of aspirin" and the visual image in which two aspirin tablets are replaced by a tube of Aspercreme (IDFs 85–89).

Our own examination of the net impressions conveyed by these ads also causes us to conclude that they suggest that Aspercreme contains aspirin. We agree with the ALJ's view that various elements in the ads suggest aspirin content. We further note the absence of any elements giving a contrary impression, such as express disclosures. Therefore, all the evidence from the ads themselves points to one conclusion: that the ads are likely to give consumers interpreting them reasonably a net impression that Aspercreme contains aspirin.

Although we do not find it necessary from our perspective to look

[17] The ALJ did not distinguish between express and implied representations. He also did not focus separately on the net impression given by CXs 1 and 2. Rather, he analyzed whether or not individual words, phrases, or visual images used in one or more of Thompson's ads implied aspirin content. As we noted in the text, above, our method of analysis looks at the net impression created by the interaction of different elements in a given ad, not at the elements by themselves.

at extrinsic evidence in evaluating CXs 1 and 2, Thompson has offered some in support of its theory that consumers would interpret CXs 1 and 2—and all the other Aspercreme ads, as well—to mean that Aspercreme provides relief like aspirin [17] without actually containing aspirin as an ingredient (RPF 240–60). Because Thompson offered extrinsic evidence, we are obliged to consider it. However, our review of Thompson's evidence does not change our views regarding CXs 1 and 2.

One type of extrinsic evidence offered by Thompson consisted of testimony by marketing experts. (*See, e.g.,* Ross, Tr. 5983–88; Jasper, Tr. 4736; Silver, Tr. 5654–55) and the results of a consumer survey, the Video Storyboard Test (RX 165). Having examined the testimony, we find it unpersuasive.[18] [18]

Thompson also has claimed that the results of the Video Storyboard Test (RX 165) show that CXs 1 and 2 do not leave a net impression of aspirin content with consumers who interpret the ads reasonably. The Video Storyboard Test is, of course, consumer survey research, and as such is the type of evidence to which we would give considerable weight if it were methodologically sound. However, we agree with the ALJ's conclusion (IDF's 117–19) that the Video Storyboard Test was improperly designed for the objective of providing data on whether CXs 1 and 2 communicate a net impresssion of aspirin content to consumers.

Although the report of the Video Storyboard Test does not include a protocol describing what the study was designed to measure and how the methodology chosen would do so (in and of itself a factor we view negatively when assessing the quality of a study), it appears that the survey was designed to measure the comparative effectiveness of CX 1 and CX 2 in conveying important attributes of Aspercreme to potential users (RX 165A-M). In order to collect this information, the Video Storyboard Test used a shopping mall intercept sample to obtain 100 participants. The respondents were qualified by age, *i.e.,* 45 years and older, and by whether they "occasionally have symptoms

[18] For example, Thompson's principal marketing expert, Dr. Ross, speculated on whether the percentage of consumers coming away from CXs 1 and 2 with the impression that Aspercreme contains aspirin rose above an "irreducible minimum, but he provided little factual or analytical support for his observations." *See e.g.,* Tr. 5985–86:

> Q. Is it possible, Dr. Ross, that some consumers might have taken away the impression from CX-1 that Aspercreme is aspirin?
>
> A. Yes, I think it is possible. I think that some may have and I think that that impression would occur simply from the analogy between Aspercreme and internal analgesics. That is, some may think if it relieves the same way, it is aspirin.
>
> But I think that is a kind of irreducible minimum percentage kind of thing of a perception, of a misperception, in that I think if you are going to compare any external rub product to any internal product, any internal analgesic product, that some are going to assume that you mean aspirin, since that is the word that they use for such internal tablets or product.
>
> So, in perceiving that the ad is representing that Aspercreme has aspirin, all the consumer is really thinking or saying is that it has an analgesic in it.

of arthritis" (CX 165–O). Fifty participants were shown CX1 and the other fifty viewed CX 2. Immediately after viewing either CX 1 or CX 2, participants completed the survey questionaire.

Although the sample was a non-probability sample (*i.e.*, its results are not projectable to the national population as a whole) and rather small, there is no apparent reason why the [**19**] persons surveyed would not be reasonably representative of a typical subset (those over 45 who suffer occasional symptoms of arthritis) of those persons who generally might be interested in purchasing analgesics to relieve arthritis pain. However, CX 51 does not provide probative information about the participants' beliefs about aspirin content in Aspercreme for two reasons. First, it does not contain any questions that directly elicit ingredient information. Second, the verbatim responses were not placed on the record and the data from the study were not coded to determine the percentage of responses that included mentions of ingredients (Ross, Tr. 6310). The questionnaire used in the Video Storyboard Test was concerned with the persuasiveness of each commercial (question 1), the impact of the messages or copypoints in each commercial (questions 2, 3, 4, 9, 10, 11 and 12), the perceived uniqueness of Aspercreme (questions 5 and 6), the relative effectiveness of Aspercreme compared to aspirin (questions 7 and 8), and demographics (age and sex of respondents). The way in which these questions were phrased makes any information provided about ingredients in general, and aspirin content in particular, incidental to the information gathered about the relative effectiveness of CX 1 and CX 2 as commercials. Of course, some participants nonetheless may have mentioned ingredients in their responses to the questions being asked. If the record contained information showing how many participants gave such responses, we would examine whether enough had done so to make the results reasonably reliable. However, no [**20**] such information was supplied with CX 51. Therefore, we find that CX 51 is of no probative value in determining the consumers' beliefs about whether Aspercreme contains aspirin.

While we thus find the extrinsic evidence relied on by Thompson not to be probative, we find that complaint counsel's evidence does not provide extrinsic evidence consistent with the conclusions we reach from analyzing the ads themselves. Complaint counsel cite to the Mapes and Ross Test (CX 50), which was conducted for Thompson in 1979, prior to the start of this litigation. Although Thompson now criticizes the design of this survey (RAB 53–54), we find that its methodological strengths far outweigh its weaknesses. Specifically, its research methodology (or close variants of it) is frequently used in copytests. For example, the use of prerecruited groups of subjects, lotteries to provide incentives for viewing, the attempts to "bury" the

commercials in programmatic material, and day-after unaided recall, aided recall and brand preference measures are typical of advertising copytests. In addition, although the study did not employ a probability sample and discussed neither survey response rates nor non-response bias, we cannot detect any obvious reason why the sample is not reasonably representative of consumers viewing CXs 1 and 2. Such methodology is adequate for the results to be of some probative value, assuming the survey asked probative questions.

Like the Video Storyboard Test, the Mapes and Ross survey contained questions that attempted to elicit participants' recall of the information contained in CX 1 and CX 2 and did not contain direct questions about ingredients. However, unlike the Video [21] Storyboard Test, the Mapes and Ross final report contains the verbatim responses provided by the participants so that the percentage of respondents who mentioned aspirin as an ingredient can be determined. From the resulting responses come two estimates of the percentage of relevant market females who, given one exposure to a televised Aspercreme commercial, perceive that Aspercreme contains aspirin. The first estimate is contained in the Mapes and Ross final report, which calculates the percentage of survey participants who thought Aspercreme "Works Like/Contains Aspirin" after viewing CX 1 or CX 2. The second estimate is contained in a memo from an Ogilvy and Mather researcher who reviewed the verbatim transcripts of the data collected in the study and independently calculated the percentage of respondents who believed Aspercreme contained aspirin (CX 116–A). The data from both sources are provided below:

Table 1

Respondents Perceiving:	CX–1 Visible Man %	CX–2 Stand-Up Presenter %
Aspercreme "Works Like/Contains Aspirin" (CX50–H)	23	35
Aspercreme product contains aspirin-recallers only; (Oglivy and Mather memo, CX116–A)	21	30 [22]

Although there are some biases in the Mapes and Ross Test,[19] its results support our conclusion that one reasonable interpretation

[19] The test contains several potential sources of bias which may have affected the estimate of the percentage of people who believe Aspercreme contains aspirin. On one side, the screening process used to obtain the sample may have alerted participants about the nature of the study. If so, respondents would have paid more attention to the commercials than they otherwise might have. On the other side, one exposure to the advertisements is less than the three recommended for maximum recall and comprehension in a natural viewing situation. *See* H. Krugman, *Why Three Exposures May Be Enough*, Journal of Advertising Research, Dec. 1972, 11–14. The omission of aided questions or probes about ingredients probably caused the estimates of the proportion of respondents believing that Aspercreme contained aspirin to be understated.

consumers would make of these two ads is that Aspercreme contains aspirin.

Thus the Mapes and Ross Test, the only reasonably reliable extrinsic evidence regarding CX 1–2, supports our conclusion that it is reasonable for consumers to interpret CXs 1 and 2 as making an implied claim of aspirin content.

(2) The TV Ads With Visual Disclosures—CXs 3 and 4

The next two Aspercreme television ads, CXs 3 and 4, are essentially similar to the earlier ads, CXs 1 and 2 respectively, with one difference. Both CX 3 and CX 4 have video supers that read: "contains no aspirin." Thus, the question presented by CXs 3 and 4 is whether the video supers are sufficiently clear **[23]** and conspicuous to overcome the impact of other elements in the ads, elements which caused somewhere between 21% and 35% of the persons viewing CXs 1 and 2 to believe that Aspercreme contains aspirin.

The extrinsic evidence relating to CXs 3 and 4 is not of the sort we perfer to rely on in evaluating the possible existence of implied claims, but is sufficient for us to reach the conclusion that the ads' net impression upon reasonable consumers is one of aspirin content. There is no survey research pertaining directly to CXs 3 and 4, and we are not persuaded by the expert opinions presented at trial as to what consumers would interpret the ads to mean (*See* Cohen, Tr. 213–18; Ross, Tr. 6016–18, 6185–98) because we find them to be inadequately supported.[20] However, copy testing performed on an Aspercreme ad with what appears to be a more prominent disclosure of non-aspirin content, CX 9, found that one net impression given to consumers was that the **[24]** product contains aspirin.[21] CX 9 was sufficiently similar to CXs 3 and 4 that we consider it permissible to infer from the CX 9 results that an even higher percentage of consumers would come away with such a net impression after watching CXs 3 and 4.

Additional extrinsic evidence in the form of generally recognized marketing principles also leads to the conclusion that the disclosures were insufficiently clear and conspicuous. The disclosures were placed in the middle of the ads and were distracted from by the

[20] The ALJ's initial opinion also cites the views of CBS and the National Association of Broadcasters (NAB) that the disclosures were inadequate as evidence that the disclosures were so. The opinion does not clearly alert readers to the ALJ's ruling at trial (Tr. 637) that the opinions of CBS and NAB were to be admitted into evidence not as primary evidence, but only as confirmatory evidence (Tr. 637). (The opinion does describe the CBS and NAB views as "confirmatory", but fails to indicate that the word has any special significance.) We agree with the ALJ's view at trial that this evidence cannot be relied on to establish in the first instance whether or not the video supers were adequate. As was argued by Thompson (Tr. 633–36), the record does not show the qualifications of the individuals at CBS and NAB who reached the conclusion that the supers were inadequate, the facts that were before these individuals, or the standards they applied to the facts. However, we see no logical basis for the ALJ's decision to use these opinions as "confirmatory" evidence and, accordingly, do not rely upon them ourselves.

[21] *See* our discussion of CX 9, below at pp. 33–42.

conceptually uncorresponding audio message being communicated while they were on the screen. Studies of consumer behavior show that individuals will better remember either information presented to them first (primary effect) or information presented to them last (recency effect), depending upon the delay between presentation of the messages and evaluation of the recipients' responses. In any event, however, recall typically is a U-shaped function, with the worst recall being of messages presented in the middle. A distracting situation lowers ability to recall at all points along the curve.[22] **[25]**

(3) The Print Ads With Common Headlines—CXs 6–7, and 10–11.

Six print ads for Aspercreme were introduced into evidence in this proceeding. Four of them, CXs 6–7 and 10–11, have common elements. Principal among these is an identical headline. The ads begin in large print:

> At last! A remarkable breakthrough
> for arthritis pain: Aspercreme.

Below this and in smaller print, the headline continues:

> Aspercreme is an effective arthritis medicine
> which concentrates all the strong relief of aspirin
> directly at the point of pain.

All four ads also contain a visual representation of an Aspercreme tube and bottle. Both display the brand name "Aspercreme" and the statement, "external arthritic pain medication."

Two of the ads, CXs 6 and 7, have additional elements that would contribute to their net impression concerning aspirin content. Below their headlines, each shows a drawing of a man's body, with numbered lines pointing to various body parts. Associated with each line is text in smaller print that the headlines. CX 6's text compares Aspercreme to aspirin in two ways: (1) "Aspirin tablets go through your body. But Aspercreme concentrates the relief of an effective aspirin-like analgesic **[26]** directly at the point of arthritis pain . . ."; and (2) "Aspercreme, like aspirin itself, has no liniment smell." CX 7's text has three comparisons between Asprecreme and aspirin: (1) "Aspirin tablets go throughout your body. But Asprecreme concentrates the relief of two aspirin directly at the point of arthritis pain . . ."; (2) "Aspercreme works faster than aspirin because you rub it right where you hurt"; and (3) "Aspercreme, like aspirin itself, has no liniment smell."

[22] *See* B. Sternthal and C. Craig, *Consumer Behavior, An Information Processing Perspective* 102–03, 282–83 (1982) and works cited therein.

We conclude that it would be reasonable to interpret all four print ads as conveying a message of aspirin content. For three of the ads, CXs 7, 10–11, we reach this determination based solely upon our examination of evidence from the ads themselves. In particular, we conclude that the language in the headline ("Aspercreme . . . concentrates all the strong relief of aspirin . . .") is readily susceptible to the interpretation that Aspercreme contains aspirin and that the language would be so interpreted by consumers. Given this fact, and given that no other elements in these ads suggest other than that Aspercreme contains aspirin, we conclude that at least one of the net impressions communicated by the ads is of Aspercreme's aspirin content.

One of the ads, CX 6, does include textual language amounting to an implied representation that Aspercreme does not contain aspirin. It states: "Aspercreme concentrates the relief of an effective aspirin-like analgesic . . ." The most direct conclusion to draw from a statement that Aspercreme is "like" aspirin would be that it is similar to but not the same as aspirin. Because this element in the ad conflicts with the [27] element stating that Aspercreme "concentrates all the strong relief of aspirin," we require something in addition to evidence from the ad itself before determining whether or not consumers would interpret CX 6 to state that Aspercreme contains aspirin.

The additional element in the case of CX 6 is the general marketing principle, acknowledged by Thompson's marketing expert (Ross, Tr. 6198–99) as well as complaint counsel's (Cohen, Tr. 223), that persons reading a print ad often will read only the headline, and will take their sole impression of the ad from it. The special significance of headlines has previously beeen recognized in Commission cases, which hold that even an express disclosure in the text of an ad may not be enough to change the ad's net impression upon consumers.[23] Applying this principle to CX 6, complaint counsel's marketing expert testified that a great many people reading CX 6 would believe Aspercreme to contain aspirin (Cohen, Tr. 233).[24] We also find that application of the general principle to this specific situation suggests such a [28] result. Upon this basis, we conclude that one net impression consumers reasonably would understand CX 6 to be conveying is that Aspercreme contains aspirin.

[23] *See, e.g., Litton Industries, Inc.*, 97 F.T.C. 1, 70 n.5 (1981); *Giant Food, Inc.*, 61 F.T.C. 326, 348–49 (1962), *aff'd*, 322 F.2d 977 (D.C. Cir. 1963), *cert. denied*, 376 U.S. 967 (1964).

[24] Thompson's marketing expert argued that the headline itself does not imply aspirin content (Ross, Tr. 6020–21, 6060–61), from which it would follow that persons reading the headlines alone would not believe Aspercreme contains aspirin. While we are obliged to consider this opinion because it was offered as evidence, we find it unpersuasive.

(4) The Other Print Ads—CXs 8, 37.

The other two print ads, CXs 8 and 37, are different from the other four and from each other. We first examine CX 8.

Beginning with its headline, CX 8 repeatedly contrasts Aspercreme with aspirin. The headline states:

There's always been aspirin . . .
Now there's ASPERCREME[25]
Works faster, safer than aspirin—relieves pain in minutes.

