IN THE MATTER OF

AMERICAN HOME PRODUCTS CORPORATION, ET AL.

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

Docket 8918. Complaint, Feb. 23, 1973—Final Order, Sept. 9, 1981

This order requires, among other things, a New York City manufacturer of Anacin, Arthritis Pain Formula (APF), and other non-prescription drug products to cease misrepresenting that Anacin will relieve tension, nervousness and depression; or that it will enable users to cope with ordinary stresses of everyday life. Should the company make any comparative efficacy claims for Anacin or APF, it would be required to disclose that the analgesic ingredient in the product is aspirin. The order also prohibits misrepresentations concerning the extent or results of product testing; and bars any unsubstantiated performance claim unless accompanied by a conspicuous disclosure that such claim has not been proven. The company is further precluded from representing that its products contain any unusual or special ingredient, when, in fact, such ingredient is commonly used in similar products. Additionally, the order prohibits the C.T. Clyne Company, Inc., an advertising agency, from knowingly making unsubstantiated "superior performance" or "unusual ingredient" claims for Anacin, APF or for any other non-prescription internal analgesic product.

Appearances

For the Commission: *Melvin H. Orlans, James H. Skiles, W. Benjamin Fisherow, Ira Nerken, Judith A. Neibrief* and *Richard A. Bloomfield.*

For the respondents: *Samuel W. Murphy, Jr., John J. McGrath, Jr., Donald J. Frickel,* and *E. Thomas Sullivan, Donovan Leisure Newton & Irvine,* Washington, D.C., for American Home Products Corporation, and *Irving Scher* and *Deborah M. Lodge, Weil, Gotshal & Manges,* Washington, D.C., for The C.T. Clyne Company, Inc.

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 American Home Products Corporation, a corporation, (hereinafter referred to as "Amho"), and Clyne Maxon, Inc., a corporation, (hereinafter referred to as "Maxon"), hereinafter referred to as respondents, have violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest,

hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. For purposes of this complaint the following definitions shall apply:

1. *Commerce* means commerce as defined in the Federal Trade Commission Act.

2. *False advertisement* means false advertisement as defined in the Federal Trade Commission Act.

PAR. 2. Respondent American Home Products Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located at 685 Third Ave. in the City of New York, State of New York.

Respondent Clyne Maxon, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York with its principal office and place of business located at 245 Park Ave. in the City of New York, State of New York. [2]

PAR. 3. Respondent Amho Corporation is now, and has been for more than one year last past, engaged in the manufacturing, advertising, offering for sale, sale and distribution of non-prescription internal analgesic preparations which fall within the classification of drugs, as the term "drug" is defined in the Federal Trade Commission Act.

The designation used by respondent for said preparations, the active ingredients thereof and directions for use are as follows:

1. *Designation:* "Anacin"

   Active Ingredients (One Tablet):
   Acetylsalicylic Acid
   Caffeine Anhydrous

   Dosage: One to two tablets with water. Repeat if necessary, one tablet every 3 hours. For children under 6 consult a doctor.

2. *Designation:* "Arthritis Pain Formula"

   Active Ingredients (One Tablet):
   Acetylsalicylic Acid (micro-fine)
   Aluminum Hydroxide, Dried Gel
   Magnesium Hydroxide, NF

Dosage:	Convenient daily schedule for adults is one or two tablets first thing in the morning; then repeat one or two tablets as needed at lunch, dinner and bedtime. Do not exceed 8 tablets in any 24 hour period. Not recommended for children.

PAR. 4. Respondent Maxon is now, and for some time last past has been, the advertising agency of respondent Amho, and now, and for some time last past, has prepared and placed for publication, and has caused the dissemination of, advertising material, including but not limited to the advertising referred to herein, to promote the sale of "Arthritis Pain Formula", which comes within the classification of "drug," as the term "drug" is defined in the Federal Trade Commission Act. [3]

In the course and conduct of its business, respondent American Home Products Corporation causes the said products, when sold to be shipped from its plant and facilities in various States of the United States to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondent American Home Products Corporation maintains, and at all times mentioned herein has maintained, a substantial course of trade in said products in commerce.

PAR. 5. In the conduct of its business at all times mentioned herein, respondent Amho Corporation has been in substantial competition, in commerce, with corporations, firms, and individuals in the sale of non-prescription internal analgesic products.

In the conduct of its business at all times mentioned herein, respondent Clyne Maxon, Inc. has been in substantial competition, in commerce, with other corporations, firms, and individuals in the advertising business.

PAR. 6. In the course and conduct of their business, as aforesaid, respondents have disseminated, and caused the dissemination of, certain advertisements concerning the said products by the United States mail and by various means in commerce, including, but not limited to, advertisements inserted in magazines and other advertising media, and by means of television and radio broadcasts transmitted by television and radio stations located in various States of the United States, and in the District of Columbia, having sufficient power to carry such broadcasts across state lines, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said products, and has disseminated, and caused the

dissemination of, advertisements concerning said products by various means, including but not limited to the aforesaid media, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said drugs in commerce.

PAR. 7. Among and typical of the statements and representations contained in said advertisements as hereinabove mentioned are those relating to the product "Anacin" contained in two (2) television commercials' story-boards and one newspaper advertisement which have been reproduced, attached to this complaint, and made a part hereof,* and the following: [4]

A. For "Anacin"

1. Turns Off Headache Pain, So Relaxes Its Tension, Helps Lift Its Depression–Fast

In 22 seconds after entering your bloodstream this special fortified formula is speeding relief to your nervous headache. It promptly relieves the pain, so relaxes its tension and helps lift its depression. You can bounce back fast–able to carry on and do your work. This effective headache relief is Anacin (R)–a special fortified combination of ingredients and only Anacin has this formula. Anacin Analgesic Tablets contain the medication doctors recommend most for headache pain. In fact, Anacin gives you more of it than any leading headache tablet. Next time–try medically proven Anacin Tablets.

2. When Nervous Tension And Fatigue Bring On "Housewife Headache" . . .

The busy mother and homemaker has many repetitious tasks she must perform daily to make life pleasant for her family. And it's understandable how tensions and fatigue can build up during the day and result in what is now known as "housewife" headache. For this type of headache you need strong yet safe relief. So next time take Anacin (R). Anacin gives you 100% more of the strong pain-reliever doctors recommend most for headaches than the other leading extra-strength tablet. Minutes after taking Anacin, your headache goes, so does its nervous tension and fatigue, Anacin lets you feel better all over–able to carry on. Despite its strength, Anacin is safe taken as directed. It doesn't leave you depressed or groggy. Next time take Anacin Tablets! [5]

3. What's Best To Take For A Nervous Tension Headache?

Why not the strong pain-reliever doctors recommend most? You'll find it in Anacin (R). Anacin is a special fortified formula that turns off headache pain in minutes, so . . . relaxes its nervous tension and relaxes its painful pressure on nerves. Anacin lets you feel better all over.

4. Takes The "Pressure-Pain" Out Of Your Nervous Headache In Minutes.

. . . so relaxes its nervous tension, releases painful pressure on nerves . . . you feel great again.

* Exhibits not reproduced because of poor quality.

The pressures of today's hectic world often give people today's nervous tension. And nervous tension causes the most common headache of all. Tension presses on nerves and tiny blood vessels in your head, then brings on a "painful pressure" headache. You want the quick strength of Anacin (R) for relief.

Anacin is a special fortified formula that turns off headache pain in minutes, so relaxes its tension, releases painful pressure on nerves. Helps you feel great again. And the soothing effect continues for hours.

Anacin gives you 100% more of the specific pain-reliever doctors recommend most for headaches–than the other leading extra-strength tablet. Powerful Anacin helps relieve a painful pressure headache but doesn't dull your senses. Smooth, gentle acting too, next time take Anacin Tablets.

5. New Clinical Study Indicates Anacin Treats Headaches As Effectively As The Most Widely Prescribed Pain-Relief Compound . . . yet has fewer side effects and is more economical.

6. Compared To The Other Extra-Strength Tablet: Gives You *Twice As Much* Of The Pain-Reliever Doctors Recommend Most For Headaches And twice as many people now use it! . . . Anacin gives real fast relief from tension headache pain, so its tension goes–you function better and do a better job. **[6]**

7. *Survey Of Doctors Of Internal Medicine Report:* Twice As Many Doctors Prefer This Extra-Strength Pain-Reliever For Headaches. And Another Medical Research Report Proves This Same Tablet Relieves Nervous Tension Headaches As Effectively As The Leading Prescription Pain-Reliever.

Replies from over 1600 doctors who specialize in internal medicine showed twice as many preferred the formula of extra-strength Anacin for headache pain over that of the other leading extra-strength tablet. These doctors certainly know their pain-relievers and this was verified by another medical report that proved Anacin gives the same powerful pain relief from headaches as the leading prescription. Yet Anacin needs no prescription. And costs far less. Extra-strength Anacin Tablets work fast. Headache goes in minutes so its nervous tension goes, too. Anacin lets you do a better job–lets you function better. Despite its strength Anacin is not narcotic. Not habit-forming. It makes good sense to take fast acting, extra-strength Anacin (R)–the pain-reliever preferred by twice as many doctors.

8. The Most Exciting Headache News In Years!

Results of doctor's tests in treating tense, nervous headaches now made public.

If you are one of millions who get tense, nervous headaches–these latest tests by doctors should be of the utmost importance.

Whitehall Laboratories who make world-famous Anacin (R) Tablets have always known Anacin is a powerful, fast-acting pain reliever. Anacin is a special fortified combination of ingredients. Millions of sufferers must consider Anacin superior because it's America's largest selling analgesic.

Having the greatest confidence in the high quality of relief Anacin offers, the makers of Anacin decided to compare its effectiveness for headaches with that of the leading pain-relief prescription of doctors . . . **[7]**

The results showed Anacin is just as effective to give complete relief from nervous headaches as the expensive, leading pain-relief prescription. Tests verified beyond a

doubt that Anacin has the same pain-relief power for headaches as this prescription for which doctors wrote 21 million prescriptions last year . . .

An advantage of Anacin is that it is not a narcotic. Not habit forming. You can take Anacin without getting dizzy or an upset stomach . . . .

So next time you get a nervous headache–you owe it to yourself to take Anacin–proved in doctors' tests to be equally effective for headache relief as the most powerful, most widely prescribed pain reliever. Yet Anacin needs no prescription and is far more economical.

B. For "Arthritis Pain Formula"

1. Arthritis Sufferers:

Wake Up Tomorrow Morning Without All That Stiffness! New Pain Formula. 50% stronger than a regular aspirin. So you take it less often. Yet so gentle you can take it on an empty stomach . . . a new formula for arthritis minor pain that (1) is so strong you can take it less often and still wake up in the morning without all the pain's stiffness and (2) is so gentle you can take it on an empty stomach. This means you get both extra medication and extra protection; extra medication because each tablet contains 50% more pain reliever than regular or buffered aspirin tablets. Extra protection because each tablet contains two antacids and is micronized (which means the tablet particles are so fine the pain reliever is more readily absorbed). Called Arthritis Pain Formula, it was specially developed by the makers of Anacin (R) to give arthritis sufferers an easier, less upsetting way to wake up without all that early morning stiffness and enjoy hours of relief.

PAR. 8. Through the use of the said advertisements and others similar thereto not specifically set out herein, respondents have represented and are now representing, directly and by implication: [8]

A. By respondent Amho for "Anacin"

1. That Anacin contains more pain-dulling ingredients per tablet than any other non-prescription internal analgesic product on the market.

2. That Anacin's analgesic ingredient is unusual, special, and stronger than aspirin (acetylsalicylic acid).

3. That Anacin contains more than twice as much of its analgesic ingredient as any other analgesic product on the market.

4. That within approximately 22 seconds after taking Anacin a person may expect relief from headache pain.

B. By respondents Amho and Maxon for "Arthritis Pain Formula"

1. That Arthritis Pain Formula's analgesic ingredient is unusual, special, and stronger than aspirin (acetylsalicylic acid).

2. That Arthritis Pain Formula will eliminate all pain, stiffness

and discomfort usually experienced by arthritis sufferers in the morning.

PAR. 9. In truth and in fact:

A. For "Anacin"

1. There are other analgesic products on the market which contain as much or more pain dulling ingredients per tablet than does Anacin.

2. Anacin's analgesic ingredient is ordinary aspirin (acetylsalicylic acid).

3. Anacin does not contain more than twice as much of its analgesic ingredient as all other analgesic products on the market. **[9]**

4. Relief from headache pain is not obtained within approximately 22 seconds after taking Anacin.

B. For "Arthritis Pain Formula"

1. Arthritis Pain Formula's analgesic ingredient is aspirin (acetylsalicylic acid).

2. Arthritis Pain Formula will not eliminate all pain, stiffness or discomfort usually experienced by arthritis sufferers in the morning.

PAR. 10. Further, through the use of the advertisements referred to in Paragraph Seven above and others similar thereto but not specifically set out herein, it has been represented and is being represented, directly and by implication:

A. By respondent Amho that it has been established that a recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other non-prescription internal analgesic.

B. By respondents Amho and Maxon that it has been established that Arthritis Pain Formula will cause gastric discomfort less frequently than any other non-prescription internal analgesic.

PAR. 11. In truth and in fact, neither of said representations referred to in Paragraph Ten has been established, for reasons including, but not limited to, the existence of a substantial question, recognized by experts qualified by scientific training and experience to evaluate the efficacy and safety of such drugs, as to the validity of such representations.

PAR. 12. Further, through the use of the advertisements referred to in Paragraph Seven above and others similar thereto but not

specifically set out herein, it has been represented and is being represented, directly and by implication:

A. By respondent Amho that a recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other non-prescription internal analgesic.

B. By respondents Amho and Maxon that Arthritis Pain Formula will cause gastric discomfort less frequently than any other non-prescription internal analgesic. **[10]**

PAR. 13. At the time respondents made the representations referred to in Paragraph Twelve above, there existed a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug products, concerning the validity of such representations.

PAR. 14. Furthermore, respondents made the representations referred to in Paragraph Twelve above without disclosing the existence of a substantial question, as alleged in Paragraph Thirteen above, as to the validity of each representation. In light of the representations made, the existence of such a substantial question is a material fact, which, if known to consumers, would be likely to affect their consideration of whether or not to purchase such products. Thus respondents have failed to disclose material facts.

PAR. 15. Further, through the use of the advertisements referred to in Paragraph Seven above, and others similar thereto but not specifically set out herein, respondent Amho did represent and is representing, directly and by implication, that a recommended dose of Anacin relieves nervousness, tension, stress, fatigue and depression and will enable persons to cope with the ordinary stresses of everyday life.

PAR. 16. In truth and in fact, there existed at the time of the representations referred to in Paragraph Fifteen above no reasonable basis for making said representations in that respondent had no competent and reliable scientific evidence to support such representations.

PAR. 17. Further, through the use of the advertisements referred to in Paragraph Seven above and others similar thereto but not specifically set out herein, respondent Amho has represented and is now representing, directly and by implication, that certain scientific tests or studies conducted by or on behalf of respondent Amho prove that Anacin is as effective for the treatment or relief of headache pain as the leading prescription analgesic product and more effective for the treatment or relief of such pain than any other non-prescription internal analgesic product.

PAR. 18. At the time respondent made the representations referred to in Paragraph Seventeen, there existed a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug products, concerning the validity, significance or interpretation of such tests or studies as they related to such representations. [11]

PAR. 19. Furthermore, respondent made the representations referred to in Paragraph Seventeen above without disclosing the existence of a substantial question, as alleged in Paragraph Eighteen above, as to the validity of each representation. In light of the representations made, the existence of such a substantial question is a material fact, which, if known to consumers, would be likely to affect their consideration of whether or not to purchase such products. Thus respondent has failed to disclose material facts.

PAR. 20. Further, through the use of the advertisement referred to in Paragraph Seven, item (A)(7), above, and others similar thereto but not specifically set out herein, respondent Amho has represented and is now representing, directly and by implication, that:

1. Twice as many specialists in internal medicine prefer Anacin for the treatment or relief of headache pain to any other non-prescription internal analgesic product.
2. More physicians recommend Anacin for the treatment or relief of headache pain than any other non-prescription internal analgesic product.
3. Such recommendation or preference constitutes convincing proof that Anacin will treat or relieve headache pain more effectively than any other non-prescription internal analgesic product.

PAR. 21. In truth and in fact, neither the design of the survey cited by respondent Amho, nor the responses to said survey, provides a reasonable basis for the representations referred to in Paragraph Twenty above.

PAR. 22. Further, respondent Amho marketed and advertised Anacin, and respondents Amho and Maxon marketed and advertised Arthritis Pain Formula, without disclosing in the advertising for such products that such products contain aspirin and that Anacin contains caffeine.

PAR. 23. In truth and in fact, aspirin and caffeine are well-known, commonplace substances, widely available in many products. Moreover, the use of aspirin or caffeine may be injurious to health and may cause undesirable side effects. Thus, respondents have failed to disclose material facts which, if known to certain consum-

ers, would be likely to affect their consideration of whether or not to purchase such products. [12]

PAR. 24. The advertisements referred to in Paragraph Seven above as alleged in Paragraphs Nine, Eleven, Fourteen, Nineteen, and Twenty-Three constituted and now constitute false advertisements.

PAR. 25. The making of representations as alleged in Paragraphs Thirteen, Sixteen, Eighteen, and Twenty-One constituted and now constitutes unfair or deceptive acts or practices in commerce.

PAR. 26. The use by respondents of the aforesaid deceptive representations, and the dissemination of the aforesaid false advertisements 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 respondents' drugs by reason of said erroneous and mistaken belief.

PAR. 27. The aforesaid acts and practices of respondents, as herein alleged, including the dissemination of the false advertisements as aforesaid 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 commerce and unfair or deceptive acts or practices in commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

INITIAL DECISION BY

MONTGOMERY K. HYUN, ADMINISTRATIVE LAW JUDGE

SEPTEMBER 1, 1978

PRELIMINARY STATEMENT

On February 23, 1973, the Federal Trade Commission ("Commission") issued a complaint charging American Home Products Corporation ("American Home") and Clyne Maxon, Inc. with violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended (15 U.S.C. 45 and 52), [2]in connection with certain advertisements for Anacin and Arthritis Pain Formula ("APF"). Similar complaints were issued at the same time against Bristol-Myers Company (Docket No. 8917) and Sterling Drug Company (Docket No. 8919), in connection with certain advertisements for certain over-the-counter ("OTC") internal analgesic products marketed by these firms.

On May 29, 1973, respondents filed their respective answers to the Complaint, each denying that it had violated the Federal Trade

Commission Act. Administrative Law Judge William K. Jackson, originally assigned to this proceeding, entered a Prehearing Order, dated April 4, 1974, setting forth the issues of fact and law to govern the adjudicatory proceeding. This case was assigned to me upon Judge Jackson's retirement, effective January 1, 1975. By Order dated January 7, 1976, the Prehearing Order of April 4, 1974 was modified in certain respects.

The parties were allowed extensive pretrial discovery. Numerous 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 orders, the following issues are matters for determination in this proceeding:

(a) Whether the challenged advertisements represented that:

(i) Anacin contains more pain-dulling ingredients per tablet than any other non-prescription internal analgesic product on the market (Comp. ¶ 8(A)(1)).

(ii) Anacin's analgesic ingredient is unusual, special, and stronger than aspirin (acetylsalicylic acid) (Comp. ¶8(A)(2)).

(iii) Anacin contains more than twice as much of its analgesic ingredient as any other analgesic product on the market (Comp. ¶8(A)(3)).

(iv) Within approximately 22 seconds after taking Anacin a person may expect relief from headache pain (Comp. ¶ 8(A)(4)).

(v) Arthritis Pain Formula's analgesic ingredient is unusual, special, and stronger than aspirin (acetylsalicylic acid) (Comp. ¶8(B)(1)). **[3]**

(vi) Arthritis Pain Formula will eliminate all pain, stiffness and discomfort usually experienced by arthritis sufferers in the morning (Comp. ¶ 8(B)(2)).

(vii) A recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other non-prescription internal analgesic (Comp. ¶ 12(A)).

(viii) Arthritis Pain Formula will cause gastric discomfort less frequently than any other non-prescription internal analgesic (Comp. ¶ 12(B)).

(ix) A recommended dose of Anacin relieves nervousness, tension, stress, fatigue and depression (Comp. ¶ 15).

(x) A recommended dose of Anacin will enable persons to cope with the ordinary stresses of everyday life (Comp. ¶ 15).

(xi) It has been established that a recommended dose of Anacin is

more effective for the relief of pain than a recommended dose of any other non-prescription internal analgesic (Comp. ¶ 10(A)).

(xii) It has been established that Arthritis Pain Formula will cause gastric discomfort less frequently than any other non-prescription internal analgesic (Comp. ¶ 10(B)).

(b) Whether the representations in paragraph (a) (xi) and (xii) above, if made, have been established (Comp. ¶ 11).

(c) Whether there existed at the time of the alleged representations set forth in paragraph (a) (vii) and (viii), a substantial question, recognized by qualified experts, as to the validity of said representations (Comp. ¶ 13).

(d) Whether there existed at the time of the alleged representations set forth in paragraph (a) (xi) and (xii), a substantial question, recognized by qualified experts, as to the validity of said representations (Comp. ¶ 11). [4]

(e) Whether the existence of a substantial question, if established, was a material fact of which the failure to disclose constituted an unfair or deceptive advertising practice (Comp. ¶ 14).

(f) Whether the alleged representations set forth in paragraph (a)(ix) and (x), if made, were based on a reasonable basis (Comp. ¶16).

(g) Whether American Home, through advertising, represented that certain scientific tests proved that Anacin is as effective for the treatment or relief of headache as the leading prescription analgesic product and is more effective for the treatment or relief of such pain than any other non-prescription internal analgesic product (Comp. ¶17).

(h) Whether there existed a substantial question, recognized by qualified experts, concerning the validity, significance or interpretation of the tests referred to in paragraph (g) as they relate to such representations (Comp. ¶ 18).

(i) Whether the existence of a substantial question, if established in relation to paragraph (h), was a material fact of which the failure to disclose constituted an unfair or deceptive advertising practice (Comp. ¶ 19).

(j) Whether the alleged advertisement referred to in paragraph 7, item (A)(7), of the Complaint represented that:

(i) Twice as many specialists in internal medicine prefer Anacin for the treatment or relief of headache pain to any other non-prescription internal analgesic product.

(ii) More physicians recommend Anacin for the treatment or relief of headache pain than any other non-prescription internal analgesic product.

(iii) Such recommendation or preference constitutes convincing proof that Anacin will treat or relieve headache pain more effectively **[5]**than any other non-prescription internal analgesic product (Comp. ¶ 20).

(k) Whether the design of, or responses to, the survey referred to in paragraph 7, item (A)(7) of the Complaint provided a reasonable basis for the alleged representations in paragraph (j) (Comp. ¶ 21).

(l) Whether American Home marketed and advertised Anacin without disclosing in such advertising that Anacin contained aspirin and caffeine (Comp. ¶ 22).

(m) Whether respondents marketed and advertised Arthritis Pain Formula without disclosing in such advertising that APF contained aspirin (Comp. ¶ 22).

(n) Whether the use of aspirin or caffeine in customary or recommended doses in the products involved in this case can be injurious to health and cause undesirable side effects.

(o) Whether a significant number of certain consumers do not know that Anacin contains aspirin and caffeine and that Arthritis Pain Formula contains aspirin.

(p) Whether the failure to disclose in advertisements that Anacin contains aspirin and caffeine would be likely to affect the consideration of purchasing such product by certain consumers in the light of other information about the ingredients of such product, such as the labeling and packaging for such product.

(q) Whether the failure to disclose in advertisements that Arthritis Pain Formula contains aspirin would be likely to affect the consideration of purchasing such product by certain consumers in light of other information about the ingredients of such product, such as the labeling and packaging for such product.

(r) Whether the presence of aspirin and caffeine in Anacin is a material fact in light of the challenged advertising or material with respect to the consequences which may result from the **[6]**use of said product under the conditions prescribed in said advertising or under such conditions as are customary or usual.

(s) Whether the presence of aspirin in Arthritis Pain Formula is a material fact in light of the challenged advertising or material with respect to the consequences which may result from the use of said product under the conditions prescribed in said advertising or under such conditions as are customary or usual.

(t) Whether the use by respondents of the representations referred to in paragraph 25 of the Complaint, and the advertisements referred to in paragraph 24 of the Complaint, has had and

now has the tendency and the capacity to mislead members of the purchasing public into the erroneous and mistaken belief that said statements and representations were true, and into the purchase of substantial quantities of Anacin and Arthritis Pain Formula by reason of said erroneous and mistaken belief (Comp. ¶ 26).

(u) Whether the alleged advertising representations, if made, have caused the purchase of substantial quantities of Anacin and Arthritis Pain Formula by reason of erroneous and mistaken belief.

(v) Whether the alleged advertising representations, if made, are sufficiently likely to have continuing injurious effects upon consumers and/or competitors, so as to warrant corrective advertising.

(w) Whether the representations involved in this proceeding were made by respondents in good faith compliance with the applicable legal standards in effect at the time the representations were made.

By Order dated February 16, 1977, a joint hearing was ordered with respect to certain common documents and witnesses for the presentation of complaint counsel's cases-in-chief in the three companion OTC internal analgesic cases (Docket Nos. 8917, 8918 and 8919). Joint evidentiary hearings commenced on June 6, 1977 and continued until August 15, 1977. The separate evidentiary hearings for the presentation of complaint counsel's case-in-chief in this case began on [7]November 1, 1977 and continued until December 19, 1977. My disposition of respondents' motion to dismiss the Complaint filed at the close of complaint counsel's case was deferred until completion of the defense hearings. Respondents commenced their defense on January 30, 1978 and continued until March 22, 1978. The evidentiary record was closed on April 13, 1978.[1] The parties filed simultaneously their proposed findings of fact, conclusions of law, order and supporting briefs and subsequent replies. An oral argument on the proposed findings was heard on July 7, 1978. Some 40 witnesses, including 27 expert witnesses, testified. Transcripts of hearings for the joint and separate hearings number some 11,600 pages. Some 400 documentary exhibits, including numerous copy tests, penetration and image studies, and medical-scientific studies were received in 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

[1] By orders dated May 3 and June 28, 1978, the Commission extended the due date of this Initial Decision to September 1, 1978.

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.

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: [1A] [8]

FINDINGS OF FACT

I. Introduction

A. *Identity of Respondents and the Nature of Their Business*

1. American Home Products Corporation is a corporation organized, existing, and doing business under the laws of the State of Delaware, with its administrative headquarters located at 685 Third Ave., New York, New York. American Home is now and has been manufacturing, offering for sale, advertising, selling, and distributing non-prescription internal analgesic preparations designated "Anacin" and "Arthritis Pain Formula," which fall within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act (Ans. of American Home, ¶¶ 2 and 3).

2. In the course and conduct of its business, American Home causes Anacin and APF to be shipped from its plant and facilities in various States of the United States to purchasers located in various other States of the United States and the District of Columbia. It maintains a substantial course of trade in said products in commerce. In the conduct of its business, it has been in substantial

[1A] 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	-	American Home's Proposed Findings.
RB	-	American Home's Post-Trial Memorandum.
RRB	-	American Home's Post-Trial Reply Memorandum.
Tr.	-	Transcript of hearings, sometimes preceded by the name of the witness.
JTr.	-	Transcript of joint hearings, sometimes preceded by the name of the witness.
CX	-	Complaint counsel's documentary exhibit.
RX	-	American Home's documentary exhibit.
Comp.	-	Complaint.
Ans.	-	Answer.

competition in commerce with corporations, firms and individuals in the sale of non-prescription internal analgesic products (Ans. of American Home, ¶¶ 4 and 5).

3. Consumer sales for Anacin have been in excess of $52 million annually since 1965 and have increased in each successive year to approximately $41 million for the first half of 1977. Consumer sales for APF have been in excess of $1 million annually since 1969 and have increased in each successive year to approximately $7 million for the first half of 1977. Anacin's share of the non-prescription internal analgesic products market has been between approximately 14% and 17% from 1965 through the first half of 1977. APF's market share has been between 0.2% and 2.6% from 1969 through the first half of 1977 and has increased throughout this period (CX 611Z157–Z160; RX 240; RX 241; RX 243).

4. In the course and conduct of its business, American Home has disseminated, and caused the dissemination of, certain advertisements concerning Anacin and APF by the United States mail and by various means in commerce including, but not limited to, advertisements inserted in magazines and other advertising media, and television and radio broadcasts transmitted by television and radio stations having sufficient power to carry such broadcasts across state lines, for the purpose of inducing the purchase of said products (Ans. of American Home, ¶ 6). **[9]**

5. In promoting these products, American Home has spent more than $17 million annually on Anacin advertising since 1965 and approximately $16 million on such advertising in the first half of 1977. American Home has spent at least $500,000 annually on APF advertising since 1969 and approximately $3 million on such advertising in the first half of 1977 (Ans. of American Home, ¶ 7; CX 611Z140, Z157, Z160, Z170-Z174, Z176, Z177; RX 242, RX 243).

6. John F. Murray Advertising Agency ("Murray") is a wholly owned subsidiary of American Home. It has developed and disseminated the advertising for Anacin since February 1968 (CX 611Z146; DeMott, Tr. 4648–50).

7. Whitehall Laboratories ("Whitehall") is the division of American Home that markets Anacin and APF (CX 611Z146; DeMott, Tr. 4643). Whitehall shared in the development of advertising copy for APF; the approval of the president of Whitehall was necessary prior to the production of an APF advertisement (CX 611Z167).

8. The C.T. Clyne Company, Inc., the corporate successor to Clyne Dusenberry, Inc. and to Clyne Maxon, Inc. (hereinafter, collectively, "Clyne"), is a corporation organized, existing, and doing business under the laws of the State of New York, with its principal office and

place of business located at 1270 Avenue of the Americas, New York, New York (Ans. of Clyne, ¶ 2; CX 610, Stip. 1; CX 611Z165).

9. Since 1969, Clyne, an advertising agency, has been employed by American Home. In the course and conduct of its business, it has disseminated, and has caused the dissemination of, advertising to promote the sale of APF (Ans. of Clyne, ¶ 4; CX 610, Stip. 2, 3, 5; CX 611Z165; DeMott, Tr. 4649). Clyne participated with American Home in developing the challenged APF advertisements and, in conjunction with American Home and Murray, made certain arrangements for the dissemination of some of the challenged APF advertisements including, but not limited to, placing advertisements with advertising media for spot broadcasting (CX 610).

10. In the conduct of its business, Clyne has been in substantial competition in commerce with other corporations, firms and individuals in the advertising business (Ans. of Clyne, ¶ 5). **[10]**

B. *General Findings*

11. The active ingredients in one tablet of Anacin are 400 mg. (6.15 gr.) aspirin[2] and 32.5 mg. (0.35 gr.) caffeine. The active ingredients in one tablet of APF are 486 mg. (7.5 gr.) microfined aspirin, 20.14 mg. dried aluminum hydroxide gel and 60.42 mg. magnesium hydroxide (Ans. of American Home ¶ 3; RX 244Z003; Forrest, Tr. 464; Plotz, Tr. 1053; Sliwinski, Tr. 1136).

12. The active ingredients, directions for use and indicated uses of Anacin and APF appear on the labels and packages of these products (Comp. ¶ 3; Ans. of American Home, ¶ 3). The directions for use of each product, as reflected by the recommended dosage, are as follows:

(a) *Anacin:*

One to two tablets with water. Repeat if necessary, one tablet every 3 hours. For children under 6, consult a physician.

(b) *Arthritis Pain Formula:*

Convenient daily schedule for adults is one or two tablets first thing in the morning; then repeat one or two tablets as needed at lunch, dinner and bedtime. Do not exceed 8 tablets in any 24 hour period. Not recommended for children.

The indicated uses of each product are as follows:

[2] Aspirin is the commonly adopted name for acetylsalicylic acid ("ASA"), a member of the group of analgesic agents known as salicylates (CX 367E, Z011).

(a) *Anacin:*

relieves pain of headache, neuralgia, neuritis, muscular aches, discomforts and fever of colds, pain caused by tooth extraction, distress associated with normal menstrual periods. Also relieves minor aches and pains of arthritis and rheumatism.

(b) *Arthritis Pain Formula:*

relief from the minor aches and pains of arthritis and rheumatism and low-back pain. Also relieves the pain of [11]headache, neuralgia, neuritis—the discomforts and fever of colds, pain caused by tooth extractions, distress associated with normal menstrual periods.

13. The standard dosage unit for marketed products containing aspirin alone is generally 325 mg. (5 gr.) aspirin per tablet (Forrest, Tr. 467; Moertel, Tr. 958–59; CX 367M).

14. Aspirin, either as a single ingredient or in combination with other ingredients, is the most widely used analgesic drug in the United States; in fact, almost 19 billion dosage units are sold annually (Complaint Counsel's Admission, RX 244Z002; CX 367Z012). Aspirin is generally recognized as a safe and effective analgesic (Forrest, Tr. 502–03; Moertel, Tr. 998–99; Lasagna, Tr. 4096–97; CX 367Z012). Dried aluminum hydroxide gel and magnesium hydroxide, at certain dosage levels, are generally recognized as safe and effective antacid active ingredients (Complaint Counsel's Admission, RX 244Z006-Z007).

15. The complaint does not allege that American Home did not have a reasonable basis for making an advertising claim that a recommended dose of Anacin is more effective than a recommended dose of regular aspirin, nor does it allege that respondents did not have a reasonable basis for making an advertising claim that Arthritis Pain Formula causes gastric discomfort less frequently than regular aspirin (Complaint Counsel's Admission, RX 244Z026–Z027).

II. Expert Witnesses Who Testified Regarding Marketing and Medical Issues

A. *Marketing Witnesses*

16. On the issues related to advertising claims, product images and remedy, complaint counsel called Drs. Leavitt, Ross and Rossi; American Home called Drs. Blattberg, Jacoby, Kuehn, Maisel, Sen and Smith.

17. Dr. Robert C. Blattberg, Professor of Marketing at the University of Chicago School of Business, has done extensive research and writing in the areas of mathematical and econometric modeling, advertising effects and advertising carryover effects, consumer purchase decisions, and the use of consumer diary panel data, as well as survey data, in analyzing consumer behavior. In addition to numerous consulting assignments relating to the marketing of consumer [12]goods and a continuing consulting arrangement with the research department of Leo Burnett & Co., Dr. Blattberg serves on the editorial boards of several distinguished journals of marketing and marketing research. He is currently one of the primary consultants to a research program being funded by the Advertising Research Foundation to collect and analyze empirical data on the effects of advertising (Blattberg, Tr. 6812–27; RX 2 (Rev.)).

18. Dr. Jacob Jacoby is a Professor in the Psychological Sciences Department at Purdue University, where he heads the Consumer Psychology Program which is widely known for its innovative and extensive work regarding the application of the science of psychology to the study of consumer behavior. In addition to his teaching, Dr. Jacoby has done extensive empirical research and has published numerous articles dealing with consumer decisionmaking and behavior and the effects of various factors, including advertising, upon consumers (Jacoby, Tr. 5189–97; RX 4 (Rev.)).

19. Dr. Alfred Kuehn was formerly a Professor of Marketing at the Carnegie-Mellon University School of Industrial Administration. After doing some of the initial work on the econometric modeling of consumer purchasing patterns and the determination of the "carryover" or "lag" effects of advertising, Dr. Kuehn established Management Science Associates, Inc. ("MSA"). MSA specializes in the analysis of all types of marketing data. In the course of the ongoing work performed at MSA, Dr. Kuehn has been constantly involved in measuring consumer attitudes towards various products and in empirically determining the carryover effects of advertising (Kuehn, Tr. 6225–43; RX 5).

20. Dr. Richard Maisel, Associate Professor of Statistics in the Graduate Department of Sociology at New York University, specializes in the statistical analysis of consumer survey data, sample design and survey methodology. In addition to his teaching, Dr. Maisel serves as a consultant to a number of large industrial concerns and market research organizations for the purpose of analyzing the meaning and statistical significance of surveys (Maisel, Tr. 4766-75; RX 10).