The first sentences of the text, (in considerably smaller print than the headline) continue this comparison approach by stating: "Aspirin has been helping sufferers of minor arthritis pain for years. Now there's a different way to get relief. ASPERCREME." Other comparisons in the text similarly contrast Aspercreme with aspirin. In addition, there is a visual depiction of an Aspercreme tube in its display packaging. Visible on the display packaging, in print slightly smaller than the text of the ad, is the statement: "An effective aspirin-like analgesic for temporary relief of occasional minor pain . . ." [29]

We are not able to conclude with adequate confidence by looking solely at evidence from the ad itself whether or not one message conveyed to consumers by CX 8 is that Aspercreme contains aspirin. The general tone of the ad contrasts Aspercreme with aspirin, emphasizing the supposed difference between the products rather than their similarities.[26] These contrasts might create among average consumers the impression that Aspercreme is different from aspirin. On the other hand, it might also be that the perceived difference would be means of application (external rather than internal), not identity of active ingredients.

In this situation, we cannot find the ad to convey an implied message without sufficiently probative extrinsic evidence upon which to base our conclusions. We do not find any such evidence here. There was no consumer survey research on CX 8 or any other Aspercreme advertisement similar enough to CX 8 to permit the drawing of inferences about CX 8 from it. The testimony of the marketing experts also does not permit us to reach reasonably confident conclusions. Complaint counsel's principal marketing expert argued that most people looking at a newspaper ad such as CX 8 would only look at the headline, which links Aspercreme with aspirin (Cohen, Tr. 226), but he did not show that the link created by such a headline would equate Aspercreme and aspirin; instead, consumers might interpret the link to suggest that Aspercreme is a new product similar to but [30] different

[25] This part of the headline is in significantly larger print than other parts.

[26] The other Aspercreme ads we have reviewed up to now emphasized similarities, *e.g.*, "aspirin's relief."

from aspirin.[27] Thompson's principal marketing expert, on the other hand, emphasized the fact that CX 8 contrasts Aspercreme with aspirin, concluding from this that if consumers understand aspirin as a specific ingredient, the headline would communicate that Aspercreme is not aspirin (Ross, Tr. 6026–27). However, he provided no evidence to exclude a possible consumer interpretation of the headline that Aspercreme provides the clinically active ingredient of aspirin tablets in a cream form. While both sides have thus failed to present adequate extrinsic evidence concerning CX 8, the burden was on complaint counsel to do so. In light of that failure, we cannot find CX 8 to contain an implied message of aspirin content.

We next turn our attention to the remaining print ad, CX 37. The headline of CX 37 characterizes Aspercreme as "a remarkable analgesic" and as "an effective alternative to pills for minor arthritis pain." The first paragraph of the text, which is in bolder print than the remainder, states: "Aspercreme contains salycin, an effective *non*-aspirin pain reliever that concentrates relief right at the point of pain. You get hours of relief without the side effects pills may cause." Further on, the text additionally states: "Aspercreme has a *non*-aspirin pain reliever, so it can't cause aspirin's stomach upset or any of aspirin's side effects" and "Aspercreme's active pain reliever—[31] *salycin*—is clincally proven . . ." (emphasis in original). All of these elements suggest a difference between the active ingredient in Aspercreme and the active ingredient in aspirin. Nor is there any element in the ad except for the brand name that even arguably could be viewed as implying that Aspercreme and aspirin are the same. It may be that the brand name alone would be enough to convince some readers that the product contains aspirin, and that the disclosures would be insufficient to overcome this misimpression. However, we would require that such a conclusion be supported by extrinsic evidence.

Our conclusion diverges from the ALJ's, who found that CX 37 did represent aspirin content (IDF 84). However, the ALJ's discussion of this particular ad is flawed by his analytic approach, which was to look at each element that was in one or more ads and then to decide whether or not the element, considered by itself, represented aspirin content. Not only do we believe this approach to be less analytically desirable than considering the net impression which different elements in an ad combine to give, but in this case the approach caused the ALJ to lump CX 37 together with several of Thompson's television advertisements, all of which are quite different from CX 37. Thus, the

[27] We will not presume generally that consumers interpreting advertisements reasonably under the circumstances will always read a comparative ad to imply that the products being compared are the same. For example, we seriously doubt that persons reading "Buy a racing car. It provides faster, more enjoyable transportation than a station wagon." would interpret the ad to imply that the products were the same.

ALJ incorrectly wrote that the affirmative statements in several ads, including CX 37, were required by the television networks. Obviously, the networks had no control over print ads such as CX 37. Likewise, where the ALJ cited extrinsic evidence as to why the affirmative statements in various ads were ineffective disclosures (IDF 84), the evidence itself pertained only to the television advertisements, not to CX 37 [32]

The one point made by the ALJ that appears specifically to apply to CX 37 is his observation that the phrase "contains salycin, a non-aspirin pain reliever," found in both CX 37 and several television ads, is ambiguous because it does not negate the impression that Aspercreme may contain *both* aspirin and "salycin." We find this point unpersuasive for two reasons. First, while it is literally true, as a nicety of English semantics, that the statement "contains salycin" would not absolutely negate the possibility that Aspercreme also contains aspirin, nothing in CX 37 expressly states that Aspercreme has more than one active ingredient. Nor do we find that the brand name "Aspercreme" or any other element in CX 37 implies the product contains two active ingredients.[28] Therefore, in considering how consumers probably would interpret the ad, rather than how it is technically possible for someone to read it, we find it irrelevant that the statement in CX 37 does not specifically exclude the possibility of two active ingredients. Second, even if one thought average adults were sticklers for English semantics, there is a statement in CX 37, one which the ALJ overlooked, that does negate the possibility of aspirin content. It is the statement that Aspercreme's "active pain [33] reliever" is salycin. Since the ad refers to "pain reliever" in the singular, it excludes the possibility of there being a second active ingredient.

(5) The TV Ads With Audio Disclosures—CXs 5, 9 and 21–22

The most recent television ads for Aspercreme, the ones on which most of the Aspercreme advertising dollars were spent (CX 25A), contain audio disclosures that either expressly or impliedly state that Aspercreme does not contain aspirin. Three of the ads, CXs 5, 9 and 21, are testimonials whose main focus is to show various men and women endorsing the product. Among the individuals' statements are those that Aspercreme relieved their arthritis, did not upset their stomachs, was odorless, or relieved their pain for hours. These ads do not mention the word "aspirin," liken Aspercreme's relief to that provided by aspirin, or liken Aspercreme to "pills." Each also contains a disclosure in a middle frame of the ad (rather than at its beginning or end) stating that Aspercreme does not contain aspirin. In CX 5, it

[28] The name "Aspercreme" may imply that Aspercreme contains aspirin as an active ingredient. However, the name does not suggest whether or not the product has more than one active ingredient.

is the express audio statement "aspirin free," coupled to a visual image of an Aspercreme tube. In CXs 9 and 21, it is the statement "Aspercreme contains salycin, a strong non-aspirin pain reliever." coupled to the visual image of an Aspercreme tube and the video super "contains salycin."

In the remaining TV ad, CX 22, a woman compares Aspercreme with "pills," stating that Aspercreme provides long lasting relief without the side effects pills may cause. Insofar as "pills" is an implied reference to aspirin tablets, CX 22 is an [34] ad that contrasts the two forms of medication. In the middle frames of the ad the woman states "Aspercreme relieves arthritis pain because it contains salycin, a strong non-aspirin pain reliever." while the visual portion of the ad shows her applying Aspercreme to the back of one of her hands.

We would not find CXs 5, 9 and 21–22 to convey an implied aspirin content message if we were to rely solely upon an examination of evidence from the ads themselves. The contradictory elements in these ads preclude us from determining with sufficient certainty what message(s) viewers would take away from the ads concerning the aspirin content of the product. On the one hand, there is the disclosure that Aspercreme contains a non-aspirin pain reliever, coupled to the absence of any language or visual imagery likening the product to aspirin tablets. On the other hand, there is the "Aspercreme" brand name itself. The brand name was visually displayed in each ad, as well as being repeated beween four and six times on the ads' voice tracks. Moreover, the brand name of a product is the most powerful single stimulus in an ad. Consumers are more likely to recall brand names than specific copy points in advertisements (Cohen, Tr. 559; Ross, Tr. 6317–19). A net impression based primarily upon a message derived from the brand name could be that Aspercreme contains aspirin.

In this situation, we require extrinsic evidence to help us determine how reasonable consumers actually perceive the ads. The record contains three surveys that we believe shed light on the question of what consumers believe CX 9 to mean: the FRC Test (CX 35/RX 520), and the Lieberman Test (CX 32/RX 500), which [35] were both sponsored by Thompson, and the ASI Theater Test (CX 27), which was sponsored by complaint counsel. The results from each of these studies and significant details about their methodologies are summarized below. However, the conclusion we draw from the surveys can be stated at the outset: consumers interpreting CX 9 reasonably could and did think that Aspercreme contains aspirin.

(a) *The FRC Test (CX 35/RX 520) and the Lieberman Test (CX 32/RX 500)*

In 1981 Davis and Gilbert, Thompson's counsel, contracted with Ken Warwick and Associates, Inc. to design a copytest of CX 9. Based on background information contained in the FTC complaint and discussions with Davis and Gilbert, Warwick designed and conducted the FRC copytest (CX 35/RX 520). After the FRC study was completed and the results were in, Warwick redesigned the survey questionnaire used in CX 520 and completed a second study, the Lieberman copytest (CX 32/RB 500).

Both the FRC and Lieberman studies were intended to determine the percentage of respondents who, after viewing CX 9, believed Aspercreme contained aspirin. The methodology was the same for both studies and involved showing respondents, who were recruited and screened with shopping mall intercepts, the advertisement CX 9 and asking them a short series of questions. Respondents were shown CX 9 twice and no distracting materials such as other ads were included. This methodology increases the probability that respondents paid attention to CX 9. Thus, if [**36**] there was any bias in the methodology used in the Warwick studies, it was in the direction of increasing the percentage of respondents who remembered the information presented in CX 9.

Although there were few differences in the research design between the FRC and Lieberman studies, there were important substantive differences in the survey questionnaires used in each study. The questionnaire in the first study contianed four questions probing consumer perceptions as to the ingredients of Aspercreme and two other analgesic rubs:

> Q1. First, what was the name of the ingredient in the product you just saw advertised?
>
> Q2. Based on the commercial you just saw, does the product in the commercial contain aspirin?
>
> Q5. Does Ben-Gay contain aspirin?
>
> Q6. Does Mentholatum contain aspirin? (RX 520; Warwick, Tr. 5332)

The second study contained only one question probing such consumer perceptions:

> Q1. What was the name of the ingredient in Aspercreme, the product advertised? (RX 500–E)

Findings from the FRC and Lieberman studies are summarized in Table 2: [**37**]

Table 2
Unaided and Aided Recall Results to Questions About the Ingredients in Topical Analgesics

Ingredients Mentioned With Unaided Recall	FRC Survey Question 1*	Lieberman Survey Question 1**
Salycin	95 (45.9%)	(25%)
Aspercreme	43 (20.8%)	(2%)
Aspirin	6 (2.9%)	(5%)
Blank/Don't Know	47 (22.7%)	(65%)
Others	16 (7.7%)	(3%)
n (totals)	207 (100%)	212 (100%)

Aided Recall Perception of Whether Aspirin is an Ingredient in...*	FRC Survey Yes	No	Don't Know	Total
Aspercreme (question 2)	22.2%	67.6%	10.1%	99.9%
Ben-Gay (question 5)	6.3%	39.1%	54.6%	100.0%
Mentholatum (question 6)	4.8%	43.5%	51.7%	100.0%

*RX 520–G
**Warwick, Tr. 5321.

The results from the unaided recall questions (the first question contained in each survey) indicate that between 25 and 46 percent of the participants identified Salycin as the ingredient in [38] Aspercreme.[29] Thus, less than half of the respondents were able to provide this response after seeing the commercial twice. However, in both surveys very few of the respondents mentioned aspirin as an active ingredient in Aspercreme. Thus, the unaided recall question in both surveys tends to support Thompson's position.

The results from the aided recall questions in the FRC survey (questions 2, 5 and 6) tell an entirely different story. That is, when queried directly about whether Aspercreme contains aspirin, 22 percent of the respondents replied affirmatively. Conversely, only 6 percent of the respondents thought aspirin was an ingredient in Ben-Gay and less than 5 percent perceived that aspirin was contained in mentholatum.

These results show that CX 9 did, in fact, cause average viewers to believe that the product being described contains aspirin. Specifically, the difference in the response percentages between Aspercreme, on

[29] No information is contained in the record explaining why the percentage of respondents who identified Salycin as the active ingredient in Aspercreme varied so dramatically between the FRC and Lieberman studies. Although the wording of the unaided recall question (Q1) was changed between the two surveys to decrease the percentage of participants who responded "Aspercreme" (Warwick, Tr. 5325), there is no reason to expect that this change would influence the percentage of "Salycin" responses. We would expect that the change in wording in question 1 between the FRC and Lieberman studies would reduce the percentages of participants giving the response "Aspercreme" from 20 to close to 0 percent and cause a corresponding increase in "don't know" responses, *e.g.*, from 23 to 43 percent. What we find is that the Lieberman study obtained roughly the decline expected in Aspercreme responses, *i.e.*, from 20 to 2 percent, 20 percent more "don't know" responses, and 20 percent less Salycin responses than expected based on the FRC results.

the one hand, and Ben-Gay and Mentholatum, on the other, allows us to conclude with reasonable **[39]** confidence that the results of the FRC Test were not caused by survey bias. The questions about the content of Ben-Gay and Mentholatum acted as controls for the survey, and permitted an estimate of the "noise level" generated by various possible random factors, such as confusion on the part of consumers being surveyed or "yeasaying bias" in response to aided questions.[30] The significant difference between the percentage of consumers who thought Aspercreme contains aspirin and those who thought it was contained in the other rubs clearly supports the conclusion that CX 9 generated a net impression of aspirin content among its viewers.[31] **[40]**

(b) *The ASI Theater Test (CX 27)*

The effectiveness of the disclosure in CX 9 that aspirin is not an ingredient in Aspercreme was also examined in the ASI Theater Test (CX 27) sponsored by complaint counsel. The methodology involved recruiting two groups of subjects to a theater for the ostensible purpose of evaluating a pilot television show. Each group of subjects was shown the same "pilot" show, a standard control commercial for Papermate Flair pens and one of two topical analgesic commercials, *i.e.*, one for Aspercreme and one for Mobisyl (CX 27–E). The next day as many viewers as could be contacted were telephoned and asked unaided and aided recall questions about the products advertised in the theater test and the ingredients they might contain (CX 27–E-H).

It is likely that the responses to the ASI Theater Test show a bias toward relatively increased estimates of the confusion about the information contained in CX 9. This is due to the fact that CX 9 was shown only once, that it was shown along with programmatic material and another commercial, and that participants were not asked questions about the ingredients in these topical analgesics until the next day. Thus, it is likely that the ASI Theater Test resulted in an inflated

[30] If roughly no more respondents had answered that Aspercreme contains aspirin than answered that Ben-Gay or Mentholatum did, we would conclude that the extrinsic evidence did not show CX 9 to give a net impression of aspirin content. However, three times as many respondents perceived Aspercreme to contain aspirin even after twice viewing a disclosure to the contrary, than perceived that aspirin was an ingredient in Ben-Gay or Mentholatum.

[31] Dr. Warwick, the expert who originally designed the FRC Test for Thompson, argued that it was flawed through use of aided recall questions and that this is the reason why he designed a second test omitting them. However, we agree with the ALJ's observations (IDF 109) on why the second study, the Lieberman Test, omitted the aided recall questions found in the earlier study:

> Although Dr. Warwick testified that this was an improvement over the FRC Test design, which he characterized as "flawed," the evidence is also consistent with the conclusion that the direct ingredient question was dropped because it had produced results unfavorable to Thompson in the FRC Test.

Dr. Warwick's testimony to the contrary is unpersuasive in light of the fact that the aided recall questions are widely used in advertising research and the fact that there are numerous ways of reducing the yeasaying bias Dr. Warwick argued such questions can create. For example, one can use controls as Dr. Warwick himself had done in the FRC Test.

estimate of the percentage of respondents who, as a result of CX 9, believe aspirin is an ingredient in Aspercreme (or conversely, a deflated estimate of the effect of the affirmative disclosure that Aspercreme does not contain aspirin). The results from the unaided and aided recall questions contained in the ASI Theater Test are shown in Table 3 below: **[41]**

Table 3
Percentages of Participants Who Though Ingredients Were Contained in Aspercreme and Mobisyl

Unaided Recall Mentions of Ingredients In Each Product:*

	Aspercreme Commercial Viewers:	Mobisyl Commercial Viewers:
Aspirin	17%	1%
Salycin	4	0
All other ingreds.	2	5
"No aspirin"	5	0
"None"	4	8
Don't know	68	87
No answer	2	0
(Number of Participants)	(130)	(100)

*The unaided recall question was, "Now thinking about the Aspercreme commercial, as best you can recall, what ingredient or ingredients, if any did the commercial say Aspercreme contained?", followed by the probe, "Were there any other ingredients mentioned in the commercial for Aspercreme?" (CX 27–Z115)

Percentages of Respondents to Aided Recall Agreeing That Various Ingredients Were Contained in These Products:**

	Aspercreme Commercial Viewers:	Mobisyl Commercial Viewers:
Aspirin	38%	5%
Salycin	20	12
Hydrocortisone	32	34
Lanolin	23	22
Menthol	15	19
(Number of Participants)	(130)	(110)

The aided recall question was, "I'm going to read you a list of ingredients. As I read each one, please tell me if the commercial indicated whether *that particular* ingredient is present in the product even if you mentioned it to me before." (CX 27–Z115) **[42]

The results of the aided recall questions are consistent with the hypothesis that a yeasaying bias exists, because a relatively large percentage of participants indicated that the control ingredients of

hydrocortisone, lanolin and menthol were ingredients in both Aspercreme and the control product, Mobisyl. Nonetheless, the unaided recall results indicate that a sizable percentage of participants did not perceive or remember the disclosure that Aspercreme does not contain aspirin and that a much larger percentage of participants associated aspirin than salycin with Aspercreme. Similarly, the aided recall results indicate that a much larger percentage of those who viewed CX 9 believed Aspercreme contains aspirin than do those who saw the Mobisyl commercial. In addition, despite the likelihood of yeasaying bias which appears to exist in the ASI Theater Test data, the overall results indicate that the net impression conveyed by CX 9 to at least one group of average listeners was that Aspercreme contains aspirin.

(6) What "aspirin" means to reasonable consumers.

In our above discussion, we found that most of Thompson's advertisements have implied representations that Aspercreme contains aspirin. As we noted to begin with, however, one argument Thompson put forward for the proposition that such representations are not deceptive is that consumers understand "aspirin" as a generic description for products that are pain relievers, not only products containing acetylsalicylic acid. Thompson's argument raises the question of whether ordinary or [43] average consumers would interpret the word "aspirin" to imply a specific ingredient or whether they only net impression they would receive would be that of a generic pain reliever, leaving only an unrepresentative subset of consumers to think of aspirin as a specific drug.

The ALJ's initial opinion did not specifically address this point, perhaps because Thompson did not raise it before him with any great degree of clarity (*See, e.g.,* RMF 121, RAB 5). Thompson's argument as we interpret it is that consumers consider "aspirin" to be a generic reference to analgesics, so that representations that Aspercreme contains aspirin do not refer to acetylsalicylic acid. To support the allegations in Paragraphs 10(a), 11(a), 16 and 17 of the complaint—which allege that Thompson falsely represented Aspercreme to contain aspirin—Thompson's argument suggests complaint counsel must show that the product does not contain an effective analgesic.[32]

The controlling question presented by this argument is what reasonable consumers understand "aspirin" to be. It is insufficent for these purposes to note simply that scientists and medical experts understand "aspirin" to mean acetylsalicylic acid, since average con-

[32] Claims that Aspercreme or TEA/S are effective analgesics are not alleged in the complaint to be false, but to be unsubstantiated. Thus there is little direct evidence of falsity, and we would have difficulty concluding that Aspercreme or TEA/S have been proved ineffective.

sumers might not understand "aspirin" as would a scientist or doctor.[33] The conflicting expert opinions [44] offered by the parties on this question, drawing on research designed for other purposes, provide little assistance.[34] [45]

There are, however, three reasons why we are willing to conclude that at least some consumers within the mainstream do not consider "aspirin" to be a generic reference to all types of pain reliever. In the first place, Thompson's own ads repeatedly distinguish between Aspercreme and aspirin. Indeed, several specifically state that Aspercreme does *not* contain aspirin, or that it contains salycin. Thus, the evidence from Thompson's own advertising indicates that asirin is not a generic reference to all analgesics. Second, for aid in interpreting the common meanings of a word we occasionally look to dictionary definitions. They are derived from the ordinary usage of words and, as such, are of some use to us as indication of how [46] reasonable consumers would understand these words.[35] In this case, we have

[33] On the contrary, we note that scientific and popular understandings are known to vary on occasion. For example, an average person would consider a spider to be an insect. To an entomologist, however, spiders are an order (Araneida) of animals in the class of Arachnida, whereas insects are animals in an entirely separate class (Insecta) of the phylum of articulate invertebrates (Arthropoda).

[34] Complaint counsel's witness testified that the findings in CX 26 (whose methodology we discuss below, at note 90), indicated consumers refer to aspirin as a specific type of internal analgesic rather than as a generic term for OTC pain relievers (Cohen, Tr. 163). However, CX 26's findings do not allow conclusions of this type to be drawn. The objective of CX 26 was to "find out whether or not the name Aspercreme led consumers to the inference that this product contained aspirin as an ingredient" (CX 26–B). Its objective was not to find out what consumers meant by "aspirin" when they stated that "Aspercreme" suggested aspirin content. There clearly is nothing in CX 26 which would allow inferences about whether consumers consider "aspirin" to refer to one specific type of internal analgesic or to be a generic phrase for many types of pain relievers with different chemical formulations.

Thompson's witness cited to the Mentholatum focus groups as supporting the opinion that people use the term "aspirin" to refer to a variety of analgesics with different chemical formulations (Ross, Tr. 5972–76). However, the Mentholatum focus group results, while supporting his testimony, conflict with the results contained in the reports from the Schneider (CX 52) and Nicholas (CX 53) focus groups, which support complaint counsel's position because participants in them believed Aspercreme contained aspirin and distinguished between aspirin and other pain relievers. *See* discussion below, at note 82. In any event, focus groups are not a research tool whose methodology permits use of their results as the basis for drawing generalizable conclusions. *Id.*

Thompson's witness also cited to the answers participants in the FRC Test (CX 35/RX 520) gave to the study's Question 3 as evidence that consumers understand "aspirin" as a generic pain reliever (Ross, Tr. 5976–79). Question 3 asked "What is aspirin?" The most frequent responses characterized it as a pain reliever (55%), a pain killer (11%), or as something that relieves headaches (7%) or pain (4%). Relatively few participants (2%) described it by giving a particular chemical name (*e.g.*, salicylic acid) or otherwise characterized it as a chemical, substance, or compound (2%) (RX 520H-J). Thompson's witness argued from this that fewer than 8% of consumers associate the word "aspirin" with a specific ingredient (RX 520C-D; Ross, Tr. 5978). However, Question 3 was too ambiguously framed to permit drawing such conclusions from it. The fact that many participants first associated the word "aspirin" with pain relief does not necessarily mean that they thought of the drug as a generic reference to all pain relievers. any more than the fact that people might first describe a Buick as a "car" would necessarily mean that they think "Buick" is a generic reference to automobiles. Further probing would have been necessary to show whether or not consumers distinguish between aspirin and analgesics based on other chemical compounds. Indeed, the answers to Question 4 of the same study strongly suggest that persons who characterized aspirin as a pain reliever in response to Question 3 did not necessarily think of the word as a generic reference to analgesics. Question 4a asked participants if they knew the chemical name for aspirin. The relatively small number (14) who answered "yes" were asked by Question 4b what the name was. Several of the participants who correctly described aspirin's specific chemical name as acetylsalicylic acid were among those who had responded to Question 3 by saying aspirin was a pain reliever (RX 520L; RX 517A-D).

[35] Definitions are less reliable than survey research as an indicator of how consumers understand advertisements because they can only provide the meanings generally used for words, rather than the specific meanings of the words in a particular context. The usage of a word in an advertisement may, of course, communicate a meaning at variance with the word's dictionary definitions, such as when it is used as slang. ("You can drive this lovely,

(footnote cont'd)

examined two widely used dictionaries, both of which define "aspirin" either as acetylsalicylic acid or as aspirin tablets. Neither of the dictionaries defines it as a generic reference to pain killers.[36] In the third place, we note the extensive advertising contemporaneously with Aspercreme of analgesics whose active ingredient is something other than aspirin, *e.g.*, acetaminophen (CX 54–Z042 to Z047). If there ever was a time when the only analgesics being marketed had aspirin as [47] their active ingredient, so that reasonable consumers might only think of "aspirin" as synonymous with pain killer, that time appears to us to be long past.

We recognize that consumers today might not be aware that aspirin's proper chemical name is, in fact, "acetylsalicylic acid." Nor do we exclude the possibility that reasonable consumers interpret the word "aspirin" in more than one way, with some thinking of it as a generic pain killer in the manner suggested by Thompson. Indeed, some consumers probably both are unaware of aspirin's chemical name and think of it as a generic pain killer. What we conclude, however, is that those persons who viewed or read the Asprecreme commercials and interpreted them to mean the product contains "aspirin," and who further thought "aspirin" is a specific chemical, fall within the range of persons who would be average or ordinary members of the adult population and, as such, are reasonable consumers. We therefore conclude that one net impression conveyed by Thompson's commercials is that Aspercreme contains acetylated salicylate.

3. *Recent Development of Aspercreme—Paragraph 10(b)*

The ALJ found that Thompson has represented Aspercreme to be a recently discovered or developed drug product (IDF 126, ID 135–36). Thompson has not argued on appeal that this finding was in error. [48]

We agree with the ALJ that the claims were made, but view them as implied rather than express. The representation that Aspercreme is a new product is contained in the headlines of five print ads, CXs 6–8, 10–11. Four of those ads, CXs 6–7, 10–11, contain identical lan-

late model car home for just two thousand five hundred bananas.") However, we will consider dictionary definitions to be indicators of a word's meaning unless other extrinsic evidence or our own examination of the advertisement gives us reason to think that the context of a word makes dictionary definitions inapposite. It appears that the word "aspirin" is being used in CXs 3 and 4 in an ordinary manner. Therefore, reference to definitions to learn how consumers might interpret the word appears appropriate.

[36] Webster's Third New International Dictionary 130 (1976) defines "aspirin" as follows:

> 1: a white crystalline compound $CH_3COOC_6H_4COOH$ of salicylic acid used esp. in tablet form as an antipyretic and analgesic like the salicylates but producing fewer undesirable effects—called also *acetylsalicylic acid*
> 2: a tablet of aspirin.

A Supplement to the Oxford English Dictionary, Volume I 135 (1972) describes "aspirin" in this manner:

> A white crystalline compound, acetylsalicylic acid, used esp. as an analgesic and antipyretic; with *an* and *pl.*, a dose of this in tablet form. Also *attrib.*

guage: "At last! A remarkable breakthrough for arthritis pain: Aspercreme." The headline of the other ad, CX 8, states: "There's always been aspirin . . . Now there's Aspercreme." Both headlines create an implied representation that Aspercreme is a new product by use of phrases that suggest Aspercreme was not hitherto available for purchase. The logical inference is that it was unavailable for purchase because it did not exist. Because the language used in the headlines clearly conveys a message of newness, and because there are no other elements in the ads which might alter the net impression created by the headlines, we find that the implied claims were made. **[49]**

4. *Aspercreme Is More Effective Than Aspirin Tablets—Paragraph 12(c).*

The ALJ found all of the nationally distributed Aspercreme ads to represent that Aspercreme is more effective than aspirin tablets because it works faster than aspirin tablets, or works without aspirin's side effects such as upset stomachs, or both (IDF 133). Thompson has asserted on appeal that its advertisements contained no such comparative superiority claims (RAB 5, 33).

Our own review of the record leads us to agree with the ALJ that seven of the ads, CXs 1–4, 7–8, and 37, made superiority claims. However, we conclude that there is inadequate information on the record from which to determine whether the remaining ads cited by the ALJ, CXs 5–6, 10–11, and 21–22, would be understood by ordinary consumers to state that Aspercreme is more effective than aspirin tablets.

The seven ads that we find to make comparative efficacy claims do so expressly. They contain either or both of two different superiority claims: (1) Aspercreme provides faster relief than aspirin tablets; and (2) Aspercreme does not cause the side effects of aspirin tablets.

One ad, the print ad CX 8, makes both claims. The headline of CX 8 states that Aspercreme "Works faster, safer than aspirin—relieves pain in minutes." **[50]**

Three other ads, the TV ads CXs 1 and 3 and the print ad CX 37, claim that Aspercreme lacks the side effects of aspirin tablets. In CXs 1 and 3, an announcer tells viewers that Aspercreme has ". . . none of aspirin's possible side effects." In CX 37, the text of the ad states that Aspercreme "has a *non*-aspirin pain reliever, so it can't cause aspirin's stomach upset or any of aspirin's side effects."

In yet another three ads, the TV ads CXs 2 and 4 and the print ad CX 7, the claim is made that Aspercreme works more quickly than aspirin tablets. In CXs 2 and 4, it is made expressly by a combination of visual and audio elements. As an announcer states "When you take regular aspirin, it goes throughout your body like this." the visual portion of the ads show the outline of a man's body with a few rays

streaming outward from the stomach. One of these rays is shown reaching the man's left shoulder. The announcer then continues, "But, in seconds, Aspercreme starts concentrating all the temporary relief of two aspirin directly at the point of minor arthritis pain" while the video portion of the ad shows a heavy concentration of rays streaming outward from a point on the left shoulder to the rest of the shoulder. Given the announcer's claim that the outlines compare the ability of Aspercreme and aspirin to provide relief, the fact that the visual images show Aspercreme providing more rays to the shoulder area than aspirin tablets at the same point of time makes an explicit message that Aspercreme provides relief to the area of arthritis pain more quickly than aspirin tablets. In the print ad, CX 7, the text states that Aspercreme [**51**] "is actually faster and more effective than aspirin in relieving minor arthritis pain." It also states that Aspercreme "works faster than aspirin because you rub it in right where you hurt."

The remaining ads, CXs 5–6, 9–11, and 21–22, contain no explicit comparisons between Aspercreme and aspirin. Instead, they only make statements about the attributes of Aspercreme itself, without contrasting these attributes and those of aspirin. The ads state that Aspercreme does not upset the stomach (CXs 9 and 21–22), or that it has "no side effects" (CXs 10-11), or both (CX 6). None of the ads expressly states that aspirin tablets do upset the stomach or that they have unspecified side effects.

It may be that some consumers think of aspirin in association with stomach upset and that, upon hearing in an ad that Aspercreme does *not* cause stomach upset or other side effects, they would connect the two thoughts and conclude that the ad implies that Aspercreme is superior to aspirin. However, it is equally plausible that consumers would not make this connection. A simple examination of the ads does not provide us with sufficient information to determine whether reasonable consumers come away from these ads with the impression complaint counsel suggest. Therefore, this is a situation where we require extrinsic evidence before we can conclude with confidence that the ads imply Aspercreme is superior to aspirin.

Having examined the record, we do not find sufficient probative evidence to support complaint counsel's position that the ads make superiority claims. The evidence cited in the [**52**] initial decision (IDFs 134–37) was the opinion of marketing experts to the effect that various Aspercreme ads state the product to be more effective than aspirin. Having looked at the testimony ourselves, however, we note that it was not in reference to CXs 5–6, 9–11, or 21–22. Rather, it referred to those Aspercreme ads that we already have found to make express superiority claims. Therefore, we conclude that the record is insuffi-

cient for us to find that CXs 5–6, 9–11, and 21–22 make an implied representation of greater efficacy for Aspercreme than aspirin.