21. Dr. Clark Leavitt is a Professor of Marketing at the Ohio State University, concentrating in various subdisciplines of Psychology including social psychology, consumer behavior and research methodology (Leavitt, Tr. 1247, 1255). He supervises graduate and post-graduate student research and conducts research for publication in professional journals (CX 507). He has had extensive training and experience in the implementation, design and analysis of research which measures consumers' images and beliefs about products and the effects of advertising (Tr. at 1245–63; CX 507). As a consultant for clients [13]which include advertising agencies, he also designs and conducts applied research (Leavitt, Tr. 1255–56). Many of his projects have involved the development of rating scales to measure consumer perceptions or pre-dispositions (Leavitt, Tr. 1248–56). Dr. Leavitt's research has often involved the measurement of the relationship between the repetition of advertising and the stability of people's opinions or attitudes. Over half of the articles he has published in professional journals have involved research measuring attitudes, beliefs or images. Dr. Leavitt is a former President of the Division of Consumer Psychology of the American Psychological Association (Leavitt, Tr. 1260–61; CX 507).

22. Dr. Ivan Ross is a Professor of Marketing at the University of Minnesota, College of Business Administration, and is a licensed consulting psychologist. Dr. Ross has had extensive training and experience in the fields of consumer psychology and behavior, marketing and marketing research (CX 502; Ross, Tr. 1797–1829, 1833-38, 2404–07). This has included evaluating advertising and the effects of advertising over time on consumers and upon their attitudes and beliefs. It has also included conducting and interpreting research in these areas. In addition to his academic training (Ross, Tr. 1797) and academic work (Ross, Tr. 1797, 1799–1800, 1811–12), Dr. Ross has had experience working with advertisers and advertising agencies on advertising content and strategy for a variety of consumer goods and services and with various consumer research techniques such as focus groups, copy tests, penetration studies and image studies (Ross, Tr. 1800–11, 1824–29, 1833–35). Dr. Ross has also been a consultant with the Food and Drug Administration's ("FDA") Bureau of Foods, involved in recommending, conducting, and evaluating consumer research designed to improve labeling information on prescription and OTC drugs by improving FDA's understanding of consumption practices for health care and drugs. As part of this research effort, Dr. Ross has interviewed consumers regarding their understandings of the concept of "effectiveness" of drugs (Ross, Tr. 1806, 2404–07). He has also served as an editor and

reviewer of articles and papers on consumer behavior and advertising research for journal publication and presentation before various professional organizations (Ross, Tr. 1815). Additionally, Dr. Ross has presented papers before professional organizations in the areas of his expertise; his articles, studies, and other writings have been published in journals subject to peer review and other publications (Ross, Tr. 1816–19; CX 502). [14]

23. Dr. Peter Rossi, Professor of Sociology at the University of Massachusetts and Director of the Social and Demographic Research Institute at the University, has specialized in the design, conduct and analysis of sample surveys on matters of public interest throughout his career. His various academic and research positions have involved the supervision of researchers in the design and implementation of research (Rossi, Tr. 1557–59, 1565). Dr. Rossi is or has been an editor of various scholarly journals and monographs in his field of expertise (Rossi, Tr. 9560–61). He has published books and articles which are predominantly based on data gathered in sample surveys (Rossi, Tr. 1561–63A). Dr. Rossi has been consultant to marketing research organizations and has received grants to conduct research from the Ford, Carnegie and Russell Sage Foundations. He has received awards in the field of social science research and has been elected a Fellow in the American Association for the Advancement of Science (Rossi, Tr. 1568, 1561A; CX 503).

24. Dr. Subrata K. Sen is an Associate Professor of Marketing at the University of Rochester Business School. His primary research and teaching interests include marketing research and marketing models, the effects of advertising, product policy and behavior with particular emphasis on consumers' brand choice processes. Dr. Sen has done extensive research and writing concerning the analysis of panel data for the purposes of studying consumer behavior and has done substantial work on the question of the interrelationship of images, attitudes and consumer behavior. He has served as an editor or reviewer for most of the learned journals dealing with consumer research and consumer behavior (Sen, Tr. 7148–57; RX 16).

25. Dr. Joseph Smith has had extensive training and experience in the fields of marketing, experimental and consumer psychology with particular emphasis on the learning process, interpreting advertising and the duration of advertising's impact on consumer behavior (Smith, Tr. 5502–07, 5515–17; RX 17 (Rev.)). In 1956, Dr. Smith and another psychologist founded Oxtoby-Smith, Inc., a consumer research and consulting firm. The company is staffed by approximately 20 professional psychologists and marketing researchers with about 40 support personnel. Oxtoby-Smith, Inc.

conducts nearly 200 surveys a year; about one-half of these are related directly to advertising (Smith, Tr. 5497–5501, 5523). In a substantial number of these studies, Dr. Smith is actively engaged in the design of the study and/or the analysis of the data obtained (Smith, Tr. 5523–25). In a [15]consulting capacity, he is often called on to render expert opinion in lieu of a consumer survey, particularly in the area of consumer reactions to advertisements (Smith, Tr. 5500). Dr. Smith and his organization have conducted two substantial studies of consumer views and attitudes concerning the analgesics market, the first in 1967 and the second in 1970 (Smith, Tr. 5502; CX 451 and CX 452; RX 17(Rev.)).

B. *Medical Witnesses*

26. On the issues related to medical and scientific substantiation of the claims made in the advertisements and the medical aspects of the need for ingredient disclosure, complaint counsel called Drs. Azarnoff, DeKornfeld, Farr, Forrest, Grossman, Moertel, Plotz, Rickels, Sliwinski and Stevenson; American Home called Drs. Falliers, Kantor, Lasagna, McMahon, Okun and Shapiro, and Mr. Wallenstein.

27. Dr. Daniel L. Azarnoff, Distinguished Professor of Medicine and Pharmacology at Kansas University Medical Center and Director of the University's Clinical Pharmacology-Toxicology Center, is an eminent clinical pharmacologist with recognized expertise in the clinical testing and use of drugs, including analgesics (Azarnoff, Tr. 577, 593, 597, 598–99; CX 519A). He has received a number of honorary awards for his outstanding work in medicine and pharmacology including election as a Markle Scholar in Academic Medicine, election as a Burroughs Wellcome Scholar in Academic Medicine, election as a Burroughs Wellcome Scholar in Clinical Pharmacology and designation as a Fullbright Scholar (Azarnoff, Tr. 585–86; CX 519B). He has served as a consultant to the FDA as a member of the Endocrine Metabolism Advisory Committee. In this capacity, he reviewed foreign therapeutic trials of various drugs with regard to the evaluation of the safety of these drugs. He has also served as a consultant to the World Health Organization for the evaluation of drugs in human beings, and is currently serving as Secretary of the Clinical Pharmacology Section of the International Union of Pharmacologists (Azarnoff, Tr. 584–85, 587–91; CX 519C). In addition to extensive teaching commitments, he has also been involved in research activities and clinical hospital service. His research has involved him in approximately 150 studies, 10 to 15 of which focused on the therapeutic effects of various drugs on human beings

(Azarnoff, Tr. 578–79, 582, 594). Dr. Azarnoff's clinical research has given him a considerable background in the measurement of patients' subjective responses. In each of the 10 to 15 therapeutical [16]studies in which he has participated, he has been involved in all phases of the study, ranging from the initial development of the protocol through the implementation of the study, and then on through the analysis of the data (Azarnoff, Tr. 581–82). Dr. Azarnoff is also an editor of or advisor to several noted journals (Azarnoff, Tr. 589–90; CX 519C).

28. Dr. Thomas J. DeKornfeld, Professor of Anesthesiology at the University of Michigan Medical School, is one of the foremost authorities on analgesic testing. His involvement in the clinical testing of analgesics dates back to the late 1950's, when he began working with Dr. Louis Lasagna (DeKornfeld, Tr. 2762–63). Since that time, he has conducted between 30 and 40 clinical studies on a variety of drugs; the majority of these studies were conducted with analgesics, both OTC and prescription products (DeKornfeld, Tr. 2765–66; CX 512E). In his clinical practice, Dr. DeKornfeld has dealt extensively with the use of analgesics on patients experiencing pain (DeKornfeld, Tr. 2772–73). Dr. DeKornfeld has also held positions which have required him to exercise considerable responsibility in evaluating the designs and methodologies of clinical tests performed by other researchers. For example, he was the Director of Therapeutic Research for Parke, Davis and Company, a major pharmaceutical corporation, where he was charged with supervising all of the company's clinical research activities which were performed in the United States and Canada (DeKornfeld, Tr. 2763–65, 2769; CX 512A). Dr. DeKornfeld has been serving as Secretary to the University of Michigan Medical School's Committee to Review Grants for Clinical Research and Investigation Involving Human Beings for the last 12 years. Along with other committee members, he evaluates the design and safety of approximately 600 annual grant proposals for experiments dealing with human subjects that are to be conducted under the auspices of the University's Medical School (DeKornfeld, Tr. 2768–69; CX 512C). He is also a member of the Consulting Board to the United States Veterans Administration Cooperative Analgesic Study (DeKornfeld, Tr. 2768). Dr. DeKornfeld has published many articles in respected medical journals involving analgesics and analgesic testing (CX 512D-H).

29. Dr. Constantine J. Falliers is an expert in the field of allergies, including the relationship between aspirin and asthma. After practicing medicine for two years following his residencies, Dr. Falliers received a two-year fellowship in pediatric allergy and

clinical research at Jewish National Home for Asthmatic Children and Children's Asthma Research Institute & Hospital (CARIH) [17] in Denver, Colorado. He was appointed Director of Clinical Services at CARIH in 1959, Medical Director in 1963 and Chief of the Clinical Research Division in 1969. Dr. Falliers has served on the faculty of the University of Colorado Medical Center since 1961. He serves also as an Attending Allergist at Children's Hospital, St. Joseph Hospital and Research Center in Denver. He is board certified as a Diplomate of the American Board of Pediatrics with subspecialty certification in Pediatric Allergy. In addition to publishing nearly 100 articles and books, Dr. Falliers has received numerous research grants from the United States Public Health Service and private foundations. He has served also as the Chairman of the Psychosomatic Section and of the Rehabilitation Therapy Committee, Research Council of the American College of Allergists. In 1970, he served as Consultant to the Bronchiopulmonary Section of the Integrated Research Program on Chronobiology, International Biological Program of the United States Public Health Service. Dr. Falliers has served as a member of the editorial board of the *Annals of Allergy*. In addition to his present teaching duties at the University of Colorado Medical Center, Dr. Falliers is director of an allergy and asthma clinic in Denver (Falliers, Tr. 3169–87; RX 19).

30. Dr. Richard S. Farr, Chairman of the Department of Medicine of the National Jewish Hospital in Denver, is a recognized teacher and researcher in immunology. He has had extensive training and experience in the diagnosis, management and clinical testing of bronchial asthma and allergy, including the asthma and allergic effects attributable to aspirin. He previously headed the allergy/immunology sections at the University of Pittsburgh and the Scripps Clinic in La Jolla, California, and is also known for the development of the so-called Farr test which is still widely used in immunology research. Dr. Farr has been deeply involved in the clinical study of aspirin side effects since 1969 and is responsible for the development of the aspirin challenge procedure originating at National Jewish Hospital. His publications in this area have appeared in respected journals. Dr. Farr has served as the president of the American Academy of Allergy and has been connected with other professional associations that complement his work in asthma and allergy. Dr. Farr is also a Distinguished Service Professor of the University of Chicago and the recipient of the Borden Award for his outstanding work in the area of immunology (Farr, Tr. 2541–62).

31. Dr. William H. Forrest is an Associate Professor of Anesthesiology at Stanford University. He is a recognized expert in the field of

analgesic testing who has had extensive [18]experience evaluating analgesics; indeed, he has spent half of his time supervising, performing or evaluating clinical research on analgesics (Forrest, Tr. 408). Dr. Forrest has spent much time working with and developing subjective response methodologies. His introduction to clinical research came while he was a research fellow at Stanford in 1962. During that year, he worked under Dr. J.W. Belville, a respected researcher in the field of analgesic evaluations and Chairman of the FDA Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Products ("FDA OTC Internal Analgesics Panel"). Dr. Forrest later became Chairman of the Veteran's Administration Cooperative Analgesic Study. In the Cooperative Study, individual analgesics were evaluated through use of a subjective response methodology in five to seven Veterans Administration hospitals located throughout the country. The results of the Cooperative Study demonstrated that carefully trained and supervised nurses and researchers could perform the same work in several different settings and obtain sound data relating to the efficacy and relative potency of a variety of intramuscular and orally administered analgesics. The Cooperative Study spanned a 14–year period and involved over 100 clinical analgesic studies (Forrest, Tr. 419–23; CX 510A-B). During the last 14 years, Dr. Forrest has been actively involved in various capacities with the National Research Council of the National Academy of Sciences ("NAS/NRC"). He was involved in the 1960's in the planning phases of the National Halothane Study which was sponsored by the Council; he has acted as a consultant to the Council on anesthesia; and he has been invited to attend annual meetings sponsored by the Council for researchers working in the field of analgesics. At these meetings, Dr. Forrest has presented numerous papers on his own work (Forrest, Tr. 417, 434–35; CX 510B). In addition, he has published over 60 articles dealing with analgesics, clinical testing and the subjective response methodology (CX 510D-I).

32. Dr. Morton Grossman, Chief of the Gastroenterology Section of the Veterans Administration Wadsworth Hospital in Los Angeles, is recognized as a preeminent researcher and practitioner of gastroenterology. Dr. Grossman, who currently directs the Center for Ulcer Research and Education in Los Angeles, is one of only six people in the country to hold the title of Senior Medical Investigator in the Veterans Administration. He is also a professor of medicine and physiology at the University of California at Los Angeles, has taught at major medical schools throughout the country and has served as a member of or advisor to many distinguished professional

groups, including the National Academy of Science, National Research Panel on Gastrointestinal Drugs, the FDA's OTC Panel on Antacids and the Gastrointestinal Drug Advisory [19]Committee of the FDA. Dr. Grossman's experience includes years of clinical practice with patients suffering gastrointestinal diseases, as well as considerable research in the areas of physiology and gastroenterology. He has done research on the mechanism and effects of aspirin ingestion on the gastrointestinal tract and has published many articles on this topic which appear in the literature. He has also served on various editorial boards of scientific journals and currently chairs the editorial board of *Gastroenterology*, the official journal of the American Gastroenterological Association. Dr. Grossman has published over 345 articles and has contributed to scores of text books and other resource works on gastroenterology. Dr. Grossman has been the recipient of major awards and honors in his field, including the Freeden-Wald medal of the American Gastroenterological Association, which is its highest award. He has also held high offices with many of the professional societies concerned with problems of gastroenterology (Grossman, Tr. 814–23; CX 516).

33. Dr. Thomas Kantor, a clinical pharmacologist and rheumatologist at New York University, has conducted approximately 75 clinical investigations on drugs, many of which involved the testing of graded doses of aspirin. Following his medical school and post-medical school training, he became board certified in 1955 as a Diplomate of the American Board of Internal Medicine. In 1960, Dr. Kantor was appointed Assistant Professor of Medicine and Chairman of the Section of Clinical Pharmacology of the Department of Medicine at New York University. He was appointed Professor of Clinical Medicine in 1972 and is currently the Chairman of the Clinical Pharmacology Section of New York University's School of Medicine. Dr. Kantor also serves as attending physician at Bellevue Hospital, Veterans Administration Hospital, University Hospital and Goldwater Memorial Hospital, all in New York City. In addition to his teaching, clinical research and practice, Dr. Kantor has published extensively on many aspects of the evaluation of drugs and analgesic testing. He served as a member of the NAS/NRC Analgesic Drug Efficacy Panel, which was chaired by Dr. Louis Lasagna. From 1971 to 1972, he served as consultant to the Bureau of Drugs of the FDA, and from 1971 to 1974 served as Chairman of the Section of Rheumatology of the American Society for Clinical Pharmacology and Therapeutics. In 1973, Dr. Kantor was appointed Chairman of the FDA's OTC Topical Analgesic Drug Review Panel, a position he still holds (Kantor, Tr. 3534–54; RX 23). [20]

34. Dr. Louis Lasagna, Chairman of the Department and Professor of Pharmacology and Toxicology and Medicine at the University of Rochester School of Medicine, is a leading authority on analgesia and the testing of analgesic drugs. Following his medical school and post-medical school training, Dr. Lasagna took a post-doctoral fellowship in 1950 in the Department of Pharmacology and Experimental Therapeutics at the School of Medicine at Johns Hopkins University. He retained an academic appointment there until 1970, except for a teaching and research position at Massachusetts General Hospital, Boston University and Harvard University, where he studied under and worked with the late Dr. Henry Beecher, pioneering researcher and preeminent analgesic authority. During the time that Drs. Lasagna and Beecher worked together, they were engaged in developing the methodology for evaluating subjective responses to drugs, and they conducted evaluations of numerous analgesic drugs, including aspirin. The results of their research led to the development of a methodology for performing clinical evaluations and comparisons of drugs which is characterized by subjective responses. This research resulted in the publication of a number of joint and individual works by Dr. Lasagna and Dr. Beecher on the subject of the testing and evaluation of analgesic drugs. For 16 years, Dr. Lasagna served as Director of the Division of Clinical Pharmacology at Johns Hopkins Medical School. In 1970, Dr. Lasagna was appointed Professor of Medicine, Pharmacology and Toxicology and Chairman of the Department at the University of Rochester School of Medicine, where he teaches courses in therapeutics and pharmacology. In addition to approximately 300 published articles, Dr. Lasagna has had an extensive career in testing and evaluating drugs and is considered by his peers as one of the foremost clinical pharmacologists in the evaluation of analgesic drugs. He has served as a consultant to the National Cancer Institute, National Institute of Mental Health, American Rheumatism Association, National Institute of General Medical Sciences, National Heart Institute and American Society for Clinical Pharmacology and Therapeutics. He has also served on the editorial board of several respected journals. He received the Modern Medicine Award of 1972 for his contribution to the evaluation of drugs; the Oscar B. Hunter Award given by the American Society for Pharmacology and Experimental Therapeutics for his significant contribution to therapeutics; and the American Society for Pharmacology and Experimental Therapeutics Award for his contributions to experimental therapeutics. Dr. Lasagna was selected as Chairman of the NAS/NRC Analgesic Drug Efficacy Study which was sponsored by

and under contract with the FDA. The NAS/NRC Panel reviewed prescription and some OTC analgesics marketed between 1938 and 1962 to determine their efficacy [21]and safety. In 1962, he was commissioned by the Federal Trade Commission to perform a controlled clinical study comparing the effectiveness of five leading OTC analgesics (Lasagna, Tr. 4020–43; RX 6; Forrest, Tr. 506–08; Azarnoff, Tr. 635–37; Lewis, Tr. 782).

35. Dr. Gilbert McMahon, Professor of Medicine and Chairman of the Therapeutics Section of the Department of Medicine at Tulane University School of Medicine, presently serves as President-elect of the American Society of Clinical Pharmacology and Therapeutics and Vice-President of the International Society of Clinical Pharmacology. He is an expert in the field of pharmacology. In 1968, he was appointed Chairman of the Therapeutics Section, Department of Medicine at Tulane University and also Senior Visiting Physician at Charity Hospital in New Orleans. In addition to his academic appointments, Dr. McMahon has held various other positions such as Director of Clinical Research for the Upjohn Company from 1960–1964, Vice-President in charge of Medical Research for the Ciba Pharmaceutical Company from 1964–1967 and Executive Director in charge of Clinical Research for Merck, Sharp and Dohme from 1967–1968. In addition to his extensive teaching and research work, he has served as either an editor or manuscript reviewer for the New England Journal of Medicine, American Journal of Medicine, American Heart Journal, Journal of Clinical Investigation and the Journal of Laboratory and Clinical Medicine. Dr. McMahon is also Chairman of the Drug Regulatory Committee of the American Society for Clinical Pharmacology and Therapeutics, Chairman of the Pharmacy and Therapeutics Committee of Tulane University Hospital and Clinic, and Chairman of Charity Hospital's Human Research Committee. Among over 100 articles or books written by Dr. McMahon is the 15–volume treatise, *Principles and Techniques of Human Research and Therapeutics*, for which he served as senior editor (McMahon, Tr. 3668–99; RX 11).

36. Dr. Charles G. Moertel is Director of the Mayo Clinic's Comprehensive Cancer Center, Chairman of its Department of Oncology and Professor of Medicine at the Mayo Medical School. He is an expert in the clinical testing of drugs and in evaluating patients' subjective responses to analgesics (Moertel, Tr. 914; CX 511A). At the Mayo Clinic, Dr. Moertel is involved in the evaluation of therapeutic agents with respect to all of the Clinic's treatment programs designed to deal with malignant diseases starting in the gastrointestinal tract. He has extensive experience in the evaluation

of the symptomatic and supportive care of the cancer patient; this work encompasses the evaluation of analgesic, anti-emetic and diuretic agents [22](Moertel, Tr. 923–25). Since a predominant part of Dr. Moertel's practice was to treat advanced cancer patients, who could no longer be helped by surgery but who suffered from mild to severe pain, Dr. Moertel developed an interest in the comparative efficacies of the available analgesics. He conducted two studies involving numerous OTC and prescription oral analgesics to determine their comparative efficacies in relieving pain. Both of these studies were published in leading medical journals and subjected to peer review (Moertel, Tr. 925–27; CX 511J, N). Dr. Moertel has also evaluated some of the newer agents developed by pharmaceutical companies for analgesic purposes (Moertel, Tr. 927–28). He has conducted a number of clinical studies using anti-emetic and chemotherapeutic drugs (Moertel, Tr. 929–32). In all of these studies, Dr. Moertel has been involved in the analysis and evaluation of patients' subjective responses (Moertel, Tr. 932–33). In addition to contributing articles focusing on specific research studies, Dr. Moertel has also submitted articles for publication dealing with analgesics in the broader context as well as touching on his overall clinical experience in the management of cancer pain. These articles have appeared in several textbooks of which he has been either the primary author or a contributor (Moertel, Tr. 933). Dr. Moertel is a member of the Editorial Board of the *Journal on Cancer*, and an Associate Editor of *Cancer Medicine*, a standard textbook in medical oncology (Moertel, Tr. 918–19). As a practicing physician, Dr. Moertel prescribes, administers and advises patients on a daily basis in the usage of analgesics. In his clinical practice, he has had occasion to prescribe aspirin (Moertel, Tr. 934–35). Dr. Moertel was invited by the FDA to join its Oncologic Drugs Advisory Committee. As a member of this Committee, he advises the FDA on the conducting of clinical protocols of new drugs contemplated for use in the treatment of cancer patients. His broad expertise in the area of clinical testing was further recognized when he was invited to serve as a member of the Phase One Study Group of the National Cancer Institute. In this capacity, he helps to evaluate the types of protocols that will be most appropriate to determine the clinical value of new agents for the treatment of malignant diseases (Moertel, Tr. 918–23; CX 511).

37. Dr. Ronald Okun is Associate Professor of Medicine and Medical Pharmacology and Therapeutics at the University of California (Irvine) School of Medicine and Director of Clinical Pharmacology at Cedars-Sinai Medical Center in Los Angeles,

California. He is an expert in the field of clinical pharmacology. He was the recipient of a post-doctoral fellowship in clinical pharmacology at Johns [23]Hopkins University where he studied, and worked with Dr. Louis Lasagna in the clinical testing of various drugs. Prior to assuming his current academic appointment, Dr. Okun served on the medical school faculty of the University of California in Los Angeles from 1963 to 1970. Dr. Okun has served since 1969 as the Scientific Advisor to the Board of Directors at the Cedars-Sinai Medical Center. In addition to extensive experience conducting clinical investigations on drugs, approximately 75 to 100 in number with about 25 involving aspirin, he has also served in a consulting role in the design of over 100 clinical investigations. Many of his research projects from 1963 to 1976 were done in collaboration with Dr. Henry Elliot, the Chairman of the FDA OTC Internal Analgesics Panel until the time of his death. Dr. Okun served from 1973 to 1975 as President of the American Academy of Clinical Toxicology, and in 1973 was appointed co-director of the National Cooperative Gallstone Study which received the largest grant ever awarded by the Digestive Diseases Section of the National Institutes of Health. Throughout his professional career, he has published widely in the field of pharmacology and has served as an Editor of the Annual Review of Pharmacology (Okun, Tr. 4279–4301; RX 13).

38. Dr. Paul H. Plotz is a senior investigator of the Arthritis and Rheumatism Branch of the Institute of Arthritis, Metabolism and Digestive Diseases of the National Institutes of Health ("NIH"). He is a member of the Arthritis Advisory Committee of the FDA and head of the Subcommittee on the Study of Long Acting Drugs. Dr. Plotz has lectured, consulted and written on topics related to rheumatologic diseases. He has done extensive research on the basic mechanisms of rheumatologic diseases, much of which has involved the study of aspirin and aspirin-containing drugs. Several of these studies have been published. Dr. Plotz also has experience in the clinical testing of drugs in humans and has long been active in the review of clinical tests conducted by others. He maintains a clinical practice involving many referral patients at NIH and has acted as attending physician at two local Washington, D.C. hospitals. The majority of Dr. Plotz's patients suffer from rheumatologic diseases and are treated primarily with aspirin and aspirin-containing products. Dr. Plotz is a member of various scientific and medical associations that complement his expertise in rheumatologic diseases and their treatment (Plotz, Tr. 1034–43; CX 523).

39. Dr. Karl Rickels, Professor of Psychiatry and Pharmacology at the University of Pennsylvania, is an eminent practitioner with

extensive training and experience [24]in the diagnosis and management of patients exhibiting non-psychotic symptoms such as anxiety and tension. He directs the Private Practice Research Group, funded by NIH, which is the only unit in the country conducting research on a large scale with private patients, referred by family physicians, who suffer from tension and stress. Dr. Rickels, Director of the Psychopharmacology Research Unit of the University of Pennsylvania since 1962, was recently appointed to an endowed chair in Human Behavior. He has lectured widely and currently is a member of the Clinical Pharmacology Study Session of the National Institute of Mental Health ("NIMH"). Dr. Rickels has had extensive experience in the design, execution and review of clinical tests of drugs, including aspirin, for tension relief. He has often served as a consultant to industry on the development of protocols for such clinical tests. For three years, Dr. Rickels chaired FDA's OTC Panel on Nighttime Sleep-Aids, Daytime Sedatives and Stimulants, where the role of caffeine was explored. He has many publications on psychopharmacological topics, including the effects of aspirin on tension relief (Rickels, Tr. 1175–92; CX 515).

40. Dr. Howard Shapiro is Clinical Professor of Medicine at the University of California in San Francisco, Director of the Endoscopy Clinic and Co-Director of the Gastrointestinal Diagnostic Center at the University of California in San Francisco. He is board certified in internal medicine with a subspeciality in gastroenterology. He also presently serves as President of the Executive Medical Board of the Medical Staff (Chief of Staff of the Medical School Hospital) at the University of California in San Francisco. Dr. Shapiro is a consultant to the United States Public Health Hospital in San Francisco and is the author of numerous articles in the field of gastroenterology. In addition to his teaching responsibilities at the medical school, which include courses in gastroenterology and post-graduate courses for interns and residents, he also engages in the private practice of medicine, specializing in gastroenterology (Shapiro, Tr. 2916–23; RX 15).

41. Dr. Anthony F. Sliwinski, an Assistant Professor of Medicine at Georgetown University, is a recognized expert on rheumatic diseases. Dr. Sliwinski, who is also a consultant in rheumatic diseases to the Bethesda Naval Hospital and the Malcolm Grow Hospital at Andrews Air Force Base, has had extensive experience in the design and execution of clinical tests of rheumatologic drugs, including aspirin and aspirin-containing drugs. He has collaborated with others in a cooperative program for the clinical testing and evaluation of drugs for the [25]treatment of rheumatoid arthritis.

Dr. Sliwinski has had substantial training and experience in the development and review of clinical testing protocols. He is a member of various scientific societies and associations that complement his specialization in rheumatic diseases and has published on the subject. In addition, Dr. Sliwinski maintains a clinical practice involving 40–50 patients with various rheumatologic diseases (Sliwinski, Tr. 1102–20; CX 522).

42. Dr. Donald D. Stevenson is a member of the allergy/immunology division at the Scripps Clinic in La Jolla, California. Dr. Stevenson, who also has a clinical appointment in the Department of Internal Medicine at the University of California, has extensive training and experience in the clinical diagnosis and management of patients suffering from various allergies and asthmatic conditions, including those associated with aspirin. He has designed and conducted clinical tests of drugs to determine their safety and effectiveness in treating asthmatic and allergic conditions, and has conducted clinical tests utilizing oral challenge procedures in order to determine the asthmatic and allergic effects of aspirin ingestion. Dr. Stevenson has lectured and taught generally on the subject of immunology and specifically on the asthmatic and allergic effects of aspirin ingestion. He has published articles and studies relating to these topics. Dr. Stevenson is associated with various scientific and medical groups, including the American Academy of Allergy and the West Coast Allergy Society, which complement his specialization in asthma and allergy, and has participated in meetings and conferences held by such organizations (Stevenson, JTr. 1454–71).

43. Mr. Stanley Wallenstein has been an analgesic researcher at Memorial Sloan-Kettering Institute for Cancer Research since 1951. He and Dr. Raymond Houde have been engaged in hundreds of clinical trials involving the evaluation of analgesic drugs in postoperative and cancer pain models. He is recognized as an expert biostatistician and analgesic researcher, and has published over 100 articles. He has served as a consultant to the Veterans Administration Analgesic Study and the Federal Trade Commission (Wallenstein, Tr. 3415–23; Lasagna, Tr. 4099–4100; RX 32).

III. The Meaning Of The Challenged Advertisements

A. *Introduction*

44. The primary evidence in this proceeding on the meaning of the challenged advertisements and what they might [26]reasonably

have conveyed to consumers consists of the advertisements themselves.

45. In addition, there is secondary evidence in the form of:

(a) The expert testimony of Drs. Ivan Ross and Joseph Smith;

(b) Certain copy tests on Anacin television commercials, including the 20 ASI Audience Reaction Tests ("ASI tests") with emphasis on the verbatim comments of consumers (CX 402, 404–07, 409, 412, 414, 415 and 417–25);

(c) Certain consumer studies, including the 1969 Excedrin Study (CX 462), on consumer understanding of certain attributes of OTC internal analgesic products, such as effectiveness, strength and speed in relieving pain (CX 462Z112, Z114, Z115, Z143, Z144); and

(d) Certain documents from American Home's files evincing its awareness that certain advertising themes and presentational techniques were effective marketing devices.

46. In reaching his expert opinion as to whether the representations alleged in the Complaint were made in Anacin and APF advertising, and in coming to his conclusions as to whether the challenged advertisements could reasonably have been understood by consumers as making the representations alleged in the Complaint, Dr. Ross testified that, based on [27]his experience with consumers, he adopted their frame of mind which included, indirectly, their background or prior experience (Ross, Tr. 2313–14, 2353–55). He further testified that his judgments as to the representations made in the challenged advertisements for Anacin and APF were his independent expert opinion and were reached without reference to, or reliance upon, data contained in ASI tests or internal memoranda from the files of American Home (Ross, Tr. 1843, 2677). However, he made use of the latter materials as confirmatory evidence supporting his conclusions (Ross, Tr. 1841–43).

47. The mode of analysis utilized by Dr. Smith to determine whether the challenged advertisements made the representations alleged in the Complaint, and whether the challenged representations could reasonably have been understood by consumers as making the representations alleged in the Complaint, included the consumer's perception of a particular claim and the consumer's retention of that claim for some definite period of time (Smith, Tr. 7438–39). Consequently, Dr. Smith relied, in rank order, upon the following factors:

(a) the penetration studies;

(b) his own opinion based on looking at the advertisements and applying his model for interpreting advertising;

(c) the image studies; and

(d) the ASI tests (Smith, Tr. 5785, 7517).

48. Dr. Smith admitted that if one is interested in whether or not a particular advertisement made a particular claim, his reliance in his direct examination upon the evidence set forth above (F. 47, *supra*) would have been inappropriate. When the meaning of particular advertisements must be determined, he agreed that the ASI test data would be the only relevant material available. If he were to address this question, Dr. Smith stated that he would form his opinion based on his model for interpreting advertising, with the ASI data contributing to it. He testified that he would not rely on data in the penetration or image studies because such data do not address the question of whether or not a particular advertisement made a particular claim (Smith, Tr. 7442–49, 7454–58, 7518, 7562).

49. Therefore, in determining whether an advertisement makes a particular representation, the standard that has been used is whether, taken as a whole, the representation [28]constitutes one reasonable interpretation of the advertisement which some consumers might reasonably have understood the advertisement as making. In arriving at such a determination for each representation alleged to have been made in the Complaint, I have relied on my own knowledge and experience in viewing each advertisement, and have further utilized the opinions of the expert witnesses along with the ASI tests as confirmatory evidence of my conclusions.

B. *The ASI Audience Reaction Tests*

50. Among the various kinds of data which are useful in determining the message that consumers take from a particular advertisement are copy tests. Copy tests are typically conducted in a controlled environment on a specific advertisement or advertisements shortly after respondents have been exposed to such advertisement(s). The tests collect data from those surveyed on the content or meaning of such advertisements, generally without the use of a probing technique. The ASI tests conducted on Anacin television commercials were copy tests of those advertisements[3] (Ross, Tr. 2014–15, 2679; Smith, Tr. 7463–64).

[3] Another type of copy test, conducted on respondents who have seen an advertisement in an "at home" setting, is the Burke test. In a Burke test, planned commercials are interspersed throughout normal television programming. Approximately 24 hours after the advertisement has been shown, individuals are contacted by telephone and upon confirming that the respondents were viewing the program when the advertisement was run,

(Continued)

51. The 20 ASI Audience Reaction Tests in the record (See F. 44, *supra*) were conducted by Audience Studies, Inc. ("ASI") for Ted Bates & Company, Anacin's advertising agency at the time, to measure the effectiveness of certain Anacin advertisements. The tests are of standardized design, the purpose of which was to evaluate consumer reactions to advertisements in terms of persuasiveness, involvement and recall (CX 402D). **[29]**

52. Gerald Lukeman, President of ASI, testified for complaint counsel concerning the design and general procedures of ASI testing (Lukeman, Tr. 204). Roger Seltzer testified for complaint counsel concerning the mechanics of conducting the ASI tests. Mr. Seltzer is the Executive Vice-President of ASI and is responsible for conducting the copy tests in ASI's theatre in Los Angeles, California (Seltzer, Tr. 312).

53. ASI's specialty involves research in communications, especially advertising. It has measured the effectiveness of advertising in all of the commonly used media, and it tests audiences' reactions to approximately 1,500 commercials every year. Its clients tend to be manufacturers and advertising agencies (Lukeman, Tr. 206–08).

54. ASI tests are conducted in a theatre in Los Angeles, housing an audience of approximately 350 respondents. The audience for each night is recruited from the Los Angeles metropolitan area, either in person or by telephone, to attend a preview of television programs with no charge or obligation except that they will be asked for their opinions of the programs they see. The tests are run almost every evening, so audiences are recruited on a continuing basis (Seltzer, Tr. 317–19).

55. As the audience enters the theatre, they are given seats, one-half of which contain dials which record the audience's instantaneous reactions to the commercials. Each member of the audience is given a questionnaire folder and, while seating is being completed, he or she is asked to answer questions about various demographic characteristics, television programming preferences, and use and preferences regarding different brands of products. Finally, the respondent is presented a list of products and asked which he or she would prefer to receive as a door prize (Seltzer, Tr. 322–24; CX 402Z027–Z031).

56. After the preliminary questionnaires have been filled out, the respondents are shown a warm-up cartoon. Next, they are shown a regular length television program, then a series of five commercials.

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they are asked to state how much, if anything, they recall about the particular advertisement. In general, only 22% of those contacted even remember seeing a particular commercial. No such copy tests were available in this proceeding (Smith, Tr. 5538–39, 5544–45, 5568–69).

Immediately after each commercial, the audience members fill out their responses to a page of questions about the advertisement (comprehension questions). At the conclusion of the five commercials, the audience views another television program. They fill out a brief questionnaire about the program and are asked to again indicate their preference from a list of products which may be offered as door prizes. They are **[30]**then shown a second cartoon, and are asked to complete a recall document which requests that the respondents write down all that they can remember about the five commercials they have seen (recall question). Thus, the respondents are presented with the recall question approximately 30 to 40 minutes after they have seen the commercials (Seltzer, Tr. 337). The evening is concluded when door prizes are awarded (Seltzer, Tr. 325–27).

57. ASI's audience recruitment procedures were carefully designed to produce a representative sample of the Los Angeles metropolitan area. The desired quota of respondents in each age and sex group are selected from 125 different sampling points in the Los Angeles area. Two selection procedures are used. Some respondents are recruited through personal contacts at high-traffic locations, such as shopping centers, while others are selected by telephone, using a reverse directory. Reverse directories list telephone numbers by street addresses, thereby helping ASI to ensure a geographic balance among the respondents recruited by telephone (Seltzer, Tr. 317–18).

58. Several controls are utilized on the night of the presentation in order to minimize any sampling error that may have arisen in the selection of respondents. Of the 350 viewers in the audience who fill out questionnaires, usually only 250 will be used. This is because certain segments of the population tend to be overrepresented in the theatre audience, and ASI requires that the sample it analyzes approximate the distribution of the Los Angeles population (Seltzer, Tr. 319–20). In addition, a control commercial is shown at the beginning of the set of five commercials. If the audience's answers to the questions asked about the control commercial vary significantly from the norms established by ASI through extensive prior experience with the commercial, then ASI has a good indication that significant sampling error has occurred. If that were to happen, the whole test would be conducted again before a different audience in order to assure ASI that the test results would be reliable (Seltzer, Tr. 325–27).

59. Based on these procedures, the data produced in ASI tests are reasonably representative of the effectiveness of commercials in

communicating messages to the residents of Los Angeles. Audience reaction tests run in other parts of the country by ASI have produced results similar to those obtained in Los Angeles (Seltzer, Tr. 321). [31]

60. ASI maintains an experienced and qualified department to assign numerical codes for keypunching and tabulating the audiences' verbatim responses in the recall document administered at the end of the testing session. Recall coding outlines are carefully devised based upon an examination of the responses submitted by at least one-half of the sample (Seltzer, Tr. 345–47).

61. Keypunching and tabulations are performed by ASI's own computer staff. The computer printouts of the data are verified for accuracy by the operator, the project director and the editing department. After tabulations are delivered to the project director, he performs the analysis of the responses and prepares the final report. In the Anacin copy tests, the tabulations of both the coded and the analyzed responses, along with the verbatim responses themselves, are available (See, *e.g.*, CX 402 O-R, Z021–Z026).

62. The technique used by ASI (a combination of comprehension and recall questions) does not elicit an exhaustive playback from respondents regarding all of the things that they might have perceived a tested advertisement as saying, showing or meaning (Ross, Tr. 1843–44, 2677–78).

63. The absence of verbatim comments indicating that respondents understood a tested Anacin advertisement as making an alleged representation does not, however, preclude the possibility that such representation was made or was understood by consumers as being made in that advertisement. A calculation of the absolute number of verbatim comments indicating that respondents understood a particular Anacin advertisement as making a certain representation is not sufficient, in and of itself, to prove (or disprove) whether such representation was made or was understood by consumers as being made in that advertisement (Seltzer, Tr. 363–68; Ross, Tr. 1844, 2677–78).

64. While complaint counsel's witnesses, Mr. Seltzer and Mr. Lukeman, testified that a minimum response rate of 7% to 10% for a particular claim or theme is required before they would conclude that a given advertisement communicated any message, they agreed that one must look at all of the surrounding circumstances (*i.e.*, the advertisement tested, the particular verbatim comments involved) before concluding that an intended message in a particular advertisement was not communicated (Lukeman, Tr. 237–38, 241–44, 247–48; Seltzer, Tr. 361–68). [32]

65. Of the 20 ASI tests in the record (F. 44, *supra*), 18 were conducted on advertisements which are either also in the record or were so similar to advertisements in the record that any differences are inconsequential (CX 402, 404, 406, 407, 409–12, 414, 415 and 418–25. See also Ross, Tr. 1850, 1859, 1867–68, 1876–77, 1879–80, 1882, 1884–85, 1889–90, 1893, 1897–98, 1901, 1906, 1920, 1923, 1924–25, 1930–31, 1952, 1954–58, 1970, 1978–79, 1989–90, 1993, 1995, 2002). Of the two remaining test reports, CX 405 concerned a tested advertisement which is sufficiently similar to CX 7 that evidence on consumers' understanding of the tested advertisement is relevant to the issue of how consumers would have understood CX 7 (Ross, Tr. 1980–81, 1984–87). Although CX 417 reports the results of a test on an advertisement which is not in the record, it contains evidence on how consumers would have understood a representation that Anacin had been proven as effective for the treatment or relief of headache pain as the leading prescription analgesic product (Ross, Tr. 1938–41).

C. *The Specific Allegations Relating To Anacin Advertising*

1. *Complaint Paragraphs 8(A)(1) and (3)*

66. American Home has represented that Anacin contains more pain-dulling ingredients per tablet than any other non-prescription internal analgesic product on the market (Comp. ¶ 8(A)(1)) and more than twice as much of its analgesic ingredient as any other analgesic product on the market (Comp. ¶ 8(A)(3)). These representations were made in the following Anacin advertisements: (a) CX 1, 5, 9, 10, 13–15, 20–23, 25, 38–40, 50–54, 56–61, 89–90, 92–97, 99–100, 102–07, 115–17, 119, 121–24, 142–44, 146–56, 160–64, 166, 169–73 and 181–85 made the representation contained in Paragraph 8(A)(1); and (b) CX 9, 10, 21–23 and 160–64 made the representation contained in Paragraph 8(A)(3).

67. The fact that Anacin advertisements made these representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 66, *supra*; Ross, Tr. 1849–50, 1852–55, 1865, 1868–72, 1874–79). Confirmatory evidence is contained in reports of the following ASI Audience Reaction Tests: (a) CX 404, 407, 409, 414, 415, 420 and 425 for the representation contained in Paragraph 8(A)(1); and (b) CX 407 and CX 415 for the representation contained in Paragraph 8(A)(3) (Ross, Tr. 1850, 1858–59, 1861–64, 1867–68, 1875–77). **[33]**

68. These representations were made through a variety of express and implied statements comparing the quantity of analgesic

in Anacin with the quantity of analgesic in various other non-prescription internal analgesic products.

69. In certain of the challenged advertisements, Anacin is represented as superior to all other leading headache tablets. For example:

(a) Of all the drugs to choose from, doctors most often recommend one pain-relieving ingredient. And Anacin has more of it than any leading headache tablet. (CX 13A and CX 14A).

(b) Anacin Tablets have more of the one strong pain reliever doctors specify most. More than any other leading headache tablet. (CX 20A. See also CX 25A, 39A, 40A and CX 142 through CX 144 for similar language).

(c) STRONGEST IN THE PAIN RELIEVER DOCTORS RECOMMEND MOST. Anacin contains more of this fast-acting pain reliever than any leading headache tablet. Anacin is strongest in the pain relieving medication doctors recommend most. That's why an Anacin tablet gives you extra power to relieve headache pain. (CX 153).

70. In certain of the challenged advertisements, Anacin is represented as superior to aspirin, buffered aspirin and other extra-strength products. For example:

(a) 2 Anacin Tablets have more of the one pain reliever doctors recommend most than 4 of the other leading extra strength tablets . . . . 2 Anacin contain more of this specific pain reliever than 4 of the others. (CX 21A and CX 22A. See also CX 1A, 9A and 163 for similar language).

(b) With all the pain relievers in the world to choose from, doctors most often recommend one specific ingredient for [34]headaches. Two Anacin Tablets have more of this ingredient than four of the other leading extra strength tablets. (CX 23A and CX 164).

(c) [T]wice as much of the strong pain reliever doctors recommend most as the other leading extra strength tablet. (CX 89, 90, 92, 93 and 95).

(d) . . . Anacin gives you 100% more of this pain reliever than the other leading extra strength tablet. (CX 115 through CX 117. See also CX 119 and CX 121 through CX 124 for similar language).

(e) Anacin's fortified formula has more of this specific pain reliever than any other leading headache tablet. In fact, Anacin is formulated twice as strong in the amount of this specific pain reliever as the other leading extra-strength tablet. (CX 170 and CX 171).

(f) EXTRA POWER . . . Anacin contains the pain reliever doctors recommend most. And Anacin gives you more of this pain reliever than an aspirin, buffered aspirin or the "so-called" extra-strength tablet . . . . See if Anacin tablets do not work better for you. CONTAINS WHAT 2 OUT OF 3 DOCTORS CALL THE GREATEST PAIN FIGHTER EVER DISCOVERED. (CX 152).

(g) [P]lain aspirin tablets even with buffering added have this much pain reliever. Anacin tablets go further and add an extra slice. All this extra pain reliever in every Anacin Tablet. (CX 30A).

(h) Doctors know Anacin contains more of the specific medication they recommend most for pain than the leading aspirin, buffered aspirin, or extra-strength tablets. (CX 105 and CX 107. See also CX 106 for similar language).

(i) [A]ll three leading pain relievers [aspirin, buffered aspirin and Anacin superimposed as part of a graph] reach [35]an effective level in your bloodstream in

minutes. But in the final analysis the highest level is reached by Anacin. This higher level is the extra pain reliever Anacin provides. (CX 50A through 53A).

71. Challenged advertisements such as those cited (F. 66(a), *supra*) made the representation alleged in Paragraph 8(A)(1) because consumers would have understood them as representing that, whatever the composition of Anacin's pain reliever was (*i.e.*, whatever the chemistry of its pain-dulling or relieving ingredient(s) was), Anacin contained a greater amount of pain reliever than that contained in any other non-presciption internal analgesic product (Ross, Tr. 1851). Thus, consumers would have understood a claim regarding the greater quantity of pain reliever to mean more of what relieves pain, regardless of whether it consists of one ingredient or several.

72. Certain of the challenged advertisements (F. 66(b), *supra*) also made the representation alleged in Paragraph 8(A) (3), which is a more extreme version of the representation alleged in Paragraph 8(A)(1), because, if consumers understood an advertisement as representing that Anacin contained more than twice as much of its analgesic ingredient, then they would also have understood it as representing that Anacin contained more pain reliever per tablet than any other non-prescription internal analgesic product (Ross, Tr. 1852, 1875).

73. The representation alleged in Paragraph 8(A)(1) was made in a variety of ways in the challenged Anacin advertisements (Ross, Tr. 1868–69). Among the statements and techniques used are the types of comparative superiority representations for which examples have been given (F. 69 and 70, *supra*).

74. The challenged advertisements comparing Anacin with other leading analgesic products would have been understood by consumers as representing that Anacin was superior in the quantity of pain reliever it contained to the products which otherwise are the best in the non-prescription internal analgesic product category (Ross, Tr. 1870).

75. Dr. Smith, respondents' expert, agreed that, based on his model for interpreting advertising, some not insignificant number of consumers could have understood advertising comparing Anacin with other leading headache tablets to be a comparison with the best products in the product class or to **[36]**include all of the major products in the product class. He admitted that an everyday principle of our lives as consumers is that if you are better than the best, you are necessarily better than everything else (Smith, Tr. 7505–07, 7516).

76. The challenged advertisements comparing Anacin with aspi-

rin, buffered aspirin and the other extra-strength product would have been understood by consumers as a comparison with all other non-prescription internal analgesic products on the market and, therefore, as representing that Anacin contained more pain-dulling ingredients or pain reliever per tablet than any other non-prescription internal analgesic product on the market (Ross, Tr. 1854, 1872). Anacin's main competitors in the non-prescription internal analgesic market have been Bayer Aspirin, Bufferin, Excedrin, and variations thereof (and, after the complaint in this proceeding was issued, Tylenol) (CX 611Z146).

77. Dr. Smith admitted that all of the major products in the non-prescription internal analgesic product class fell into one of these three categories (*i.e.*, aspirin, buffered aspirin or extra-strength) when at least some of the challenged advertising was disseminated. He agreed that, based on his model for interpreting advertising, some not insignificant number of consumers could have considered these enumerated categories as representing an exhaustive list of all of the types of products in this product class (Smith, Tr. 7503–05).

78. The challenged advertisements comparing Anacin with the other extra-strength product or the other leading extra-strength product, *i.e.*, Excedrin (Smith, Tr. 7503), would have been understood by consumers as representing that Anacin contained more pain-dulling ingredients or pain reliever than any other non-prescription internal analgesic product on the market (Ross, Tr. 1854–55, 1859–63, 1865 1868).

79. As previously noted (F. 75, *supra*), superiority over the recognized best in the product category in a particular respect implies superiority over the entire category. Therefore, where the challenged advertising represented that Anacin had more than twice as much pain reliever, as opposed to merely having more or twice as much, the representation alleged in Paragraph 8(A)(3) was made (Ross, Tr. 1875–79). **[37]**

80. The challenged advertisements which represented that Anacin contained more, or more than twice as much, of the pain reliever doctors recommend most than other products would have been understood by consumers as representing that Anacin contained more, or more than twice as much, total pain reliever than other products, *i.e.*, more of whatever it is in such products that relieves pain. Thus, consumers would not pause to think about whether Anacin had more of one ingredient as opposed to having more pain reliever overall (Ross, Tr. 1854–55, 1878–79).

81. This understanding is confirmed by documentary evidence provided by the verbatim comments in ASI Audience Reaction Tests

on Anacin advertisements, where respondents rarely distinguished between more ingredients and more of a particular ingredient (See, *e.g.*, CX 409 and CX 415; Ross, Tr. 1859–63, 1867–68, 1876–77).

82. Dr. Smith conceded that it is difficult to draw such a distinction and, therefore, that consumers might view advertisements such as CX 1 as representing that Anacin contained more pain reliever, whether that pain reliever is a single ingredient or a group of ingredients (Smith, Tr. 7502–03, 7521). Based on his model for interpreting advertising, he testified that advertisements such as this might communicate to consumers that Anacin has more of whatever is necessary to relieve pain than aspirin, buffered aspirin and Excedrin, the other extra-strength product, or more than twice as much pain reliever as Excedrin in the case of advertisements such as CX 9 (Smith, Tr. 7496–97, 7503, 7508–09).

83. In addition to perceiving the representations alleged in Paragraphs 8(A)(1) and (3), consumers would have understood advertising representations that Anacin contained more pain relieving ingredients, or pain reliever, than other products as representing that Anacin was stronger and provided more pain relief than other products (Ross, Tr. 1854, 1855–58, 1862–64). Indeed, American Home itself regarded representations about Anacin's greater quantity of pain reliever as representations of superior strength and more pain relief (CX 306B and CX 327; DeMott, Tr. 4743–44, 4747–48).

84. Dr. Smith testified that, based on his model for interpreting advertising, some consumers might have understood CX 23 to mean that Anacin was stronger than at least Excedrin because it had more of the best pain reliever (Smith, Tr. 7566–67, 7570–71). [38]

2. *Complaint Paragraph 8(A)(2)*

85. American Home has represented that Anacin's analgesic ingredient is unusual, special, and stronger than aspirin (Comp. ¶ 8(A)(2)). This representation was made in the following Anacin advertisements: CX 1, 5, 26, 28, 41–45, 47–49, 59–60, 62–63, 65, 81–84, 89, 93–94, 115–17, 119, 121–24, 142–44, 146–48, 151, 154–56, 169–73 and 176 through 178.

86. The fact that Anacin advertisements made this representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 85, *supra*; Ross, Tr. 1872, 1879–82, 1889, 1892–96). Confirmatory evidence is contained in reports of the following ASI Audience Reaction Tests: CX 404, 421 and 422 (Ross, Tr. 1879, 1882, 1889–90, 1893.

87. This representation was made through a variety of express

and implied statements conveying that Anacin was qualitatively different from and better than aspirin, and that it either contained no aspirin or it contained some additional pain relieving ingredient which made it a better formulation for pain relief than aspirin.

88. In certain of the challenged advertisements, Anacin is specifically contrasted with aspirin. For example:

(a) Anacin starts with as much pain reliever as the leading aspirin tablet. Then adds an extra core of this specific fast acting ingredient against pain. (CX 41A through CX 45A).

(b) Of the 3 leading pain relievers, only Anacin has this special combination of ingredients that relieves pain fast, also its tension, irritability and depression. (CX 151).

(c) [W]hile ordinary aspirin, buffered aspirin and Anacin start with the same amount of pain reliever, Adult Strength Anacin adds 23% more . . . . [T]hen Anacin adds an extra ingredient not found in the others. (CX 63. See also, CX 59, 60 and 65).

89. In certain of the challenged advertisements Anacin is described as a different, distinctive, or unique product. For example: **[39]**

(a) An exceptional formula . . . . (CX 26A and CX 28A).

(b) An adult strength pain reliever. Not even recommended for young children. (CX 62).

(c) . . . special fortified formula . . . . (CX 89, 93, 94, 142–44 and 156).

(d) [A] special fortified combination of ingredients and only Anacin has this formula. (CX 115 through CX 117. See also, CX 142 through CX 144).

(e) Anacin Tablets are so effective because they are like a doctor's prescription. That is a combination of ingredients. Anacin contains the pain reliever most recommended by doctors plus an extra active ingredient not found in leading or buffered aspirin . . . . The big difference in Anacin makes a big difference in the way you feel. (CX 151).

(f) Only Anacin has this fortified combination of ingredients . . . . (CX 154 through CX 156).

90. Challenged advertisements such as those cited (F. 85, *supra*) made the representation alleged in Paragraph 8(A)(2) because consumers would have understood them as representing that Anacin was qualitatively different from aspirin; that is, either it contained no aspirin or, in addition to aspirin, it contained a non-aspirin component which was of fundamental importance to Anacin's effectiveness as a pain reliever when compared with aspirin (Ross, Tr. 1880–82, 1889, 1894–96).

91. The representation alleged in Paragraph 8(A)(2) was made in a variety of ways in the challenged Anacin advertising (Ross, Tr. 1892, 1896). Among the statements and techniques used are those for which examples have been given (F. 88 and 89, *supra*).

92. Whenever there is a reference to aspirin in the challenged

advertisements that made the representation in Paragraph 8(A)(2), it is by way of comparing Anacin to aspirin (Ross, Tr. 1880, 1882, 1896). The thrust of these advertisements is to differentiate Anacin from aspirin (Smith, Tr. 7550–51). [40]

93. Indeed, respondents' witness, George DeMott, the individual at Whitehall who bore continuous responsibility for Anacin and APF since 1968, testified that Anacin's basic ingredient was described as something other than aspirin so as to make claims in Anacin advertising distinguishable from claims in Bayer Aspirin advertising (DeMott, Tr. 4657–59).

94. Where such advertising represented that, for example, Anacin contained an "extra core" of a fast acting ingredient against pain, consumers would have understood the representation as claiming that Anacin contained an analgesic ingredient which was not aspirin (Ross, Tr. 1882–85, 1890–92).

95. Dr. Smith, respondents' expert witness, conceded that, based on his model for interpreting advertising, some consumers could have understood CX 41A as representing that Anacin's analgesic ingredient was something other than aspirin. He also testified that some consumers could have understood CX 173 as representing that Anacin's analgesic ingredient is different from aspirin (Smith, Tr. 7551–53, 7557–58).

96. Consumers would have understood advertising which represented that Anacin adds an extra ingredient as meaning that this ingredient is an analgesic or pain reliever (Ross, Tr. 1894–96).

97. Where such advertising represented that Anacin was, for example, specially fortified, a compound, an exceptional formula or a special combination of ingredients, consumers would have understood the representation as claiming that Anacin's analgesic ingredient was not aspirin or aspirin alone (Ross, Tr. 1892–96).

98. In addition to perceiving the challenged advertising as representing that Anacin's analgesic ingredient was unusual, special, stronger or in some other way qualitatively different from and better than aspirin, consumers would also have understood such advertising as representing that Anacin was more effective for the relief of pain than aspirin (Ross, Tr. 1881).

3. *Complaint Paragraph 17*

99. American Home has represented that certain scientific tests or studies conducted by or on behalf of American Home prove that Anacin is as effective for the treatment or [41]relief of headache pain as the leading prescription analgesic product and more effective for

the treatment or relief of such pain than any other non-prescription internal analgesic product (Comp. ¶ 17). These representations were made in the following Anacin advertisements: CX 81–84, 105–07, 126–37, 141, 173–77 and 179.

100. The specific tests or studies conducted by or on behalf of American Home which are referred to in the challenged advertisements are the clinical studies reported in CX 301 and CX 302. To the extent that the challenged advertisements set out specific details of clinical tests, they are the details from CX 301 and/or CX 302 (Tr. 406–07).

101. The fact that Anacin advertisements made these representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 99, *supra*; Ross, Tr. 1932–35, 1938). Confirmatory evidence is contained in a report of an ASI Audience Reaction Test (CX 417; Ross, Tr. 1938–42).

102. American Home has admitted representing that certain tests and studies (*i.e.*, CX 301 and CX 302) show that Anacin is as effective for the treatment of headache pain as the leading prescription analgesic product (Ans. of American Home, ¶ 17; Tr. 406–07).

103. In each of the challenged advertisements in which the representations in Paragraph 17 were made, there is an explicit representation that the specified scientific tests or studies (*i.e.*, CX 301 and CX 302) prove beyond a doubt, show, verify and/or substantiate Anacin's efficacy as compared with that of the leading prescription analgesic product (See advertisements listed in F. 99, *supra*).

104. The challenged advertisements further represent, through a variety of express and implied statements, that the studies referred to (*i.e.*, CX 301 and CX 302) also proved that Anacin was more effective for the treatment or relief of headache pain than any other non-prescription internal analgesic product.

105. Certain of the challenged advertisements represent that, out of the entire universe of OTC analgesic drugs, Anacin should be the drug of choice because it, and it alone, was proven equal to the best, *i.e.*, the leading prescription product. For example:

(a) But be sure it's Anacin you take because it's the tablet which these tests proved is just as effective as the leading pain relief prescription. (CX 126 and CX 127). [42]

(b) The makers of world-famous Anacin Tablets have always known Anacin is one of the most powerful and fastest acting pain relievers . . . . [They] decided to compare its effectiveness for headaches with that of the leading pain relief prescription of doctors . . . . These tests were conducted by physicians who specialize in scientific research . . . . Tests verified beyond a doubt that Anacin gives the same complete

headache relief as the product for which doctors wrote 21 million prescriptions last year. (CX 128 through CX 130).

(c) Physicians who specialize in scientific research conducted tests on 826 patients . . . . Additional tests made by other doctors verified beyond a doubt that Anacin gives the same complete headache relief as the pain reliever so powerful it needs a prescription . . . . Millions of headache sufferers must consider Anacin superior because it's America's largest selling analgesic. (CX 132, 134 and 137. See also CX 135).

(d) How do you find out how good you are? Test yourself against the best . . . . Hundreds of people in a carefully supervised clinical test proved that Anacin was just as strong as the leading prescription. (CX 173).

106. Certain of the challenged advertisements also contain explicit comparisons to other non-prescription internal analgesic products. For example:

(a) In clinical tests on hundreds of headache sufferers, it has now been proven beyond a doubt that Anacin delivers the same complete headache relief as the leading pain relief prescription . . . . Doctors know Anacin contains more of the specific medication they recommend most for pain than the leading aspirin, buffered aspirin, or extra strength tablet. Now you know that Anacin gives you the same complete headache relief as the leading pain relief prescription. (CX 105 and CX 107. See also CX 106). **[43]**

(b) Physicians conducted tests on hundreds upon hundreds of patients who complained of tension headaches . . . . Results from these tests proved beyond a doubt that Anacin gives the same complete relief . . . as the leading prescription of doctors . . . . Here is further convincing evidence of the effectiveness of Anacin. In another survey, twice as many doctors, reporting, said they prefer Anacin's formula to relieve pain to that of the other extra-strength tablet . . . . From the results of these tests . . . (CX 131).

107. Challenged advertisements such as those cited (F. 99, *supra*) made the representations alleged in Paragraph 17 because they explicitly represent that specific clinical tests proved Anacin to be as effective in treating or relieving headache pain as the leading prescription product (Smith, Tr. 5883–84).

108. Consumers would have understood such a representation as also representing that Anacin was proven by such tests to be more effective for the treatment or relief of headache pain than any other non-prescription internal analgesic product because, *inter alia*, consumers generally perceive prescription products to be stronger and more effective than non-prescription products (Ross, Tr. 1933–34, 1937–40, 1941; Smith, Tr. 7576). In addition to this inherent implication of superiority, certain of the challenged advertisements directly convey the message that the leading prescription analgesic is stronger and more powerful than other OTC analgesics, with the exception of Anacin (See, *e.g.*, CX 132, 134, 137 and 173).

4. *Complaint Paragraph 20*

109. American Home has represented that based on a survey: (1) twice as many specialists in internal medicine prefer Anacin for the treatment or relief of headache pain to any other non-prescription internal analgesic product, (2) more physicians recommend Anacin for the treatment or relief of headache pain than any other non-prescription internal analgesic product, and (3) such recommendation or preference constitutes convincing proof that Anacin will treat or relieve headache pain more effectively than any other non-prescription internal analgesic product (Comp. ¶ 20). These representations were made in the following Anacin advertisements: CX 47–49, 81–84, 131, 146–48 and 176 through 180. **[44]**

110. The fact that Anacin advertisements made these representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 109, *supra*; Ross, Tr. 1929–32). Confirmatory evidence is contained in a report of an ASI Audience Reaction Test which was conducted on CX 47, an advertisement (CX 424; Ross, Tr. 1930–31).

111. These representations were made in each of the challenged advertisements citing the survey of doctors referred to in Complaint Paragraph 21. Such advertisements made these representations through a variety of express and implied statements about the preferences and recommendations of physicians and the convincing nature of such preferences or recommendations in proving the superior efficacy of Anacin as compared with other non-prescription internal analgesic products. For example:

(a) DOCTORS' CHOICE . . . Anacin formula 2 to 1 [superimposed on the screen]. Of the doctors who chose between the formulas of the two leading extra strength tablets [,] twice as many chose the Anacin formula for pain relief [,] that's the Anacin formula two to one! (CX 47A. See also CX 48A and CX 49A).

(b) Here is other convincing evidence about Anacin. Replies from a survey of over 1600 specialists in internal medicine showed twice as many doctors said they would recommend their patients use the Anacin formula to relieve pain over that of the other leading extra-strength tablet. Just consider that—twice as many doctors prefer Anacin. (CX 81 through CX 84).

(c) Physicians conducted tests on hundreds upon hundreds of patients . . . . Results . . . proved beyond a doubt that Anacin gives the same complete relief . . . as the leading prescription . . . . Here is further convincing evidence of the effectiveness of Anacin. In another survey, twice as many doctors, reporting, said they prefer Anacin's formula to relieve pain to that of the other extra-strength tablet. (CX 131). **[45]**

(d) [T]ake Anacin for fast, effective, doctor-proved relief. You see, Anacin contains more of the pain reliever doctors recommend most. In fact, in a national survey, doctors were asked to choose between the leading extra-strength pain relief formulas,

and of those who did, twice as many chose the Anacin formula—the extra-strength pain relief formula doctors prefer 2 to 1. (CX 146 through CX 148).

(e) You certainly don't want to settle for second best relief . . . . Replies from over 1600 doctors who specialize in internal medicine showed twice as many doctors prefer extra-strength Anacin Tablets over the other leading extra-strength tablet . . . . [T]hey consider Anacin the better formula for headaches. Not surprising because another medical research report proves Anacin . . . . as effective . . . as the leading prescription. (CX 176).

(f) It's one thing to think you're good, but it's something extra when someone else proves it . . . . [T]his survey we made where we asked doctors who specialize in internal medicine which formula they prefer for headache pain . . . . They didn't just pick Anacin's. [T]he doctors responding preferred Anacin's two to one over the other extra-strength tablet. Specialists preferred Anacin's two to one. (CX 180).

112. Challenged advertisements such as those cited (F. 109, *supra*) made the representations alleged in Paragraph 20 for the following reasons: (1) consumers would have understood advertising based on the results of a survey of specialists in internal medicine as representing that the survey was a representative one that fairly reflected medical opinion and, therefore, that twice as many doctors, physicians or specialists in internal medicine preferred Anacin for the treatment or relief of headache pain; (2) consumers would have believed that such physicians would act on their preferences in recommending a non-prescription internal analgesic; and (3) consumers would have understood any **[46]**advertising representation based on doctors' preferences or a survey of doctors favoring Anacin as evidence or proof that Anacin would treat or relieve headache pain more effectively (Ross, Tr. 1928–32).

113. Certain of the challenged advertisements explicitly represented that this survey of doctors constituted convincing evidence about Anacin (CX 81 through CX 84; Ross, Tr. 1931–32).

114. Dr. Smith testified that a scientific survey of medical experts constitutes convincing proof that Anacin is preferred over Excedrin by doctors. He admitted that certain challenged Anacin advertising conveyed the message to consumers that there was convincing proof that twice as many specialists in internal medicine chose Anacin as chose the other leading extra-strength tablet in this survey. Finally, Dr. Smith agreed that a preference by doctors could reasonably be interpreted by at least some consumers as a claim of greater effectiveness (Smith, Tr. 5903, 7598).

115. Since consumers would have understood representations comparing Anacin with the other extra-strength product, or the other leading extra-strength product, as a comparison with the product that is otherwise the best in the product category, these advertisements represented that Anacin was superior to any other non-prescription internal analgesic product (See F. 75, *supra*).

5. *Complaint Paragraph 12(A)*

116. American Home has represented that a recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other non-prescription internal analgesic (Comp. ¶12(A)). This representation was made in the following Anacin advertisements: CX 1, 5, 9–10, 13–15, 20–23, 25, 38–40, 47–54, 56–61, 81–84, 89–90, 92–97, 99–100, 102–07, 115–17, 119, 121–24, 126–37, 142–44, 146–56, 160–64, 166 and 169 through 185.

117. The fact that Anacin advertisements made this representation is demonstrated by the advertisement themselves and confirmed by expert testimony (Advertisements listed in F. 116, *supra*; Ross, Tr. 1897–98, 1900–01, 1905–06, 1919–20). Confirmatory evidence is contained in reports of the following ASI Audience Reaction Tests: CX 404, 407, 409, 414, 415, 420, 424 and 425 (Ross, Tr. 1861, 1900, 1906–07, 1920–21, 2683). Confirmatory ASI verbatim comments **[47]** include not only those concerned with comparative pain relief, but also those concerned with comparative strength, speed and quantity of ingredient(s) (See F. 120 and 121, *infra*).

118. This representation was made through a variety of express and implied statements concerning Anacin's superiority to other products in terms of pain relief, or in terms of particular attributes or dimensions of pain relief such as strength, power and speed. For example:

(a) There's not much difference in pain relievers that you can see. But in your bloodstream, the differences are very real. While all three leading pain relievers reach an effective level in minutes, in the final analysis, only one of them hits and holds the highest level. Anacin. This difference is the extra pain reliever Anacin provides . . . . The difference in Anacin is the higher level of pain reliever. (CX 54A. See also CX 149, 182 and 183 for similar language).

(b) No tablet you can buy has the strong yet safe formulation in Anacin. See if Anacin Tablets don't work better for you. (CX 153).

(c) See if the special fortified formula in Anacin Tablets doesn't work better for you. (CX 156).

(d) It gives you extra medication for extra pain-relief power. Headache sufferers need extra pain-relief power. And that's what Anacin gives. (CX 155).

(e) Only today's Anacin has this fortified combination of ingredients with the medication doctors prescribe most for pain-relief. And today's Anacin is now twice as strong in this medication as any other extra-strength tablet. (CX 156).

(f) [W]e can promise you extraordinary relief with Anacin. Anacin with more to give. (CX 172). **[48]**

(g) It's time to stop thinking there's no difference in pain relievers. Doctors' tests prove the differences are very real. (CX 184).

119. Challenged advertisements such as those cited (F. 116, *supra*), made the representation alleged in Paragraph 12(A) because

consumers would have understood them as representing that Anacin was a more effective pain reliever than any other non-prescription internal analgesic product (Ross, Tr. 1899).

120. Effectiveness in reducing pain is the essential purpose for the analgesic product category. Advertisers of analgesic seek to convey the message of superior effectiveness in reducing pain by distinguishing brands in terms of themes such as speed, strength, quantity of ingredients and doctors' recommendations because these themes are regarded by consumers as symbols for effectiveness in reducing pain (Smith, Tr. 5772–74, 7558).

121. Certain of the challenged advertisements, which focus on Anacin's superiority to other products on a variety of attributes or dimensions such as strength or speed, would have been understood by consumers as claims of superior pain relief because speed and strength are among the meanings consumers give to effectiveness (Ross, Tr. 1900, 1902–05, 2017, 2019–23, 2404–07; CX 462Z112, Z114, Z115, Z117, Z143, Z144; CX 306B and CX 327).

122. The challenged representation of greater effectiveness was also made wherever advertising represented that Anacin contained more pain-dulling ingredients or pain reliever than any other non-prescription internal analgesic. Moreover, consumers could readily translate "more pain reliever" to "more pain relief." For these reasons, consumers would have understood such advertisements as representing that Anacin provided more pain relief than other products, *i.e.*, that Anacin was more effective for the relief of pain (Ross, Tr. 1852–55, 1858–63; See F. 83, *supra*). Therefore, the representation alleged in Paragraph 8(A)(1) or 8(A)(3) was made.

123. The challenged representation of greater effectiveness was also made in advertisements which represented, *inter alia*, that Anacin contained more of the pain reliever doctors recommend most than other products (Ross, Tr. 1853–55). **[49]**

124. It was also made in advertisements which represented, *inter alia*, that Anacin provided more pain reliever or relief than Excedrin, the other extra-strength or other leading extra-strength product (Ross, Tr. 1858–59, 1861, 1868, 1899–1901. See F. 78, *supra*).

125. Respondents' witness, Dr. Smith, conceded that, based on his model for interpreting advertising, those consumers who understood an advertisement such as CX 23 to mean two Anacin are equal to four Excedrin might interpret that to mean equality in terms of effectiveness. He also admitted that at least some consumers could interpret a claim that the advertised product is better than the one which is recognized as the best to be a superiority claim vis-a-vis the entire product category (Smith, Tr. 7520, 7566, 7568).

126. The challenged representation was also made in advertisements which represented, *inter alia*, that Anacin's extra pain reliever enables it to reach the highest effective level in the bloodstream (CX 50–54 and CX 56 through CX 58; Ross, Tr. 1907–09. See also CX 356A-D, G, I and CX 340).

127. Dr. Smith agreed that, based on his model for interpreting advertising, the explicit representation in CX 54 that Anacin reaches a higher, more effective blood level than the other two leading pain relievers could be interpreted by some consumers as representing that Anacin provides more effective pain relief than the other two leading products (Smith, Tr. 7561–62, 7564).

128. Finally, the challenged representation of greater effectiveness was also made in advertisements such as CX 21, which compares the pain reliever content of Anacin and the other leading extra-strength tablets. This theme was played back in the ASI test reported in CX 415 not only in terms of quantity of ingredients, but also in terms of comparative speed, strength and effectiveness (Smith, Tr. 7542–44).

129. The representation that Anacin was unusual, special, stronger, or in some way qualitatively different from another product or products would have been understood by consumers as claiming that Anacin was more effective for the relief of pain than such other product or products. Therefore, wherever the representation alleged in Paragraph 8(A)(2) was made, the representation that Anacin was more effective for the relief of pain than aspirin was also made. **[50]** Furthermore, in certain of these advertisements, Anacin was represented as unusual, special, stronger, or in some way qualitatively different from all other non-prescription internal analgesics; such advertisements also made the representation alleged in Paragraph 12(A) (Ross, Tr. 1863, 1920–21. See F. 98, *supra*).