5. *Thompson Had Substantiation for Its Claims That Aspercreme Is Effective—Paragraphs 10c, 14.*

The Commission requires that advertisements containing objective product claims be supported by a reasonable basis.[37] If the advertisements contain express representations regarding a particular level of support that the advertiser has for the product claim (*e.g.*, "tests prove") or when the ad implies to **[53]** reasonable consumers that the firm has a certain level of support, the Commission expects the firm to have that level of substantiation. If the ad does not expressly or impliedly refer to a particular level of substantiation, the Commission determines the adequacy of the advertiser's existing substantiation using a number of factors—such as the ease of obtaining substantiation or the cost of a false claim—identified in *Pfizer, Inc.*, 81 F.T.C. 23 (1972) and subsequent cases.[38]

The complaint in this matter charges Thompson both with representing that it had a particular level of substantiation for claims that Aspercreme is effective (Paragraph 10c) and with making objective product claims (the efficacy claims) that imply the existence of substantiation without representing a particular level for it (Paragraph 14). We conclude that Thompson did make both types of representation. In our discussion, we first will explain why we conclude that several Aspercreme ads represented the existence of a particular level of substantiation. Then we identify, for the remaining ads, the objective product claims implying the existence of a reasonable basis. **[54]**

The ALJ concluded that two Aspercreme ads, CXs 7–8, represent that valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of minor pain of arthritis and rheumatic conditions (IDF 129). We agree with the ALJ concerning CXs 7–8, and further find that another print ad, CX 37, also represents that efficacy claims for Aspercreme have been scientifically proven. Moreover, we find the claims in all three ads to have been expressly made.

---

[37] For example, in three other recent analgesics cases we have required that efficacy claims be supported by a reasonable basis. *See Bristol-Myers Co., supra* note 8; *Sterling Drug, Inc.*, 102 F.T.C. 395 (1983), *aff'd*, No. 83-7700 (9th Cir. August 28, 1984); *American Home Products Corp.*, 98 F.T.C. 136 (1981), *aff'd*, 695 F.2d 681 (3rd Cir. 1982). We discuss the operation of our reasonable basis requirement in more detail in Part IV of this decision. However, we note here that the rationale for it under a deception theory is that objective product claims carry with them an express or implied statement that the advertiser has some amount of support for the claim. Consumers find these representations of support to be important information in evaluating the reliability of the product claims. Therefore, injury is likely if the advertiser lacks support for the claims.

[38] *Pfizer* used an unfairness analysis to reach the conclusion that the failure to have a reasonable basis violates Section 5(a) of the FTC Act. We do not rely upon such an analysis here. Rather, we find Thompson's failure to have a reasonable basis is deceptive by using the analysis first used in *National Dynamics Corp.*, 82 F.T.C. 488 (1973), *aff'd and remanded on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974); *reissued*, 85 F.T.C. 391 (1976).

Two of the ads, CXs 7–8, use similar language. Both state that Aspercreme was "tested" by a leading arthritis specialist on his own patients, with the results indicating that Aspercreme is actually faster and better than aspirin. CX 8 additionally refers to the test as a "controlled clinical test." The references to tests by a medical specialist, or "clinical tests," are an express reference to the type of test acceptable to the medical scientific community. Because the ads contain these express claims, we find it reasonable for consumers to expect that the claims that Aspercreme is faster and more effective than aspirin would be substantiated in a manner acceptable to the [**55**] medical scientific community.[39] The third ad, CX 37, does not compare Aspercreme's effectiveness to that of aspirin, but does expressly claim that Aspercreme's active pain reliver "is clinically proven to give strong, effective relief at the point of arthritis pain." Therefore, we operate on a presumption, which may be rebutted by extrinsic evidence (but was not in this proceeding), that reasonable consumers would expect scientifically acceptable evidence to support the claim that Aspercreme provides effective relief.

Because the representations that scientific substantiation exists are express, we need not consider whether the product claims for which the substantiation supposedly exists are objectively verifiable ones. If an advertiser states that he has substantiation of a given sort for assertions about his product's characteristics, we presume reasonable consumers would believe the substantiation capable of having been acquired by the advertiser. [**56**]

Having identified three Aspercreme ads that expressly represent the existence of a particular level of substantiation, we next examine whether any additional advertisements contain implied representations that Thompson had a particular level of substantiation for its Aspercreme efficacy claims. We conclude that the record is insufficient for us to find that any do.

Most of the remaining Aspercreme advertisements contain no elements whatsoever that might give reasonable consumers a net impression about a particular level of substantiation. However, four of the ads, CXs 2–4 and 6, contain visual elements that might create in the minds of reasonable consumers a net impression that Thompson was claiming to have scientific or medical substantiation for Asper-

[39] On appeal, Thompson has argued that Commission consideration of the fact that CXs 7 and 8 refer to a scientific test as the basis for efficacy claims should be influenced by the fact that "these two print advertisements were disseminated to such a limited extent as to have had virtually no impact in the marketplace" and because the claims were "not prominent" in the body copy of the advertisements (RRB 18). We reject both these contentions. In the first place, our inspection of the ads shows us that the claims Thompson characterizes as being "not prominent" were no more or less prominent than other claims in the body of CXs 7 and 8. In the second place, we reject as fundamentally erroneous the implicit suggestion that an advertiser may avoid responsibility for express representations by later claiming that the representations were not widely distributed. Such arguments may have some bearing on the extent of the relief ordered by the Commission. They have no bearing on the issue of liability for deceptive acts or practices.

creme's efficacy claims. These visual elements are models that some consumers might consider scientific looking (CXs 2 and 4) or line drawings of the human body that also might carry with them a scientific aura (CX 6).[40] Consumers might further draw from such elements, at least where used in drug advertising, the inference that Thompson had performed tests acceptable to the scientific and medical community. On the other hand, it might be that ordinary persons viewing the ads would think no further than that the models and drawings were visual aids to assist the announcer in making points. Because we are unable to interpret these visual elements **[57]** as implied claims of scientific support and in the absence of extrinsic evidence to assist us in understanding how consumers actually understand these ads, we cannot say whether or not one net impression the ads leave is of the fact that there is scientific support for the assertions that Aspercreme is an effective pain reliever.[41]

Given our conclusion that only three Aspercreme ads expressly represent the existence of a particular level of substantiation, and given our further conclusion that the record does not demonstrate any other Aspercreme ads to make such a **[58]** representation impliedly, we finally must consider whether the efficacy claims in the remaining Aspercreme ads are objective product claims impliedly representing an unspecified level of substantiation, or whether they are "puffing" representations that do not.[42] The issue is not a difficult one to decide. The record in this proceeding contains ample evidence that efficacy claims for OTC pain relievers can be and are objectively verified (*See, e.g.*., CXs 268–69). Indeed, Thompson did not argue that its efficacy claims were puffery, but rather that it had adequate substantiation for them (RAB 9–23). We therefore conclude that all ef-

[40] These sorts of visual elements also are found in CXs 7–8 and 37, ads which we have already found to represent expressly through other elements contained in them that Thompson had scientific evidence to support its efficacy claims for Aspercreme.

[41] Our approach here is consistent with that we followed in our two other recent analgesics cases, *Bristol-Myers* and *Sterling Drug*, where we concluded that similar visual images were insufficient to show an implied claim of scientific proof. For example, we stated in *Bristol-Myers*, *supra* note 8, at 323:

> [I]n CX 61, 63 and 64, a computer typewriter prints out a column made up of the words "Bufferin" and "aspirin" on graph paper at the same time as the announcer speaks about scientific tests. * * * Although the computer typewriter enhances the implication [of scientific support created by phrases such as "scientific tests show"], . . . we do not think that it alone can create the impression of scientific support for the claim. Similarly, we do not think that glass models of people with Bufferin and aspirin tablets crumbling in their stomachs and reforming in their heads indicates that Bufferin's superior speed has been scientifically established.

The difference between our opinions here and in *Bristol-Myers*, one of emphasis, is due to a refinement in our analysis since we decided that case. There we concluded the visual elements did *not* convey an impression of scientific support. Here we merely say that complaint counsel failed to provide extrinsic evidence demonstrating that they created a net impression which did. We do not attempt to use our judgment to reach any substantive conclusion. Where the implied meanings of an advertisement are unclear absent extrinsic evidence, our expertise is no more reliable in permitting conclusions that an interpretation is unreasonable than that it is reasonable.

[42] "[T]here is a category of advertising themes, in the nature of puffing or other hyperbole, which do [*sic*] not amount to the type of affirm ative product claims for which either the Commission or the consumer would expect documentation." *Pfizer*, *supra* p. 53, at 64.

ficacy claims in the Aspercreme ads are objective product claims.[43]

III. WERE THE CLAIMS MATERIAL?

After having determined which claims were made by Thompson's advertisements, we next turn to examine whether or not those claims were material. A "material" misrepresentation or practice is one that is likely to affect a consumer's choice of or conduct regarding a product. In other words, it is information that is important to consumers. **[59]**

The Commission considers certain categories of information presumptively material. First, the Commission presumes that express claims are material. Similarly, when evidence exists showing that a seller deliberately made an implied claim, the Commission presumes materiality. The underlying rationale in both instances is the assumption that the willingness of a business to promote its products reflects a belief that the consumers are interested in the advertising.

In this case, Thompson itself has acknowledged making claims about Aspercreme's basic efficacy in relieving the pain and other symptoms associated with minor pain of arthritis and rheumatism.[44] Because this acknowledgement clearly demonstrates Thompson's intent, we presume that all basic efficacy claims for Aspercreme, whether express or implied, are material. We also have found that several Aspercreme ads expressly represent Aspercreme to be more effective than aspirin tablets and that **[60]** another set of ads expressly represents Aspercreme's efficacy to have been proven by the results of scientific tests. Therefore, we presume these claims are material.[45]

However, the two remaining claims at issue in this proceeding are implied claims that Thompson has not acknowledged deliberately making. These are the claims that Aspercreme contains aspirin and that it is a new product. In assessing the materiality of such implied claims, we are required to make our own evaluation of whether or not reasonable consumers would consider the information in the claims important. One aid to us in doing so for many claims is the fact that over the years our cases have established several categories of claims pertaining to the central characteristics of a product or service, such

[43] *See* our discussion of efficacy claims below, at pp. 78–85.

[44] By "basic efficacy claims," we refer to the claims listed in Paragraphs 12a–12c and 12e of the complaint.

[45] In considering the materiality of claims, we are mindful of the Supreme Court's observation in *F.T.C. v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965), that the Commission's inference of materiality must be "within the bounds of reason." Accordingly, we do not use our presumption as an inflexible rule that eliminates our need to look at materiality on a case-by-case basis. On the contrary, the presumption simply reflects our general judgment that substantive claims in advertisements (in other words, claims other than "puffery" or window-dressing) would not have been made except to affect a consumer's choice or conduct regarding a product. Thus, the very existence of the claim ordinarily is sufficient evidence for us to conclude it is material. However, respondent is always free to counter this evidence either with arguments pertaining to the content of the ad itself or with extrinsic evidence. Moreover, the presumption does not preclude us from exercising our own judgment and concluding from evidence in the advertisement (or extrinsic evidence) that a claim is not material even if the respondent does not dispute materiality.

as those relating to its purpose, safety, efficacy, or cost. We now presume that any implied claim in one of these categories is material. **[61]**

However, neither the claim that Aspercreme contains aspirin nor the claim that it is a new product appears to fall into any of the above-mentioned categories of claims. Therefore, we must look at the facts on the record to determine whether or not reasonable consumers would consider the claims important.

The ALJ already has analyzed the materiality of the claim that Aspercreme contains aspirin (IDFs 162–64).[46] He found that consumer research in the record shows a significant portion of test subjects preferred an aspirin product over a non-aspirin product for pain relief (IDF 163). For example, in the Lieberman Study 53% of the arthritics tested expressed a preference for an aspirin product (RX 500F, Warwick, Tr. 5333–34).[47] The ALJ also found that Thompson's expert witnesses did not dispute the proposition that aspirin is a drug of choice for treatment of minor arthritic pain (IDF 162). Having reviewed the ALJ's findings, we agree with them and consider them a sufficient basis for concluding aspirin content claims to be material. **[62]**

The ALJ did not, however, explicitly discuss why claims that Aspercreme is a new product are material.[48] Accordingly, we must examine that issue ourselves.

We conclude that these newness claims are material because they imply product efficacy to arthritis sufferers. Rheumatoid arthritis and osteoarthritis are chronic diseases having no cure (O'Brien, Tr. 3946–47). Arthritis diseases cause suffering to their victims and cripple tremendous numbers of persons each year (CX 268, p. 35,455). As a result, arthritis sufferers are constantly looking for cures, with more money being spent on unproven arthritis remedies than on legitimate arthritis research (Roth, Tr. 1537). Testimony by arthritis specialists (Roth, Tr. 1540; Ehrlich, Tr. 4109–11) and medical literature cited in the record (*See, e.g.,* O'Brien, Tr. 3775–76) show that in this context, where no existing remedy is fully adequate, arthritis sufferers enthusiastically try new remedies in the hope that these remedies will provide relief beyond that they are obtaining from existing remedies.

---

[46] The aspirin content claim is the only one whose materiality the ALJ discussed. Because a finding as to materiality is integral to a determination that a representation is deceptive, such findings should be made with respect to any claim upon which a respondent is found liable for deceptive advertising.

[47] By citing to a specific percentage figure (which happens to be over the fifty percent level), we do not mean to imply that any particular level of expressed preference must be reached before we would conclude a claim like this one to be material. A lower level than that found in this case clearly could also suffice, depending upon the circumstances surrounding the claim and the intensity of the preference expressed by consumers.

[48] We presume from the general tenor of the ALJ's discussion of this claim (IDFs 126–28, ID 135–36) that he did, in fact, believe newness claims to be material.

These facts warrant the conclusion that the Aspercreme ads representing the product as "new," CXs 6–8 and 10–11, also impliedly represent it as a product effective in providing relief of arthritis pain. Efficacy claims are one category of claims **[63]** that our previous cases have found to concern central product characteristics.[49] Therefore, efficacy claims are presumptively material.

Evidence from the ads themselves confirms our conclusion that Thompson was making implied efficacy representations when it represented Aspercreme to be a new product. Four of the ads, CXs 6–7 and 10–11, use the words "remarkable breakthrough" in describing the product. The headlines in the four ads state: "At last! A *remarkable breakthrough* for arthritis pain: Aspercreme" (emphasis added). A "breakthrough" is something new in the sense that it did not exist for more than a short time before. But it is more than that. A breakthrough is something resulting from a significant advance in scientific knowledge. Use of the word "remarkable" to modify the word "breakthrough" makes even stronger the implied message that the product is the result of a major scientific advance. The net impression left with reasonable consumers may be not merely that Aspercreme, like other products, is an effective arthritis remedy, but that it is a more effective arthritis remedy than the others. However, we find that the newness claims constituted, at a minimum, implied representations of basic efficacy. **[64]**

IV. WERE THE REPRESENTATIONS ONES LIKELY TO MISLEAD CONSUMERS ACTING REASONABLY?

1. *Factually Inaccurate Claims, Generally.*

To this point, our analysis has shown that Thompson made a variety of express and implied claims that were material to reasonable consumers. However, material claims are not deceptive if the messages they convey to reasonable consumers are accurate. Thus, to make a case that advertising is deceptive, the Commission has the burden of showing that the material claims communicated to reasonable consumers by the advertising are false in some manner.[50] In other words, deceptive representations must be "likely to mislead."[51]

There are two different analytic routes by which complaint counsel can prove advertisments are likely to mislead. One is to carry the

[49] *See, e.g., Bristol-Myers, supra* note 8, *Sterling Drug, supra* note 37, *J.B. Williams Co.*, 68 F.T.C. 481 (1965), *aff'd*, 381 F.2d 884 (6th Cir. 1967).

[50] *See, e.g., Bristol-Myers, supra*note 8, at 320: "If an ad conveys more than one meaning to reasonable consumers and one of those meanings is false, that ad may be condemned. *National Commission on Egg Nutrition v. F.T.C.*, 570 F.2d 157, 161 n.4 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978)."

[51] Not only representations are capable of being "likely to mislead." Commission precedent also treats as likely to mislead both practices conveying a material false impression and omissions of material information doing the same. This case involves neither such practices nor such omissions. Therefore, the discussion in the text refers solely to representations. However, the analysis applies equally to other forms of deceptive conduct.

burden of proving that the express or implied message conveyed by the ad is false. The other is to show that the advertiser lacked a reasonable basis for asserting that the [65] message was true.[52] For example, if an advertisement claims that a new brand of orange juice is more nutritious than others on the market, the Commission could put on its own evidence showing the claim to be false or it could show that the substantiation the advertiser had to support the ad did not provide a reasonable basis for the claim of greater nutritional value. Because the two forms of proof are different, we keep them analytically separate even where a complaint charges, as does this one, both that the advertiser made false claims and that it made claims lacking a reasonable basis.