130. The representation alleged in Paragraph 12(A) was made wherever the representations alleged in Paragraph 17 were made (See F. 99–108 and advertisements listed in F. 99, *supra*).

131. The representation alleged in Paragraph 12(A) was made wherever the representations alleged in Paragraph 20 were made (See F. 109–115 and advertisements listed in F. 109, *supra*).

6. *Complaint Paragraph 10(A)*

132. American Home has represented that it has been established that a recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other non-prescription internal analgesic (Comp. ¶ 10(A)). This representation was made in

the following Anacin advertisements: CX 1, 5, 9, 10, 13–15, 20–23, 25, 38–40, 47–54, 56–58, 61, 81–84, 89, 90, 92–97, 99, 100, 102–07, 115–17, 119, 121–24, 126–37, 142–44, 146–56, 160–64, 166 and 169 through 185.

133. The fact that Anacin advertisements made this representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 132, *supra*; Ross, Tr. 1921–28). Confirmatory evidence is contained in reports of the following ASI Audience Reaction Tests: CX 409, 414, 424 and 425 (Ross, Tr. 1923–24).

134. This representation was made through a variety of express and implied statements conveying that Anacin's comparative superiority for the relief of pain was based on scientific or medical fact or opinion.

135. In certain of the challenged advertisements, explicit reference is made to underlying scientific or medical proof. For example:

(a) "[M]edically proved Anacin overpowers headache pain" or "medically proved Anacin overpowers pain." (CX 50A through CX 53A). [51]

(b) "[M]edically proven" or "medically proved." (CX 115-17, 142–44 and 149).

(c) "[D]octor-proved relief." (CX 146 through CX 148).

(d) "Medical research has definitely established that the most reliable medication in the treatment of arthritis . . . is the compound in today's Anacin Tablets . . . . Anacin's great pain fighter is the first choice of doctors . . . ." (CX 154).

(e) In each of the advertisements in which the representations alleged in Paragraph 17 or Paragraph 20 are made, there is reference to tests, studies and/or surveys (Advertisements listed in F. 99 and 109, *supra*).

136. In certain of the challenged advertisements, graphs, scientific formulas and/or symbols are used in making this representation (See, *e.g.*, CX 14A, 15A, 50A–54A, 56A–58A, 61 and 149).

137. In certain of the challenged advertisements, the approval or approbation of doctors is used in making this representation. For example:

(a) [M]ore of the specific pain reliever doctors recommend most . . . . (CX 9A. See also CX 20A–23A, 25A, 39A, 40A, 146–48, 163 and 164 for similar language).

(b) Of all the drugs to choose from, doctors most often recommend one pain relieving ingredient. And Anacin has more of it than any other leading headache tablet. (CX 13A and CX 14A).

138. Consumers would have understood challenged advertisements such as those cited (F. 132, *supra)* as representing that Anacin's superiority to other non-prescription internal analgesics had been established because such advertisements were based, at

least in part, on the opinions of doctors, the use of scientific symbols or formulas or, in some other way on scientific or medical fact, proof, evidence, authority or opinion (Ross, Tr. 1922–28). Therefore, the representation alleged in Paragraph 10(A) was made. **[52]**

139. As respondents' own expert witness, Dr. Smith, indicated, consumers believe that: (1) advertisers have reasonable grounds for the advertising claims they make; (2) advertisers are not allowed to make claims unless they have good reasons for believing that they are true; and (3) with a serious product category, such as a drug, advertisers need to have a generally higher level of support or better grounds for making claims (Smith, Tr. 7584–86).

140. Consumers would have understood the challenged advertisements which explicitly represented that Anacin was medically proved or proven as representing that Anacin's superior efficacy for the relief of pain had been established (Ross, Tr. 1926).

141. For instance, CX 154 expressly represents that the superior efficacy of the compound found in Anacin has been definitely established by medical research. Dr. Smith agreed that when advertising copy makes a statement such as in CX 154 (F. 135(d), *supra*), consumers will believe that that statement is true, could not be made unless it is true and is adequately supported (Smith, Tr. 7590–91).

142. Dr. Smith admitted that an advertising claim will be perceived by consumers as having been established if it is supported by scientific evidence such as tests (Smith, Tr. 7583).

143. The challenged advertisements which made the representations alleged in Paragraphs 17 (See F. 99–108 and advertisements listed in F. 99, *supra*) or 20 (See F. 109–15 and advertisements listed in F. 109, *supra*) would also be understood by consumers as making the representation alleged in Paragraph 10(A) (Ross, Tr. 1922).

144. For instance, Dr. Smith agreed that if advertisements such as CX 81 represented that Anacin was more effective than other OTC analgesics, then the reference in that advertisement to clinical tests would constitute scientific evidence such that consumers would perceive this claim as established (Smith, Tr. 7588).

145. Consumers would have also understood this representation to have been made in the challenged advertisements which made use of graphs, scientific formulas and/or symbols (F. 136, *supra*). **[53]**

146. For example, consumers would have understood the claim regarding the difference among pain relievers in the bloodstream in CX 54A as based on authoritative medical opinion (Ross, Tr. 1924–25). Upon being confronted with a scientific graph measuring blood levels, at least some consumers would understand those blood levels

as having been ascertained through a scientific test (Smith, Tr. 7588–89). Also, Dr. Smith admitted that an advertisement such as CX 14 could be perceived by some consumers as a doctor reaching for a medical treatise. Many consumers would believe that there is scientific evidence behind medical treatises (Smith, Tr. 7589–90).

147. Finally, consumers would have also understood this representation to have been made in the challenged advertisements which referred to the approval or approbation of doctors (F. 137, *supra*) for several reasons. First, medical approbation or approval of an advertised product is important to, and respected by, consumers. Second, consumers believe that doctors have good reasons for recommending the products they do (Smith, Tr. 5817, 5936). Third, when an Anacin advertisement talked about doctors' approval, respondents in ASI Audience Reaction Tests said doctors approve, doctors recommend or doctors prefer with some frequency in their verbatim comments (Smith, Tr. 7593).

7. *Complaint Paragraph 8(A)(4)*

148. American Home has represented that within approximately 22 seconds after taking Anacin a person may expect relief from headache pain (Comp. ¶ 8(A)(4)). This representation was made in the following Anacin advertisements: CX 1, 142–44, 151 and 153.

149. The fact that Anacin advertisements made this representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements in F. 148, *supra*; Ross, Tr. 1942–51, 1960–C, 1962, 1964–67).

150. This representation was made through a variety of express and implied statements, and through the use of visual and audio techniques claiming that within approximately 22 seconds after taking Anacin, consumers could expect to begin to perceive some relief from headache pain. The representation alleged in Paragraph 8(A)(4) appeared in both television and print advertisements (See advertisements listed in F. 148, *supra*). For example: **[54]**

(a) So quickly that in the short time it takes you to kiss a baby [,] in . . . just . . . twenty-two seconds to be exact [,] twenty-two seconds . . . after Anacin is in your bloodstream, its already starting to work on your headache. (CX 1A).

(b) In 22 seconds after entering your bloodstream this special fortified formula is speeding relief to your nervous headache. It promptly relieves the pain . . . . You can bounce back fast . . . . (CX 142 through CX 144).

(c) Anacin acts fast! In 22 seconds after entering your bloodstream, Anacin is speeding relief to your headache. Pain goes quickly . . . (CX 153. See also CX 151 for similar language).

151. Challenged advertisements such as those cited (F. 148

supra) made the representation alleged in Paragraph 8(A)(4) because consumers would have understood them as representing that within approximately 22 seconds after taking Anacin, they could expect to perceive some relief from headache pain, even though all of their headache pain would not necessarily be gone (Ross, Tr. 1943).

152. Consumers would perceive the specific reference to "twenty-two seconds" to be directed towards the intended effect of Anacin, which is the relief of headache pain.

153. In CX 1A (the storyboard of a television advertisement), the video portion (showing a woman with a headache who, in the 22 seconds it takes to kiss a baby, begins to feel better) is consistent with and supportive of this representation (Ross, Tr. 1944–45, 1947, 1962). In this advertisement, the dominant claim was the benefit of taking Anacin and having it start to work on your headache in twenty-two seconds (Ross, Tr. 1947).

154. Frame 2 of CX 1A, which states "[w]hile you won't feel it for minutes," contradicts the remainder of the advertisement and would not have been perceived or understood by consumers as restricting or qualifying their understanding that the representation alleged in Paragraph 8(A)(4) was made (Ross, Tr. 1943–49). This type of qualification would be overlooked because it is found at the very beginning of the **[55]**advertisement, before its importance could become apparent. Moreover, qualifications on this order (*i.e.*, qualifications inconsistent with the dominant claim) are not perceived by consumers to the same extent as the dominant advertising claim is perceived; consequently, such qualifications are forgotten more quickly than the dominant claim (Ross, Tr. 1946, 1948–49, 1960, 1961–66). This qualification does not even appear in the print advertisements in which this representation is alleged to have been made (CX 142–44, 151 and 153; Ross, Tr. 1950).

155. The phrases "after Anacin is in your bloodstream," or "after entering your bloodstream," (See, *e.g.*, F. 150, *supra*) would not have been understood by consumers as restricting or qualifying their understanding that the representation alleged in Paragraph 8(A)(4) was made because it draws a distinction between presence in the bloodstream and relief from headache pain that would not have been perceived by consumers (Ross, Tr. 1945, 1948–49).

8. *Complaint Paragraph 15*

156. American Home represented that a recommended dose of nacin relieves nervousness, tension, stress, fatigue and depression ıd will enable persons to cope with the ordinary stresses of

everyday life (Comp. ¶ 15). This representation was made in the following Anacin advertisements: CX 3, 5–8, 10, 15–18, 20–22, 25, 26, 28, 30–32, 34, 36, 38–49, 81–87, 89, 90, 92–97, 99, 100, 102–04, 115–17, 119, 121–24, 126–37, 142–44, 146–49, 151–56, 160, 162–63, 165–67, 169–72, 174–79 and 181.

157. The fact that Anacin advertisements made this representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 156, *supra*; Ross, Tr. 1951–54, 1969–70, 1979, 1980, 1988–89, 1992–93, 1995, 2001, 2002, 2004–09). Confirmatory evidence is contained in reports of the following ASI Audience Reaction Tests: CX 402, 404–07, 409–12, 414, 415 and 418 through 424 (Ross, Tr. 1951–52, 1954–58, 1960, 1970–84, 1989–99, 2002–04, 2681, 2682. See also CX 404E).

158. This representation was made through a variety of express and implied statements, and through the use of suggestive audio and visual techniques creating an imagery indicative of Anacin performing a mood function or having **[56]**mood effects, such as those set forth in Paragraph 15, wholly apart from Anacin's efficacy as a headache or pain reliever.

159. A number of the challenged advertisements placed extra emphasis upon such words as "tension," "anxiety," "nerves," "stress," "fatigue" and "depression" (See, *e.g.*, CX 3, 5, 7A, 8A, 15A, 17A, 21A, 25A, 26A, 27A, 39A, 40A, 44A, 46A, 89, 115 and 155). For example:

(a) Anacin relaxes the tension as it relieves pain. (CX 6A through CX 8A).

(b) Nerves, stress, headache pain . . . . Anacin has what it takes to relieve headache pain and its tension. (CX 26A).

(c) When Boredom and Emotional Fatigue Bring on "Housewife Headache" . . . . Making beds, getting meals, acting as family chauffeur—having to do the same dull, tiresome work day after day—is a mild form of torture. These boring yet necessary tasks can bring on nervous tension, fatigue, and what is now known as "housewife headache" . . . . See if you don't feel better all over with a brighter outlook after taking 2 Anacin tablets. (CX 89 and CX 93. See also CX 90–92, 94 and 95 for similar language).

(d) TURNS OFF HEADACHE PAIN SO RELIEVES PAIN'S TENSION [,] HELPS LIFT ITS DEPRESSION . . . . You feel great again after taking Anacin. (CX 115 through CX 117).

(e) Calms Anxiety [,] Tension as it relieves headache pain . . . . Anacin . . . contains a specific ingredient that relieves pain and its anxiety . . . fast. You feel relaxed. You calm down. Then Anacin keeps exerting its soothing effect for hours. Keeps you feeling great. (CX 155).

160. Many of the challenged advertisements not only emphasize words such as those listed in F. 159, *supra*, but also depict a variety of situational tensions (tensed or stressed circumstances). In these advertisements, the verbal content of a message (showing tension

associated with pain) is pushed into the background through the effective use of aural-visual techniques (*i.e.*, sound effects, music, camera) which create a vivid imagery of situational [57]tension, wholly apart from headache pain, that is relieved by Anacin. For example:

(a) CX 8A shows a ladder knocking a lamp, a screen ripping and a man going about his home doing assorted household chores while mumbling, "One day off . . . . I gotta change the screen . . . paint the woodwork . . . fix the roof [, . . . c]lean the basement . . . ." The man's face visibly depicts a stressful situation. The announcer states in a voice-over, "Pain, headache pain. Its tension drains everything out of you. Reach for help. Reach for Anacin. Anacin relaxes the tension as it relieves pain." After taking Anacin, the man is visibly relaxed and relieved from the stresses of what is part of ordinary, everyday life. He states, "Mmmm, good as new."

(b) CX 22A shows a woman running who drops all of her books and papers. She is depicted as visibly agitated prior to entering a room where she begins her work. The announcer states in a voice-over, "You're under pressure. It piles up . . . . Pain. It's tension. You reach for Anacin." After taking Anacin, the woman appears relaxed and smiling at her desk.

(c) CX 31A shows a bank teller at work on payday, with a long line of customers at his window. The announcer states in a voice-over, "Payday, a good day . . . . Unless you're on the receiving end with headache pain and the tension that goes with it. Discover what Anacin can do to help." After taking Anacin, the bank teller is shown in a visibly calm mood with a smile on his face, while still at work.

(d) CX 40A depicts a woman holding the side of her head with an expression of anguish on her face. There is the noise of a saw, shown initially being operated by her husband, in the background. The woman states, "No headache is going to make me shout at my husband." After taking Anacin, [58]the woman appears smiling and cheerful. She says to her husband, "Anacin did it again." (See, *e.g.*, CX 41A showing motorcycle noise, CX 42A showing the noise of a teenager on the telephone, CX 43A, CX 44A showing the noise of young children at a birthday party, CX 45A showing the noise of banging pots and pans and CX 47A showing the noise of a busy airport. Each of those advertisements creates a similar imagery of situational tension).

(e) "WOMAN: Big parties scare the wits out of me. All those people. I never know what to say. And my husband doesn't help; the

jokes he comes out with. Makes me so tense and nervous, it's awful. I'm upset enough as it is with things at home. Why can't Mom let us bring up our own children, for instance . . . . ANNCR: Headache pain . . . tension . . . depression . . . . that's when you need Anacin." (CX 170).

(f) "HE: You say you've been getting these headaches for no reason at all. SHE: Seems like it, I just go about my housework—you know—cleaning, and shopping . . . and . . . well . . . . HE: . . . picking up after the kids . . . . SHE: Uh, huh, all the regular day in and day out stuff. SHE: Tired? Well, not physically tired so much, but . . . well . . . I cry a lot . . . HE: Emotionally then? SHE: (SIGH) Yes, I guess I'd have to admit to that. Doing all those jobs isn't exactly the most satisfying work I've ever done—as an individual I mean . . . . ANNCR: There you have the anatomy of Housewife Headache. A seemingly endless cycle of boredom and fatigue. One approach . . . is to rely on Anacin." (CX 171).

161. Challenged advertisements such as those cited (F. 156, *supra*) made the representations alleged in Paragraph 15 because they used words or phrases, or presented a setting and environment, which created an imagery of a mood function or mood effects. Taking each advertisement as a total communication, consumers would have understood them as representing that Anacin performed a mood function or had mood **[59]**effects, such as relaxing or relieving tension, quelling stress or resulting in tranquility and calm, wholly apart from its efficacy with respect to relieving headache pain (Ross, Tr. 1952–58, 1967–71, 1972–77, 1981–84, 1989, 1991–95, 2002, 2005–06, 2681–82).

162. In certain of these advertisements, the dominant theme or benefit represented for Anacin was mood effects and not relief from headache pain (Ross, Tr. 1969–70, 1973, 1975, 1981–83, 1992, 1995, 2005–09). For example, stress and tension are frequently emphasized over pain in terms of the amount of advertising space. Also, the advertisements often present a forceful image such as by depicting the individual in the advertisement as tension-free after having taken Anacin (Smith, Tr. 7628, 7631).

163. Certain of the challenged advertisements represent that Anacin can relieve the tension attributable to a tense or unhappy situation (some advertisements present problematic situations, fraught with tension and stress, such as problems with a job, children, housework, etc.). Since substantial numbers of consumers are expected to desire mood effects, such as tension relief, they become less likely to perceive or accept any qualification of a

dominant advertising representation of mood effects than would otherwise be the case (Ross, Tr. 1967–68, 1973).

164. The presentational techniques utilized in a number of the challenged advertisements would have contributed to consumers' understanding that Anacin would perform a mood function or would have mood effects wholly apart from its efficacy with respect to relieving headache pain (Ross, Tr. 1968–70, 1979–80, 1987–88, 1994, 2002–04).

165. The effectiveness of such techniques was well recognized. American Home itself concluded, based on its review of certain ASI tests, that the following factors, among others, typified the most successful Anacin advertisement: "a 'set-up' in the beginning of the commercial which creates a feeling of tension/anguish/pain via a combination of devices which . . . all support the creation of a mood" through the use of sound and inanimate objects or visual effects such as blocks crumbling, and where "[t]he Anacin 'pay-off' was supported by the diminution or complete elimination of the visual or sound effects accompanying the disappearance of the symptoms, in the sufferer's behavior." (CX 329). **[60]**

166. Respondents' expert witness, Dr. Smith, testified that one of the major components in the evaluation of advertisements is the symbolic, implicit or covert meanings that are carried within the messages. He stated that such meanings may be conveyed through the use of color, environment and other visual and/or audio techniques (Smith, Tr. 5556–57).

167. Dr. Smith also observed that the entire content of an advertisement must be taken into account in determining how consumers would understand it. He agreed that both express and implied claims in an advertisement should be given equal weight, since they make up the entire communication. Dr. Smith conceded, however, that much of his testimony focused primarily on the specific language contained in the advertisements (*i.e.*, the audio portion) (Smith, Tr. 7493–94).

168. The following are examples of advertisements in which presentational techniques conveying situational tension contribute to making the challenged representation:

(a) CX 5 begins by showing a person with stress and fatigue, and presents situational tension which is further dramatized by distressing audio effects such as the demanding voices of children. There is a strong visual component in CX 5 depicting fatigue, stress and nervousness building up to the breaking point, which is symbolized by children's blocks lettered F, S and N. This advertisement shows

that, after taking Anacin, calm is restored, the stressful situation relaxed and the fatigue relieved. The major video and audio portion of CX 5 emphasizes tension and stress, rather than pain (Smith, Tr. 7615–16, 7619). Dr. Smith conceded that, based on his model for interpreting advertising, CX 5 could represent to at least some consumers that Anacin can relieve not only headache pain, but also the tension that caused it. He further testified that if consumers understood CX 5 as representing that Anacin can relieve the tension that can cause headaches, they could understand the advertisement as representing that Anacin can relieve all tension (Smith, Tr. 7621–22).

(b) The first seven frames of CX 7A present situational tension, and would convey to consumers those ideas associated with being **[61]**uptight, tense and under stress. This advertisement has a strong visual component, a tightening rope approaching the breaking point, which specifically focuses on tension and nerves rather than pain. The situational tension, headache and additional tension attributable to the headache are all shown as being relieved by Anacin in this advertisement (Smith, Tr. 5848–50, 7622–23).

(c) The larger, bold-faced type in the title of a print advertisement, such as in CX 155, is more likely to be perceived than smaller type in the title or the body of an advertisement. The major thrust in the title of CX 155 is that Anacin calms anxiety and tension; the remainder of the title is subordinate to this anxiety and tension claim (Smith, Tr. 7627–28).

169. The challenged Anacin advertisements present tension in so many different contexts relative to headache pain that any relationship between the two would be unlikely to be understood by consumers. Thus, consumers could reasonably be expected to perceive tension and pain as distinct symptoms which can be alleviated by Anacin regardless of whether they occur simultaneously or independently of each other (See, *e.g.*, Ross, Tr. 1969–79, 2006; Smith, Tr. 7632).

170. The verbatim comments in certain of the ASI Audience Reaction Tests provide confirmatory evidence that a tension relief claim was made (F. 157, *supra*). Dr. Smith, respondents' expert witness, admitted that, based on his own recodification of the ASI verbatims (RX 124), the comments in the tension category make no link between tension and pain or headache, and are directly supportive of this complaint allegation (Smith, Tr. 7633–35). Dr. Smith's figures tend towards the conservative side because the stringent standards he applied resulted in the exclusion of relevant,

or possibly relevant, tension responses. Therefore, even under Dr. Smith's standard, the tension relief claim was communicated, or had consequence, in certain of the challenged advertisements (Smith, Tr. 5592–93).

D. *The Specific Allegations Relating To Arthritis Pain Formula Advertising*

1. *Complaint Paragraph 8(B)(1)*

171. American Home and Clyne have represented that APF's analgesic ingredient is unusual, special, and stronger than **[62]** aspirin (Comp. ¶ 8(B)(1)). This representation was made in the following APF advertisements: CX 201–07, 210, 217 and 218.

172. The fact that APF advertisements made this representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 171, *supra*; Ross, Tr. 2303–05). There is no consumer research relevant to this issue.

173. In certain of these advertisements, the analgesic ingredient in APF was specifically contrasted with aspirin. For example:

(a) I'm on something different . . . . Arthritis Pain Formula . . . . 50% more pain reliever than a regular aspirin. So strong you don't need it so often. (CX 201A).

(b) Now you can take a different tablet. Arthritis Pain Formula . . . . Compared to regular aspirin tablets Arthritis Pain Formula contains 50% more of this medication that doctors recommend most. (CX 206A).

(c) Special compound with 50% more pain relief medication than regular or buffered aspirin. (CX 210A).

174. In all of these advertisements, prominence is given to the name of the product and, in certain of them, additional representations are made about its formulation. For example:

(a) The special compound . . . . (CX 210A).

(b) This special pain-relieving compound . . . . (CX 217 and CX 218).

175. Challenged advertisements such as those cited (F.171, *supra*) made the representation alleged in Paragraph 8(B)(1) because consumers would have understood them as representing that APF was qualitatively different from aspirin. This understanding would have arisen out of the implicit claims that either APF did not contain aspirin or, if it did contain aspirin, its principal active pain relieving ingredient was something other than aspirin (Ross, Tr. 2303–05). Consumers would have understood this representation as being made where the analgesic ingredient in APF was specifically contrasted with aspirin. **[63]**

176. Consumers also would have understood the name of the

product, Arthritis Pain Formula, which was prominently embodied in the challenged advertisements, as making this representation, especially where additional representations were made about the formulation of APF (Ross, Tr. 2304–05).

177. Finally, in CX 201, 217 and CX 218, the dominant theme was the strength or strong performance of APF (Ross, Tr. 2305). Respondents' expert, Dr. Smith, agreed that certain challenged APF advertisements would have conveyed the message to arthritis patients that APF was a stronger medicine than plain aspirin (Smith, Tr. 5938).

2. *Complaint Paragraph 8(B)(2)*

178. American Home and Clyne are alleged to have represented that APF will eliminate all pain, stiffness and discomfort usually experienced by arthritis sufferers in the morning (Comp. ¶ 8(B)(2)). This representation was not made in any of the challenged advertisements, which include CX 201 through CX 205.

179. The fact that APF advertisements did not make this representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 178, *supra;* Smith, Tr. 5928–30, 7642–44). There is no consumer research relevant to this issue.

180. No APF advertisement has expressly or impliedly claimed that the product will completely relieve pain and stiffness in the morning, nor have consumers understood the advertisements to have made such a claim. The phrase, "get moving without all that pain or its morning stiffness," would be interpreted by consumers as an idiomatic expression conveying the meaning "without as much pain and stiffness as you would otherwise suffer." Arthritis sufferers, at whom these advertisements were directed, are experienced in the pain and stiffness of arthritis and would not interpret any of the challenged advertisements as promising total and absolute relief from the pain and stiffness of arthritis (Smith, Tr. 5928–30, 7642–44; CX 201 and CX 202).

3. *Complaint Paragraph 12(B)*

181. American Home and Clyne have represented that APF will cause gastric discomfort less frequently than any other non-prescription internal analgesic (Comp. ¶ 12(B)). This representation was made in the following APF advertisements: CX 203 through CX 206. **[64]**

182. The fact that APF advertisements made this representation

is demonstrated by the advertisements themselves and confirmed by expert testimony (Advertisements listed in F. 181, *supra;* Ross, Tr. 2307–08).

183. This representation was made through express and implied statements to the effect that APF would cause less stomach disorders or less stomach upset than any other non-prescription internal analgesic. For example:

(a) 50% more pain reliever than regular aspirin tablets . . . . And double buffering to be gentle on the stomach. (CX 203A).

(b) . . . Arthritis Pain Formula contains 50% more of this medication that doctors recommend most. And double buffering makes it gentle on your stomach. (CX 205A and CX 206A. See also CX 204A for similar language).

184. Challenged advertisements such as those cited (F. 181, *supra*) made the representation alleged in Paragraph 12(B) because consumers would have understood advertising that represented that APF had double buffering to mean that APF was more buffered than the product which is otherwise the most buffered in the product category and, therefore, that APF would cause less stomach disorders or less stomach upset than any other non-prescription internal analgesic (Ross, Tr. 2306–08).

185. Many consumers, such as arthritis sufferers, perceive that buffered products are gentler to the stomach than unbuffered products. Therefore, the challenged advertisements which represent that APF has double buffering also carry with them the representation that APF is gentler to the stomach than regular, unbuffered aspirin (Smith, Tr. 7645). Thus, the claim is one of uniqueness in this respect.

4. *Complaint Paragraph 10(B)*

186. American Home and Clyne have represented that it has been established that APF will cause gastric discomfort less frequently than any other non-prescription internal analgesic (Comp. ¶ 10(B)). This representation was made in the following APF advertisement: CX 204. **[65]**

187. The fact that CX 204 made this representation is demonstrated by the advertisement itself and confirmed by expert testimony (CX 204; Ross, Tr. 2309–10).

188. This representation was made in CX 204A through express and implied statements to the effect that the representation that APF would cause less stomach disorders or less stomach upset than any other non-prescription internal analgesic was based on scientific or medical fact or opinion. The advertisement stated that ". . .

Arthritis Pain Formula Tablets contain . . . 50% more of this medication that doctors choose most for arthritis. Another thing: double buffering makes it gentle on the stomach." The following titles were superimposed on the screen: "the Doctors Choice" and "Double Buffering." (CX 204A).

189. CX 204A made the representation alleged in Paragraph 10(B) because consumers would have understood the advertisement as representing that scientific or medical fact or opinion had established that APF would cause less stomach disorder or less stomach upset than any other non-prescription internal analgesic (Ross, Tr. 2309–10).

IV. The Medical And Scientific Substantiation For The Claims Made In The Advertisements

A. *Introduction*

190. The complaint does not charge that American Home lacked a reasonable basis for comparative efficacy or freedom from side effects claims (F. 15, *supra*). Nonetheless, respondents introduced limited evidence attempting to demonstrate that they possessed substantiation in the form of a reasonable basis for claims that were imputed to their advertising (Complaint Counsel's Admissions, RX 244Z027. See also Shaul, Tr. 3279–85, 3296–3309, 3340, 3358, 3382, 3398).

191. The substantiation put forth by respondents for any claims made consisted, *inter alia,* of: (1) expert opinions rendered by preeminent clinicians and pharmacologists who were experts in the area of analgesic evaluation; (2) results of numerous clinical investigations that were performed on aspirin and aspirin-containing products; (3) medical articles and books which are accepted as authoritative treatises in the area of analgesia and pharmacology; and (4) the review of the so-called Peer Review Group commissioned by American Home to evaluate the medical and scientific research and literature regarding the safety and efficacy of Anacin and APF. The evidence adduced by American Home with regard to **[66]**the Peer Review Group warrants the conclusion that respondents had some rational basis for comparative efficacy and freedom from side effects claims for Anacin and APF.

B. *It Has Not Been Established That Anacin Is A More Effective Pain Reliever Than Aspirin Or Any Other Non-Prescription Pain Reliever*

1. *General Background*

192. A recommended dose of Anacin is one or two tablets, for a two-tablet total of 800 mg. aspirin and 65 mg. caffeine (F. 11, *supra*). A comparable two tablet dose of common 5 grain aspirin contains 650 mg. aspirin (F. 13, *supra*). Thus, one tablet of Anacin differs from one tablet of common 5 grain aspirin by 75 mg. more aspirin and the addition of 32.5 mg. caffeine; the two tablet dose differs by 150 mg. more aspirin and 65 mg. caffeine.

193. Anacin does not contain more than twice as much of its analgesic ingredient as all other analgesic products on the market (Non-Contested Issue of Fact 12).

194. There are other analgesic products on the market which contain as much or more pain relieving ingredients per tablet than does Anacin (Non-Contested Issue of Fact 11). Anacin contains at least 23% more aspirin than Bayer Aspirin, Bufferin, Excedrin, Empirin, Norwich Aspirin and all other brands and generic forms of regular aspirin. Four commonly available products, Arthritis Pain Formula, Arthritis Strength Bufferin, Cope and Midol contain more aspirin than Anacin (Forrest, Tr. 477).

195. In order to establish a scientific or medical proposition, the truth of the proposition must either be generally recognized as self evident by experts in the field or proved by evidence which reduces the chance of error to a scientifically acceptable minimum (Azarnoff, Tr. 600; Moertel, Tr. 1028; DeKornfeld, Tr. 2777).

196. The only record evidence which purports to demonstrate Anacin's superiority to common 5 grain aspirin as a pain reliever falls into three categories:

(a) evidence purporting to demonstrate the existence of an ascending dose response curve for aspirin above 650 mg. and, thereby, the superiority of a two tablet **[67]**dose of Anacin, which contains 150 mg. more aspirin than a two tablet dose of 5 grain aspirin;

(b) evidence purporting to demonstrate the analgesic benefit of caffeine; and

(c) the results of two clinical tests conducted for American Home by Dr. Gilbert McMahon, and reported in RX 31.

This evidence fails to establish Anacin's analgesic superiority over common 5 grain aspirin.

2. *Two Well-Controlled Clinical Studies Are Necessary To Establish The Comparative Efficacy Or Safety Of Analgesic Products*

197. The best type of evidence for the purpose of establishing the comparative efficacy of OTC analgesics is well-controlled clinical testing, *i.e.,* rigorously regulated observation and analysis of pain and pain relief in real patients, suffering real pain, treated in a clinical setting (Forrest, Tr. 447, 472–73; Azarnoff, Tr. 601; Moertel, Tr. 942–43; DeKornfeld, Tr. 2778; Lasagna, Tr. 4177; CX 367Z074).

198. Due to the inherent nature of pain, clinical studies establishing the comparative efficacy of OTC analgesics employ a subjective response methodology, *i.e.,* an approach based on the subject's own report of the pain experienced and the degree of relief obtained after administration of the test drug (Forrest, Tr. 422, 443, 485–87, 560–70; Moertel, Tr. 945, 946; Lasagna, Tr. 4123; CX 367Z007, Z074).

199. Since at least the early 1950's, the medical and scientific community has required well-controlled clinical studies to establish absolute or comparative analgesic efficacy (Moertel, Tr. 1021–25; Rickels, Tr. 1228–29; DeKornfeld, Tr. 2785–86, 2827; Wallenstein, Tr. 3490; Lasagna, Tr. 4119).

200. Two or more independently conducted, well-controlled clinical studies are required to establish the comparative efficacy of OTC analgesics for the relief of mild to moderate pain. The tests should conform in design, execution and analysis to generally recognized standards and criteria for clinical studies (Forrest, Tr. 449–50; Azarnoff, Tr. 601, [68]609–10; Moertel, Tr. 942, 956–57; DeKornfeld, Tr. 2778, 2780–81; Lasagna, Tr. 4142–44, 4178; CX 367Z001, Z074–Z075). These fundamental principles for testing the comparative efficacy of OTC analgesics have been recognized by the FDA OTC Internal Analgesics Panel (CX 367Z074–Z075; F. 201–17, *infra.* See also CX 367Z001–Z002).

201. A threshold requirement for an adequate and well-controlled clinical study is an independent and unbiased investigator, experienced in both the area of inquiry and the experimental technique to be utilized (Forrest, Tr. 462–63; Moertel, Tr. 943–44; DeKornfeld, Tr. 2778–79). Clinical investigators are susceptible to influence by extraneous factors. While good controls can eliminate or compensate for many of these factors, investigator bias can nonetheless enter into and affect all phases of clinical studies (Moertel, Tr. 943–44; DeKornfeld, Tr. 2778–79; Lasagna, Tr. 4142).

202. The nurse or other person employed as the "observer," administering treatments and recording subjects' responses, must also be trained and experienced in order to prevent error or bias from entering into the study (Forrest, Tr. 462; Moertel, Tr. 951; DeKornfeld, Tr. 2784; Lasagna, Tr. 4125).

203. The development of a written protocol prior to commence-

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ment of the study is an essential aspect of a well-controlled clinical investigation. An acceptable written protocol should set out in detail, among other things, the purpose of the study, the type of patients to be studied, the treatments and dosages to be administered, the parameters to be evaluated and the analytic techniques, including the statistical analysis, to be employed in evaluating the results (Azarnoff, Tr. 604–05, 608–09; Moertel, Tr. 947–48; DeKornfeld, Tr. 2778; Lasagna, Tr. 4124). By adhering to a protocol set out in advance, the investigator protects against biases which might develop and otherwise influence the course of the study's execution or analysis, *e.g.*, by later "peeking" at and/or "massaging" the data (Azarnoff, Tr. 604, 643; Moertel, Tr. 952; DeKornfeld, Tr. 2783; Lasagna, Tr. 4858–59). A written protocol facilitates any subsequent peer review of the study and judgment as to its reliability.

204. To establish the comparative efficacy of OTC analgesics for a particular type of pain, such as headache pain, at least one of the required two clinical studies must employ an appropriate pain model. That is, the pain selected for testing must respond to analgesic medication in a manner similar to that for which the analgesic is ultimately intended (Forrest, Tr. 443–44, 447–49; Azarnoff, **[69]**Tr. 610–11; DeKornfeld, Tr. 2778–80; Lasagna, Tr. 4144–45). The best pain model is that type of pain for which the drug is to be used, *e.g.*, for which a claim of efficacy may later be made (Forrest, Tr. 447–49; DeKornfeld, Tr. 2780).

205. Clinical studies can be and have been conducted on headache pain. One such study, conducted by Murray, was published in *Clinical Pharmacology and Therapeutics*, Volume 35, No. 1 (1968) (Wallenstein, Tr. 3467; Lasagna, Tr. 4132). Indeed, clinical studies were conducted for American Home on relief from pain due to headache (CX 301 and CX 302). Such studies can be undertaken in a relatively short amount of time; the Murray study, for example, took only 12 weeks (Lasagna, Tr. 4166–67).

206. Other pain models which have been employed in clinical studies of OTC analgesics are post-partum pain (including pain resulting from intra-uterine cramping and episiotomy), cancer pain, post-operative pain and pain due to trauma (See F. 245–55, 279, 286 and 290, *infra*). Intra-uterine cramping pain results from spasms due to continued contractions of the uterus, sometimes for several days, after a woman has given birth (Kantor, Tr. 3554). Episiotomy pain results from a surgical incision in the wall of the vulva which allows the birth canal to open slightly wider, thereby facilitating the birth; the incision is sutured after the birth (Kantor, Tr. 3555).

207. An appropriate number of patients should be used to study

each treatment administered in the study. For clinical studies of OTC analgesics, each treatment group should contain between 30 and 60 subjects (Forrest, Tr. 444; DeKornfeld, Tr. 2781–82; Kantor, Tr. 3554; Okun, Tr. 4499; CX 367Z074).

208. The subject population must be randomly distributed among the treatment groups. Randomization balances out variables and potential biases not otherwise controlled for in the study (Forrest, Tr. 444; Azarnoff, Tr. 601; Wallenstein, Tr. 3488; Lasagna, Tr. 4123; CX 367Z074).

209. Furthermore, in a single dose study, where each patient receives only one of the test treatments, the subject population should be stratified as to important variables (*e.g.*, degree of pain), and then be randomly distributed. Such a procedure assures that these variables will fall equally into all treatment groups (Moertel, Tr. 949–50; Azarnoff, Tr. 602). **[70]**

210. In working with OTC analgesics, where products are well known and readily identifiable by their shape, color or other distinctive attribute, the pain relief obtained can be dramatically affected by pre-existing biases or expectations toward the products on the part of the subjects, investigator, observer or others involved in the execution of the study (DeKornfeld, Tr. 2782). Those conducting the study can communicate their biases to the subjects, as well as be influenced themselves in the execution and evaluation of their work. Differences in taste, shape and form, regardless of whether a product's identity is perceived, can differentially affect placebo responses, *i.e.*, generate a greater or lesser degree of relief based on expectations alone, apart from the pharmacologic activity or inactivity of the drug.

211. To eliminate this major source of bias, the clinical study must be double-blinded. Neither the subject nor those conducting the study should be able to identify the test drugs. All treatments should be made to appear identical in every respect, and the actual identity of the treatments must remain undisclosed to those conducting the study until after preliminary analysis of the data is completed. With the exception of circumstances where single blinding (*i.e.*, blinding only the subject) is ethically necessary, double-blinding is a prerequisite of a well-controlled clinical study (Forrest, Tr. 444, 457, 458; Moertel, Tr. 948; DeKornfeld, Tr. 2778, 2782; Wallenstein, Tr. 3488; Lasagna, Tr. 4123, 4126, 4128).

212. In most instances, a well-controlled clinical study should include a placebo control. This is the customary practice in two-drug comparison studies. The placebo, a pharmacologically inactive

treatment, acts as a built-in measure of the sensitivity of the study (Forrest, Tr. 459–61).

213. In clinical studies of mild to moderate pain, the placebo response rate, *i.e.*, the rate of positive responses (perceived relief) in the presence of a pharmacologically inactive drug, is commonly between 30% and 60% (Forrest, Tr. 496; Lasagna, Tr. 4133). A study done by Murray on headache pain patients showed a placebo response rate of 57%, while a headache study done by Jellinek showed a placebo response rate of 52% (Lasagna, Tr. 4131–32).

214. The ability of a clinical study to differentiate between a placebo and a known active drug, such as aspirin, by showing a higher response rate for the latter, is a direct measure of test sensitivity since the effect of [**71**]the placebo is often to mimic the effect of the drug under study (Forrest, Tr. 444, 446, 460–61; Azarnoff, Tr. 605–06; Moertel, Tr. 950; DeKornfeld, Tr. 2785; Lasagna, Tr. 4134).

215. A placebo also controls for spontaneous changes in the course of the subject's pain experience, *e.g.*, where pain is self-limiting and would be relieved regardless of a drug's pharmacologic activity (Lasagna, Tr. 4128, 4130).

216. In order to be accepted as showing a difference among drugs tested in a study, the results must demonstrate that the differences observed are statistically significant at the 95% level of confidence. That is, the likelihood that the results obtained were due to chance cannot be greater than 5% (Forrest, Tr. 456; Azarnoff, Tr. 608; Moertel, Tr. 954–55; DeKornfeld, Tr. 2784; Lasagna, Tr. 4136–37; Okun, Tr. 4420).

217. Subjecting a clinical study to peer review, which occurs when a study is submitted for publication in a reputable journal, adds an extra guarantee of reliability to the study (Forrest, Tr. 463; Moertel, Tr. 956).

218. The individual consumer of OTC analgesics can perceive and report pain and the degree of relief obtained from pain. This ability forms the basis of the subjective response methodology that is employed in the clinical studies of OTC analgesics and other drugs (Forrest, Tr. 485–87). However, when a consumer of OTC analgesics experiences pain relief in the uncontrolled environment of daily life, he is unable to distinguish the pharmacologic contribution, if any, of the OTC analgesic from a host of other factors (Forrest, Tr. 501; Azarnoff, Tr. 626, 655; Moertel, Tr. 943, 947; DeKornfeld, Tr. 2794–97). He cannot, for example, differentiate a true pharmacologic response from a response due to the suggestion and expectation surrounding the taking of a drug, *i.e.*, a placebo response (Azarnoff,

Tr. 626, 655; Moertel, Tr. 942; F. 214, *supra*). The consumer cannot determine whether pain relief in a given instance has occurred spontaneously or as a result of medication. Mild to moderate pain, such as headache pain, is self-limiting, eventually disappearing if left to itself (Moertel, Tr. 942; DeKornfeld, Tr. 2795; CX 367I).

219. Furthermore, the consumer lacks reliable means for comparing his experiences with the same or different OTC analgesics. In addition to the problem of memory, the consumer has no way of accounting for differences in the intensity of pain each time he has sought relief from an analgesic (Azarnoff, Tr. 626, 655). **[72]**

220. A large number of substances which enjoyed wide consumer acceptance as effective remedies have been shown in clinical studies to be totally ineffective and have been removed from the market (DeKornfeld, Tr. 2797). Dr. Lasagna demonstrated that, even on a blinded basis, individual consumers are unable to distinguish the comparative therapeutic effect of five OTC analgesics (Lasagna, Tr. 4185).

221. Measurements of absolute and comparative analgesic efficacy in animals have failed to predict with any degree of consistency the performance of analgesics in man (Forrest, Tr. 447–49; Azarnoff, Tr. 646; Okun, Tr. 4462; CX 367Z074). The ultimate conclusion as to the analgesic efficacy of a drug must be based on clinical tests conducted on humans, not animals (McMahon, Tr. 3992).

222. No correlation has as yet been established between the amount of analgesic in the bloodstream and the degree of pain relief. Thus, blood level studies are not an accepted basis for predicting comparative analgesia (Forrest, Tr. 449, 556; Azarnoff, Tr. 617, 620–21; Moertel, Tr. 958; DeKornfeld, Tr. 2786–87; Okun, Tr. 4325, 4329, 4424; CX 367 O, Z004, Z007).

223. The clinical experience of doctors with their individual patients is not a sufficient basis upon which to make a determination of the absolute or comparative efficacy of mild analgesics in the general population (DeKornfeld, Tr. 2797) because an individual (doctor or patient) cannot evaluate various mild analgesics on an unblinded basis and make a scientifically sound determination about comparative pharmacological efficacy (DeKornfeld, Tr. 2794–96; F. 218 and 219).

224. Tests employing experimental pain models (pain that is artificially induced in humans) have proven poor predictors of the clinical performance of analgesics in humans (Lasagna, Tr. 4144–45; Okun, Tr. 4461–62; CX 367Z074).

225. Thus, consumers cannot evaluate for themselves the actual pharmacologic efficacy or comparative efficacy of OTC analgesics.

Attempts to measure absolute and comparative efficacy of mild analgesics other than by well-controlled clinical trials have not been shown sufficiently reliable to establish absolute or comparative efficacy in man.

3. *The Dose-Response Curve*

226. The dose-response curve for a drug is a graphic expression of the anticipated relationship between the size of [73]the drug dosage and the degree of therapeutic response based on tests of two or more graded doses of the drug. The classic dose-response curve for most active drugs is positive; that is, as you increase the dosage you get an increase in the therapeutic effect until the curve reaches a plateau, beyond which no additional benefit is obtained by increasing the dosage (Forrest, Tr. 556–57; Kantor, Tr. 3561; Lasagna, Tr. 4102: Okun, Tr. 4317–18).

227. The dose-response curve is plotted as follows: clinical studies relating graded doses of aspirin to degrees of pain relief obtained generate a series of data for each dosage tested; by averaging the results of the observations for each dosage tested, a mean is obtained; the mean results for the graded doses are then plotted on a graph (usually with dosage on the horizontal axis, and change in pain intensity on the vertical axis); and, finally, a line connecting the data points (mean results) is mathematically drawn (Okun, Tr. 4489–91, 4519–20; Lasagna, Tr. 4953).

228. Since the points actually plotted on the curve are means, there will be individuals who fall above the mean (more pain relief than the average) as well as individuals who fall below the mean (less pain relief than the average) at each data point (Lasagna, Tr. 4953–55). The spread of the cluster of observations around each data point representing a dosage level (compact or sloppy) affects the significance that can be attached to the mean; the more scattered the actual observation points in relation to each mean are, the less reliable the dose-response curve becomes (Okun, Tr. 4492–93, 4497–98).

229. The dose-response curve is generally accepted by clinical pharmacologists as a useful statistical tool in guessing the efficacy of a drug dosage in terms of its anticipated potency based on clinical data obtained from actual tests of graded dosages. As such, it is based on extrapolation (Kantor, Tr. 3656; Lasagna, Tr. 4106–07; Okun, Tr. 4323–24, 4339–40, 4495–96. See also Forrest, Tr. 529, 530–36; Azarnoff, Tr. 669–70; DeKornfeld, Tr. 2815–16).

230. The line that is fitted to the mean points, and thus

represents the dose-response curve, is based on inference and assumption since not all points (dosages) along the line are tested. Indeed, respondents' experts, Drs. Kantor, Lasagna and Okun, conceded that a dose-response curve is merely a best estimate of the points being measured and that the belief that unmeasured points will fall along [74]such a curve is premised only upon a likelihood, albeit a great one (Kantor, Tr. 3571–72, 3656; Lasagna, Tr. 4271–73; Okun, Tr. 4506–09).

231. The mere fact that a drug (*i.e.*, Anacin) has a greater amount of active ingredient (*i.e.*, aspirin) than another drug (*i.e.*, common 5 grain aspirin) does not necessarily mean that the extra amount of active ingredient provides an extra amount of therapeutic effect. The precise shape of the dose-response curve, including its plateau level and the dosage point where reverse response, if any, begins, must be determined empirically. An extra amount of active ingredient may not be of clinical significance if increasing the dosage produces only very small changes in response before a plateau level is reached (Azarnoff, Tr. 639–42; DeKornfeld Tr. 2804; Kantor, Tr. 3612–13; Lasagna, Tr. 4102, 4246–48; Okun, Tr. 4510–12).

232. The term clinical significance, as used in this proceeding, commonly refers to the practical application of a drug. For example, a drug may be proven safe and effective but may only work for a 15-minute duration, thus destroying its clinical utility. On the other hand, the term "statistical significance," as used in this proceeding, is a scientific term; it refers to the quality and quantity of data deemed essential to establish a fact in medicine (DeKornfeld, Tr. 2825–26). Dr. DeKornfeld stated that if the comparative efficacy of a pharmacologic agent is established to a statistically significant degree, then he would be willing to assume that the drug would be clinically effective providing it had no features rendering it clinically unusable (DeKornfeld, Tr. 2826–27).

233. Respondents' expert, Dr. Okun, admitted that the dose-response curve does not allow one to project statistical significance for points on the line that are not based on actual data readings. Thus, the curve does not serve the function of predicting whether the differences observed on the graph between different dosage levels and the degrees of pain relief obtained are or are not statistically significant (Okun, Tr. 4476, 4493–94).

234. The relationship of increased aspirin dosage to increased analgesia is not linear; rather, the effect is recognized as proportional to the logarithm of the dosage (Azarnoff, Tr. 645; DeKornfeld, Tr. 2804; CX 367T).

235. Whether a suggested difference between two dosage levels of

a drug is or is not statistically significant can only be determined through a clinical trial **[75]**that actually tests the drug at the two pertinent dosage levels (Okun, Tr. 4476).

236. A substantial portion of the testimony of respondents' expert witnesses addressed the issue of the dose-response curve for aspirin, contending that an ascending curve is established and is scientifically accepted as evidence for the proposition that Anacin is more effective in the relief of pain than a regular dose of aspirin.

237. Dr. Lasagna testified that there is evidence that the additional amount of aspirin contained in Anacin provides increased pain relief compared to 650 mg. aspirin. He stated his belief that there is no substantial question that there is a dose-response curve for aspirin above 650 mg. (Lasagna, Tr. 4107–08).

238. In fact, in Dr. Lasagna's opinion, as the dosage of aspirin is increased, analgesic response will increase at least until the range of approximately 1200 to 1800 mg. is reached. Dr. Lasagna made reference to clinical studies by Dr. Raymond Houde and Mr. Stanley Wallenstein, Drs. Kantor, Parkhouse, McMahon, Murray and Forrest, which purport to demonstrate a statistically significant positive linear slope for the aspirin dose-response curve from which judgments and conclusions based on estimates are made concerning intervening points on the curve (Lasagna, Tr. 4103, 4105–06, 4257, 4262–63, 4265–71, 4276, 4903–05, 4906, 4913–14, 4932–33).

239. According to Mr. Wallenstein, there is no substantial question as to the existence of a dose-response relationship for aspirin given the replication of his findings in many different clinical investigations performed on many types of pain (F. 245, *infra*). In his opinion, the recommended dose of Anacin will afford greater analgesia than 650 mg. aspirin (Wallenstein, Tr. 3466–68, 3470–73, 3476–77).

240. Dr. Kantor testified that a dose-response curve is established for aspirin. He stated there is substantial evidence of the fact that when more aspirin is administered, more pain relief is obtained. In his view, a majority of experts support this proposition, and it is not open to substantial question. In Dr. Kantor's opinion, 800 mg. aspirin would be higher on the dose-response curve than 650 mg. aspirin, and an 800 mg. dose of aspirin would produce more analgesic activity than a 650 mg. dose of aspirin (Kantor, Tr. 3554–66, 3582–83, 3619–20, 3623, 3632–38, 3654–55). Dr. Kantor, therefore, has concluded **[76]**that two Anacin have more analgesic effect than 650 mg. aspirin (Kantor, Tr. 3568).

241. Dr. Okun testified that the existence of the dose-response relationship for aspirin is established, and that the proposition that

aspirin's analgesic effectiveness increases as the dosage is increased up to at least 1200 mg. is unquestioned. Based on reports of clinical investigations and his own clinical experience, Dr. Okun concluded that, because 800 mg. was within the parameters of the dose-response curve established for aspirin, 800 mg. aspirin is more effective than 650 mg. (Okun, Tr. 4317–25, 4485–86).

242. In Dr. McMahon's opinion, the aspirin dose-response curve reported in the medical literature is established and is consistent with clinical experience. He testified that the positive ascending slope of the curve demonstrated in the various studies establishes that if increased doses of aspirin are administered, increased effectiveness will be achieved through the range from 200 mg. to approximately 1200 to 1800 mg. Therefore, Dr. McMahon concluded that 800 mg. aspirin is more effective than 650 mg. (McMahon, Tr. 3788–90, 3896–98).

243. Despite the opinions of respondents' expert witnesses, numerous clinical studies have been unable to conclusively demonstrate the existence of a positive dose-response curve for aspirin; increased doses of aspirin have not consistently been shown to produce greater analgesia than lower doses (F. 245–55, *infra*).

244. Indeed, graded dose studies on aspirin suggest that, if a curve exists, it is extremely shallow, or nearly flat (Azarnoff, Tr. 639–42; Kantor, Tr. 3563; CX 367T. See also F. 234, *supra*).

245. Mr. Wallenstein testified that his publication, *Analgesic Studies of Aspirin in Cancer Patients* (RX 32), represents a compendium of analgesic studies done over a number of years at the Sloan-Kettering Institute. Portions of this work had previously been published in 1958 by Drs. Houde and Modell in an article, *Factors Influencing Clinical Evaluation of Drugs*, which appeared in the Journal of the American Medical Association. In comparing 400 mg., 600 mg. and 900 mg. aspirin in 14 patients suffering from cancer pain, an ascending dose-response curve with a statistically significant positive slope was demonstrated. The total effect of the aspirin increased in a straight line with the increased log of the dose; this relationship [77]was found to be statistically significant at the 95% confidence level. Statistically significant differences in effectiveness were shown between 600 and 900 mg. in terms of total analgesic effect. However, no statistically significant differences were shown among the dosages in terms of peak effect (Wallenstein, Tr. 3429–4(Lasagna, Tr. 4915–16; RX 32 at 7–8).

246. A 1976 graded dose study on episiotomy pain by Bloomfie et al., published in *Clinical Pharmacology and Therapeutics* (Volu 20, p. 449), compared 600 mg. aspirin to 1200 mg., a difference

aspirin amount four times as great as that between two tablets of Anacin and two tablets of 5 grain aspirin. He found no statistically significant difference in pain relief, and attributed this result to a ceiling or plateau effect at 600 mg. (Lasagna, Tr. 4260–61).

247. A 1968 article by Parkhouse, published in *British Journal of Anesthesia* (Volume 40, p. 433), compared dosages of 600 and 1200 mg. aspirin in five studies measuring the relief of post-operative pain. Two of the studies showed no greater pain relief obtained from 1200 mg. than 600 mg.; at no time was a statistically significant difference in pain relief shown in a direct comparison between 600 and 1200 mg. (Lasagna, Tr. 4262–63, 4919–20, 4969–71). Dr. Lasagna noted that in two of the five studies, Parkhouse found a statistically significant slope to a line drawn between points plotting dose-response data for 600 and 1200 mg. (Lasagna, Tr. 4921–24), but admitted that this related only to the manner in which the line was constructed and did not signify a statistically significant difference in response between the two doses (Lasagna, Tr. 4969–71).

248. Dr. Kantor's testimony, concerning the numerous graded dose-response studies he had conducted, revealed that those studies generally failed to show the analgesic superiority of doses larger than 600 mg. (F. 249–55, *infra*).

249. In two graded dosage studies, on intra-uterine and episiotomy pain, each using doses of 600 and 1200 mg. aspirin, the combined data failed to show a dose related effect for aspirin, although in one test the difference between 600 and 1200 mg. in relieving episiotomy pain was shown to be statistically significant for one hourly period (Kantor, Tr. 3578–81).

250. In one study by Kantor on obstetrical pain, 230, 600 and 2000 mg. aspirin were compared, along with Excedrin, using 30 patients per treatment group. The study showed no [78]statistically significant differences in total relief between 600 mg. and 2000 mg. aspirin (Kantor, Tr. 3588–95).

251. In another study on uterine and episiotomy pain, 200, 600 and 1800 mg. aspirin, along with Excedrin, were compared, using 38 patients per treatment group. There were no differences, by any parameter used, between the 600 and 1800 mg. dosages of aspirin (Kantor, Tr. 3596–98).

252. Again, in another study, using post-partum pain, Dr. Kantor compared 300, 600 and 1200 mg. aspirin, along with Excedrin, using patients per treatment group. In the 25 different parameters studied, no statistically significant differences were found between and 1200 mg. aspirin (Kantor, Tr. 3606–07).

253. Dr. Kantor also conducted a study comparing 150, 300, 450,

600, 1200 and 1800 mg. aspirin on combined uterine and episiotomy pain. No statistically significant differences were found between 600 and 1200 mg. aspirin, with only 1800 mg. showing superiority over the lower doses (Kantor, Tr. 3607–09).

254. In yet another study, this time on post-surgical and post-trauma pain, using 30 patients per treatment group, Dr. Kantor compared 600 and 1200 mg. aspirin against a test drug. He found 1200 mg. aspirin less effective than 600 mg., suggesting that if an ascending dose-response curve exists, it may begin to slope downward at some point above 650 mg. aspirin, at least for this type of pain (Kantor, Tr. 3612–13).

255. Finally, in a study on analgesic potency and anti-inflammatory drugs, published in *Arthritis and Rheumatism* (Volume 7, No. 20 (1977)), 300, 600 and 1200 mg. aspirin were compared by Dr. Kantor for relief of post-trauma pain; no statistically significant differences between 600 and 1200 mg. aspirin were found (Kantor, Tr. 3614–16).

256. In sum, the evidence regarding the existence of an ascending dose-response curve for aspirin, above 650 mg., is equivocal. This evidence suggests that, if such a curve does exist, it either is shallow and flat (F. 244, *supra*), or there is a plateau between 650 mg. and 1200 to 1800 mg. The available evidence, including the second study conducted by Dr. McMahon in RX 31, suggests a plateau between 600 and 1200 mg. aspirin for at least one type of pain, *i.e.*, uterine pain (Kantor, Tr. 3596; Lasagna, Tr. 4881). **[79]**

257. Within the dosage ranges where aspirin has been shown to be dose-responsive, a large increase in dosage is usually required in order to obtain a relatively small increase in analgesic response (F. 234 and 244, supra; CX 367T).

258. Nonetheless, based on the record evidence concerning the clinical experience of medical experts and the existence of the dose-response curve, it is reasonable to conclude that some people who fail to achieve pain relief with 650 mg. aspirin could conceivably obtain relief with higher doses (Lasagna, Tr. 4103–05, 4154–58, 4243–44, 4275–76; RX 32; CX 367Z041-Z042).

259. Respondents' expert witnesses agreed that the proposition that a recommended dose of Anacin would fall on the purported dose-response curve at a point statistically significantly different from that of 650 mg. aspirin was a mere inference, although based on sound pharmacological reasoning (Wallenstein, Tr. 3513; Kantor, Tr. 3633, 3642; McMahon, Tr. 3981; Lasagna, Tr. 4899. See also DeKornfeld, Tr. 2817). Given Anacin's small increment of aspirin over common 5 grain aspirin (150 mg. when two tablets of each

compared), as compared to dosages of 1200 and 1600 mg. aspirin, any claim of Anacin's superior efficacy derives little, if any, support from the available data.

260. Regardless of whether a dose-response curve for aspirin exists, it has not been established that the additional amount of aspirin in a recommended dose of Anacin makes it more effective than a recommended dose of 5 grain aspirin for the relief of mild to moderate pain, the condition for which the drugs are indicated (Azarnoff, Tr. 614; Moertel, Tr. 969–70; DeKornfeld, Tr. 2789–91).

261. A further consideration is that the addition of caffeine to the 800 mg. aspirin in Anacin raises the question of whether Anacin's dose-response curve is the same or similar to that for aspirin. Nothing is known about the dose-response curve of aspirin-caffeine combinations (Lasagna, Tr. 4265). Well-controlled clinical tests would be required to determine where Anacin, as distinguished from 800 mg. aspirin, would fall on such a curve (Wallenstein, Tr. 3514).

262. The record fully supports the proposition that well-controlled clinical trials are required to establish, in a scientific sense, the analgesic superiority of Anacin [80]over common 5 grain aspirin (Forrest, Tr. 465; Wallenstein, Tr. 3513; Kantor, Tr. 3648–49; Lasagna, Tr. 4976–77).

4. *Caffeine*

263. Caffeine is not considered an active ingredient for analgesic purposes (Forrest, Tr. 547). In therapeutics, it is mainly used as an ingredient in analgesic combinations and as an ingredient in certain preparations that are used for the treatment of migraine headaches (Lasagna, Tr. 4097; Okun, Tr. 4359–60). For instance, the FDA OTC Internal Analgesics Panel concluded that caffeine (citrated caffeine) when used alone in an adult oral dosage of 65 mg. not to exceed 600 ng. in 24 hours is safe but ineffective as an OTC analgesic ingredient CX 367Z112).

264. Caffeine is a member of a class of drugs known as xanthines)kun, Tr. 4352–53). Caffeine has been described as a central nervous stem stimulant that acts on the kidneys to produce increased cretion of urine and on the vascular system to cause a constriction blood vessels in certain parts of the body, stimulating cardiac ponse and relaxing smooth muscles. Caffeine acts on the scalp and rnal skull within the brain, causing initial constriction of blood els at first and eventual dilation of them, thereby enlarging the ieter of the blood vessels so that blood can flow more easily. This ianism acts to reduce headache pain (Lasagna, Tr. 4097; Okun,

Tr. 4354–56; CX 367Z005). Caffeine is also a known secretagogue (known stimulant in the production of hydrocholoric acid in the stomach) (Shapiro, Tr. 2969).

265. Respondents' witness, Dr. Okun, testified that caffeine tends to liberate within the body certain classes of hormones called catecholamines, which are known to cause analgesia in humans (Okun, Tr. 4358).

266. Dr. Okun stated his belief that, in doses of 50 to 100 mg., caffeine tends to offset aspirin's lethargic reaction by keeping the patient more alert. Caffeine, in usual doses, causes wakefulness and alertness and will alert the patient more to his environment and less to the pain (Okun, Tr. 4352–54). However, another of respondents' witnesses, Dr. Lasagna, stated that caffeine possibly could make an individual more aware of pain (Lasagna, Tr. 4972–73). [81]

267. For the last 50 years, "APF" has been a commonly used analgesic combination. APF tablets normally contain aspirin, phenacetin and approximately 32 mg. caffeine (Complaint Counsel's Admission, RX 244Z017–Z018). There are analgesic products sold by prescription which contain approximately 65 mg. caffeine in recommended doses which are marketed on the basis of FDA approved New Drug Applications (NDA's). In fact, during the period of July through December 1976, the FDA approved NDA's, supplemental NDA's or abbreviated NDA's for at least five analgesic drugs containing, on a per tablet basis, between 30 to 40 mg. caffeine (Complaint Counsel's Admission, RX 244Z016–Z019).

268. There is no evidence in this record to indicate that the addition of caffeine to aspirin would depress, detract or hinder the analgesic effect of Anacin's aspirin content or have any negative effect on aspirin's normal dose-response curve.

269. However, there is also no evidence, in the form of well-controlled clinical tests in humans, demonstrating that caffeine has any positive analgesic effect in combination with aspirin (Kantor, Tr. 3568; Lasagna, Tr. 4222–24; Okun, Tr. 4454–58). Dr. Okun cited studies by Vinegar on animals, which indicated an analgesic effect for caffeine (Okun, Tr. 4357–58, 4359). However, animal studies are unreliable predictors of analgesic efficacy in man and, thus, unacceptable for purposes of establishing the analgesic effect of caffeine (Lasagna, Tr. 4217). Moreover, the popularity of caffeine in combination analgesic products is not a scientific basis for concluding that it has any analgesic effect (Lasagna, Tr. 4215).

270. Testimony by four of respondents' expert witnesses indicated doubt surrounding the usefulness of caffeine in combination with aspirin. Dr. Lasagna conceded that the analgesic effectiveness o

caffeine had not been proven (Lasagna, Tr. 4227). Dr. Kantor stated that he had not yet come to an absolute conclusion on the value of caffeine, but was currently conducting a test on that precise question (Kantor, Tr. 3567–68). Mr. Wallenstein also conceded the need for further study to determine if caffeine adds to the analgesic effect of aspirin (Wallenstein, Tr. 3512). Dr. McMahon testified that he had published an article in 1971 calling for the removal of caffeine from analgesics as worthless (McMahon, Tr. 3985); although he stated that his mind has since changed, he did indicate that he still is uncertain that the addition of caffeine to analgesic products is worthwhile (McMahon, Tr. 3985–88). Furthermore, [82]the FDA OTC Internal Analgesics Panel reported that the combination of aspirin with caffeine requires additional testing to demonstrate efficacy because of insufficient evidence of the effectiveness of this combination as an OTC analgesic product at the present time (CX 367Z001, Z112). Also, *The AMA Drug Evaluation* (CX 362), a highly reliable and recognized text on drug therapy (Forrest, Tr. 488; Azarnoff, Tr. 625; Lewis, Tr. 781–84; Moertel, Tr. 990–91; Shapiro, Tr. 3108), and *The Medical Letter on Drugs and Therapeutics* (CX 363), another highly reputable and reliable source of information on drug safety and efficacy (Forrest, Tr. 487; Azarnoff, Tr. 625; Moertel, Tr. 990; Sliwinski, Tr. 1152; DeKornfeld, Tr. 2771), reported that they found that it had never been established that the addition of caffeine to aspirin resulted in any differential effect on analgesic activity (CX 362X, CX 363B).

271. A clinical investigation demonstrating caffeine's contribution to analgesia was discussed by Mr. Wallenstein. Dr. Houde and Mr. Wallenstein conducted a clinical trial comparing aspirin, caffeine and paracetamol (acetaminophen) in different combinations. The study was designed to determine the effects of one and two tablets of each combination, and the contribution of each of the active ingredients. The results from the one-tablet administration of each drug showed the effects of the combination drugs to be somewhat superior to the effects of either drug alone, but the differences were not statistically significant at the 95% confidence level. However, the results of the two-tablet administration revealed that only the combination drug containing caffeine was better than ther drug alone and this difference was statistically significant at e 99% confidence level, indicating that caffeine may have increased or added to the analgesic effect (Wallenstein, Tr. 3460–64).

272. Mr. Wallenstein testified that the results of this study gest that 60 mg. of caffeine may produce an effect not seen in er doses in terms of increased analgesic effect, and that Dr.

Houde has written (R. Houde, *Study of Aspirin N-Acetyl-p-Aminophenol and Caffeine Combinations*) that the data from these caffeine studies provide some evidence to show that caffeine contributes to the efficacy of these drugs (Wallenstein, Tr. 3461–64, 3519; RX 32 at 8–9; CX 367Z113–Z114).

273. However, the Wallenstein study did not compare aspirin with and without caffeine, but rather aspirin versus a combination of aspirin, paracetamol (acetaminophen) and caffeine. Mr. Wallenstein never tested caffeine alone in combination with aspirin (Wallenstein, Tr. 3464, 3504). The [83]report by Mr. Wallenstein of his study specifically concluded that "the results with caffeine must be considered equivocal" (RX 32). Indeed, Mr. Wallenstein testified that the studies in RX 32 were not proof that caffeine enhances analgesia (Wallenstein, Tr. 3501–02), since, when the two studies including caffeine combinations were combined, any significant increase in effect which might have been attributed to caffeine disappeared (Wallenstein, Tr. 3463).

274. CX 361, a study by Dr. Moertel, entitled *Relief of Pain by Oral Medication—A Controlled Evaluation of Analgesic Combinations,* published in *The Journal of the American Medical Association,* Volume 229 (1974), is the only clinical study which has directly compared aspirin with and without caffeine (Lasagna, Tr. 4220). The combination of aspirin and caffeine was not shown to afford greater pain relief than aspirin alone, and actually performed more poorly although not at a statistically significant level (Moertel, Tr. 965).

275. However, Dr. McMahon, testifying on behalf of respondents, criticized CX 361 as seriously flawed in its methodology. As explained by Dr. McMahon, the methodology utilized was experimental and unproven. Only outpatients were used; hourly observations or interviews by trained personnel were not done; patients recorded the percentage of pain relief without any verification of the accuracy of recordation; patients were instructed not to take medication more than six hours apart, but there was no evidence that this instruction was complied with; and there was an unsupported assumption that patients took medication as scheduled from 10 different envelopes. In Dr. McMahon's opinion, the instruction that patients should compare their pain intensity or degree of relief at the end of the study period with their baseline pain would be an almost impossible task for outpatients to perform accurately (McMahon, Tr. 3994–97).

276. In the absence of well-controlled clinical studies directly comparing aspirin with and without caffeine, caffeine's pharmacological effect as an adjuvant in an analgesic preparation is unknown.

277. The record, as a whole, demonstrates that the effect of caffeine as a potentiator or adjuvant to aspirin has not been established (Forrest, Tr. 474, 475, 521, 522, 524; Azarnoff, Tr. 613; Moertel, Tr. 960; DeKornfeld, Tr. 2789; CX 367Z001, Z112). [84]

278. Therefore, it has not been established that the 65 mg. caffeine contained in a recommended dose of Anacin makes Anacin more effective for the relief of pain than a recommended dose of common 5 grain aspirin.

5. *The McMahon Studies*

279. The McMahon studies (RX 31) denote the report on two clinical studies (referred to here as the first and second McMahon study, respectively) comparing a recommended dose of an Anacin-like formulation, a recommended dose of aspirin and placebo on each of four measurements: pain intensity, pain relief, pain analog and global response (McMahon, Tr. 3711, 3717, 3871).

280. Pain intensity was graded on a numerical scale ranging from zero to four, with zero being no pain and four being very severe pain (only persons with a pain intensity score of at least two, *i.e.*, moderate pain, were selected for study). Pain relief was measured on a numerical scale of zero to four. Evaluations of pain were also made by utilization of pain analog scores, where the patient marked the degree of pain on a line 200 mm. long, going from no pain to the worst pain ever felt. A global impression of pain relief measured by a numerical scale of zero to five was used at the beginning of the study and after the last hourly observation to measure the patient's overall impression of the medication's benefit (McMahon, Tr. 3721–29; RX 28; RX 31).

281. The studies were conducted by Drs. McMahon, Adesh Jain and Jerome Ryan during the period 1974 to 1977. Dr. Jain, Assistant Professor of Medicine in Clinical Pharmacology at Tulane University Medical School, is a specialist in obstetrics and gynecology. Dr. Jerome Ryan, Professor of Medicine and former President of the medical faculty at Tulane Medical School, is a specialist in internal medicine and drug metabolism (McMahon, Tr. 3710–13).

282. The Tulane team conducted two double-blinded, randomized clinical trials (McMahon, Tr. 3711, 3719–20; RX 31).

283. The McMahon studies were undertaken at the behest of American Home, which made a grant in 1974 directly to the Tulane University Medical School to support the clinical tests (McMahon, Tr. 3713). In 1976, prior to the completion of the second study, Dr. McMahon became aware that the studies [85]were being conducted

for possible use in litigation by American Home (McMahon, Tr. 3713, 3834–35).

284. Dr. McMahon admitted that his initial reluctance to even consider such a study was overcome in large part by American Home's promise to increase the amount of grant money to Tulane University, which in part was to be used to support his research group. As Dr. McMahon stated: ". . . American Home Products was willing to pay Tulane University an awful lot of money and we are a poor school and the school needed the money. So, when they raised the grant, to tell the truth, we just—needed the money to support our group and to support the school" (McMahon, Tr. 3716).

285. The protocols for the studies were designed by American Home's Medical Department in consultation with Drs. Lasagna, Arthur Grollman and Kenneth Melmon. The protocols were also reviewed and approved by Drs. McMahon, Jain and Ryan (McMahon, Tr. 3715–17).

286. The first study was conducted on patients with moderate to severe uterine cramping and episiotomy pain. Patients with uncomplicated vaginal delivery were screened by a history and physical examination; those who met the entrance criteria were admitted into the study. The patients were evenly divided between episiotomy and uterine cramping pain, and were randomized into three treatment groups: 24 received 650 mg. aspirin, 24 received Anacin and 22 received placebo. The initial baseline pain intensity was severe in 34 patients and moderate in 36 patients (McMahon, Tr. 3719–22; RX 28; RX 31).

287. Two tablets of each medication were given as a single dose in a randomized manner without the patient, nurse observer or supervising physician aware of which medication was being given (McMahon, Tr. 3717–20; RX 28; RX 31).

288. Patients were closely watched by a trained nurse observer at one hour, two hours, two and one-half hours, three hours, three and one-half hours and four hours after administration of the medication for purposes of assessing the patients' pain and pain relief (McMahon, Tr. 3722; RX 28; RX 31).

289. The first study did not demonstrate any statistically significant differences between the Anacin-like formulation and plain aspirin in any of the parameters measured during any phase of the study (McMahon, Tr. 3874; Lasagna, Tr. 4865–66). **[86]**Therefore, this study does not establish the superiority of Anacin over aspirin to the satisfaction of scientists (Lasagna, Tr. 4866). Moreover, when the results on patients in moderate pain only (*i.e.*, the degree of pain for

which such products are actually used) are examined separately, the two drugs appear virtually identical (Lasagna, Tr. 4866).