In this case, Paragraph 11 alleges that three of the claims made by Thompson were "false, misleading, or deceptive." In other words, the complaint signals that complaint counsel must carry the burden of proving the claims to be false. These three claims are: (1) that Aspercreme contains aspirin (Paragraph 10a); (2) that it is a recently discovered or developed drug product (Paragraph 10b); and (3) that valid studies have scientifically proven it to be more effective than aspirin tablets for the relief of the symptoms of arthritis and rheumatic conditions (Paragraph 10c). We therefore are required to determine whether the evidence put on by the Commission shows the claims to be false. [66]

For the claim that Aspercreme contains aspirin, our above discussion has already demonstrated falsity. The active ingredient in "aspirin" is acetylated salicylate, whereas the active ingredient in Aspercreme is TEA/S. The two are not the same. Therefore, the claim that Aspercreme contains aspirin is false.

The second allegedly false claim is that Aspercreme is a recently discovered or developed drug product. The ALJ's disposition of this issue was not explicitly listed by Thompson as a ruling on which the ALJ erred (RAB 5). However, the company did argue on appeal that most consumers generally had no knowledge of TEA/S products prior to 1979, when Aspercreme national advertising commenced, because Aspercreme itself had only been marketed in Ohio and two other OTC drug products containing TEA/S were: (1) more expensive; and (2) sold mainly through physician recommendation (RAB 3). We infer from this that Thompson believes it was legitimate for CXs 6–8 and 10–11 to claim that Aspercreme was a "new" drug product.

The ALJ found that Thompson had made the representations al-

[52] This method of proof is only available to the Commission for objective product claims. For such claims, the representation "X is true" carries with it the implied representation that "The claim 'X is true' is supported by a reasonable basis." The Commission proves that the advertising is likely to mislead by proving that it is *not* supported by a reasonable basis. This does not preclude the possibility that the claim "X is true" is correct, although the possibility typically is an unlikely one.

leged in Paragraph 10b (IDFs 126–28, ID 135), but was persuaded that such claims were not likely to mislead because they were made "during the period when Aspercreme was being nationally advertised for the first time" (ID 136). Despite finding that Thompson's newness claims were not deceptive when made, the ALJ nonetheless included in his proposed order a ban on making any [67] further such claims, stating, "In any event, Thompson should not make new drug claims for Aspercreme in the future" (ID 136). We disagree with the ALJ's analysis, though not with his result.

As we described above, Thompson's advertising described Aspercreme as a recently discovered or developed drug product, thus representing that the product itself or its drug ingredient was new. In contrast, paragraph 11b of the complaint alleges:

> Aspercreme is not a recently discovered or developed drug product; it has been available for purchase since at least 1971 and its active ingredient has been in existence since at least 1954.

Thompson's arguments and the ALJ's decision both appear to focus only on the "new product" aspects of the complaint allegations in discussing the propriety of the company's claims. The record shows that Aspercreme was not marketed nationally prior to 1979 and that it had only limited availability between 1971 and 1979. In light of this evidence, we cannot conclude that the "new product" claims for Aspercreme are false as alleged.

However, we believe that an order provision prohibiting "new drug" claims is appropriate on the basis of a different paragraph, Paragraph 12. Paragraph 12 states that Thompson made express and implied efficacy representations for Aspercreme. As our discussion in Part III of this opinion shows, the newness claims for Aspercreme also were implied efficacy claims. All [68] Thompson's efficacy claims are deceptive for failure to have a reasonable basis.[53] Therefore, we conclude that an order provision barring the newness/efficacy claims is warranted.

The third claim the complaint alleges to be false is the claim that Thompson possessed a particular level of substantiation for its efficacy claims, that level being scientific tests. This claim was made in three of the Aspercreme ads (CXs 7–8 and 37).[54] To prove these claims false, complaint counsel had to establish the standards a test must meet to pass muster in the view of the medical community as support for the types of claims Thompson was making, and then show that Thompson's tests did not meet these standards. This burden was met.

[53] Our discussion below, at pp. 81–83, explains why we conclude that Thompson lacked a reasonable basis for its efficacy claims.

Both our discussion below and the ALJ's findings (IDFs 214–42) reach the conclusion that the standard generally adhered to by the medical scientific community for testing the efficacy of a drug is the possession of two well-controlled clinical tests. The ALJ's careful and methodical examination of every test introduced into the record by Thompson (IDFs 246–333) establishes that the tests fall short of this standard. It follows that Thompson's claims to possess one or more tests acceptable to the scientific community were false. **[69]**

2. *Claims Lacking a Reasonable Basis.*

In addition to charging that Thompson made false claims the complaint alleges (in Paragraph 13) that Thompson lacked a reasonable basis for the objective product claims listed in Paragraph 12. These are the various claims that Aspercreme is an effective drug for the relief of arthritis pain.[55] Thompson's admissions or our own findings have established that the company did, in fact, make such claims. Now we must determine what level of substantiation Thompson should have had for them and consider if Thompson did possess such substantiation for the advertisements in question.[56]**[70]**

Starting with *Pfizer*,[57] and *National Dynamics*,[58] our reasonable basis cases have identified several factors that we will weigh in determining the appropriate level of substantiation for objective advertising claims. We recently summarized the factors, as developed by our prior cases, in a policy statement on advertising substantiation. That policy statement is attached to this opinion as an appendix. The factors it summarizes include: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable.[59]**[71]**

---

[55] Paragraph 12 itself identifies three different sorts of efficacy claims found in Thompson's ads: (1) claims that Aspercreme is an effective drug; (2) claims that Aspercreme is as effective a drug as aspirin tablets; and (3) claims that Aspercreme is a more effective drug than aspirin tablets. As a legal matter, it might have been possible for Thompson to possess a reasonable basis for only one or two of the three claims, but not for all of them. For example, Thompson might have tests showing that TEA/S is effective, but not tests comparing TEA/S's efficacy to that of aspirin tablets. In this case, however, none of the evidence offered by Thompson was adequate to support any one of the three types of efficacy claims identified in the complaint. Our discussion therefore does not distinguish among them.

[56] The advertisements in question are CXs 1–6, 9–11, and 21–22. We already have found three other Aspercreme ads, CXs 7–8 and 37, to have expressly represented the existence of scientific proof for Aspercreme efficacy claims. Accordingly, the efficacy claims in those ads would have to be supported by scientific proof regardless of whether or not our analysis here concluded such substantiation was necessary for the remaining Aspercreme ads.

[57] *Supra*, p. 53.

[58] *Supra*, note 38.

[59] This case is similar to three other recent Commission cases involving OTC analgesics, *American Home Products*, *supra* note 37, *Sterling Drug*, *supra* note 37, and *Bristol-Myers*, *supra* note 8. Those cases speak of "establishment claims" for OTC analgesics and state that if a claim is an "establishment claim," it must be substantiated by two well-controlled clinical tests. We do not use the term "establishment claim" here. However, our analysis is consistent with that we employed earlier. "Establishment claims" are claims that the efficacy of a drug has been scientifically proved, *i.e.*, "established." In our three recent cases, we stated that we require such

(footnote cont'd)

Applying those factors here leads us to conclude that Thompson should possess two well-controlled clinical tests to have a reasonable basis for its Aspercreme efficacy claims. The first criterion we consider is the type of product. In this [72] case, the product is a drug whose application is supposed to improve the physical welfare of its users by reducing pain and the other symptoms of minor arthritis. In past cases involving health or safety issues, we have required a relatively high level of substantiation, typically scientific tests.[60]

The second factor we consider is the type of claim. Our past cases have identified at least two types of claims that require a high level of substantiation, such as scientific or engineering tests. One is a claim that refers to specific facts or figures, rather than making generalized descriptions of the product's capabilities.[61] The other is a claim whose truth or falsity would be difficult or impossible for consumers to evaluate by themselves.[62] This case involves the latter, [73]

---

claims to be substantiated by evidence sufficient to satisfy the relevant scientific community of the claim's truth. We further stated that the appropriate level of substantiation for other claims would be determined by considering factors such as the harm to consumers if the claim were false. (These are the factors developed in *Pfizer* and subsequent cases.) *See, e.g., Bristol-Myers, supra* note 8, at 321.

Our analysis here does not employ the term "establishment claim" to avoid creating the impression that claims for an advertiser's possession of scientific proof will be treated by us as a unique category of claims. There is no conceptual or practical reason to single out such claims for special treatment. They are but one example of an express or implied claim that an advertiser possesses a particular level of substantiation. Other such claims might include claims that a particular flower's ability to grow in hot, dry weather had been field-tested (we might require that such claims be substantiated by field tests conducted according to recognized horticultural standards) or that surveys show consumers prefer one brand of orange juice to another (we might require that such claims be backed by appropriate survey research).

Considered from a rigorously analytical perspective, none of these claims actually falls within the advertising substantiation principles set forth in *Pfizer* and subsequent cases. *Pfizer* holds that the Commission itself may identify the appropriate level of substantiation for ads that do not expressly or impliedly claim a particular level of substantiation. It also lays out the factors we will consider in setting the appropriate level of substantiation. We do not have to perform such an evaluation where an advertisement itself makes express or implied substantiation claims. We treat such claims like any other representations contained in the ad. We verify that it is reasonable to interpret the ad as making them, that the claims are material, and that they are false. If so, they are deceptive under Section 5(a) of the FTC Act.

Such an analytic approach is easier for us to employ than if we have to evaluate a case using the *Pfizer* factors. However, the end result in either event, assuming we find liability, is an order requiring the advertiser henceforth to have substantiation for the objective product claims being made. From the perspective of the final result, therefore, all cases ending up in a substantiation order can be considered ad substantiation cases.

This case involves both ads expressly claiming a particular level of substantiation and those to which we must apply the factors outlined in *Pfizer*. The express substantiation claims are those in CXs 7–8 and 37, ads representing that scientific tests prove Aspercreme to work faster and more effectively than aspirin tablets. We discussed those claims at pp. 58–60, above. However, the remaining Aspercreme advertisements did not make express or implied claims to a particular level of substantiation. Therefore, in this section of the opinion we employ the *Pfizer* factors to identify the proper level of substantiation for those advertisements.

[60] *See, e.g., Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 475 (1972), *aff'd*, 481 F. 2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973) (safety and performance claims for automobile tires must be substantiated by "competent scientific tests"); *National Commission on Egg Nutrition*, 88 F.T.C. 89, 192 (1976), *aff'd*, 570 F.2d 157 (7th Cir.), *cert. denied*, 439 U.S. 821, *reissued*, 92 F.T.C. 848 (1978) ("Parties making claims about the attributes of products—and particularly about the safety of products—owe to the public a high degree of precision and care."); *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 885 (1977), *aff'd*, 605 F. 2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (claims that any food, drug, or device can help a user achieve any result, such as weight loss, must be substantiated by "competent scientific or medical tests or studies").

[61] *See, e.g., National Dynamics Corp., supra* note 38 (valid laboratory tests would provide reasonable basis for claims concerning specific attributes of battery additive, such as claims for "quick starts in −40 degrees" or "increases brightness of lights by 25%").

[62] *Bristol-Myers, supra* note 8; *Sterling Drug, supra* note 37; *American Home Products, supra* note 37.

not the former type of claim.[63] As the ALJ's opinion explains in some detail (IDFs 196–206), arthritis pain is a phenomenon that is not constant. The pain ebbs and flows, making it hard for individual consumers to assess for themselves whether the relief they feel at a given moment is due to a particular treatment they are taking or is a natural phenomenon. This difficulty would be compounded for a new product such as Aspercreme by the "placebo effect," a phenomenon whereby patients' hopes and expectations cause them to believe, often for extended periods of time, that a clinically ineffective medication is providing them with real relief.[64] (The same placebo effect is also capable of influencing doctors' judgments about drugs they are testing or [74] prescribing if they know a drug's identity.) Thus, efficacy claims for Aspercreme are precisely the sort that consumers would not be able to verify easily for themselves.[65]

We often consider the third and fourth *Pfizer* factors in conjunction with each other. The third factor is the benefit of a truthful claim. The fourth factor is the ease of developing substantiation for the claim. Our concern in analyzing these factors is to ensure that the level of substantiation we require is not likely to prevent consumers from being told potentially valuable information about product characteristics. In this case, the benefit to consumers from the advertising messages in dispute would be significant if Aspercreme provided both faster relief and relief with fewer side effects than aspirin tablets. However, the record in this case does not suggest that requiring two well-controlled clinical tests as substantiation of efficacy claims for this product (or similar analgesics) would significantly reduce the likelihood of consumers being told about effective remedies for the relief of arthritis pain. The market for such remedies is large, being in excess of 18 million persons [75] in the United States alone.[66] The

[63] Some Aspercreme ads refer to the product as providing relief in "seconds." It could be argued that these ads refer to specific figures for the speed with which the product acts. On balance, however, we do not find these references to be the sort of specific figures (*e.g.*, "provides 50 amps starting power at zero degrees Farenheit") referred to in the cases holding advertisers who make such claims to a higher level of substantiation than otherwise.

[64] Two additional factors noted by the ALJ also would make it difficult for consumers to evaluate the efficacy of Aspercreme in a nonclinical setting. Many consumers use other medications as well as Aspercreme. This would make it hard for them to separate out which product is the source of the relief they feel (IDF 198). Furthermore, the method of applying Aspercreme is by rubbing. Rubbing itself is known to have a soothing effect upon musculoskeletal pain (IDF 199). The relief generated by rubbing might be attributed to a nonexistent medical effect of the product being rubbed, masking the product's ineffectiveness.

[65] The fact that consumers and doctors in uncontrolled environments cannot readily evaluate the efficacy of Aspercreme is a principal reason why we reject Thompson's claims that efficacy of the product can be substantiated by evidence such as the clinical observations of doctors or marketing data (RAB 20).

[66] The report of the FDA Panel on OTC Internal Analgesics (CX 268, p. 35,455) provides the following statistics:

Incidence of rheumatic disease [arthritis] in the United States during 1974

Rheumatic disease	Number of persons (millions)
Osteoarthritis	12
Rheumatoid arthritis	5
Gout	1

(footnote cont'd)

potential sales for such a remedy are correspondingly large, as is evidenced by the fact that Thompson's 1981 sales of Aspercreme approached $6 million (IDF 74). By comparison, the cost of a well-controlled clinical trial of an analgesic's efficacy would be between $10,000 and $15,000 (Adriani, Tr. 1176–77, Roth, Tr. 1562). This means the total cost of complying with the reasonable basis requirement we establish for Aspercreme would not exceed approximately $30,000. In view of the large potential market and likely high demand for analgesics suitable for treating arthritis symptoms, these costs should not deter the development or advertising of new arthritis remedies.

The fourth factor we consider is the consequences of a false claim. In this connection, the ALJ's opinion stated that use of an ineffective drug (*i.e.*, one not significantly different from a placebo) to treat arthritis would be both injurious to health (IDFs 207–09) and economically harmful to consumers (IDF 210). Having reviewed the evidence, we agree with the ALJ's finding that the failure to treat arthritis with effective remedies can **[76]** cause significant economic harm to the consumer. Those costs result from the repeated purchase of an ineffective product by consumers who are unable to evaluate drug efficacy in an easy manner. However, we differ with the ALJ's findings regarding the health effects of Aspercreme.