290. The second McMahon study was conducted on patients with severe episiotomy or uterine cramping pain. A minimum 60% baseline pain intensity on the pain analog scale was required for admission into this study, which was also double-blinded and included 70 post-partum patients, 47 with severe episiotomy pain and 23 with severe uterine cramping pain. Patients were randomized into three treatment groups: 23 received 650 mg. aspirin, 23 received Anacin and 24 received placebo (McMahon, Tr. 3717, 3720, 3761–63, 3764).

291. Observations were made by the nurse observer at hours 0, 1, 2, 3 and 4. The pain intensity and pain relief scores were recorded on an ordinal scale of zero to 8, rather than zero to 4 as in the first study, because it was determined that the zero to 8 range would provide additional sensitivity and reliability. A visual analog pain scale and a global performance rating were also used in the second study (McMahon, Tr. 3762–67; RX 29; RX 31).

292. The second study did not show any statistically significant differences between the two test drugs for the test population, as a whole. However, the Anacin-like formulation was statistically significantly better than aspirin on the subgroup of severe episiotomy pain during the second and third hours after administration on two of the four parameters (pain intensity and pain analog). There were, however, no statistically significant differences between the two test medications either in the subgroup suffering from severe uterine cramping pain alone or in the combined population of severe episiotomy pain patients and severe uterine cramping pain patients (McMahon, Tr. 3773–75, 3881–82; Okun, Tr. 4527–31).

293. As set forth in detail below (F. 294–311, *infra*), the claimed superiority of Anacin over common 5 grain aspirin that is reported in RX 31 cannot be taken at face value for the reason that the methodology adopted and employed in the studies was seriously flawed in several important respects.

294. One of the fundamental requirements for a good clinical test design is that the purpose of the study be set out in advance (F. 203, *supra*). The subjective response **[87]**methodology that is generally utilized in the clinical testing of mild analgesics will conventionally set out the so-called null hypothesis which assumes that the drugs being tested cannot be differentiated from one another. The purpose of the study is to demonstrate that this null hypothesis is either correct or incorrect. Assuming anything but the null hypothesis introduces an opportunity for bias which can distort the data and

render the results invalid. With regard to both studies in RX 31, Dr. McMahon believed, and the written protocol in the first study presumed, that the Anacin-like formulation would prove superior in pain relief to plain aspirin. In fact, Dr. McMahon admitted that, from the outset of the study, he was unequivocally convinced that the additional aspirin in Anacin made the product superior to plain aspirin (McMahon, Tr. 3896–98).

295. The stated purpose of the first clinical study conducted by Dr. McMahon was to assess pain relief resulting from the administration of the three study medications, Anacin, aspirin and placebo, in 70 post-partum pain patients, and to test the sensitivity of the testing methodology utilized. Each Anacin tablet contained 400 mg. aspirin and 32 mg. caffeine; each aspirin tablet contained 325 mg. aspirin. The physical properties of all three tablets were identical (*i.e.,* same size and color, with no embossing) to assure that the procedure was double-blinded (McMahon, Tr. 3717, 3720; RX 31C).

296. In order to make clinical test results applicable to a commercial product, it is important that either the commercial product itself be used or that the test medication be analyzed to assure that its chemical and bioavailability characteristics are equivalent to the commercial product in question. In this light, the conclusions in RX 31 pertaining to Anacin are questionable. The methodology called for using a medication other than commercially available Anacin; no effort was made independently to determine how the test medication compared to Anacin. Dr. McMahon admitted that he had no idea how the test medications actually compared to the commercially available products in terms of bioavailability or other characteristics (McMahon, Tr. 3838–39; Lasagna, Tr. 4867). [88]

297. Dr. McMahon conceded that, although he opted not to use actual Anacin tablets, there were ways in which the commercially available products could have been used without compromising the double-blinding. These methods include putting the Anacin tablet in a capsule or actually placing the Anacin tablet in the patient's mouth (McMahon, Tr. 3840). On the other hand, four tablets could have been given to each subject, with two tablets containing the distinctive Anacin insignia and two remaining unmarked; however, one set of tablets (either the marked or the unmarked) would have been a placebo (DeKornfeld, Tr. 2820–22).

298. Another important criterion in the design and execution of clinical tests utilizing the subjective response methodology is that the written protocol which is prepared in advance of the study be rigorously adhered to throughout the course of the testing. Failure to

adhere to the written protocol provides an opportunity for bias which can diminish the reliability of the test results (F. 203, *supra*). The methodology employed in RX 31, however, was defective in this regard because Dr. McMahon departed from the written protocol as it applied to sleeping patients (McMahon, Tr. 3864–66).

299. First, the protocol required that sleeping patients be awakened. If this were not possible, then they were to be assigned their prior score. There were three instances in the first 15 patients in the first study where neither of these instructions was followed. Dr. McMahon failed to catch these errors at the conclusion of the study and failed to review the impact of the errors to determine whether or not the data on those patients should be discarded (McMahon, Tr. 3864–68). Respondents' witness, Dr. Lasagna, stated that such errors should have been caught by the investigator and their impact evaluated in terms of potential bias (Lasagna, Tr. 4858–59).

300. The methodology employed in the studies reported in RX 31 is further flawed in that, throughout the course of the testing, test data was reported on a continuing basis to American Home, which held the code to the medications and analyzed the test results. Ongoing "peeking" and evaluation of data by the party most interested in favorable results for one medication is generally recognized as injecting bias into a study and necessitates a more critical review of the ultimate conclusions (McMahon, Tr. 3837–38, 3841–42; Lasagna, Tr. 4864; F. 203, *supra*).

301. Another basic criterion in the design of a subjective response clinical test methodology is that the type of statistical analysis to which the data will be subjected **[89]**should be set forth in the protocol and followed (F. 203, *supra*).

302. A statistical analysis of the first study was performed by Dr. I. Lee, a biostatistician from Ives Laboratory, a division of American Home, using a multivariate analysis based on a split plot design, to determine whether there were statistically significant differences between the three test medications with respect to the reduction of pain intensity, pain relief and pain analog (McMahon, Tr. 3730–31; RX 28; RX 31). A separate, independent statistical analysis was also done by another firm (McMahon, Tr. 3731; RX 28). Three separate analyses were performed based on all cases, "severe" cases only and "moderate" cases only (McMahon, Tr. 3730–36; RX 28; RX 31).

303. Statistical analyses of the second study were conducted by two independent biostatisticians: Dr. Sylvia Wassertheil-Smoller of the Albert Einstein College of Medicine in New York City and Dr. Bruce Schneider, the head of the Biostatistics Section of Wyeth

Laboratories, Inc., an ethical pharmaceutical division of American Home (McMahon, Tr. 3767–68; RX 29; RX 31).

304. Both parametric and non-parametric tests were used in the statistical analysis. Tests for differences among treatments in the 47 patients with severe episiotomy pain were performed by the non-parametric Kruskal-Wallis analysis on the actual scores, on change from baseline scores and on percentage change from baseline. An analysis was also performed by one-way analyses of co-variance, which adjusts the scores for baseline differences. In all, 12 one-way analyses of variance were done: one for each of the four time periods for each of the pain categories—episiotomy, uterine and uterine plus episiotomy. The analyses compared the analgesic effects of Anacin, aspirin (650 mg.) and placebo as measured by the pain analog, pain intensity, and pain relief scores at baseline 1, 2, 3 and 4 hours (McMahon, Tr. 3768; RX 29; RX 31).

305. The methodology employed in both studies was defective because, notwithstanding the fact that the protocol specified a "fixed sample" analysis of 90 to 130 patients, the studies were actually subjected to a "sequential analysis." However, a fixed sample statistical method was utilized to evaluate the sequential data. Use of the sequential analysis caused the study to be terminated when, after "peeking" at the data, American Home determined that statistical significance had been reached for the Anacin-like formulation (McMahon, Tr. 3843–44). **[90]**

306. Dr. McMahon admitted that the written protocol called for neither a sequential analysis nor for termination once statistical significance had been reached for the Anacin-like formulation (McMahon, Tr. 3844). Dr. Lasagna commented that such a procedure is highly unusual and injects bias into the results (Lasagna, Tr. 4860).

307. Dr. Lasagna further stated that a sequential analysis would have required that the study stop once statistical significance was reached for either of the active test medications (Lasagna, Tr. 4861).

308. It is reasonable to conclude that the McMahon study would not have been stopped if aspirin, at any point, had achieved statistical significance (McMahon, Tr. 3844).

309. The methodology employed in RX 31 is further flawed in that the analysis by separate subgroups of episiotomy and uterine cramp pain patients was conceived after the initial analysis of both studies failed to demonstrate any statistically significant difference between test medications on the combined episiotomy and uterine cramp pain population (McMahon, Tr. 3756, 3757, 3775, 3883). Such an analysis arose only out of hindsight and demonstrates further

deviation from the statistical analysis that was set out in advance to provide assurance against "massaging" the data (Forrest, Tr. 463; Azarnoff, Tr. 604, 643; Moertel, Tr. 955; DeKornfeld, Tr. 2778–79, 2783–84; Kantor, Tr. 3619; CX 367Z074–Z075). Dr. Lasagna noted that the more one looks at the data after the test is completed, the more one might get "statistical slippage," *i.e.*, a greater chance that differences will be found (Lasagna, Tr. 4876).

310. In addition to the numerous and serious deficiencies in methodology, the actual report itself is flawed in that data unfavorable to American Home was omitted from the final draft. Dr. McMahon agreed that the studies, as reported in RX 31, omitted certain data (McMahon, Tr. 3884–86).

311. The data omitted from RX 31 would have demonstrated that the second study failed to show any statistically significant differences between aspirin and the Anacin-like formulation in the combined episiotomy and uterine cramp pain subgroups, a result which Dr. Lasagna indicated would not have been surprising (Lasagna, Tr. 4873–75. See also McMahon, Tr. 3775, 3881–82; Okun, Tr. 4527–28). **[91]**

312. Respondents' experts' contention boils down to a belief that if something works for severe pain, then it will work for mild to moderate pain (headache pain) as well (See, *e.g.*, Lasagna, Tr. 4068–69; Okun, Tr. 4332–35, 4337–38, 4341, 4352). However, the record does not support the view that all pain is alike (F. 204, 313–17, *infra*).

313. Drs. Kantor, Lasagna and Okun agreed that uterine cramping pain responses differ from episiotomy pain responses (Kantor, Tr. 3559–60; Lasagna, Tr. 4883–84; Okun, Tr. 4537–39, 4547–48). Dr. Lasagna also testified that migraine headache pain does not respond to aspirin because of its different etiology (Lasagna, Tr. 4069–70; CX 367H-I).

314. Even if the results of the McMahon studies were to be taken at face value, their applicability to headache pain is open to serious doubt. Dr. McMahon admitted that the comparative efficacy of some analgesics may vary, depending on the type of pain involved (McMahon, Tr. 3834). Dr. Lasagna noted that there was no way to guess which of the two types of pain studied in RX 31 (*i.e.*, uterine cramp pain or episiotomy pain) is more like headache pain (Lasagna, Tr. 4883).

315. Furthermore, although Dr. McMahon felt that the failure of the first study to show any statistically significant differences between aspirin and the Anacin-like formulation was due to the "insensitivity" of a pain model which covered the broad spectrum of moderate to severe pain, he admitted that other qualified investiga-

tors have obtained statistically significant differences between aspirin and placebo in studies utilizing a similar pain model (McMahon, Tr. 3875).

316. Dr. Lasagna conceded that comparative efficacy of one analgesic drug over another must be shown in several different types of pain before generally assuming that the drug would be superior to another in untested types of pain (Lasagna, Tr. 4968). Drs. Kantor and Okun also admitted that the type of pain involved may affect the relative efficacy of two analgesic drugs (Kantor, Tr. 3645–46; Okun, Tr. 4422).

317. Complaint counsel's witnesses insisted that at least one of the two well-controlled clinical studies necessary before claims of comparative efficacy can be considered to have been established must make use of an appropriate pain model, *i.e.,* the particular pain in question, before the results can be applied to that type of pain (F. 204, *supra*). **[92]**

318. The first McMahon study, when broken down into subgroups, demonstrated no statistically significant differences between Anacin and aspirin. Dr. McMahon admitted that statisticians would not accept any of his conclusions from the first test as showing Anacin's superiority. He further admitted that the Anacin-like formulation did not achieve the 95% confidence level of superiority, generally required among scientists to constitute statistical significance on any parameter (McMahon, Tr. 3752, 3754).

319. The second McMahon study does not demonstrate superiority for the Anacin-like formulation on the overall population tested. The data does not reveal any statistically significant differences between aspirin and the Anacin-like formulation in the uterine cramp pain subgroup, even though that pain model was sufficiently sensitive to significantly discriminate between the active medications and placebo (McMahon, Tr. 3887, 3891).

320. While the McMahon study (RX 31), whether considered alone or in conjunction with the dose-response curve evidence for aspirin, may arguably provide a reasonable basis for the claim that Anacin is more effective than regular aspirin in the relief of pain, including the pain of headache (McMahon, Tr. 3733, 3742–43, 3758, 3775, 3875, 3883, 3923, 4008; Lasagna, Tr. 4052–53, 4058–60, 4072, 4074–75, 4960; Okun, Tr. 4337–38, 4341–46, 4381), it does not demonstrate that the claim has been scientifically established.

6. *Blood Level Studies*

321. The record indicates that no correlation has as yet been

established between the amount of analgesic in the bloodstream and the degree of pain relief. Thus, blood level studies are not an accepted basis for predicting comparative analgesia (F. 222, *supra*).

322. Furthermore, the FDA OTC Internal Analgesics Panel has concluded: "In the case of analgesic agents, the relationship between blood levels and pharmacologic effectiveness has not been well established. A comparison **[93]**of blood levels may offer a basis of comparison between different formulations of the same agent but are at present almost meaningless in comparing chemically different classes of analgesic agents." (CX 367Z007. See also CX 367 O, Z004).

7. *Conclusion*

323. Both complaint counsel's and respondents' witnesses generally concurred that the superiority of Anacin to OTC internal analgesics other than aspirin has never been scientifically established (Forrest, Tr. 470; Azarnoff, Tr. 612; Moertel, Tr. 960, 978; DeKornfeld, Tr. 2788; McMahon, Tr. 3812–13; Lasagna, Tr. 4112–18).

324. The standard for establishing the superior efficacy of Anacin to OTC analgesics other than aspirin is the same as that for aspirin: two well-controlled clinical tests (Lasagna, Tr. 4112–13). No such clinical tests exist.

325. The challenged representation in Paragraph 10(A) of the Complaint, that it has been established that a recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other non-prescription internal analgesic, is not only unfair to consumers but also false since the greater effectiveness of Anacin has not been scientifically established. In light of the evidence, there existed a substantial question recognized by experts qualified by scientific training and experience to evaluate the efficacy of such drugs as to the validity of such representations.

C. *The Scientific Tests Cited In The Challenged Advertisements Do Not Prove That Anacin Is As Effective A Pain Reliever As Darvon Compound 65 Or More Effective Than Any Other Non-Prescription Pain Reliever*

326. Darvon Compound 65, in approximately 1970, was the leading prescription analgesic product on the market (Moertel, Tr. 993).

327. The results of two clinical investigations evaluating Anacin and Darvon in the relief of headache pain were the basis of a limited series of print advertisements which stated that clinical investigations had shown Anacin to be as effective as the leading prescription

analgesic for the relief of headache pain (Ans. of American Home, ¶ 17; Shaul, Tr. 3362–74). Advertisements referring to these tests further represented **[94]**that Anacin was more effective for the treatment of headache pain than other OTC analgesics (F. 99–108, *supra*).

328. The two clinical studies conducted on behalf of American Home were carried out under the direct supervision of Dr. Bernard Teschner at the Bulova Watch Company (CX 302) and Dr. James Lay at Texas Instruments Company (CX 301); the studies compared the effectiveness of Anacin to Darvon Compound 65 (Shaul, Tr. 3362–74).

329. Dr. Bernard Teschner, Medical Director of Bulova Watch Company, conducted the first study (CX 302) comparing Anacin to Darvon Compound 65. The protocol for the study was designed by Dr. Leo Winter of Leo Winter Associates, an organization specializing in designing, conducting and supervising clinical evaluations, and approved by Dr. Shaul. The Darvon capsules used in the study were purchased commercially and remained unaltered so as not to modify the bioavailability of the drug. The Anacin tablets formulated for this study had the embossed arrow deleted so that the pills could not be identified by the patients if they accidentally observed the pill before swallowing it from the opaque vial. A total of 400 patients participated in the study (Shaul, Tr. 3362–69; CX 302).

330. Statistical analysis of the Teschner study was performed by Dr. Nathan Jaspen, an independent biostatistician, who confirmed that no statistically significant differences existed between the drugs for either the amount of pain relief provided or the speed of onset of relief, although Anacin had fewer adverse side effects than Darvon Compound 65 (Shaul, Tr. 3369–76; RX 93; CX 302).

331. A second Anacin-Darvon study was conducted by Dr. James V. Lay, Medical Director at Texas Instruments Company. The study was done under the same general conditions as the Teschner study, except for the inclusion of identical-looking placebos for both compounds. The Lay study involved 638 patients suffering from tension headache (Shaul, Tr. 3371–73; CX 301).

332. The data of the Lay study showed that the placebos were ineffective in comparison to the active drugs, indicating that the test methodology was sensitive. Dr. Nathan Jaspen, a biostatistician, reviewed the data from the Lay study and confirmed that there were no statistically significant differences regarding the effectiveness for pain relief or speed of onset of pain relief between Anacin and Darvon Compound 65, and that **[95]**Anacin had fewer adverse side effects (Shaul, Tr. 3373–76; Moertel, Tr. 977; RX 95; CX 301).

333. Complaint counsel's expert witness, Dr. Moertel, stated that

he would accept the Lay study as evidence of the proposition that two Anacin tablets are essentially equivalent to one Darvon Compound 65 capsule (Moertel, Tr. 977). Moreover, Drs. Forrest, DeKornfeld and Moertel conceded that Anacin is as effective as Darvon Compound 65 (Forrest, Tr. 513; Moertel, Tr. 995, 997–98; DeKornfeld, Tr. 2819–20).

334. Dr. Moertel also testified that it is well-known in the medical community that two Anacin tablets were equally effective or probably more effective than one Darvon Compound 65 capsule, and that his own clinical studies on Darvon reached the same conclusion (Moertel, Tr. 993–98; RX 92; CX 360; CX 361D; CX 362P).

335. However, neither CX 301 nor CX 302 constitute adequate scientific support for claims that Anacin is equal in effectiveness to Darvon Compound 65. While the tests do attempt to compare Anacin to Darvon Compound 65 for the relief of headache pain, serious flaws in their design and execution render their results unreliable (F. 336–40, *infra*).

336. Neither Dr. Teschner nor Dr. Lay had previous experience in conducting clinical tests on analgesic drugs (CX 611Z142, Z143).

337. The Teschner study (CX 302) failed to include a placebo and was not double-blinded since Darvon was given in capsule form and Anacin in tablet form (Forrest, Tr. 481; Moertel, Tr. 972–73).

338. The Teschner study also failed to stratify patients for important pain parameters. The result was that the group of persons receiving Darvon had more severe headache and sinus headache pain than the group receiving Anacin. This would tend to introduce a bias into the study favoring Anacin (Moertel, Tr. 972–73).

339. While the Lay study (CX 301) incorporated a placebo, it was not truly double-blind. Although the active ingredients looked identical, the placebos looked like the drugs they represented (Darvon capsules and Anacin tablets), thus making them identifiable and distinguishable (Forrest, Tr. 478; Moertel, Tr. 974–75, 977–78; DeKornfeld, Tr. 2820). **[96]**To eliminate patient expectation due to the form of the dosage administered, each administration should have included one capsule and one tablet, *i.e.*, a capsule and tablet placebo, Anacin and a capsule placebo, or Darvon and a tablet placebo (DeKornfeld, Tr. 2820). The failure to double-blind resulted in the "Darvon" placebo having several times more side effects than the "Anacin" placebo, although both placebos were inert (Moertel, Tr. 974).

340. Therefore, the tests reported in CX 301 and CX 302 do not prove that Anacin is as effective as the leading prescription analgesic drug, Darvon Compound 65, in the relief of pain.

341. Furthermore, even assuming that the tests reported in CX 301 and CX 302 did prove that Anacin is as effective as Darvon Compound 65, they would provide no support whatsoever for the claim that Anacin is more effective for the relief of pain than any other OTC analgesic (Forrest, Tr. 483; DeKornfeld, Tr. 2794; Lasagna, Tr. 4202; Okun, Tr. 4436). The tests did not compare Anacin to other OTC analgesics, but rather to Darvon Compound 65, and there is no reason to believe that the latter, although a prescription product, is more effective than OTC products including 5 grain aspirin (Forrest, Tr. 514; DeKornfeld, Tr. 2820).

342. The only means of establishing Anacin's superiority to other OTC analgesics is through well-controlled clinical studies comparing Anacin to those analgesics (F. 197, 199, 200 and 225, *supra*).

D. *Anacin Does Not Relieve Tension*

343. Tension is recognized as a term difficult to define precisely. Complaint counsel's expert witness, Dr. Karl Rickels, chairman of the FDA Advisory Review Panel on Over-The-Counter Sedative, Tranquilizer and Sleep-Aid Drug Products ("FDA OTC Sedative Panel"), testified that tension refers to a state, originating from a large group of emotional factors, which may exhibit as its symptoms fearfulness, panic, irritability, heart palpitations and perspiration (Rickels, Tr. 1199, 1201–02, 1212). He further associated tension more with muscle spasms and anxiety related to the emotional aspects just described (Rickels, Tr. 1201). **[97]**

344. The FDA OTC Sedative Panel views tension as an umbrella term, and includes depression, anxiety, somatic complaints attributed to emotional factors and psychoneurotic states as several forms of tension. Indeed, tension is sometimes used synonymously with the term "anxiety" (Rickels, Tr. 1201–03; CX 366Z002).

345. Tension may exhibit headache pain as one of its symptoms in the same way that tension may exhibit fearfulness or irritability as a symptom. In such instances, the headache pain is caused by the underlying tension. This situation is referred to as the "tension-headache-tension" cycle (Rickels, Tr. 1219, 1240).

346. Underlying tension may, however, exist simultaneously with, although independently of, headache pain. In this case, the headache pain is caused by factors other than the underlying tension. The headache pain may also aggravate the tension state (Rickels, Tr. 1198–99).

347. Underlying tension is commonly treated by psychiatric counseling, tranquilizers or a combination of the two. Such treatment will act to relieve the tension and should relieve any symptoms

associated with it, such as headache pain (Rickels, Tr. 1182–86, 1199, 1205–06, 1240; CX 367I).

348. The tension-headache-tension cycle is also treated with tranquilizers. This treatment is recommended by the FDA OTC Sedative Panel (Rickels, Tr. 1240; CX 366Z003).

349. In order to establish the tension-relieving action of a drug, well-controlled, randomized, double-blinded clinical studies in populations in which the drug might be expected to be effective are necessary (Rickels, Tr. 1186–88; F. 197, 200 and 225, *supra*). Such tests have been required for proof of absolute or comparative efficacy of prescription and non-prescription drugs since the late 1950's (Rickels, Tr. 1228–29; F. 199, *supra*).

350. In a well-controlled, double-blinded clinical study of Compoz, Librium, aspirin and placebo, with normal doses administered to patients suffering moderate degrees of tension, aspirin was found not to be significantly superior to placebo in tension relief (Rickels, Tr. 1195–97). The study showed no differences in results whether or not the population was combined or broken down into those who also suffered moderate headache pain and those who did not (Rickels, Tr. 1197). **[98]**

351. The literature regarding the tension-relieving properties of aspirin is consistent with the results of the "Compoz study," and confirms that it is erroneous to consider a therapeutic dose of aspirin as a tension reliever (Rickels, Tr. 1198, 1205). In addition, the FDA OTC Internal Anaglesics Panel has concluded that non-prescription internal analgesics are "clearly ineffective" for "nervous tension" (CX 367K). Similarly, the FDA OTC Sedative Panel determined that aspirin was "ineffective" as a "daytime sedative" product, which the Panel defined as one that claims "daytime mood-modifying indications such as for the relief of occasional simple nervous tension" (CX 366E, Z002). The weight of the evidence does not support the conclusion that aspirin and OTC analgesics will relieve tension, unless the tension is a symptom of headache pain.

352. Where an individual is suffering from tension, which manifests headache pain as one of its symptoms, aspirin is neither appropriate nor indicated for the treatment of the underlying tension (Rickels, Tr. 1203–04). Aspirin can only aid in relieving pain and, consequently, will have no lasting effect on underlying tension (Rickels, Tr. 1204–05; 1226, 1235–39). If underlying anxiety or tension are present along with headache pain, then aspirin will, at the most, provide only temporary relief; once the effects of the aspirin wear off, the underlying tension can be expected to return (Rickels, Tr. 1205, 1218–20).

353. Respondents' witness, Dr. Lasagna, agreed with Dr. Rickels on the relationship between analgesics and tension caused by headache pain, underlying tension and tension existing independent of headache pain (Lasagna, Tr. 4198–99).

354. The only sense in which aspirin can be considered a tension reliever is that it may indirectly and secondarily relieve tension caused wholly by pain, while not affecting underlying tension (Rickels, Tr. 1204, 1236; Lasagna, Tr. 4198).

355. Caffeine, a known central nervous system stimulant useful in the treatment of physical fatigue in daily doses of 100 to 200 mg. (which exceeds the amount in Anacin), is contraindicated for the treatment of nervousness, stress and tension. Stimulant drugs generally counteract states of physical fatigue. A combination of caffeine with aspirin (*i.e.,* Anacin) is ineffective for the treatment of nervous tension (Rickels, Tr. 1207–10; F. 264, 266, *supra*). **[99]**

356. Both the president and medical director of Whitehall Laboratories, the division of American Home responsible for Anacin and APF, admitted that American Home did not have a reasonable basis for the claim that Anacin relieves tension (Shaul, Tr. 3398; DeMott, Tr. 4765).

357. Therefore, Anacin does not relieve nervousness, tension, stress, fatigue or depression, nor will it enable persons to cope with the ordinary stresses of everyday life.

E. *It Has Not Been Established That APF Will Cause Gastric Discomfort Less Frequently Than Any Other Non-Prescription Internal Analgesic*

358. A recommended dose of APF is one or two tablets, for a two-tablet total of 972 mg. micronized aspirin, 40.28 mg. dried aluminum hydroxide gel and 120.84 mg. magnesium hydroxide (F. 11, *supra*).

359. Micronized aspirin refers to aspirin formulated in smaller than the usual size particles (Plotz, Tr. 1060; Sliwinski, Tr. 1136; CX 367Z006).

360. The micronized aspirin in APF, in combination with the above-mentioned antacids, is compressed into tablet form (Sliwinski, Tr. 1136; Shapiro, Tr. 3115).

361. Bioavailability may be defined as "[t]he rate and extent of absorption as determined by the measurement of the blood levels of the parent drug and/or its active metabolites relative to a standard product. The standard product chosen must be one which has been demonstrated to be safe and effective." (Azarnoff, Tr. 581; CX 367Z007).

362. Drug absorption is influenced not only by the formulation of

the drug, but also by physiological variables of the gastrointestinal function (such as gastric emptying, intestinal transit time and intestinal and hepatic metabolism) (Shapiro, Tr. 3113–15; CX 367Z007).

363. Gastric discomfort includes pain and discomfort in the upper portion of the abdomen, heartburn and nausea. These are subjective symptoms (Grossman, Tr. 849; Plotz, Tr. 1047).

364. Respondents' expert witness, Dr. Shapiro, testified that finely milled aspirin in small particle size (*i.e.,* **[100]**micronized aspirin) enhances dissolution and, therefore, allows for more rapid absorption (bioavailability) from the gastrointestinal tract with the results that there will be less gastric discomfort than with a plain aspirin formulation (Shapiro, Tr. 2965, 3163; CX 367Z007).

365. However, Dr. Shapiro conceded that, since the ingredients in APF are compressed into tablet form, it is difficult to ascertain the ultimate particle size and any theoretical advantage to micronization may be lost (Shapiro, Tr. 3115, 3163–64).

366. The only study which Dr. Shapiro relied upon for his opinion that micronized aspirin caused less gastric distress was by Gyory and Steil. He admitted, however, that the Gyory study used capsules (*i.e.,* uncompressed micronized aspirin) and addressed blood loss as opposed to dyspepsia. Dr. Shapiro conceded that he was in error in relying on the Gyory study (Shapiro, Tr. 3111–15).

367. Dr. Sliwinski, complaint counsel's expert witness, stated that particle size alone will not determine the amount of gastric discomfort. Other operative factors include how the particles are stuck together and the rate of dissolution (Sliwinski, Tr. 1136–37, 1165). Dr. Plotz also indicated that particle size is one of several factors that may be expected to play some role with regard to gastrointestinal effects (Plotz, Tr. 1089–90).

368. The relationship between the rate of absorption of an analgesic and gastrointestinal discomfort has not been established (Grossman, Tr. 850–52, 869–70; Sliwinski, Tr. 1154–55, 1165). The FDA OTC Internal Analgesics Panel reported that "there is little meaningful difference between the rates of absorption of sodium salicylate, aspirin and the numerous buffered preparations of salicylates." (CX 367Z008).

369. There is no evidence that micronization of aspirin particles confers any favorable properties to aspirin beyond those found with plain aspirin (Plotz, Tr. 1078, 1089–90; CX 367Z006). "Favorable properties," as used in this context, refers to a decrease in the incidence of gastric discomfort (Plotz, Tr. 1079–80).

370. Therefore, it has not been established that micronized

aspirin particles in a tablet (*e.g.,* APF) result in less gastric discomfort than ordinary aspirin (Grossman, Tr. 850–52; Plotz, Tr. 1061–62; Sliwinski, Tr. 1149, 1165). **[101]**

371. Dried aluminum hydroxide gel and magnesium hydroxide are recognized as antacid, or buffering, agents (F. 14, *supra;* CX 367F). An antacid may be defined as "[a]n agent that reacts with acid, such as the hydrochloric acid in the stomach (gastric acid), to neutralize it (decrease its amount)." (CX 367Z003).

372. Dr. Shapiro testified that buffers reduce the incidence of gastric discomfort as compared with ordinary aspirin (Shapiro, Tr. 2964–66, 3042–45).

373. Dr. Lasagna testified that the buffers that are present in aspirin preparations may be important in terms of gastric irritation if they affect the dissolution rate of a drug because the quicker the aspirin gets into solution, the less likely it is to cause gastric irritation and discomfort (Lasagna, Tr. 4192–93. See also F. 361, 362, 364 and 365, *supra*). However, he conceded that, while he was chairman of the NAS/NRC Panel (F. 34, *supra*), the Panel concluded that most of the published studies indicated little difference in the incidence or intensity of gastric discomfort after ingestion of Bufferin or plain aspirin (Lasagna, Tr. 4192–93).

374. The FDA OTC Internal Analgesics Panel reported that: "[C]urrent evidence indicates that properly formulated preparations . . . can be expected to (1) increase the rate of absorption of aspirin relative to a plain aspirin tablet; (2) decrease the incidence of subjective gastric intolerance in some of the relatively small percentage of persons in the general population who regularly experience gastric intolerance with OTC doses of plain aspirin tablets." (CX 367Z100. See also CX Z004–Z005). However, the Panel also stated: "Based upon the total evidence available to the Panel, it concludes that the evidence is insufficient to substantiate the claims that buffered or highly buffered aspirin solution is safe for use in patients who should not take regular, unbuffered (plain) aspirin." (CX 367Z101).

375. Two well-controlled clinical studies are required to establish that APF causes less gastric discomfort than other OTC internal analgesics (Plotz, Tr. 1049; Sliwinski, Tr. 1130; Shapiro, Tr. 3103, 3104; F. 197, 199, 200 and 225, *supra*). The tests must, *inter alia,* be double-blinded (Plotz, Tr. 1049; Sliwinski, Tr. 1129–31; Lasagna, Tr. 4135; F. 210 and 211, *supra*), randomized and the study population carefully defined (Plotz, Tr. 1049; Sliwinski, Tr. 1130–31; F. 203 and 207–09, *supra*).

376. There have been no well-controlled clinical studies that

demonstrated that buffered aspirin causes less [102]gastric discomfort than plain aspirin (Grossman, Tr. 862, 869–70). The Paul study cited by the FDA OTC Internal Analgesics Panel, for example, lacked proper controls such as double-blinding and failed to use a control group (Shapiro, Tr. 3069, 3090, 3097).

377. CX 304, a study entitled "Arthritis Pain Formula Evaluation," is the only clinical study known by respondents to have evaluated the extent to which APF causes gastric bleeding and gastric discomfort or distress (CX 611Z144). The study, conducted for American Home by Dr. Jerome Rotstein, compared APF to a placebo and to commercial buffered aspirin (CX 304B).

378. CX 304 reported that APF demonstrated significantly less gastrointestinal irritation and occult bleeding than buffered aspirin (CX 304). However, CX 304 is not an acceptable well-controlled clinical test for purposes of establishing that APF causes gastric discomfort less frequently than other OTC internal analgesics (F. 379–82, *infra*).

379. The stated purpose of the clinical trial reported in CX 304 was to compare the efficacy of APF and 5 grain buffered aspirin (CX 304F). The study did not question patients about gastric discomfort (CX 304; Plotz, Tr. 1055, Sliwinski, Tr. 1141).

380. The authors of the study utilized a stool guaiac test, which measures the amount of occult blood loss, as support for their finding that APF demonstrated significantly less evidence of gastrointestinal irritation than other OTC analgesics. Stomach distress, however, is a subjective symptom (Shapiro, Tr. 3069), and the amount of blood in the stool is irrelevant in evaluating such discomfort. Dr. Plotz considered the use of a stool guaiac test for this purpose inadequate and discounted it entirely (Plotz, Tr. 1055–58).

381. The study is also seriously flawed by the different dosage schedules used for the two products. The buffered aspirin was not only given more often, but also more frequently on an empty stomach when gastric irritation is more likely to occur. The different schedules eliminated any possibility that the study was double-blind (Plotz, Tr. 1054–56; Sliwinski, Tr. 1139, 1161).

382. Drs. Plotz and Sliwinski found CX 304 so defective as to render its results useless. The study is inadequate [103]to support the conclusion that APF causes gastric discomfort less frequently than other buffered products, much less any other OTC analgesic (Plotz, Tr. 1054–60, 1079; Sliwinski, Tr. 1138–47, 1161–62).

383. It has not been established that the addition of buffers (antacids) of the amount and kind present in APF reduces the incidence of gastric distress attributable to aspirin (Grossman, Tr.

850–53; Plotz, Tr. 1053, 1062–63, 1084–86; Sliwinski, Tr. 1148–49; Lasagna, Tr. 4192).

384. Therefore, the challenged representation in Paragraph 10(B) of the Complaint, that it has been established that APF will cause gastric discomfort less frequently than any other OTC analgesic, is false inasmuch as the greater safety of APF has not been established. Moreover, there existed a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety of such drugs, as to the validity of the representation.

F. *The Other Representations In Respondents' Advertisements Are False Or Unfair*

385. American Home has represented that Anacin contains more pain dulling ingredients than any other OTC internal analgesic, that its analgesic ingredient is unusual, special and stronger than aspirin, and that the product contains twice as much of its analgesic ingredient as other marketed products (F. 66–98, *supra*). These representations are false.

386. There are other analgesic products on the market which contain as much or more pain dulling ingredients than does Anacin (Ans. of American Home, ¶ 9; F. 194, *supra*).

387. Anacin's analgesic ingredient is not unusual, special or stronger than aspirin, since it is nothing other than aspirin (F. 11 and 14, *supra*). Anacin's only other ingredient, caffeine, is not an analgesic (F. 263, *supra*). Indeed, both aspirin and caffeine are commonplace substances, available in many products (Ans. of American Home, ¶ 23).

388. Anacin does not contain more than twice as much analgesic ingredient as all other analgesic products on the market (Ans. of American Home, ¶ 9; F. 193 and 194, *supra*).**[104]**

389. American Home has also represented that within 22 seconds after taking Anacin a person may expect relief from headache pain (F. 148–55, *supra*). This representation is false, since relief from Anacin is not obtained within that period of time (Non-Contested Issue of Fact 16).

390. Respondents American Home and Clyne have represented that APF's analgesic ingredient is unusual, special and stronger than aspirin (F. 171–77, *supra*). This representation is false.

391. As with Anacin, APF's analgesic ingredient is ordinary aspirin (F. 11 and 14, *supra*). Micronization of the aspirin in APF has not been shown to confer any special analgesic qualities to the aspirin (F. 365–67 and 369–70, *supra*), nor do antacids play any

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analgesic role, having been shown only to have a buffering potential (F. 371–74 and 383, *supra*).

392. Through reference to a "Doctors' Survey," American Home also made certain representations regarding doctors' preferences for Anacin, as set forth in Complaint Paragraph 20 (F. 109–15, *supra*). These representations are unfair and deceptive because the survey on which they were based does not provide a reasonable basis for the representations (CX 342; CX 343; Rossi, Tr. 1621–25; F. 393 and 394, *infra*).

393. The response rate to the Doctors' Survey was 10%; this is too low to provide a basis for any advertising representation or for generalizing to any group of physicians (CX 342A, CX 343; Rossi, Tr. 1623). A response rate of at least 50% to a mail survey, such as the one at hand, is necessary before the results can be generalized; where a precise estimate is desired, the response rate should be at least 70%. Such minimum levels of acceptability must be met because it is possible to obtain a higher response rate in a mail survey than in a telephone or face-to-face survey. A respondent who does not respond to a survey questionnaire received through the mail may be reacting to the content of the questionnaire which makes the likelihood of response bias higher than in a telephone or face-to-face survey where the respondent is less aware of the content of the survey when he or she chooses whether or not to participate (Rossi, Tr. 1623–25). Moreover, American Home conducted no follow-up mailings to attempt to increase the unacceptable level of return in this survey (CX 611Z154).

394. The sample in this survey was comprised of physicians with a primary speciality in internal medicine, **[105]**under the age of 65 years, in private practice in the 50 states and who do not object to receiving promotional mail (CX 342A). To the extent that such a group of physicians is different from physicians with the same specialty, but who object to receiving promotional mail, a further bias is injected into the survey (Rossi, Tr. 1624).

V. Disclosure of Aspirin and Caffeine

A. *General Background*

395. The Complaint charges that respondents failed to disclose the alleged material fact that Anacin contains aspirin and caffeine and that APF contains aspirin; that these are well-known and commonplace substances widely available in many products; that they may be injurious to health; and that, if this were known, it would likely affect certain consumers' consideration of whether to

purchase such products. Disclosure of these facts is sought for all of the advertising of Anacin and APF (Comp. ¶ 23).

396. The essential questions posed by the Complaint on the question of ingredient disclosure are: (a) whether the side effects of aspirin and caffeine are so serious and widespread as to pose a hazard to the consuming public; and, if so, (b) whether disclosure in all advertising is required to bring knowledge of these ingredients to that group of the population which may be "at risk" from the ingestion of these drugs.

397. Both Anacin and APF contain aspirin; in addition, Anacin also contains caffeine (F. 11, *supra*).

398. Aspirin is a well-known and commonplace substance. It is generally recognized as safe and effective (F. 14, *supra;* Moertel, Tr. 998–99).

399. Caffeine is a well-known and commonplace substance widely used in consumer products such as coffee, tea, cocoa and cola-based soft drinks (RX 244Z039).

400. The active ingredients and directions for use of Anacin and Arthritis Pain Formula are clearly disclosed on the packaging and labeling of these products (F. 12, *supra*).

401. Anacin advertising did not disclose that aspirin or caffeine is an ingredient in Anacin (Ross, Tr. 1880; Smith, **[106]**Tr. 7550; Ans. of American Home, ¶¶ 7 and 22). Advertisements for APF did not disclose that APF contains aspirin (Ans. of American Home and Ans. of Clyne, ¶¶ 7 and 22).

402. Both complaint counsel's and respondents' expert witnesses generally agree that some consumers are unaware of the ingredients of products like Anacin and APF, and that this is an area of concern (See, *e.g.,* Farr, JTr. 2592; Grossman, Tr. 858, 909; Moertel, Tr. 985; Shapiro, Tr. 2984–85; Falliers, Tr. 3228–30, 3263–64; Lasagna, 4195).

403. Certain groups of individuals, including those suffering from rheumatoid arthritis, contain a substantial number of chronic users of aspirin and aspirin-containing products. Such individuals as a group would, therefore, be more susceptible to possible adverse reactions from aspirin ingestion than the general population (Plotz, Tr. 1040, 1043–44, 1052; Sliwinski, Tr. 1111).

404. Complaint counsel's witness, Dr. Moertel, admitted that the side effects from aspirin are clinically insignificant except for a small group of individuals for whom they could be severe (Moertel, Tr. 998. See also Falliers, Tr. 3232; Shapiro, Tr. 2942–43). Respondents' expert witnesses are generally in accord with this statement (See, *e.g.,* Shapiro, Tr. 2938, 2971; Falliers, Tr. 3192–95). Nevertheless,

there are groups of individuals who will suffer serious adverse effects from aspirin, some of which can be life-threatening (F. 406-52, *infra*).

405. If a consumer is unaware of the fact that he or she should avoid aspirin, disclosure of aspirin in advertising would provide no benefit to that individual (See, *e.g.*, Farr, JTr. 3635; Falliers, Tr. 3269).

B. *Gastrointestinal Side Effects*

1. *Aspirin*

406. Aspirin can result in adverse reactions in the gastrointestinal tract. The possible side effects include dyspepsia (discomfort, pain, nausea and heartburn that occur in the upper abdominal area), occult (unseen) gastrointestinal bleeding, massive gastrointestinal bleeding, gross and microscopic damage to gastric mucosa (lesions), gastric ulcers and initiation or exacerbation of stomach ulcers (Grossman, Tr. 825–26, 829–30, 839–40, 849; Moertel, Tr. 984; Shapiro, Tr. 2940–41, 2944–45; CX 367Z014, Z020). **[107]**

407. Dyspepsia due to ingestion of aspirin is a common occurrence (Grossman, Tr. 825; Shapiro, Tr. 2945). The estimated incidence of dyspepsia in individuals who take small doses of aspirin over short periods of time is 5 to 10% (Grossman, Tr. 826; CX 367Z017). The estimated incidence among those who take larger doses over longer periods of time, such as arthritics, is 20 to 30% (Grossman, Tr. 826–27; Plotz, Tr. 1048).

408. While the symptoms of dyspepsia are frequently associated with peptic ulcer disease and gall bladder disease, when the symptoms occur in the absence of these two diseases the dyspepsia is usually temporary (Shapiro, Tr. 2944–45).

409. All individuals experience some occult bleeding (*i.e.*, imperceptible loss of blood) from the gastrointestinal tract after aspirin ingestion. However, such bleeding is not clinically important. Any relationship between such occult bleeding and massive gastrointestinal bleeding or gastric discomfort has not been established (Grossman, Tr. 837–39, 871; Plotz, Tr. 1046–47; CX 367Z019–Z021).

410. Aspirin can cause unpredictable, massive and life-threatening bleeding in the gastrointestinal tract. Massive gastrointestinal bleeding is always due to some type of lesion (damage to gastric mucosa) (Grossman, Tr. 829–30, 844–45, 862–63; Moertel, Tr. 984; Shapiro, Tr. 2943).

411. Although the mechanism of action of aspirin on the gastrointestinal tract has not been definitively established, Dr. Grossman testified regarding two ways in which aspirin can cause

damage to the gastric mucosa: (a) by a topical action (Davenport effect) which involves a local action of the aspirin acting directly on the mucosa (this explains acute diffuse minor lesions); or (b) by a systemic effect in which aspirin reaches the mucosa through the blood (Grossman, Tr. 841–44).

412. Clinically important gastrointestinal blood loss can lead to weakness and shock, and may require hospitalization (Grossman, Tr. 829). Massive gastrointestinal blood loss is the most serious adverse side effect of aspirin on the gastrointestinal tract and can be lethal (Grossman, Tr. 830; CX 367Z021).

413. The incidence of massive bleeding is low, although the total occurrence is not insignificant (Grossman, Tr. 844–45; CX 367Z022). There is a recognized higher risk of massive gastrointestinal blood loss in all persons with peptic ulcers, those who have previously experienced gastrointestinal bleeding and those with dyspepsia (Grossman, Tr. 846; CX 367Z022).

414. Despite the fact that the benefit-to-risk ratio for aspirin is quite favorable on the side of aspirin's safety and massive gastrointestinal bleeding is a rare occurrence, the mortality rate associated with this condition **[108]**is 4 to 10%, including those persons whose bleeding was induced by aspirin (Grossman, Tr. 830–31).

415. Aspirin in large doses may cause gastric ulcers. Aspirin may even produce a specific kind of ulcer, not seen in its absence (Grossman, Tr. 831–32; CX 367Z020).

416. Dr. Grossman testified that gastric ulcer is a serious disease, causing significant morbidity as well as significant complications, such as bleeding, obstruction of the stomach outlet and perforation of the gastric ulcer which can produce peritonitis, that often lead to surgery on the stomach (Grossman, Tr. 833).

417. By conservative estimate, aspirin ingestion results in 10 out of every 100,000 users developing a gastric ulcer which requires hospitalization. Levy's Boston Collaborative Group study also estimated that one-eighth of all gastric ulcers were related to aspirin (Grossman, Tr. 845; CX 367Z020–Z021).

418. Dr. Grossman reported that a recent survey has shown aspirin to be the second most frequent drug implicated in hospital admissions. Of 7,017 admissions surveyed, adverse drug reactions influenced 260, or 3.7%, of the admissions, with aspirin involved in 24 out of the 260, or 9%. Thus, aspirin accounted for 0.3% of all the admissions surveyed (Grossman, Tr. 877–80; CX 367Z022 which reported on the results of a survey by the Boston Collaborative Drug Surveillance Program).

419. It is evident from the record that aspirin poses a serious

public health problem, in terms of gastrointestinal effects, to certain groups of individuals in the population.

420. It is noted that the FDA OTC Internal Analgesics Panel has recommended that the following warning appear on all aspirin-containing products, regardless of formulation: "Caution: Do not take this product if you have stomach distress, ulcers or bleeding problems except under the advice or supervision of a physician." (CX 367Z025).

2. *Caffeine*

421. Respondents' expert witness, Dr. Shapiro, testified that the amount of caffeine in two Anacin tablets is approximately the amount of caffeine in one-half cup of coffee (Shapiro, Tr. 2968–69, 2997). On this basis, he stated his [**109**]belief that the amount of caffeine in a recommended dose (two tablets) of Anacin (F. 11 and 12, *supra*) would have no physiological effect on the gastrointestinal tract (Shapiro, Tr. 2968–70).

422. Complaint counsel's expert witness, Dr. Grossman, testified that caffeine could increase the injurious effects of aspirin since it stimulates the secretion of gastric acid, although he admitted that it is not absolutely known how caffeine increases the secretion of gastric acid (Grossman, Tr. 860). However, he conceded that this proposition is not established; he stated that he viewed it as a reasonable assumption.

423. Dr. Grossman also suggested that caffeine may cause peptic ulcers (Grossman, Tr. 855, 872–77. See also Lasagna, Tr. 4194), and that it inhibits platelet aggregation (Grossman, Tr. 866–67; CX 367Z114).

424. The record shows that caffeine, when used as an adjuvant, is safe at a single dose of 65 mg. not to exceed 600 mg. in 24 hours (Shapiro, Tr. 2969–70; CX 367Z114). The recommended dosage of Anacin is within this range (F. 11–12, *supra;* Shapiro, Tr. 2969).

425. Therefore, caffeine has not been shown to pose a serious public health problem.

C. *Aspirin Intolerance Among Asthmatics And Respiratory Side Effects*

426. Aspirin can also cause respiratory side effects. These adverse reactions include effects on the respiratory system ranging from shortness of breath to severe life-threatening asthmatic attacks, and anaphylactic shock involving laryngeal swelling, blocking of air pathways and a sudden drop in blood pressure which can result

in death unless treated rapidly (Stevenson, JTr. 1481; Farr, JTr. 2571–72; Falliers, Tr. 3188–90, 3232; CX 367Z027–Z028).

427. Asthma is a reversible obstructive airway disease of unknown origin; it is not a true allergy (Stevenson, JTr. 1479–80; Farr, JTr. 2565–66).

428. An asthmatic attack involves a spasm and subsequent constriction of the bronchial tubes. Symptoms include shortness of breath, coughing and, in severe cases, hypoxia (insufficient delivery of oxygen to red blood cells), shock and occasionally death (Stevenson, JTr. 1481; CX 367Z027). **[110]**

429. Ingestion of from 3 mg. to 650 mg. aspirin may cause an asthmatic attack among those members of the asthmatic population who are aspirin-idiosyncratic (allergic to aspirin) (Stevenson, JTr. 1480–81).

430. The severity of the aspirin-induced asthmatic attack depends on the degree of bronchial constriction prior to ingestion of the aspirin; if the bronchial tubes are already partly closed, the attack can be severe or possibly life-threatening (Stevenson, JTr. 1488–89).

431. Asthmatics are made up of two subgroups: intrinsic asthmatics whose asthma is not precipitated by external or environmental causes and is characterized by nasal polyps, rhinitis, sinusitis and chronic asthma; and extrinsic asthmatics whose asthma is due to environmental factors (such as food, ragweed, dust, etc.) (Falliers, Tr. 3187–92, 3197–98; CX 367Z027).

432. A small group of severe intrinsic asthmatics, who have bronchial asthma, rhinitis and/or sinusitis may be particularly susceptible to idiosyncratic reactions from aspirin ingestion. The other intrinsic and extrinsic asthmatics are, however, unlikely to experience a higher degree of aspirin idiosyncrasy than the incidence in the general population (Falliers, Tr. 3187–92, 3197–98; Farr, Tr. 3459, 3468–69, 3486, 3490, 3544; CX 367Z028–Z029).

433. Neither micronizing aspirin, as is done in APF, nor combining aspirin with other ingredients, as is done in both APF and Anacin, will reduce the possibility of aspirin-induced side effects in asthmatics (Farr, JTr. 2575; Stevenson, JTr. 1490–91).

434. Although the number of asthmatics in the general population and the number of asthmatics who are sensitive to aspirin are not precisely known, the incidence of individuals susceptible to asthmatic attacks caused by aspirin ingestion is not insignificant (F. 435–42, *infra*).

435. The record reveals that the range of the cumulative incidence for all asthma cases in the general population is 2 to 12%,

while the prevalence incidence is 0.4 to 8% (Stevenson, JTr. 1493–95; Farr, JTr. 2576–86; Falliers, Tr. 3193–95, 3202–03; CX 367Z027).

436. Dr. Stevenson, testifying for complaint counsel, cited a 1972 study by Davis concluding that 9 million persons were under some form of medical care for asthma (Stevenson, JTr. 1494). **[111]**

437. The Tecumseh Study, an epidemiological study of the health problems of the residents of Tecumseh, Michigan, and the most thorough evidence available on the incidence of asthmatics in the general population, reported that 6% of the townspeople of Tecumseh were afflicted by conditions previously diagnosed as asthma; another 6% revealed medical histories consistent with asthma (Stevenson, JTr. 1494).

438. Figures on the incidence of aspirin intolerance in the asthmatic population vary because different populations are surveyed, different methods of classification are used and different definitions of sensitivity are assigned. As a general rule, incidence figures based on medical histories tend to be considerably lower than figures based on oral challenge procedures.

439. The record indicates that incidence figures for aspirin intolerance among asthmatics ranges from 0.1% to 28% (Stevenson, JTr. 1495–98; Farr, JTr. 2589–2605).

440. Respondents' witness, Dr. Falliers, testified that the results of a survey of case histories he conducted disclosed that only 1.9% of the asthmatics exhibited adverse reactions to aspirin ingestion. However, he admitted that his study did not involve the evaluation of aspirin sensitivity through aspirin challenge procedures, and that the medical literature involving challenges did not support his low figure (Falliers, JTr. 3192, 3219, 3238).

441. In contrast, Dr. Stevenson conducted a study in which he orally challenged with aspirin a group of asthmatics who were not known to be sensitive to aspirin. On the basis of the results of this study, he concluded that a 10% incidence of aspirin intolerance in asthmatics would be a conservative figure. The record, as a whole, supports Dr. Stevenson's conclusion (Stevenson, JTr. 1498–1501; Farr, JTr. 2597–2605).

442. It is noted that the FDA OTC Internal Analgesics Panel concluded that 6 to 20% of all asthmatics are sensitive to aspirin (CX 367Z027).

443. Therefore, the threat that aspirin presents to asthmatics who are aspirin-idiosyncratic has been shown to pose a serious public health problem. **[112]**

D. *Other Side Effects*

444. Aspirin may cause dermal allergic reactions. These adverse reactions include effects on the skin such as urticaria (hives), angioedema (giant hives and swelling) and rash (Stevenson, JTr. 1511–12; Farr, JTr. 2564; CX 367Z028).

445. While such reactions are not usually life-threatening (Stevenson, JTr. 1512; CX 367Z028), urticaria may be serious if the lining of the stomach is involved and angioedema may be fatal if swelling takes place in the vocal chords and cuts off breathing (Stevenson, JTr. 1511–13).

446. The overall incidence of allergic reactions to aspirin is such that the American Academy of Allergy, a professional organization with a membership of some 2,200 allergists, adopted the following resolution in 1973:

> While recognizing that acetylsalicylic acid (aspirin) is a valuable drug, the American Academy of Allergy recommends that a formulation containing aspirin and advertisements promoting the formulation should clearly indicate that the preparation contains aspirin and that aspirin can be harmful to some persons.

In the same year, the American College of Allergists, another professional organization of allergists, passed a similar resolution (Farr, JTr. 2608–12).

447. The FDA OTC Internal Analgesics Panel stated its agreement with the Academy resolution (CX 367Z028–Z029). It is noted that the Panel has recommended that the following warning should appear on all products containing aspirin:

> This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician. (CX 367Z029).

448. Since aspirin may present potential harm to the fetus as well as hazards to the mother during pregnancy and delivery, it should be avoided by women during the later stages of pregnancy (Lasagna, Tr. 4188; CX 367Z035).

449. The FDA OTC Internal Analgesics Panel has suggested that all aspirin-containing products should state the following warning on their labels:

> Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician. (CX 367Z035). [113]

450. Aspirin can produce adverse side effects on renal and hepatic functions, such as salicylate hepatitis. These adverse reactions can result from even small or normal doses (Plotz, Tr. 1082–83; Sliwinski, Tr. 1123).

451. It is recognized that aspirin is capable of exerting a systemic

effect on the blood, as manifested by aspirin's possible effects on the clotting mechanism which could lead to a change in platelet adhesiveness (Sliwinski, Tr. 1123).

452. Aspirin can also change the action of other medications that an individual might be taking. For instance, aspirin binds to a serum protein. If an individual were taking other medications that also bind to serum protein, then the aspirin could displace the other drugs with the result that the individual may experience greater clinical effects from those other drugs. This is true for drugs such as the anticoagulant medications and some of the diabetic medications (Sliwinski, Tr. 1123–24).

E. *Disclosure of The Presence Of Aspirin*

453. The disclosure in advertising of the presence of aspirin in Anacin and APF would be beneficial to the significant segments of the population who should avoid aspirin for the medical reasons stated above, and who may not be aware that these products contain aspirin (Stevenson, JTr. 1519, 1691–92; Farr, JTr. 2608–14; Moertel, Tr. 1019–21).

454. There are large numbers of people who should avoid aspirin and are so warned by their physicians (See, *e.g.*, Grossman, Tr. 847–48; Lasagna, Tr. 4188–89, 4198).

455. Dr. Stevenson, testifying for complaint counsel, stated that he warns patients identified as aspirin-idiosyncratic to avoid aspirin. However, he noted that most asthmatics do not know whether or not they are aspirin-sensitive; consequently, they should avoid aspirin as a precaution (Stevenson, JTr. 1502). Immunologists generally warn asthmatics to avoid aspirin (Farr, JTr. 2601, 2606).

456. Dr. Shapiro, testifying for respondents, stated that he warns patients with active ulcers to avoid using salicylate-containing compounds, including aspirin (Shapiro, Tr. 2998).

457. Many patients are unaware that an OTC analgesic, which does not contain "aspirin" in its name, contains [114]aspirin. This raises the distinct possibility that some individuals warned to avoid aspirin will take it without knowing that the OTC analgesic product they are taking contains aspirin (F. 402, *supra*).

458. Respondents' witness, Dr. Falliers, admitted that his own study of aspirin idiosyncracy revealed that patients took OTC analgesic drugs, such as Anacin, without knowing that the products contained aspirin (Falliers, Tr. 3210). Complaint counsel's witness, Dr. Grossman, was also aware of instances in which his patients took Anacin without knowing of its aspirin content (Grossman, Tr. 901).

459. A significant number of consumers do not know and have

not known for a substantial period of time that Anacin contains aspirin.

460. In a survey of consumers conducted by the Gallup organization in 1964,[4] 17% of a nationally projectable sample identified aspirin as an ingredient in Anacin on an unaided basis; 78% of the sample could not name any ingredient (CX 467H). In that same study, when consumers were directly asked whether aspirin was an ingredient in Anacin, 65% answered affirmatively (Ross, Tr. 2285–88; CX 467J).

461. In the 1967 and 1970 Oxtoby-Smith studies (CX 451 and CX 452), consumers indicated a general lack of awareness of ingredients by the magnitude of their responses to the question, "I have little idea of ingredients in the headache tablets I take." In 1967, approximately 54% of Anacin users agreed with that statement; in 1970, approximately 42% agreed with that statement (Ross, Tr. 2295; CX 1058Z480; CX 1059Z180).

462. In the 1972 Pain Reliever Telephone Study (CX 468),[5] 23% of the consumers surveyed were able to identify aspirin as an ingredient in Anacin; 71% could not name any ingredient (Ross, Tr. 2292–93; CX 468Z002–Z003).

463. Complaint counsel's expert witness, Dr. Moertel, conducted an informal survey of two samples of individuals **[115]**with whom he came in contact in his duties at the Mayo Clinic. The first sample consisted of 100 patients and their family members who came to the cancer treatment center at the Currie Pavillion of the Clinic. The second sample consisted of 100 paramedical personnel. Each respondent was given a list with a number of drugs on it and was asked to check either "yes," "no" or "don't know" regarding whether each drug contained aspirin. In the 100 patient/family member sample, 71% correctly answered "yes" to the ingredient question about Anacin; 4% said Anacin did not contain aspirin; 25% checked the "don't know" response (Moertel, Tr. 986–89).

464. The record shows that consumers do not always read or study package labels of OTC drugs before taking them in order to determine whether a particular product contains aspirin when instructed to do so by their physicians. Moreover, it is unknown whether all physicians instruct susceptible patients not only to avoid aspirin *per se*, but also other OTC drugs containing aspirin by brand name, *e.g.*, Anacin (Stevenson, JTr. 1509–20, 1727; Farr, JTr. 2557–58, 2606–07, 3568; Falliers, Tr. 3228–30; F. 402 and 457–58, *supra*). Based on these factors, Dr. Falliers, respondents' own witness, stated

[4] See Appendix I, pp. 12–13, for a description of the methodology of this study.

[5] See Appendix I, pp. 13–14, for a description of the methodology of this study.

that it is "important for the patient[s] to know they are taking aspirin" and that the ingredients in a drug product should be communicated to the public in the best way possible (Falliers, Tr. 3263–64).

465. Therefore, the fact that Anacin and APF contain aspirin is a material fact which should be disclosed in advertising in order to protect the significant number of consumers who might otherwise be misled into purchasing and ingesting aspirin, with serious adverse effects to their health (F. 419 and 443, *supra*).

466. The fact that Anacin contains caffeine is not a material fact and need not be disclosed in advertising (See F. 425, *supra*).

VI. Liability Of The C.T. Clyne Company

467. Clyne participated in the development and dissemination of some of the challenged APF advertisements in its capacity as advertising agency for American Home (F. 9, *supra*). **[116]**

468. Clyne was involved in analytical and evaluative work to determine the effectiveness of at least some of the challenged APF advertisements (CX 610, Stip. 6).

469. Throughout the relevant time period, Clyne had no scientific or medical experts on its staff. Clyne submitted each advertisement for APF to American Home for review and approval. No advertisement for APF was disseminated to the public until it had been approved by American Home's scientific and medical experts and other appropriate American Home personnel (CX 610, Stip. 4).

470. The following advertisements for APF were among those depicted in the films and storyboards admitted into evidence in this proceeding:

Films	Storyboards
CX 201	CX 201A
CX 202	CX 202A
CX 203	CX 203A
CX 204	CX 204A
CX 205	CX 205A
CX 206	CX 206A
CX 207	CX 207A
CX 210	CX 210A
	CX 217
	CX 218

(CX 610, Stip. 8).

471. Through the use of advertisements, such as some of those listed in F. 470, *supra,* the representation that APF's analgesic ingredient is unusual, special, and stronger than aspirin (Comp. ¶ 8(B)(1)) was made by respondents and would be understood by consumers (F. 171–77, *supra*).

472. The representation that APF will eliminate all pain, stiffness and discomfort usually experienced by arthritis sufferers in the morning (Comp. ¶ 8(B)(2)) was not made in any of the challenged advertisements (F. 178–80, *supra*).

473. Through the use of advertisements, such as some of those listed in F. 470, *supra,* the representation that APF will cause gastric discomfort less frequently than any other **[117]**non-prescription internal analgesic (Comp. ¶ 12(B)) was made by respondents and would be understood by consumers (F. 181–85, *supra*).

474. Through the use of advertisements, such as some of those listed in F. 470, *supra,* the representation that it has been established that APF will cause gastric discomfort less frequently than any other non-prescription internal analgesic (Comp. ¶ 10(B)) was made by respondents and would be understood by consumers (F. 186–89, *supra*).

475. Clyne was aware that aspirin was a commonplace substance, available in many products (Non-Contested Facts, ¶ 15).

476. The presence of aspirin in APF is disclosed in labeling, packaging and product inserts (Non-Contested Facts, ¶ 13).

477. Clyne should have known, from looking at APF's label, that its analgesic ingredient was aspirin. Therefore, Clyne either knew or should have known that the representation that APF's analgesic ingredient is unusual, special and stronger than aspirin was false.

478. It is reasonable to assume that Clyne relied in good faith on the substantiation information (F. 479 and 480, *infra*) furnished by American Home.

479. The only clinical evidence known to Clyne which purported to evaluate the extent to which APF causes gastric bleeding and gastric discomfort or distress was CX 304, entitled "Arthritis Pain Formula Evaluation" (CX 611Z144; F. 377, *supra*). The study was provided to Clyne by American Home's research division, Whitehall Laboratories (CX 611Z169).

480. CX 304 reported that APF showed a significantly lower incidence of gastrointestinal irritation than buffered aspirin (F. 378, *supra*).

481. Therefore, it was reasonable for Clyne to rely in good faith on the substantiation information furnished by American Home (F. 479 and 480, *supra*) with respect to the representation that it has been established that APF will cause gastric discomfort less frequently than any other non-prescription internal analgesic. **[118]**

VII. Other Relief[6]

A. *Introduction*

482. Complaint counsel seek corrective advertising to remedy the false representations that are found to have been made in the challenged advertisements.

483. Consequently, complaint counsel bear the burden of showing that members of the purchasing public currently hold an image that:

(a) it has been established that Anacin is more effective for the relief of pain than aspirin;

(b) it has been established that Arthritis Pain Formula will cause gastric discomfort less frequently than aspirin;

(c) Anacin will relieve nervousness, tension, stress, fatigue and depression and will enable persons to cope with the ordinary stresses of everyday life.

484. To warrant a corrective advertising order, complaint counsel also must show that the images referred to in F. 483, *supra*:

(a) are significantly attributable to the false advertisements;

(b) have caused and are likely to continue to cause the purchase of Anacin or APF by members of the purchasing public; and

(c) will endure for some period of time after the false representations cease in the absence of corrective messages.

485. Complaint counsel have not introduced any direct evidence concerning the images listed in F. 483 (a) and (b), *supra*. Therefore, such images must be inferred if a **[119]**corrective advertising provision directed to them were to be justified.

B. *Consumer Images Of Anacin And APF*

486. The term, "consumer image," as used in this proceeding, describes the entire context of attitudes and beliefs that consumers have about a particular product (Leavitt, Tr. 1251; Ross, Tr. 2048; Smith, Tr. 5549–50, 7454–58).

487. Although two of the alleged images for which complaint counsel seek corrective advertising are "it has been established that

[6] The issue of the disclosure of the ingredients in Anacin and APF is discussed in Section V, *supra*, entitled *Disclosure of Aspirin and Caffeine.*

Anacin is more effective for the relief of pain than aspirin," and "it has been established that APF will cause gastric discomfort less frequently than aspirin," complaint counsel did not offer any evidence to demonstrate the existence of such images, nor did complaint counsel's expert witnesses testify that any consumer held such images of Anacin and APF (F. 485, *supra*).

1. *The Penetration Studies*

488. The term, "advertising penetration," as used in this proceeding, describes the extent to which advertising themes and claims remain in consumers' minds.

489. Advertising penetration is to be distinguished from copy tests (*i.e.*, ASI Audience Reaction Tests). Copy tests (See F. 50, *supra*, for definition) determine the meanings that consumers perceive from specific individual advertisements; consumers are usually questioned within one day after exposure to an advertisement concerning what that advertisement said or meant. Advertising penetration, on the other hand, measures the extent to which advertising themes and claims have reached consumers. Advertising penetration studies do not address consumers' recall of specific, individual advertisements. Rather, they are directed at the generalized type of off-the-top-of-the-head, or unaided, recall that is picked up when consumers are asked what they can remember about a product's advertising (Ross, Tr. 2015–16; Smith, Tr. 5534, 5545–46, 7442–49).

490. By design, surveys measuring advertising penetration allow a whole panoply of environmental factors to intervene between the time consumers were exposed to a [**120**]mix of advertising and the time they are asked to recall what it said (Ross, Tr. 2015–16; Smith, Tr. 5545–46, 7442–49).

491. Four commercial consumer marketing surveys, CX 453, 455, 462 and CX 477,[7] explored the levels of Anacin advertising penetration in 1973, 1970, 1969 and 1971, respectively.

492. The questions in these surveys were, for the most part, open-ended, and were directed towards a general, unaided recall of Anacin advertising, rather than towards a particularized recall of specific, individual claims. Such open-ended questions tend to understate the true level of recall of Anacin's advertising, thereby creating a built-in aura of conservatism regarding the data; indeed, they probably establish the minimum level of the range of recall within the population surveyed (Ross, Tr. 2028–29).

[7] Appendix I contains a description of the methodology utilized in each of the surveys. See Appendix I, pp. 3–4 for CX 453, pp. 6–8 for CX 455, pp. 10–11 for CX 462 and pp. 14–15 for CX 477.

493. Evidence from CX 462, the *1969 Excedrin Study* provides support for this view. This study is the only penetration study that contained a closed-ended, or aided, recall question (CX 462Z147). The magnitude of the responses to the aided question confirms the view that responses to unaided, open-ended advertising penetration questions understate the actual registration of Anacin advertising in the minds of consumers (CX 462Z095; Ross, Tr. 2033–34). The results show that 29% of the total sample surveyed correctly associated the claim, "Has twice the amount of pain reliever doctors recommend most," with Anacin (CX 462Z095). Consumers' attribution of this claim to Anacin, coupled with their correct attribution of other competing claims to Anacin's competitors, demonstrates that consumers' advertising recall is not the result of random comminglings of claims for different products, as was contended by respondents' expert witness, Dr. Smith (Smith, Tr. 5548–49). Rather, consumers are demonstrating that they can correctly recall advertising for a particular brand (Ross. Tr. 2033–34). Moreover, the responses to this question show that Anacin's superior efficacy claims were remembered by consumers (CX 462Z095). **[121]**

494. The results from the four studies, compiled together in Table I, *infra,* demonstrate that, consistently over the four-year period from 1969 to 1973, more than one-third of the various populations sampled on advertising penetration recalled some Anacin advertising on an unaided basis, *i.e.,* off the top of their heads (Ross, Tr. 2025–27, 2035–37, 2039–42).

TABLE I

Percent of Total Respondents Who Recalled Any Advertising for Anacin

1969[1]	*1970*[2]	*1971*[3]	*1973*[4]
34%	37%	34%	46%

[1] CX 462Z090, Z146: "What do you recall being said in any advertising [during the past six months] for Anacin?"

[2] CX 455Z012, Z121; CX 456S: "Do you *recall* seeing or hearing any advertising for Anacin in the past four weeks?"

[3] CX 477C, W; CX 1009B: "What does any advertising you have recently seen or heard say about Anacin?"

[4] CX 453Z027, Z031, Z107: "Have you seen or heard any recent advertising for any headache remedies or pain relievers?" "For which products or brands?" "Do you remember hearing or seeing any recent advertising for Anacin?"

495. Table II, *infra,* indicates the percentage of consumers who demonstrated recall for the superior efficacy and tension relief claims in Anacin's advertising, using as a base those respondents who recalled anything about Anacin's advertising (Ross, Tr. 2028, 2038). In assessing the extent to which these consumers were remembering superior efficacy claims for Anacin, their recall claims pertaining to more or extra ingredients, doctors' recommendations and superior pain relieving speed and strength should also be considered, since these attributes are elements of superior pain relieving efficacy (Ross, Tr. 2017–22, 2404–07; F. 120 and 121, *supra*). **[122]**

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TABLE II

Unaided Advertising Penetration
Based On Respondents Who Recalled Any Advertising for Anacin

CX 462 (1969) 1/		CX 477 (1971) 2/		CX 453 (1973) 3/	
Stronger	9%	Stronger	9%	Stronger/Extra Strength	4%
Quick/Fast Acting	24%	Faster	15%	Faster Acting	16%
Combination of Ingredients	18%	More Ingredients	12%	Extra Ingredients/	5%
				Contains More Aspirin	1%
Two Anacin as good as four aspirins (others)	6%			More Effective Than Aspirin	4%
Works/Better 4/	6%	Better/Best/More Effective	6%		
		More Relief	6%		
Recommended by Most Doctors/ 4 out of 5 Doctors	9%				
		Tension	6%	Relieves Tension	2%

1/ CX 462, Z092; Ross, Tr. 2029-30.
2/ CX 477W; Ross, Tr. 2036-37, 2213-14.
3/ CX 453, Z035; Ross, Tr. 2042-43, 2214-15.
4/ Some of the comments coded under "works/better" may not have been comparative. Hence, the percentage of recall in this category that relates to comparative efficacy may be inflated (Ross, Tr. 2030).

[123]496. Table II, *supra,* as presented, reflects some respondents who demonstrated recall of more than one element in Anacin's advertising (Ross, Tr. 2031–32). Although the percentages in Table II overlap to that extent, it is reasonable to conclude that approximately one-third of those respondents who recalled any Anacin advertising consistently remembered Anacin as making superior pain relieving efficacy claims (Ross, Tr. 2024, 2043–45). In fact, 45% of those respondents who had any advertising recall in 1971 reflected a state of mind bearing directly on the recall of superior pain relieving efficacy claims (CX 477X; Ross, Tr. 2038).

497. In analyzing the magnitude of this *unaided* recall of superior efficacy claims, the absolute percentages are not as important as are their size relative to the recall of other types of claims (Ross, Tr. 2032, 2038–39). In CX 462, approximately 21% of the respondents recalled Anacin's advertising as claiming that it was a "pain reliever," and approximately 6% recalled claims that Anacin "relieves headaches" (CX 462Z092). In CX 477, approximately 21% mentioned "pain" related claims, approximately 7% mentioned claims that Anacin "relieves pain" and approximately 18% mentioned "headache" (CX 477W). In CX 453, approximately 7% mentioned claims that Anacin "relieves pain" and approximately 7% mentioned "relieves headaches" (CX 453Z035).