The ALJ notes (IDF's 208–09) that failure to diagnose and treat rheumatic diseases with effective medication can seriously harm an individual's health. Where an OTC product is represented or used as a long-term treatment or cure for arthritis, there is a potential for substantial consumer injury because OTC products do not prevent the progression of the two principal forms of arthritis—osteoarthritis and rheumatoid arthritis.[67] Where an OTC product is advertised or used for the temporary relief of minor arthritis pain, in contrast, there is little potential for the product to cause serious injury to consumers' health if **[77]** claims about its effectiveness in relieving pain prove false. In this case, we find that the health risk from using Aspercreme as represented to relieve minor arthritis pain is uncertain and should

Systemic lupus erythematosus ——— 0.4 to 0.5
Juvenile rheumatoid arthritis ——— 0.25

[67] Our conclusions about potential physical harm to consumers rest in large part upon the characterizations of arthritis provided by the monograph of the FDA's Panel on OTC Internal Analgesics (CX 268). The panel notes that each of the two principal forms of arthritis—osteoarthritis and rheumatoid arthritis—has a different cause, a different prognosis, and a different method of treatment. (CX 268, p. 35453) Active treatment of osteoarthritis requires physical measures and surgical management to retard progression of the disease. As the panel report notes, "[n]o medication has been shown to retard the development or progression of degenerative joint disease. (Citation omitted.) Pharmacologic agents [drugs] play a relatively minor role in the management of osteoarthritis." (CX 268, p. 35456) Aspirin is the mainstay of therapy for rheumatoid arthritis, but is must be administered in dosages much higher than those listed on labels of OTC products sold for the relief of pain in order to obtain the anti-inflammatory effects that retard progression of the disease. OTC drugs, including Aspercreme, do not prevent the progression of these common forms of arthritis, and their continued use as self-medication could result in serious health consequences to consumers.

be minimal if the product is used according to the warning on the label that a physician should be consulted if pain persists beyond a short period of time.

The sixth factor we consider is the amount of substantiation experts in the field would consider reasonable. As has been made clear in our past decisions[68] and by the ALJ's initial decision in this matter (IDFs 214–22), the substantiation standard generally applied by the scientific and medical community to claims for the efficacy of an analgesic is that they must be based on the results of at least two well-controlled clinical trials. Evidence from the record of this matter showing that this is the general standard includes the fact that regulations issued by the Food and Drug Administration[69] apply such a standard to all OTC drugs and the fact that the standard was applied to analgesics, in particular, by the panels of independent experts who evaluated OTC internal analgesics and external analgesics (including TEA/S) for the FDA (CXs 268 and 269). [78]

The FDA regulations recognize the possibility of exceptions to this general rule.[70] In fact, the panels reviewing OTC external and internal analgesics each approved a few OTC drugs without requiring two clinical tests, as Thompson has pointed out (RAB 14–15). However, the existence of these exceptions is not inconsistent with a general rule in the medical community requiring two well-controlled tests to show efficacy, any more than would be the existence of a minority body of opinion holding to some other standard.[71]

In this case, we have not only evidence of the standards generally applied by the medical community to efficacy claims for OTC drug products, but specific evidence that impartial experts do not believe TEA/S's efficacy to have been demonstrated [79] according to appropriate standards. The "active" ingredient of Aspercreme was reviewed by the Panel on OTC External Analgesics in 1979. It held that the efficacy of TEA/S had not been established (CX 269, p. 69,856). After the panel's report was submitted to the FDA, agency personnel independently evaluated the panel's findings. During FDA's evaluation period, interested persons were entitled to submit additional

[68] *See, e.g., Bristol-Myers, supra* note 8, at 338, 376–77.

[69] 21 C.F.R. 314.111(a), 330.10(a)(4)(ii) (1983).

[70] *See, e.g.,* 21 C.F.R. 330.10(a)(4)(ii):

> . . . Proof of effectiveness shall consist of controlled clinical investigations as defined in §314.111(a)(5)(ii) of the chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. General recognition of effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

[71] We do not believe it necessary in deciding this case to attempt to identify all the situations when exceptions from the general rule will be permitted. The positions of the Panel on OTC External Analgesics and of the FDA on TEA/S demonstrate that an exception is not appropriate for this particular chemical substance.

evidence supporting the efficacy of ingredients that the panel had found not to be proven effective. Accordingly, Thompson submitted to the FDA the studies it asserts in this proceeding to be well-controlled clinical tests. The results of FDA's deliberative process and its evaluation of Thompson's evidence are found in the "tentative final monograph" on OTC external analgesics, which was published for public comment in 1983. The tentative final monograph reiterates the panel's conclusion that TEA/S has not been proven effective and dismisses each of Thompson's proffered "clinical tests" as inadequate (CX 443, p. 5,855).[72] Although the tentative final monograph is subject to public comment and possible revision before the FDA publishes a final monograph, the tentative final monograph reflects the agency's considered judgment and current position on the merits.

Therefore, based upon our review of the six *Pfizer* factors, we conclude that the proper level of substantiation for Aspercreme efficacy claims is two well-controlled clinical [80] tests. We are additionally persuaded to use this level of substantiation because our above discussion indicates that this is the standard currently being required of TEA/S by the Food and Drug Administration. We believe that advertisers of drug products subject to the joint jurisdiction of the FTC and the FDA will benefit from greater regulatory certainty if they can act with reasonable assurance that the two agencies will accept the same evidence to demonstrate the safety and efficacy of a particular ingredient. Thus, we state that advertisers who comply with the FDA's requirement of well-controlled clinical tests to demonstrate efficacy have adequate substantiation to make such claims in their advertisements. Although we do not preclude ourselves from also permitting advertisers to use other types of evidence to comply with our substantiation requirement, nothing in this record suggests any rationale for our permitting a different form of substantiation for efficacy claims in Aspercreme advertisements than the FDA is prepared to establish for the product's labeling.[73] On the contrary, the inability of consumers to evaluate analgesic effect by themselves in an uncontrolled environment is a persuasive reason for consumers to expect (and us to require) appropriate scientific testing before efficacy claims are made. [81]

In reaching our conclusion that Thompson lacked a reasonable basis for its Aspercreme efficacy claims, we reject Thompson's arguments to the contrary. The first argument, relying on the testimony

[72] The FDA's position contradicts Thompson's assertion (RAB 17) that ". . . three double-blind clinical studies supported efficacy [of Aspercreme]."

[73] Consistent with this view, our order would permit Thompson to advertise Aspercreme as an effective analgesic ". . . if the Food and Drug Administration promulgates any final standard that establishes conditions under which such product is safe and effective under the Food, Drug, and Cosmetic Act," whether or not the standard requires two well-controlled clinicals. (We have no reason to think FDA would dispense with the requirement of two well-controlled clinicals.)

at trial of Thompson's expert witnesses, is that the scientific and medical community does not consider just one type of evidence (*i.e.*, well-controlled clinical tests) sufficient to demonstrate drug efficacy (RAB 13). While the argument would be true enough if it were merely an assertion of the point hitherto acknowledged by us, that the medical community may on occasion permit an exception to the general rule of well-controlled clinical tests, this is not what Thompson would have us find. Rather, the company wishes us to accept the proposition that the medical community does not, as a general matter, require well-controlled clinical tests to support claims of drug efficacy. We find this assertion contrary to the preponderance of the evidence in the record of this case and, accordingly, reject it.

Thompson next asserts that not even the FDA requires the existence of two adequate and well-controlled studies as the basis for an OTC drug efficacy claim (RAB 14–16), relying principally on the fact that FDA panels reviewing various OTC drugs have not invariably required such evidence. As we stated earlier, however, the existence of exceptions does not, in and of itself, disprove the existence of the general rule. For example, the three external analgesics approved by the FDA Panel on External Analgesics without two well-controlled clinical tests came from a group of over forty drugs reviewed by that panel (CX [82] 269, p. 69,790). Moreover, complaint counsel have presented us with persuasive explanations of why these particular exceptions were made.[74]

Third, Thompson argues that it did have three double-blind clinical studies on Aspercreme, studies that met the applicable standards of the FDA and the medical community (RAB 17–18). We find it remarkable that Thompson would make this assertion in light of the FDA's present position that Thompson's studies are [83] inadequate (CX 443, p. 5,855). Moreover, we are independently persuaded by the evidence on our own record (discussed in IDFs 246–312) that each of Thomp-

[74] Complaint counsel's answering brief states (CAB 14):

> Two of the drugs Thompson points to are counter-irritants, which are a specific class of drugs that exert their analgesic action in a unique way, by producing the sensation of warmth or coolness on the skin. Accordingly, since these drugs' mechanism of action is understood, clinical trials of various counterirritants would be adequate to document the efficacy of counterirritants as a class. (Roth, Tr. 1763–64). Moreover, in the case of all three of these external analgesics, the External Analgesic Panel specifically states that there are reports about each in the published literature and cites to authoritative compendia on drugs. In contrast, TEA/S is an obscure drug, and is not listed in any of these compendia. (F. 345). [IDF 345]

Also explanatory of the exceptions are the comments of the Panel on OTC External Analgesics itself. For example, in discussing turpentine oil, one of the two counterirritants it found effective, the panel stated:

> Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that turpentine oil is effective for use as an OTC external analgesic.
>
> No scientifically controlled studies concerning the use of turpentine oil alone for the treatment of rheumatism, arthritis, and muscular aches and pains were found. However, the use of turpentine oil for self-medication is almost an American folk tradition, and full-strength turpentine oil has been employed with impunity as a topical counterirritant. (CX 269, p. 69,840)

son's tests had one or more serious flaws that prevents it from complying with the standards for a well-controlled clinical test.

Finally, Thompson argues that its possession of a reasonable basis for its Aspercreme ads is underscored by the quality of the individuals who came forward to testify on its behalf (RAB 20–21). Unfortunately for Thompson, however, none of the factors established by *Pfizer* or our other reasonable basis cases suggests that the credentials of a respondent's witnesses should be a substitute for factual evidence as a basis for objective product claims. Moreover, the testimony of experts, no matter how well-qualified they may be, is no substitute for controlled clinical testing as a means of substantiating the drug efficacy claims at issue in this case.

In addition to the above arguments, Thompson asserts that it is inappropriate for the Commission to take action against Aspercreme before the FDA reaches a final decision on whether or not TEA/S has been proven effective (RAB 28–31).[75] In other [84] words, Thompson suggests that it is inappropriate for the Commission to reach a final decision on whether or not TEA/S has been proven effective when the issue is still an open question at the Food and Drug Administration. Thompson further implies that evidence it submitted to the FDA too late for that agency to review prior to publication of the tentative final monograph on OTC external analgesics will persuade the FDA to conclude that TEA/S has been proven effective when it publishes the final monograph on OTC external analgesics.

It is true that the FDA's proceeding is still open and that the agency could reverse its tentative decision on TEA/S. However, we have no reason to believe this will happen. As the ALJ's initial decision points out (IDFs 387–99), the new material submitted by Thompson to the FDA does not appear to contain two (or even one) well-controlled clinical tests. Therefore, if the FDA continues to apply the standards it heretofore has applied to TEA/S, it should not find the new materials any more persuasive than the old.

In any event, our decision to issue an order in this proceeding does not rely upon a guess as to how the Food and Drug Administration ultimately will come out on the question of TEA/S's efficacy. Rather, it is based upon Thompson's failure to provide us with evidence that we think provided a reasonable basis for Aspercreme's efficacy claims. Moreover, the order we issue contains language allowing Thompson to rely for substantiation of Aspercreme efficacy claims

[75] This is a favorable reading of Thompson's argument. As written, Thompson's brief merely asserts the ALJ to have "erred in holding that the External Analgesics Panel and the FDA have found TEA/S to be ineffective as a topical analgesic ingredient." However, nothing the ALJ stated in the initial decision suggests that he believed the FDA to have made a final determination. He correctly characterized the position expressed in the FDA's tentative final monograph for external analgesics (CX 443) as the FDA's "current position" (IDF 395). He stated his further belief that it is "highly unlikely" the FDA will reverse its position (IDF 400). He never expressly or impliedly stated that the FDA had finally determined TEA/S to be ineffective.

upon any evidence conforming to a final standard for efficacy promulgated by the [85] FDA. Thus, if the FDA changes its position the result amounts to an automatic modification of our order.[76]

Indeed, we see very good reason for us to take action on Aspercreme despite the pendency of the FDA's OTC external analgesics review. FDA's proceeding is a rulemaking that must focus simultaneously on many different drugs, one of which is TEA/S. As Thompson itself has noted (RAB 30), while the date set for close of comments on the FDA's external analgesics tentative final monograph was April 9, 1984, it is uncertain how much additional time FDA will need before resolving all of the issues presented to it by the rulemaking. In contrast, the proceeding before us is an adjudicative one focused specifically on Aspercreme. Perhaps for this reason, we are in a position to reach our final determination before the FDA is able to reach its final determination. Given our conclusion that the Aspercreme advertising in evidence on our record is deceptive for failure to have a reasonable basis (among other reasons), it is in the public interest for us to act expeditiously to prevent further harm from the continuation of such advertising. [86]

V. SCOPE OF RELIEF

This part of the opinion discusses the order we enter against Thompson to prohibit and prevent it from engaging in deceptive acts or practices. Our order differs in several respects from the one proposed by the ALJ. Accordingly, we first discuss the rationale for each of our changes. We then discuss why we believe it appropriate for the order to apply not only to Aspercreme, but also to other drug products marketed by Thompson. Finally, we explain why we decided not to adopt an order provision that was urged upon us by complaint counsel, one that would have required Thompson to excise the "Aspercreme" brand name.

Our first change removes from the first paragraph of Parts I and II the word "labeling." The effect of this deletion is to limit application of the order to the "advertising, offering for sale, sale or distribution" of drug products. Our revision is intended to ensure that the order cannot be interpreted as applicable to any information the Food and Drug Administration either permits or requires Thompson to place on the labels of its drug products. For example, if the FDA permits Thompson to characterize Aspercreme as an analgesic during the pendency of the FDA's OTC drug review process, our order would not bar such labeling. On the other hand, any advertising placed on

[76] We have included this language in our order because of our aforementioned view that it is advisable for us and the FDA to take a unified regulatory approach to issues brought before us where the issues appear identical or quite similar.

the label (*i.e.,* language not covered by FDA regulations) would be covered [87] by the order. The order as revised by us is identical with the orders in our three other recent analgesics cases, *American Home Products, Bristol-Myers,* and *Sterling Drug* in this respect.

The ALJ apparently added the word "labeling" to Parts I and II to address a concern of complaint counsel. They felt the disclosure mandated by Part I.A (stating Aspercreme does not contain aspirin) had to be made both in Thompson's advertising and on the product label to be effective and that, therefore, the order had to apply to labeling (CPF 487). We agree with complaint counsel's belief that the disclosure needs to be on the product label to be effective. However, Part I.A of our revised order still requires that Aspercreme labels contain the desired disclosure *if* Thompson wishes to continue using the "Aspercreme" brand name in advertising or sales or otherwise to represent in ads that the product contains aspirin. Thus, the net effect of our revision is to make continued advertising and sale of a product named "Aspercreme" conditional upon a disclosure on its label that it does not contain aspirin, but not to make the order applicable to any labeling regulated by the FDA.

Our second change in the ALJ's proposed order broadens coverage of its Part I from "over-the-counter analgesic drugs" to "over-the-counter drugs" generally. We have broadened Part I's coverage because we agree with complaint counsels' argument on appeal that the facts of this case warrant such "fencing-in" to prevent deceptive acts or practices by Thompson in the future. We discuss in more detail below our reasons for reaching this conclusion. [88]

Our third change modifies the language of Part I.A by replacing the last "or" in it with the words "*provided, however,*" and by making other conforming changes. We made this technical revision because the langugage approved by the ALJ could literally be read as permitting Thompson to represent expressly (or impliedly) that Aspercreme contains aspirin as long as Thompson's advertising and labeling contained a disclosure that it does not. Our revision makes clear that Thompson may engage in no such conduct (other than use of the brand name "Aspercreme") regardless of whether or not it uses the disclosures required by the order.

Our fourth change is a revision to Part I.A.1 of the order. That provision sets out the requirements for disclosures that Aspercreme does not contain aspirin when the disclosures are used in television advertisements. As approved by the ALJ, it not only specified that the advertisements include both a clear and prominent vocal statement at the end of each ad informing consumers that Aspercreme does not contain aspirin and a clear and prominent video super advising consumers of the same fact, but also specified that the super must be

displayed throughout the length of each advertisement. The requirement that the super be perpetually displayed throughout an entire ad strikes us as overkill. We have not imposed a similar requirement in any of our past affirmative disclosure cases and do not believe it is appropriate to do so here. Instead, we have revised Part I.A.1 to require that the visual super be displayed at the end of the ad simultaneously with the vocal disclaimer. [89]

Our fifth change from the ALJ's proposed order revises the language of Part I.B., the provision prohibiting false newness claims. We have made several changes in this provision. First, we have deleted the reference to new "mechanical" principles. Nothing in this case suggests Thompson has claimed (or plausibly could claim) that the efficacy of an OTC drug is based upon new mechanical principles. Second, we have deleted the prohibition on generally representing that a product is new (as opposed to representing that it involves new scientific principles) because the materiality of newness claims in general has not been established by the evidence before us. Third, we have deleted the language excepting from operation of the provision claims of newness made during a product's introductory period. We see no reason why Thompson, or any other advertiser, should be entitled to use the excuse of a "new" product (*e.g.*, an aspirin tablet marketed under a new brand name) to represent directly or indirectly for any period of time that the product is the result of a new scientific principle (*e.g.*, a new active ingredient) when it is not. Finally, to clarify the operation of Part I.B we have replaced the phrase "generally available for purchase" with the phrase "available for purchase as an over-the-counter drug." [90]

Our sixth change replaces a part of the order deleted by the ALJ, one that prohibits Thompson from misrepresenting the active ingredient(s) in any OTC drug products. The ALJ's initial decision does not explain why he omitted this provision, which had been included in the notice order accompanying the complaint. Whatever his rationale, we agree with complaint counsels' argument on appeal that the deletion was incorrect. Part I.D. of our order, the provision deleted by the ALJ, is based on one of the basic deceptive practices this case has shown Thompson willing to engage in—the misrepresentation of active ingredient. It prohibits such misrepresentations for any OTC drug products. Although Part I.A of the order prohibits the specific misrepresentation involved in this proceeding, misrepresentation of aspirin content, we believe Part I.D is necessary as fencing-in for the same reasons that prompt us to broaden the coverage of Part I from OTC analgesic drugs to OTC drugs generally. We discuss these reasons below.

Our seventh change is to Part II.A of the order. That part prohibits

Thompson from representing any OTC analgesic drug to be effective for the relief of symptoms of musculoskeletal disorders, unless Thompson has a reasonable basis for such claims, *i.e.,* two well-controlled clinical tests. Our revision removes a "delayed" effective date (April 9, 1984) that no longer would be in the future, given the passage of time since the ALJ issued his initial decision. An alternative would have been to extend the delay until such time as the FDA makes its final determination about TEA/S's efficacy. Unlike the ALJ, however, we question the **[91]** wisdom of such a course. Thompson already has had ample time during the pendency of this litigation to conduct the sort of tests that could establish efficacy to our satisfaction. If it has not done so, either out of conviction that it is not required to or out of fear that such tests would show Aspercreme to be no better than a placebo,[77] it will have to stop making efficacy claims in its advertising and offering for sale of Aspercreme until those tests are performed. While the inability to advertise that Aspercreme is effective will make it difficult (although not absolutely impossible) to market Aspercreme for a period of time, Thompson can always resume a full-scale selling campaign if and when it obtains the evidence of efficacy that it should have had all along.

Our eighth and final change is to add back to the order Parts IV and V, standard provisions for all our orders. Part IV requires Thompson to notify us prior to any proposed change in the corporation. Part V requires the company to file a compliance report within 60 days after service of the order upon it. These provisions appear to have been inadvertently omitted from the ALJ's proposed order. **[92]**

The order we adopt contains fencing-in provisions, *i.e.,* it would place restrictions on Thompson's ability to market products other than Aspercreme. Part II of the order requires a reasonable basis consisting of two well-controlled clinical tests if efficacy claims are made not just for Aspercreme, but for any OTC analgesic drug. Part I applies not only to analgesics, but also to any other OTC drug products Thompson might sell. We believe such fencing-in provisions are warranted in this case.

The ability of the Commission to issue orders containing fencing-in requirements is clear. *See, e.g., FTC v. Ruberoid Co.,* 343 U.S. 470, 473 (1952); *FTC v. Colgate-Palmolive Co.,* 380 U.S. 374, 394–95 (1965). The Commission has wide latitude in fashioning orders to prevent inventive respondents from pursuing a course of conduct similar to that

[77] Such a fear might well be warranted. As the ALJ's opinion notes (IDFs 376–89) five studies in evidence in this proceeding find no statistically significant difference between TEA/S and a placebo. The ALJ concluded that these studies, like Thompson's, were not well-controlled (IDF 374). However, the relative quality of these studies versus those relied on by Thompson is suggested by the fact that the FDA's Tentative Final Monograph on OTC External Analgesic Products cited to the findings of four of these studies as evidence that TEA/S has not been proven effective, and did so without critical comment, while criticizing the methodology of Thompson's three supposed clinical tests (CX 443, p. 5,855).

found to have been unfair or deceptive in the past. However, the Commission's discretion is subject to two constraints. One is that the order must be sufficiently clear and precise to be understood by the violator. *See, e.g., Colgate-Palmolive,* 380 U.S. at 392. The second is that the order must bear a reasonable relationship to the unlawful practice found to exist. *See, e.g., Jacob Siegal Co. v. FTC,* 327 U.S. 608, 612–13 (1946).

To ensure that a multi-product fencing-in order such as this one bears a reasonable relationship to the unlawful practice found to exist, the Commission considers three factors. They are: (1) the deliberateness and seriousness of the present violation; (2) the respondent's past history of violations; and (3) the transferability of the unlawful practices to other **[93]** products. The more egregious the facts with respect to a particular element, the less important it is that another negative factor be present. *See, e.g., American Home Products Corp. v. FTC,* 695 F.2d 681, 706 (3d Cir. 1982); *Sears Roebuck & Co. v. FTC,* 676 F. 2d 385, 392 (9th Cir. 1982). In considering these three factors, we find that two of them, the deliberateness and seriousness of the present violation and the transferability of the unlawful practices to other products, warrant adoption of the order we enter today.[78]

We look first at Thompson's present violations of the law. We have concluded that they are deliberate and serious. The seriousness of Thompson's violations is evidenced by the size and duration of Thompson's deceptive advertising campaign. As our above discussion shows, Thompson has been making deceptive efficacy and aspirin content claims since it began advertising Aspercreme in 1977. These claims have been made in numerous different ads on TV and in print in a campaign backed up by a multi-million dollar advertising budget (IDF 74). Such a persistent, long-term pattern of deceptive advertising evinces a **[94]** "massive, long-standing effort"[79] to persuade consumers that Aspercreme contains aspirin and that there is a reasonable basis for claiming it is effective.

The ads claiming that Aspercreme is a new breakthrough and that its efficacy is supported by scientific tests were run only in print ads, rather than in the TV commercials that commanded the bulk of Aspercreme's budget (RX 573). Even so, these ads were not insignificant. For example, the CX 6 print ad ran twice in the *Reader's Digest* and once in the *Saturday Evening Post* in 1979 (CX 25A). Print ads

[78] Complaint counsel argued on appeal that Thompson's history of past violations also provides grounds for a fencing-in order. However, the history cited by complaint counsel consists of a single consent order against Thompson issued in the early 1960s, *Thompson Medical Company, Inc.*, 59 F.T.C. 287 (1961) (CAP 17–18). Because consent orders do not constitute a legal admission of wrongdoing, we will not use a single consent order as a basis for concluding that Thompson has a history of past violations. We express no opinion on whether or not a pattern of consent orders would be a sufficient history of past violations to warrant fencing-in.

[79] *See American Home Products Corp.* v. *FTC, supra* note 37, 695 F. 2d at 707.

in such magazines of nationwide distribution would result in the objectionable representations being seen by large numbers of persons.

The seriousness of the violations also is affected by the fact that consumers could not readily judge the truth or falsity of the claims Thompson was making.[80] As our discussion above has noted, consumers cannot readily determine on their own whether or not an analgesic is effective. It would be even harder for them to determine whether or not a product advertised as a new "breakthrough" actually is one or to figure out whether supposed scientific tests showing that a product is faster and safer than aspirin would pass muster according to the general standards of the scientific community. Therefore, the claims Thompson emphasized in its advertising were ones to which consumers were particularly susceptible. **[95]**

Just as troubling as the seriousness of Thompson's violations is their apparent deliberateness. Deliberateness is shown by the consistency of Thompson's advertising themes over the years, supporting a conclusion that they were no accident or "isolated instance." *See, e.g., Jay Norris Inc. v. FTC,* 598 F.2d 1244, 1250 (2d Cir.), *cert. denied,* 444 U.S. 980 (1979).

Thompson has attempted to rebut the notion that it engaged in a deliberate campaign of deception by claiming that it did everything possible to ensure it had a reasonable basis for its Aspercreme efficacy claims.[81] We do not find it so easy to exonerate Thompson's conduct. Thompson excuses itself by asserting that it relied on the opinions of scientists it hired **[96]** as consultants, who advised it that Aspercreme was effective. Thompson seeks to avoid the charge that it should have realized those scientists were not relying on well-controlled clinical tests by arguing that it does not conduct in-house clinical investigations and lacks the expertise to evaluate such studies itself (RAB 9).

However, the facts on the record in this proceeding show a pattern of outside sources repeatedly warning Thompson that the efficacy of TEA/S had not been established. The FDA's Panel on OTC External Analgesics expressed this view in 1979. In early 1980, the National

---

[80] *Id.*

[81] *See, e.g.,* Respondent's Answering Brief, at 7:

> The record shows that the state of mind of Thompson, from the time it first purchased the product Aspercreme (and even before), was directed towards satisfying itself, and accumulating ample scientific proof, that Aspercreme was both safe and effective for the temporary relief of minor musculoskeletal pain, including that minor pain associated with arthritis and rheumatism. Towards this goal, Thompson accumulated, at great expense, extensive medical and scientific opinions, reports and clinical documentation from numerous outstanding, well recognized authorities and experts. . . .

Thompson also argues that its money-back guarantee evidences its good faith reliance on the evidence that Aspercreme is effective. *Id.* at 10. However, a money-back guarantee is not a defense to a charge of deceptive advertising. *See, e.g., Montgomery Ward & Co. v. FTC,* 379 F.2d 666, 672 (7th Cir. 1967). In this case, the placebo effect would result in some consumers purchasing the product many times before discontinuing its use and/or asking for a refund on the last bottle bought. Therefore, a money-back guarantee would not eliminate substantial sales revenues even in the unlikely event that all consumers eventually invoked it.

Association of Broadcasters and each of the television networks advised Thompson that the documentation for Aspercreme's efficacy claims was inadequate and that the tests Thompson relied on were flawed. (*See, e.g.,* CXs 88, 89, 90–91). Also in and around 1980, Thompson became aware of four studies—Roth (CX 344Z–195), Ehrlich (CX 344Z–157), Charles (CX 344Z–168), and Brown (CX 344Z–182)—showing no statistical difference between TEA/S and placebos. In 1981, the director of the FDA's Division of OTC Drug Evaluation told Thompson that TEA/S had not been shown effective. His comments are particularly significant because he reviewed the clinical studies Thompson had submitted to the FDA after publication of the OTC external analgesics panel's report, the same studies Thompson has submitted to us. He wrote to Thompson that these studies were all deficient to prove Aspercreme's efficacy (CX 342; *see also* CX 343). Again in 1983, with the adoption of its tentative final monograph (CX 443), the FDA concluded that TEA/S has not been [**97**] proven effective. Through all of this, Thompson steadfastly argues that the scientific experts it employed (*e.g.,* the persons who performed the defective studies) believed TEA/S to be effective, that its studies are valid, that its other evidence (such as a 1981 non-projectable survey of pharmacists by a magazine, a survey critiqued by the ALJ in IDFs 369–71) is adequate to support efficacy claims, and that it is acting in good faith when it continues to rely on this evidence. Our reading of the record is that Thompson has known or should have known for some time now that its efficacy claims for Aspercreme are unsubstantiated. We further conclude that Thompson has deliberately continued making efficacy claims despite this fact.

Likewise, it seems clear that Thompson deliberately sought to lead consumers into the belief that Aspercreme contains aspirin. Again, Thompson had good reason to know that one reasonable interpretation of the product's labeling and advertising was that it contains aspirin. The company was warned of this possibility by the results of two focus group studies that it had available to it as early as 1978—the Nicholas and [**98**] Schneider focus groups.[82] Consumer belief in aspi-

[82] The Nicholas focus group study (CX 52) was conducted in 1973 with two groups of eleven women, all of whom suffered from arthritis or some form of muscular aches and pains and all of whom were users of either topical analgesic or aspirin. The Schneider focus group study (CX 53) was conducted in 1978 with three groups of respondents (two groups of females and one group of males), all of whom used some sort of internal tablets or external rubs for arthritis relief. Participants in both the Nicholas and Schneider focus group studies were recruited and asked to use Aspercreme for at least ten days prior to the focus group session.

Because focus group studies are conducted with very few respondents obtained through nonprobability samples, and because the interviews are conducted in an unstructured group format, it is difficult to draw generalizable conclusions from them. Indeed, it is not unusual to obtain conflicting results from focus groups. *See, e.g.,* discussion at note 34 above. (One explanation for such conflicting results is that the moderator's control over discussions can skew them toward a particular result. It might be, therefore that 90% of the participants in a given focus group (9 out of 10 people) thought of "aspirin" as a particular chemical, and in another only 10% (1 out of 10), while a survey would show 60% of the general population to hold that belief.) Accordingly, we do not expect Thompson to have treated these focus groups by themselves as a fully reliable indication of consumers' beliefs about aspirin

(footnote cont'd)

rin content also clearly was indicated by the results of the Mapes & Ross copy test in 1979 (CX 50), which examined the earliest Aspercreme [**99**] TV ads (CXs 1 and 2).[83] The possibility of such a net impression was further communicated to Thompson by the television networks and NAB in 1979 and 1980 (*See, e.g.,* CXs 79, 80, 88D).

The fact that the ads created a net impression of aspirin content appears to have been no accident. The document "Aspercreme Brand Review," prepared for Thompson by Ogilvy & Mather in July, 1980 (CX 54), shows the purpose of Aspercreme advertising was to communicate that Aspercreme is aspirin in a rub.[84] Moreover, when the networks insisted on a revision of the early TV ads to reduce the incidence of mistaken beliefs, and Thompson accordingly approved ads with supers stating "contains no aspirin" and "relief without aspirin" (CXs 3 and 4), it appears that Thompson continued to use the audio phrase "relief of aspirin" in the revised ads hoping that the phrase would [**100**] offset the disclaimer.[85] Thompson also made no attempt to test whether or not the disclosures in CXs 3 and 4 were effective.[86] In addition, Thompson apparently continued to use CX 9 and related TV commercials (the ones with the disclosure "contains salycin, a strong non-aspirin pain reliever") after the completion in early 1981 of consumer research that it had sponsored and from which it should have realized that the ads communicated a message that Aspercreme contains aspirin.[87] All of this conduct is evidence that

---

content in Aspercreme. However, the focus groups did provide Thompson with exploratory information about those beliefs. The results of both the Nicholas and the Schneider focus group studies were consistent in demonstrating that there was a high probability that participants, would believe Aspercreme contains aspirin. Indeed, the final reports of both studies contain quotes that emphasize an aspirin association. For example, the Nicholas report states that one participant said, "When I saw it and saw 'Asper,' I right away thought it had aspirin in it. . . " (CX 52–L) and the Schneider study states "in addition, others felt they were attracted by 'Asper/Aspercreme' because 'it has aspirin in it' or is 'full of aspirin.' " (CX 53–Z56) Thus, both the Nicholas and Schneider focus group studies indicate that even after using Aspercreme for at least ten days several of the focus group participants believed that Aspercreme contained aspirin. The consistency of this finding across both studies should have been a warning signal to Thompson that potential consumers might be confused about the ingredients of Aspercreme.

[83] As discussed above, at pp 20–22, results from the Mapes and Ross Test indicated that between 21 and 35 percent of persons viewing CXs 1 and 2 believed Aspercreme contained aspirin.

[84] *See, e.g.,* CX 54Z–005:

Creative Strategy

The creative objective is to convince arthritis sufferers - men and women over 50 - that Aspercreme is the arthritis medicine that puts all the relief of aspirin directly at the point of pain.

The reason why is that Aspercreme contains the pain relieving ingredient of aspirin in a penetrating carrier so that it is taken quickly through the skin into painful joints and muscles.

[85] A 1980 conference report summarizing a meeting between Thompson and Ogilvy & Mather (CX 66) to discuss running various new ads states: "The client [Thompson] agreed [to TV ads with supers] and will pursue approval of the aspirin equivalency claim. In the meantime the agency [Ogilvy & Mather] will puruse the 'strong relief of aspirin' claim to offset the contains no aspirin super.")

[86] Thompson has suggested to us that "the networks accepted these supers because they were sufficient to clarify any possible ambiguity" (RAB 47). This is not the case. At least one network warned that the supers were ineffective. *See* CX–80 (letter from Director of Commerical Clearance for CBS to Thompson): "In the new tape, the super (relief without aspirin) accomplishes little and may only serve to confuse the issue. For that reason, we have decided not to accept the revision but to remain with the original for a period of two months, until January 15, 1980. By that time, we will hope for some better-defined message which can avoid the present difficulty."

[87] See discussion, supra, at 25–29.

Thompson has known full well for some time that consumers misunderstood the identity of the principal ingredient in Aspercreme and has continued to advertise in a manner that creates more such misunderstanding.

In addition, the "adaptability or transferability" of Thompson's violations to other products convinces us that a fencing-in order is appropriate. The scope of the order in this [**101**] case is similar to those in *American Home Products, Bristol-Myers,* and *Sterling Drug.* Those were cases that also involved claims for analgesic products. Our comments in *American Home Products,* 98 F.T.C. at 405, are equally apposite here: "The effort to misrepresent the nature of . . . [an] ingredient is a technique that could easily be applied to advertising of OTC drug products other than [this one]." Likewise, claims that tests prove a product's superiority or claims that its active ingredient is a breakthrough could readily be employed for any non-prescription drug product. Accordingly, it is necessary that Part I of this order apply to all such OTC drug products.

Part II of the order is narrower in scope than Part I, being limited to OTC analgesic drugs. It is so limited because our factual findings go only so far as to conclude that two well-controlled clinical tests are necessary as a reasonable basis for analgesic efficacy claims. Conversely, however, this analysis makes clear that no lesser standard than two well-controlled clinical tests is appropriate as a general rule for any analgesic product, whether its active ingredient is TEA/S or something else. It also is clear there is nothing inherently unique about Aspercreme or TEA/S to prevent Thompson from transferring the practice of claiming efficacy without such proof to other OTC analgesics. Thus, a fencing-in provision is warranted.

Finally, we comment on one order provision that complaint counsel urged upon the ALJ as well as upon us and that both he and we have rejected. It is an order provision that would [**102**] require Thompson to excise the "Aspercreme" brand name. Complaint counsel have asserted that brand name excision is a remedy the Commission has employed in the past when a brand name was deceptive and when no less restrictive alternative would suffice to eliminate deception (CAP 23–26). Complaint counsel further argue that such is the case here.

We agree with complaint counsel that brand name excision is a remedy available to us for use in extreme circumstances.[88] We do not find, however, that complaint counsel have made a sufficient case to warrant employing the remedy here. To order brand name excision, we would have to be persuaded that a less severe remedy, such as

[88] *See, e.g., FTC v. Algoma Lumber Co.,* 291 U.S. 67 (1934); *Resort Car Systems, Inc. v. FTC,* 518 F.2d 962 (9th Cir.), *cert denied,* 423 U.S. 827 (1975); *Continental Wax Corp v. FTC,* 330 F.2d 475 (2nd Cir. 1964); *Bakers Franchise Corp v. FTC,* 302 F.2d 258 (3rd Cir. 1962); *Moro Cigar Co. v. FTC,* 107 F.2d 429 (4th Cir. 1939).

affirmative disclosures, could not correct the misimpression that Aspercreme contains aspirin. Complaint counsel have argued that the evidence in this case leads to such a conclusion (CAP 34–38). However, we do not find that this evidence justifies brand name excision. The evidence consists in part of the testimony by complaint counsel's marketing expert. He stated that the brand name is the most salient part of a commercial to consumers and that, therefore, the misperceptions generated by the brand name "Aspercreme" cannot be overcome by any disclaimers included in ads (CAP 34–36). This line of reasoning appears to prove too much. It leads to the conclusion that the Commission must ban any brand name suggesting an [**103**] ingredient not contained in the product. As Thompson has pointed out, however, there are numerous products on the market whose names suggest an ingredient they do not contain.[89] While no evidence is before us showing whether or not consumers are confused by those names, we think it probable that a properly designed ad campaign for such products, or for Aspercreme, could convey to consumers the message that the product is similar to but not identical with the ingredient suggested by the brand name. In any event, we are not willing to discount this possibility based upon one expert's opinion.

The other evidence cited by complaint counsel (CAP 36–38) consists of the surveys on the record showing Thompson's TV disclosures that Aspercreme does not contain aspirin were [**104**] ineffective.[90] Complaint counsel argue this shows disclosures cannot work. However, complaint counsel agree with the ALJ and with us that Thompson's disclosures were "woefully insufficient" (CAP 37). Evidence that a

[89] *See* RAB 41:

> The marketplace abounds with products whose marks suggest but do not describe a character or quality of the goods, as for example Bacos (no bacon), Sugar Twin (no sugar), Egg Beater (no egg), Cremora (no cream), Silkience (no silk), Cottonelle (no cotton), Tuna Twist (no tuna), Chock Full O'Nuts (no nuts), Chicken of the Sea (no chicken), Apple Beer (no beer), and Rubbermaid (no rubber) (Ross, Tr. 6083–6085; Silver, Tr. 5662–5664). The common sense "message" inherent in these names is "similar to", *i.e.*, similar to bacon, similar to sugar, etc.

[90] We have discussed these surveys, CXs 27, 32 and 35, above. It is arguable that another survey sponsored by complaint counsel, the ASI Interlock Experiment (CX 26), provides information about whether the brand name Aspercreme inherently leads consumers to believe Aspercreme contains aspirin. However, we do not believe that the survey supports such a conclusion. The objective of CX 26 was "to find out whether or not the name Aspercreme led consumers to the inference that this product contained aspirin as an ingredient." (CX 26–B) The research design involved showing each respondent a single stimulus which included the name Aspercreme, Ben-Gay or Mobisyl as well as the phrase "for the temporary relief of minor arthritis pain" (CX 26–C). They were then asked, "What ingredient or ingredients are suggested by the name _____?" (CX 26–Z32). We find this question to be ambiguous given the nature of the objective of CX 26 because the wording is not equivalent to asking people whether they belive a topical analgesic for the temporary relief of minor arthritis pain contains aspirin. This ambiguity can be illustrated with the following example. If people were asked what ingredients were *suggested* by a cigarette with the name "Old Gold" the response "gold" would be expected from many. If they were instead asked what ingredients the product *contained*, we would expect that very few would reply "gold." The question in CX 26 is similarly flawed. Additionally, the ambiguity in CX 26 was probably heightened because respondents were not told that Aspercreme is a topical analgesic rather than one that is taken internally. Therefore CX 26 does not provide probative evidence regarding whether the brand name Aspercreme causes reasonable consumers to believe that aspirin is an ingredient in Aspercreme. In addition, nothing in CX 26 tests whether or not any incipient potential for misperception could be overcome by disclosures.

poorly designed disclosure is ineffective, an unsurprising result, does not prove the inability of a well-designed disclosure to communicate a message to consumers. **[105]**

VI. CONCLUSION

For the reasons set forth above, we affirm the administrative law judge's finding of liability and modify his initial decision as described.

APPENDIX

FTC POLICY STATEMENT REGARDING ADVERTISING SUBSTANTIATION

Introduction

On March 11, 1983, the Commission published a notice requesting comments on its advertising substantiation program.[1] To facilitate analysis of the program, the notice posed a number of questions concerning the program's procedures, standards, benefits, and costs, and solicited suggestions for making the program more effective. Based on the public comments and the staff's review, the Commission has drawn certain conclusions about how the program is being implemented and how it might be refined to serve better the objective of maintaining a marketplace free of unfair and deceptive acts or practices. This statement articulates the Commission's policy with respect to advertising substantiation. **[2]**

The Reasonable Basis Requirement

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

The Commission intends to continue vigorous enforcement of this existing legal requirement that advertisers substantiate express and implied claims, however conveyed, that make objective assertions about the item or service advertised. Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers. That is, consumers would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true.[2] Therefore, a firm's failure to possess and rely **[3]** upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.

Standards for Prior Substantiation

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

Absent an express or implied reference to a certain level of support, and absent other

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

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

evidence indicating what consumer expectations would be, the Commission assumes that consumers [4] expect a "reasonable basis" for claims. The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable. Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses.

One issue the Commission examined was substantiation for implied claims. Although firms are unlikely to possess substantiation for implied claims they do not believe the ad makes, they should generally be aware of reasonable interpretations and will be expected to have prior substantiation [5] for such claims. The Commission will take care to assure that it only challenges reasonable interpretations of advertising claims.[3]

Procedures for Obtaining Substantiation

In the past, the Commission has sought substantiation from firms in two different ways: through industry-wide "rounds" that involved publicized inquiries with identical or substantially similar demands to a number of firms within a targeted industry or to firms in different industries making the same type of claim; and on a case-by-case basis, by sending specific requests to individual companies under investigation. The Commission's review indicates that "rounds" have been costly to both the recipient and to the agency and have produced little or no law enforcement benefit over a case-by-case approach. [6]

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

Accordingly, the Commission has determined that in the future it will rely on nonpublic requests for substantiation directed to individual companies via an informal access letter or, if necessary, a formal civil investigative demand. The [7] Commission believes that tailored, firm-specific requests, whether directed to one firm or to several firms within the same industry, are a more efficient law enforcement technique. The Commission cannot presently foresee circumstances under which the past approach of industry-wide rounds would be appropriate in the ad substantiation area.

Relevance of Post-Claim Evidence in Substantiation Cases

The reasonable basis doctrine requires that firms have substantiation before disseminating a claim. The Commission has on occasion exercised its discretion, however, to consider supporting materials developed after dissemination.[4] The Commission has

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

[4] The Commission's evidentiary rule, 16 C.F.R. 3.40, has sometimes been interpreted as precluding introduction of post-claim substantiation. In fact, it does not. Section 3.40 only provides a sanction against the introduction of

not previously identified in one document the circumstances in which it may, in its [8] discretion, consider post-claim evidence in substantiation cases.[5] Such guidance can serve to clarify the program's actual operation as well as focus consideration of post-claim evidence on cases in which it is appropriate.

The Commission emphasizes that as a matter of law, firms lacking a reasonable basis before an ad is disseminated violate Section 5 of the FTC Act and are subject to prosecution. The goal of the advertising substantiation requirement is to assure that advertising is truthful, however, and the truth or falsity of a claim is always relevant to the Commission's deliberations. Therefore, it is important that the agency retain [9] the discretion and flexibility to consider additional substantiating evidence, not as a substitute for an advertiser's prior substantiation, but rather in the following circumstances:

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

First, using post-claim evidence to evaluate the truth of a claim, or otherwise using such evidence in deciding whether there is a public interest in continuing an investigation or issuing a complaint, is appropriate policy. This does not mean that the Commission will postpone action while firms create post-claim substantiation to prove the truthfulness of claims, nor does it [10] mean that subsequent evidence of truthfulness absolves a firm of liability for failing to possess prior substantiation for a claim. The Commission focuses instead on whether existing evidence that claims are true should lead us in the exercise of our prosecutorial discretion to decline to initiate a law enforcement proceeding. If available post-claim evidence proves that the claim is true, issuing a complaint against a firm that may have violated the prior substantiation requirement is often inappropriate, particularly in light of competing demands on the Commission's resources.

Second, post-claim evidence may indicate that apparent deficiencies in the pre-claim substantiation materials have no practical significance. In evaluating the adequacy of prior substantiation, the Commission will consider only post-claim substantiation that sheds light on pre-existing substantiation. Thus, advertisers will not be allowed to create entirely new substantiation simply because their prior substantiation was inadequate. [11]

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

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

Self Regulation Groups and Government Agencies

The Commission traditionally has enjoyed a close working relationship with self-regulation groups and government agencies whose regulatory policies have some bear-

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

ing on our law enforcment initiatives. The Commission will not necessarily [12] defer, however, to a finding by a self-regulation group. An imprimatur from a self-regulation group will not automatically shield a firm from Commission prosecution, and an unfavorable determination will not mean the Commission will automatically take issue, or find liability if it does. Rather the Commission will make its judgment independently, evaluating each case on its merits. We intend to continue our useful relationships with self-regulation groups and to rely on the expertise and findings of other government agencies in our proceedings to the greatest extent possible.

By direction of the Commission.

FINAL ORDER

The matter has been heard by the Commission upon the appeal of counsel for respondent Thompson Medical Company, Inc. and complaint counsel and upon briefs and oral argument in support of and in opposition to the appeals. The Commission, for reasons stated in the accompanying Opinion, has granted a portion of complaint counsel's appeal and denied that of respondent. Therefore

It is ordered, That the initial decision of the administrative law judge be adopted as the Findings of Fact and Conclusions of Law of the Commission except as is otherwise inconsistent with the attached Opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered, That the following Order to Cease and Desist be entered:

ORDER

I

It is ordered, That respondent, Thompson Medical Company, Inc., a corporation, its successors and assigns, and respondent's officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, [2] sale or distribution of any over-the-counter "drug" as that term is defined in the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Employing the brand name "Aspercreme" for such products or otherwise representing directly or by implication that an active ingredient of such product is aspirin, unless such product contains aspirin in therapeutically significant quantities; *provided, however,* that the brand name "Aspercreme" may be used for such product if its

advertising and labeling clearly and prominently disclose that the product does not contain aspirin.

(1) In television advertisements, an explicit and simple aspirin disclaimer statement (such as "ASPIRIN-FREE") shall be superimposed on the television screen simultaneously with a vocal aspirin disclaimer statement (such as "Aspercreme does not contain aspirin") at the end of each advertisement.

(2) In radio advertisements, an explicit aspirin disclaimer statement (such as "Aspercreme does not contain aspirin") shall be made at the end of each advertisement.

(3) In print advertisements, an explicit aspirin disclaimer statement (such as "ASPERCREME DOES NOT CONTAIN ASPIRIN") shall be displayed prominently and conspicuously in relation to each such advertisement as a whole.

(4) In labeling, an explicit aspirin disclaimer statement (such as "DOES NOT CONTAIN ASPIRIN") shall be prominently and conspicuously printed in the front package panel (or in the front of the container if no package is used).

B. Representing, directly or by implication, that such product involves a new scientific principle, when such product or one involving such principle has been available for purchase in the United States as an over-the-counter drug for more than one year. [3]

C. Misrepresenting the contents, validity, results, conclusions, or interpretations of any test or study.

D. Misrepresenting the identity of the active ingredient(s) in such product.

II

It is further ordered, That Thompson Medical Company, Inc., a corporation, its successors and assigns, and respondent's officers, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any OTC analgesic "drug," as that term is defined in the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing that such product is effective for the relief of minor pain and other symptoms of any musculoskeletal disorder (such as arthritis, tendonitis, bursitis, or rheumatic disorders).

B. Representing that such product is as fast as or faster than, or is as effective as, or more effective than any other drug or device in the

relief of minor pain and other symptoms of any musculoskeletal disorder (such as arthritis, tendonitis, bursitis, or rheumatic disorders);

unless at the time of the dissemination of any such representation, respondent possesses and relies upon a reasonable basis for such representation consisting of competent and reliable scientific or medical evidence. For analgesic drug products competent and reliable scientific or medical 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, independently of each other. Such persons shall be qualified by training and experience to conduct such studies. *Provided however,* with respect to any representation covered by this part other than claims of superior or comparative effectiveness or safety, if the Food and Drug Administration promulgates any final standard which establishes conditions under which such product is safe and effective under the Food, Drug and Cosmetic Act, then in lieu of the above, respondent may rely upon scientific evidence which fully conforms to such final standards as a reasonable basis for said representation. **[4]**

III

It is further ordered, That so much of the complaint as relates to Paragraph 12 (f) be, and the same hereby is, dismissed.

IV

It is further ordered, That respondent Thompson Medical Company, Inc. shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation such as a dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in its corporation which may affect compliance obligations under this Order.

V

It is further ordered, That the respondent herein shall within sixty (60) days after service of this Order upon it and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which it has complied or intends to comply with this Order.