498. These levels of recall for general claims which were admittedly made creates the context against which the magnitude of recall of superior efficacy and tension relief claims shown in Table II should be judged.

499. Although the levels of *unaided* recall for tension relief claims, shown in Table II, *supra,* are generally lower than for superior efficacy claims, they become meaningful upon comparison with similarly low levels of unaided recall for claims dealing with the relief of other symptoms for which Anacin is used (Ross, Tr. 2213–15). In CX 477, approximately 3% of the respondents (figures are, again, based on those respondents who remembered any Anacin advertising) mentioned "colds/flu," approximately 3% mentioned "general" symptoms and approximately 18% mentioned "arthritis" (CX 477W). In CX 453, approximately 1% of the respondents mentioned "muscle aches and pains" and approximately 6% mentioned [124]"arthritis" (CX 453Z035). Due to the type of questions utilized, the fact that no "tension relief" code was established for responses in CX 462 does not necessarily mean that no such claim was remembered. It may mean that there were not enough respondents who recalled the tension relief claim to justify creating a separate code, a distinct possibility in light of the fact that all of the

recall figures in all of the studies are low in an absolute sense (Ross, Tr. 2016).

500. The advertising penetration data in the record demonstrates that significant numbers of consumers recalled, on a long-term basis, the superior efficacy and tension relief claims made by American Home in its advertising (Ross, Tr. 2024, 2212–17).

2. *The Consumer Image Studies*

501. Five consumer research studies, CX 451, 452, 454, 455 and CX 457,[8] conducted in 1967, 1970, 1967, 1970 and 1975, respectively, purported to examine consumers' images of analgesic products, including Anacin.

502. Four of these studies, CX 451, 452, 454 and CX 455 were commercial consumer marketing surveys. They were conducted at different times during 1967 and 1970 by different research organizations, for different clients, using different methodologies, drawing upon different samples and with no litigation in mind. They yielded consistent findings regarding consumers' beliefs and images of Anacin and of the other major advertised OTC analgesic products (Ross, Tr. 2048, 2235–36; Rossi, Tr. 1615; Smith, Tr. 5948).

503. Although these four studies were neither perfectly designed nor flawlessly executed, they are, in general, of the kind and quality normally used by business firms to guide their marketing efforts (Smith, Tr. 5948). The fact that these studies generated consistent results over a relatively short period of time (three to four years) enhances their reliability (Smith, Tr. 5950–51). **[125]**

504. The fifth study, CX 457, was conducted for complaint counsel for use in this litigation (Leavitt, Tr. 1270; Crespi, JTr. 2456). It represents the most recent evidence adduced in this proceeding of consumers' images of Anacin (See F. 501, *supra*).

505. Although CX 457 suffers from a serious defect in that its interview completion rate was only about 50% (Crespi, JTr. 2294–96; CX 1053), it is the sole study that attempted to assess consumers' comparative images about the effectiveness of Anacin versus aspirin (Ross, Tr. 2049), the core issue in this proceeding.

a. The Commercial Studies

506. Although these older image studies (from 8 to 11 years old), CX 451, 452, 454 and CX 455, are not definitive proof of the current images that consumers hold regarding Anacin, these studies do

[8] Appendix I contains a description of the methodology utilized in each of the studies. See Appendix I, pp. 1–3 for CX 451, pp. 1–3 for CX 452, pp. 5–6 for CX 454, pp. 6–8 for CX 455 and pp. 8–10 for CX 457.

address specific consumer beliefs and the relationship of these beliefs to attitudes and images.

507. The various methodological flaws in each of these studies (See F. 501, n. 8, *supra*) are not fatal. While complaint counsel's expert witness, Dr. Rossi, conceded that each of the commercial image studies could not, standing alone, serve as the basis for any conclusion regarding Anacin's image, he appropriately maintained that the four studies could, standing together, provide a basis from which to make conclusions regarding Anacin's image (Rossi, Tr. 1725, 1728–29).

508. Each of these four studies focused on the four leading analgesics, namely Anacin, Bayer, Bufferin and Excedrin (CX 451Z084; CX 452Z087–Z088; CX 454F; and CX 455Z121).

509. Since none of the studies attempted to examine consumers' images of unbranded, generic aspirin, a surrogate for plain aspirin was used in order to assess consumers' comparative beliefs about the effectiveness of Anacin versus aspirin; that surrogate was Bayer Aspirin (Ross, Tr. 2049).

510. This method injects a bias into comparative analyses of beliefs about Anacin's and Bayer's effectiveness, and tends to understate the differences in consumers' beliefs about them. The bias results from the fact that Bayer is a well-known, heavily advertised, widely **[126]**used analgesic, in contrast with generic, store-brand aspirin (Ross, Tr. 2048–49; 2072–76; Smith, Tr. 7651–52, 7711).

511. In any event, if consumers are shown to believe that Anacin is a more effective pain reliever than Bayer, then it is reasonable to infer that they believe Anacin is a more effective pain reliever than aspirin.

512. The four studies conducted in 1967 and 1970 report the results for all respondents surveyed. Tables III and IV, *infra,* present the results on selected performance attributes directly related to efficacy for all respondents interviewed in CX 454 and CX 455, respectively.

TABLE III

RATINGS OF ANACIN AND BAYER ON SELECTED EFFICACY ATTRIBUTES TAKEN FROM CX 454*

Percentages Based Upon Total Sample

	Anacin	*Bayer*
	%	%
Good for severe headache	35	37
Relieves pain for a long period	30	29
Very strong product	28	23
Relieves pain most quickly	36	40
Average "Effectiveness" Score	32.2	32.2
BASE: 605		

* Table entries are the percentages of respondents who gave a top-box rating to each brand (on a 6-point scale) on the specified image attributes. Non-discriminators are included as well as respondents who discriminated among brands.

NOTE: These data taken from CX 454, *Assets and Liabilities Study of Adult Analgesics* (1967). Also see RX 139. [127]

TABLE IV
RATINGS OF ANACIN
Percentages Based On Respondents
Aware Of Each Brand

	Anacin %	*Bayer* %
Gives fast acting relief	50	46
Good for severe headache	30	28
Gives longer lasting relief	26	23
Is extra strength	24	11
BASE (Total Sample)	1,008	1,009

NOTE: Data taken from CX 456Z221-Z242, *Vanquish Positioning, User And Segmentation Study* (April 1970). These data are in response to Question 17 of the questionnaire. CX 456 provides the underlying data for CX 455. Also see RX 137A.

513. The results of the studies are broken down by various subgroups of respondents based upon their level of usage of the products rated. All four studies provide tabulated data for consumers who are "most often" (or regular) users of each of the products. Two studies, CX 454 and CX 455, permit further analysis of the tabulated data from consumers who do not use, or who do not regularly use, each of the products (Ross, Tr. 2052–53).

514. A separate analysis of users' and non-users' images of Anacin and Bayer on pain relieving efficacy attributes is more meaningful than an undifferentiated analysis of all respondents who gave their beliefs about the efficacy of the products (Rossi, Tr. 1783; Ross, Tr. 2051–52). Preference for "user versus user" and "non-user versus non-user" analyses is based upon the fact that the comparative, [128]rather than the absolute, beliefs and images of Anacin and Bayer are the issues in this case.

515. While an analysis of comparative beliefs based on the results of the total sample would provide an overview of the relative beliefs held by the undifferentiated sample, it would also tend to obscure differences between the brands surveyed (Ross, Tr. 2050–54).

516. As testified to by respondents' expert witnesses, it is only the total sample from which conclusions can be based about how the population at large (*i.e.*, the consuming public) views the products

being studied (Smith, Tr. 5951–55; Kuehn, Tr. 6708–09; Blattberg, Tr. 7120–21; Sen, Tr. 7174). For example, although a "user versus user" analysis or a "non-user versus non-user" analysis is acceptable for looking at subgroups for various analytical or diagnostic purposes, the results thereby obtained are not projectable to or representative of the consuming public (Ross, Tr. 2559–63; Smith, Tr. 5952–53; Kuehn, Tr. 6708–09; Blattberg, Tr. 6906–07; Sen, Tr. 7174).

517. It is recognized that users of a product tend to rate that product more favorably than do non-users (Ross, Tr. 2051; Jacoby, Tr. 5405–06; Smith, Tr. 5954, 7682, 7813). This bias, called user bias or user "halo," favors Bayer in the instant situation because Bayer was used more often than Anacin by the total population at the time the studies were done. The overrepresentation of Bayer users in the total sample of consumers surveyed would be expected to result in the percentage of the total sample that said favorable things about Bayer being proportionately higher than the same group as regards Anacin. The greater consumer usage of Bayer resulted in more frequent favorable ratings of Bayer by the total sample and obscured true differences in beliefs about Anacin and Bayer (Ross, Tr. 2050–54; Smith, Tr. 5956–57, 7814).

518. However, analysis of relative beliefs among users of both products and among non-users of both products will hold constant the otherwise unequal number, and thus the impact, of Bayer users' favorable ratings of their product (Ross, Tr. 2052). This is an accepted technique that is utilized so as to hold constant the inflating effects of differential product usage in a sample and, thereby, allow one to more properly ascertain the relative images of two brands (Smith, Tr. 7817–18). **[129]**

519. Table V, *infra,* presents the results on selected performance attributes for users of Anacin and Bayer that were reported in the four studies conducted in 1967 and 1970. None of these studies explicitly questioned consumers about the general pain relieving "efficacy" of the analgesics studied. However, the specific attributes reported on in Table V, focusing on the speed and strength of the products, have been shown to have a strong, logical relationship to a pain reliever's "effectiveness" (Ross, Tr. 2017–23; F. 120, 121 and 495, *supra*). Respondents' own expert, Dr. Smith, testified that the attributes of speed and strength were "sign posts" or "flags" for a pain reliever's effectiveness (Smith, Tr. 7558–60).

520. Additional support for concentrating on speed and strength-related performance attributes in these studies is furnished by Dr. Rossi, who performed a "regression analysis" (which is done to determine the relationship between covariables) of the raw data

generated in CX 457, the 1975 Leavitt Study. Dr. Rossi's analysis showed that respondents' ratings of "speed" and "strength" of Anacin, Bufferin and Excedrin were positively related to a high degree to their ratings of "efficacy" (Rossi, Tr. 1580–94).

521. The results shown in Table V, *infra,* show that users of both products believed Anacin to be superior to Bayer in terms of attributes directly related to speed and strength and, therefore, efficacy. The results of the four studies conducted in 1967 and 1970 demonstrate a consistent image of Anacin's superiority over aspirin among users of each across time, methodologies and consumer samples.

522. The results from CX 454 and CX 455, analyzed in terms of respondents who were not current users or current "most often" users (*i.e.,* non-users) of a brand, are presented in Table VI, *infra.* This "non-user versus non-user" analysis was another effort to remove, to the extent possible, the user bias that affects the ratings of all brands. Analysis of beliefs among non-users eliminates this bias by removing users' ratings from the analysis. This contrasts with the "user versus user" analysis, which holds the bias constant by limiting the analysis to users (Ross, Tr. 2052–53. See also F. 517 and 518, *supra*).

523. The data presented in Table VI, *infra,* show that non-users of Anacin and Bayer believe Anacin to be superior in speed and strength and, therefore, efficacy to Bayer. **[130]**

TABLE V

Beliefs About Anacin and Bayer

Percentages Based Upon Users Of Each Product

Study	Belief	Anacin	Bayer
1967-CX 451 1/	For Fast Relief	68%	55%
	Gives Long Lasting Relief	67%	53%
	Good for Severe Headaches	75%	48%
	Strong	31%	19%
	Gives Complete Relief	58%	51%
1967-CX 454 2/	Relieves Pain Most Quickly	79%	65%
	Relieves Pain for Long Period	64%	44%
	Good for Severe Headaches	64%	52%
	Very Strong Product	55%	37%
1970-CX 452 3/	For Fast Relief	65%	57%
	Long Lasting	58%	57%
	Good for Severe Headaches	60%	47%
	Extra Strength	19%	21%
	Strong	16%	25%
	Gives Complete Relief	57%	58%
1970-CX 455/56 4/	Gives Fast Acting Relief	64%	65%
	Gives Longer Lasting Relief	41%	35%
	Good for Severe Headaches	45%	40%
	Is Extra Strength	26%	12%

1/ CX 1058Z478, Z480, Z485, Z486, Z490; Ross, Tr. 2190-97. Dr. Ross' analysis was based upon the responses of males and females. The percentages displayed above simply combine those responses into a total percentage for Anacin and Bayer users.

2/ CX 454Z148, Z149; Ross, Tr. 2055-60; Rossi, Tr. 1601-02.

3/ CX 1059Z214, Z217, Z221, Z229, Z233; Ross, Tr. 2190-97. See footnote 1, *supra*, regarding the meaning of these percentages.

4/ CX 456Z221, Z222, Z225, Z226; Ross, Tr. 2080-82; Rossi, Tr. 1613-15.

[131]TABLE VI

Beliefs About Anacin and Bayer

Percentages Based Upon Non-Users Of Each Product

CX-454[1]		CX-455/56[2]	
1967		1970	
Relieves Pain Most Quickly		*Gives Fast Acting Relief*	
Anacin	Bayer	Anacin	Bayer
28%	26%	48%	41%
Relieves Pain for Long Period		*Gives Longer Lasting Relief*	
24%	21%	23%	18%
Very Strong Product		*Is Extra Strength*	
23%	15%	24%	12%
Good for Severe Headaches		*Good for Severe Headaches*	
30%	29%	28%	26%

[1] CX 454Z060, Z061, Z062, Z066, Z148, Z149; Ross, Tr. 2069–70; Rossi, Tr. 1601–02.

[2] CX 456Z221, Z222, Z225, Z226; Ross, Tr. 2078–80; Rossi, Tr. 1613–14.

524. CX 454 is the only one of the four studies conducted in 1967 and 1970 which permits a comparison of Anacin's image with that of an aspirin product other than Bayer. While Bayer ratings were included in the study and analyzed (Table V, *supra*), respondents were also asked to rate Norwich Aspirin on the same attributes as Anacin (CX 454F). The comparison of Anacin's image with that of Norwich again demonstrates the superiority of Anacin's image on all relevant pain relieving efficacy dimensions (Rossi, Tr. 1599–1600; Smith, Tr. 7650–52).

525. The results of CX 451, 452, 454 and CX 455, as shown in Table VII, *infra,* demonstrate that a significant number of Anacin users believed Anacin to be an effective tension reliever wholly apart from their beliefs concerning its efficacy in the relief of pain (Ross, Tr. 2217; Rossi, Tr. 1616–21). CX 457 serves to confirm this finding by showing that consumers had an image of Anacin as a tension reliever as late as the fall of 1975, the date this study was conducted. While only 1.4% of the respondents, or 11 individuals, surveyed in CX 457 selected Anacin as helpful for relieving tension, this figure may be explained by the fact that the tension answers were elicited in response to unaided, open-ended questions which usually tend to result in a lower level of response than aided, closed-ended questions. Furthermore, the 1.4% figure must be looked at in light of the fact that tension relief advertisements for Anacin ceased about December 1973 (Leavitt, Tr. 1316–24, 1422–23; Ross, Tr. 2233–34; CX 457X. See also F. 492, *supra*). [132]

TABLE VII

Ailments For Which Brands Are Useful

Percentages Based Upon Users Of Anacin

CX-454 1967 1/	CX-451 1967 2/	CX-452 1970 3/	CX-455/56 1970 4/
Good for Relieving Nervous Tension	Nervousness	Nervousness	Relieves Nervous Tension
41%	57%	45%	37%
Good for Pre-Menstrual Tension/Depression	Tension	Tension	
50%	72%	71%	
Good for Helping You Sleep	Sleep Problems	Sleep Problems	
26%	38%	27%	
	Depression	Depression	
	33%	28%	
	A Heavy Dragging Feeling	A Heavy Dragging Feeling	
	27%	20%	

1/ CX 454Z148; Ross, Tr. 2217-18; Rossi, Tr. 1616-17.
2/ CX 105Z470, Z473, Z474, Z475; Ross, Tr. 2229-30. Dr. Ross' tesimony reported percentages of male and female Anacin users. The data above reflect a simple combination of those percentages into a single percentage for all Anacin users.
3/ CX 105Z189, Z192; Ross, Tr. 2228-29. (See n. 2, supra).
4/ CX 456Z221; Rossi, Tr. 1617.

[133]526. Results from the *1969 Excedrin Study,* CX 462, show that, among Anacin users, 28% responded that they treat nervous tension with a pain reliever, and 73% of that 28% reported that they usually use Anacin to treat that symptom (CX 462Z052; Rossi, Tr. 1618–19).

527. Results from CX 454 and CX 455 also demonstrate that a significant number of Anacin non-users believed Anacin to be an effective tension reliever wholly apart from their beliefs concerning its efficacy in the relief of pain (Table VIII, *infra;* Rossi, Tr. 1615–16; Ross, Tr. 2217).

TABLE VIII

Ailments For Which Brands Are Useful

Percentages Based Upon Non-Users Of Anacin

CX–454 1967[1]		CX–455/56 1970[2]	
Good For Relieving Nervous Tension	16%	Relieves Nervous Tension	26%
Good For Pre-Menstrual Tension and Depression	28%	Good For Helping You Sleep	14%

[1] CX 454Z072, Z073, Z075; Ross, Tr. 2218; Rossi, Tr. 1616–17.

[2] CX 456Z221; Ross, Tr. 2219; Rossi, Tr. 1617.

b. The Leavitt Study

528. Despite the fact that the study on *Public Beliefs About Selected Analgesic Products* ("The Leavitt Study"), CX 457, [134]is marred by serious flaws in its methodology (See Appendix I, pp. 8–10, *infra*) and analysis, it represents the best evidence available on consumers' current comparative images about the efficacy of Anacin versus aspirin (F. 504 and 505, *supra*).

529. The study contained no questions designed to determine th source of the images being measured nor did it attempt to measur the impact of advertising upon consumer beliefs relating to Anaci or aspirin (Leavitt, Tr. 1339, 1364–65, 1371). The study could easi have been designed to obtain this information; it is advisable f

researchers to ask such questions when they are attempting to relate advertising to image (Jacoby, Tr. 5247–48; Smith, Tr. 6039–40).

530. The most serious, major defect in the methodology of *The Leavitt Study* lies in the inadequacy of its response rate. The response rate in CX 457 was only about 50% (F. 505, *supra;* Appendix I, p. 9), meaning that just one-half of all of the interviews attempted were successfully completed.

531. Respondents' expert witness, Dr. Jacoby, testified that well done commercial telephone surveys should have response rates of approximately 75% (Jacoby, Tr. 4276). The minimum response rate generally required in government survey work, absent special justification, is 75% (Maisel, Tr. 4081). Even complaint counsel's expert, Dr. Rossi, felt that the response rate of the Leavitt survey was not as high as he would have liked it to be (Rossi, Tr. 1726).

532. As the "non-response" rate increases, the reliability of the survey results diminishes because of the increase in non-response bias (Rossi, Tr. 1623, 1726; Maisel, Tr. 4800; Jacoby, Tr. 5274, 5276).

533. Generic aspirin was used as the standard reference term against which Anacin and the other analgesics studied in CX 457 were compared (Leavitt, Tr. 1354; CX 457B).

534. Dr. Leavitt testified that he chose to compare generic aspirin against Anacin because of aspirin's common usage and its use in Anacin advertising as a measure for comparisons (Leavitt, Tr. 1354–56, 1357–58, 1361–71).

535. However, it is impossible to know how consumers understood the term "aspirin" and, according to Dr. Leavitt, many of them could well have understood the term to mean any number of analgesic products, many of which are not even aspirin (Leavitt, Tr. 1356, 1364–69; Rossi, Tr. 1638; Jacoby, Tr. 5244–45). [135]

536. A comparison of three nationally distributed and trademarked products with a generic product has the inherent effect of causing the national brands to be rated higher than the generic brand. All of complaint counsel's marketing witnesses conceded that there is a universal favorable bias among consumers towards national brands as compared to store brands or generic brands Leavitt, Tr. 1358, 1361–62; Rossi, Tr. 1639; Ross, Tr. 2481).

537. Nonetheless, there are intrinsic problems in the use of ither store brands, generic brands or national brands, such as ayer, as the standard of comparison for Anacin (F. 509 and 510, *pra*). It is reasonable to conclude that, by choosing generic aspirin, . Leavitt chose the best available product against which to npare Anacin.

538. Dr. Leavitt did not rotate the attributes in the questionnaire

design; each attribute appeared in each position an equal number of times. For example, "effectiveness" should have been the first attribute about which respondents were asked 25% of the time, "speed" should have been the first attribute about which respondents were asked 25% of the time, etc. Failure to rotate the attributes may create additional bias (Maisel, Tr. 5036–37; Jacoby, Tr. 5263–65).

539. Another source of potential bias is found in Dr. Leavitt's failure to provide the respondent with a neutral reply option on the rating scale. Dr. Leavitt utilized an admittedly unbalanced four-point rating scale with three positively worded steps ("extremely," "very" and "fairly") and one negatively worded step ("not") (CX 457E). This created the possibility of agreement response bias by forcing people to take a position which did not necessarily coincide with their views (Jacoby, Tr. 5525–59, 5430).

540. Dr. Leavitt justified his choice of a rating scale by making the observation that people tend to rate everything more positively than negatively. A four-point scale skewed towards the positive side will allow for more differentiation among positive answers, and will provide the maximum range of choices for most respondents (Leavitt, Tr. 1279; CX 457E–F).

541. Dr. Leavitt assumed that the four steps on the rating scale he utilized were equidistant from one another. He made no independent effort to determine if people, in fact, understood them to be at equal intervals from one **[136]**another (Leavitt, Tr. 1435–46). However, based upon prior experience with such scales, it is reasonable to assume that the four steps were about at equal intervals from one another (Leavitt, Tr. 1425–26. See also Rossi, Tr. 1651–53).

542. From the base of 780 respondents who were interviewed, approximately 98% had heard of all of the four products being surveyed. Dr. Leavitt did not analyze the 17 respondents, or 2%, who were not aware of all of the products involved in the study (Leavitt, Tr. 1229). The exclusion of these 17 respondents did not affect the reliability of Dr. Leavitt's analysis (Leavitt, Tr. 1295; Smith, Tr. 6050).

543. The presentation of *The Leavitt Study* data rests upon a simple comparison of each respondent's ratings of Anacin and aspirin: a respondent was held to have a comparative image of Anacin and aspirin if, and only if, he or she rated both products. Thus, each respondent who rated both products rated Anacin superior, equal or inferior to aspirin in terms of pain relieving efficacy. The total number of respondents in each of these three

categories is simply a matter of adding together the data in CX 457Z012, Z013 and Z014 (Leavitt, Tr. 1305–07).

544. Dr. Leavitt chose to utilize absolute, rather than comparative, questions even though the objective of his study was to ascertain what comparative images, if any, existed concerning Anacin and aspirin (Leavitt, Tr. 1272–73). His reasons for so doing were that it would be easier to detect statistically significant differences between absolute answers, it would be easier to control for response error and other accidental factors, and the respondents would be less likely to deduce the purpose of the survey (Leavitt, Tr. 1274–75, 1400).

545. Tables IX, X and XI, *infra,* present the results for all 780 respondents interviewed in *The Leavitt Study.* It was the opinion of respondents' expert marketing witnesses that, based upon these tables, the images of Anacin and aspirin are essentially identical whether one looks at the top one, top two, top three or all four boxes (Maisel, Tr. 4987–89, 4998, 5018–20; Smith, Tr. 6045–70; Blattberg, Tr. 6909; Kuehn, Tr. 6370–71; Sen, Tr. 7169). **[137]**

TABLE IX

RATINGS OF "EFFECTIVENESS FOR RELIEVING PAIN"

BASED ON TOTAL RESPONDENTS INTERVIEWED */

	Aspirin %	Anacin %
Extremely effective	7.4	9.2
Very effective	19.9	19.9
Fairly effective	42.2	32.2
Not effective	9.7	3.6
Don't know	20.8	35.1
BASE: 780		

*/ In his analysis, Leavitt eliminated 17 of these respondents who claimed that they were not aware of all four of the products surveyed, but who had given ratings to each of the products (F. 542, supra).

Source: RX 108A.

NOTE: This table was developed from the underlying data collected in the Clark Leavitt/Gallup Organization study, Public Beliefs About Selected Analgesic Products (CX 457).

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TABLE X

RATINGS OF "STRENGTH FOR RELIEVING PAIN"

BASED ON TOTAL RESPONDENTS INTERVIEWED */

	Aspirin %	Anacin %
Extremely high	6.4	6.3
Very high	12.8	18.1
Fairly high	40.1	32.4
Not high	16.5	5.9
Don't know	24.1	37.3
BASE: 760		

*/ In his analysis, Leavitt eliminated 17 of these respondents who claimed that they were not aware of all four of the products surveyed, but who had given ratings to each of the products (F. 542, supra).

Source: RX 108B.

NOTE: This table was developed from the underlying data collected in the Clark Leavitt/Gallup Organization study, Public Beliefs About Selected Analgesic Products (CX 457).

TABLE XI

RATINGS OF "SPEED IN RELIEVING PAIN"

BASED ON TOTAL RESPONDENTS INTERVIEWED */

	Aspirin %	Anacin %
Extremely fast	4.9	7.3
Very fast	13.3	17.2
Fairly fast	42.6	30.0
Not fast	17.8	7.8
Don't know	21.4	37.7
BASE: 780		

*/ In his analysis, Leavitt eliminated 17 of these respondents who claimed that they were not aware of all four of the products surveyed, but who had given ratings to each of the products (F. 542, supra).

Source: RX 108C.

NOTE: This table was developed from the underlying data collected in the Clark Leavitt/Gallup Organization study, Public Beliefs About Selected Analgesic Products (CX 457).

[140]546. When standard statistical tests of significance are applied, none of the differences shown in Tables IX, X and XI, *supra,* for the base of all 780 respondents interviewed, are statistically significant at the 95% confidence level (Maisel, Tr. 5018–20; Smith, Tr. 6046–51; Blattberg, Tr. 6914–15).

547. Dr. Leavitt not only omitted from his tabulations individuals who responded "Don't Know" to both products, but also omitted individuals who had given ratings to either Anacin or aspirin and answered "Don't Know" to the other. Whenever a respondent was unwilling or unable to rate a product on the four-point scale presented to him in Questions 2 through 5, the interviewer was instructed to code "Don't Know" on the questionnaire (Leavitt, Tr. 1292–93; CX 457W).

548. Pretesting of the questionnaire had disclosed that some respondents might be unwilling to rate a product because they did not personally use it (Crespi, JTr. 2270). The questionnaire had been modified to address this possibility by changing the preamble to Questions 2 through 5 to, "Whether or not you have ever used them . . . ."

549. One effect obtained by Dr. Leavitt by omitting the "Don't Knows" from the tabulations was an inflation of the percentage of people rating Anacin in the higher categories (Kuehn, Tr. 6289; RX 203, 204A, 205A and B, 206A and B and RX 207A and B). This result is attributed to the fact that there were approximately 100 more people who rated Anacin "Don't Know" than rated aspirin "Don't Know" (Table XIV, *infra*; RX 108A; Leavitt, Tr. 1475).

550. Fifty-eight percent (58%), or 446, of the 763 respondents rated both Anacin and aspirin on their effectiveness for pain relief. Fifty-six percent (56%) rated both products on their pain-relieving speed and strength (Table XIII, *infra*). These respondents have a comparative image of Anacin and aspirin on those attributes that they rated. The remainder, 42% to 44%, of the 763 respondents did not rate one or both products on these attributes; their failure to do so indicates the absence, on their part, of a comparative image of Anacin and aspirin as measured on the four-point scale (Leavitt, Tr. 1312; Rossi, Tr. 1582; Ross, Tr. 2050–51, 2198–99; Maisel, Tr. 5186–87; Smith, Tr. 7721).

551. Table XII, *infra,* presents the data for those people that did, nd those that did not, have a comparative image of Anacin and spirin. The percentages in each row represent independent groups respondents and each response appears only once in each row respi, JTr. 2352). Dr. Leavitt testified that these percentages are asonably projectable to the population of adults who live in homes

with telephones and who are aware of these products (Leavitt, Tr. 1307; Appendix I, p. 9 *infra*). At the 95% level of confidence, given a sample of approximately 750 people, the percentages could vary by approximately plus or minus 4% (Crespi, JTr. 2346–47; CX 1048C, Table A). **[141]**

TABLE XII

	Had Comparative Image			Did Not Have Comparative Image			
	Rated Both Products						
	Rated Anacin Higher Than Aspirin	Rated Anacin Equal to Aspirin	Rated Anacin Lower Than Aspirin	Did Not Rate Both Products Did Not Rate Either Product	Rated Aspirin Only	Rated Anacin Only	Total
Effectiveness	16.3%	38.3%	3.9%	14.5%	6.4%	20.6%	763=100%
Speed	19.8%	31.7%	4.5%	15.1%	6.6%	22.4%	763=100%
Strength	17.6%	34.1%	4.5%	17.7%	6.6%	19.7%	763=100%

Definitions:

Source: CX 4572012, 4013, 4014 (Leavitt, Tr. 1302-07).

[142]552. Analysis of the data presented in Table XII, *supra,* reveals that in excess of 40% of the respondents answered "Don't Know" concerning the nationally advertised analgesics. This 40%-plus figure looms even larger in light of the fact that the "Don't Know" response was not read to the respondent and, thus, required an unaided, affirmative act on the part of the respondent to be so classified (Leavitt, Tr. 1447–48; Maisel, Tr. 4987–89; Kuehn, Tr. 6790–91).

553. Table XIII, *infra,* presents the breakdown of *The Leavitt Study's* results in terms of percentages of the limited base of people who rated both products.

TABLE XIII

Percentages Based On Those Who Rated Both Products

	I. Rated Anacin Higher Than Aspirin	II. Rated Both The Same	III. Rated Aspirin Higher Than Anacin	Total
Effectiveness	27.8%	65.5%	6.7%	446=100%
Speed	35.4%	56.8%	8.0%	427=100%
Strength	31.3%	60.7%	7.9%	428=100%

Source: CX 457Z012, Z013, Z014.

554. The percentages in Table XIII, *supra,* are related to that subgroup of the sample who had a comparative image of Anacin and aspirin. Therefore, the figures are not technically projectable, in a statistical sense, to the general population (Maisel, Tr. 4799, 4829, 5019–20, 5187; Kuehn, Tr. 6280–81, 6708–11, 6792; Blattberg, Tr. 6906–08; Sen, Tr. 7174, 7400–01, 7403–05, 7414). However, Dr. Leavitt and respondents' expert witness, Dr. Smith, testified that these percentages are reasonably projectable to the population of adults in telephone households who are aware of both products and have a comparative image of them (Leavitt, Tr. 1409; Smith, Tr. 7718–20). [143]

555. Moreover, respondents' experts did concede that *The Leavitt Study* results are of some limited value, such as for diagnostic purposes (Kuehn, Tr. 6708–09, 6749–50; Sen, Tr. 7174, 7309, 7404–05). Dr. Maisel, also one of respondents' expert witnesses, admitted that studies such as *The Leavitt Study* are often used in making important business decisions despite their defects (Maisel, Tr. 5168–69).

556. Many of the 763 respondents did not rate either Anacin or aspirin on a particular attribute; many rated aspirin only, and some Anacin only. The breakdown of these respondents is presented in Table XIV, *infra.*

TABLE XIV

	Didn't Rate Either Product	Rated Aspirin Only; Didn't Rate Anacin	Rated Anacin Only; Didn't Rate Aspirin	Total
Effectiveness	111	157	49	317
Speed	115	171	50	336
Strength	135	150	50	335

Source: CX 618, 621 and 624; RX 201 and RX 202 (Leavitt, Tr. 1471–75).

557. Of the 173 respondents, 124 rated Anacin higher than aspirin on the four-point scale in terms of effectiveness for relieving pain. One hundred fifty-one rated Anacin higher than aspirin on pain relieving speed. One hundred thirty-four rated Anacin higher than aspirin on pain relieving strength Table XV, *infra.*

TABLE XV

	Rated Anacin Higher	Rated Anacin=Aspirin	Rated Aspirin Higher	Total
Effectiveness	124	292	30	446
Speed	151	242	34	427
Strength	134	260	34	428

Source: CX 457Z011, Z012, Z013 (Leavitt, Tr. 1305–07; Rossi, Tr. 1576). [144]

558. Tables XII–XV (F. 549–57, *supra*) are premised upon three assumptions which were shown to be correct. The first assumption is that consumers who rated Anacin and aspirin were using the rating scale ordinally in the sense that they viewed an "extremely" rating as higher than a "very" rating, and so on down the scale (Leavitt, Tr. 303–04). This assumption remains undisputed and was implicitly accepted by respondents' experts (Maisel, Tr. 5118; Jacoby, Tr. 5433; Smith, Tr. 7726). The second assumption is that unless a respondent actually rated a product, one could not reasonably infer that the respondent had an image of that product (Leavitt, Tr. 1312; Rossi, Tr. 82; Ross, Tr. 2207). This assumption is supported by the testimony respondents' expert witnesses (Maisel, Tr. 5186–87; Smith, Tr.

7721). The third, and final, assumption is that Gallup's sampling procedures have been adequate and its results generalizable within certain limits. While the procedures were not completely randomized at each and every step of the sampling process, it is reasonable to conclude that the data generated are generally reliable.

559. Of the 763 respondents, 297 used neither Anacin nor aspirin, while 115 used both Anacin and aspirin. These two sets of respondents constitute two subsamples whose results can be analyzed separately to confirm the conclusions drawn from the analysis of the total sample of respondents presented in F. 566 and 567, *infra.* The results of *The Leavitt Study* for non-users are presented in Tables XVI and XVII, *infra,* and the results for users are presented in Tables XVIII and XIX, *infra.* **[145]**

TABLE XVI

297 Respondents Who Used Neither Anacin Nor Aspirin

	Rated both Products			Did Not Rate Both Products		
	Rated Anacin Higher Than Aspirin	Rated Anacin Equal to Aspirin	Rated Aspirin Higher Than Anacin	Did Not Rate Either Product	Rated Aspirin Only	Rated Anacin Only	Total
Effectiveness:	12.8%	35%	1.3%	33%	13.1%	4.4%	297=100%
Speed:	16.8%	30.3%	1.7%	33%	13.8%	4.0%	297=100%
Strength:	14.1%	31.0%	2.0%	36.7%	11.4%	4.7%	297=100%

Source: RX 202.

TABLE XVII

Percentages Based On Non-Users Of Both Anacin And Aspirin Who Rated Both Products */

	Rated Anacin Higher	Rated Both The Same	Rated Aspirin Higher	Total
Effectiveness:	26.0%(38)	71.2%(104)	2.7%(4)	146=100%
Speed:	34.5%(50)	62.1% (90)	3.4%(5)	145=100%
Strength:	29.6%(42)	64.8% (92)	4.2%(6)	142=100%

*/ The figures in parentheses represent the absolute numbers of respondents who fall within each category.

Source: Table XVI.

TABLE XVIII

115 Respondents Who Used Both Anacin And Aspirin

	Rated Both Products			Did Not Rate Both Products		
	Rated Anacin Higher Than Aspirin	Rated Anacin Equal to Aspirin	Rated Aspirin Higher Than Anacin	Did Not Rate Both Products Either Product	Rated Aspirin Only	Rated Anacin Only	Total
Effectiveness:	33.0%	57.4%	5.2%	1.7%	1%	1.7%	115=100%
Speed:	36.5%	47.0%	6.1%	5.2%	1%	4.3%	115=100%
Strength:	32.2%	53.9%	5.2%	4.3%	0%	4.3%	115=100%

Source: RX 202.

[148]TABLE XIX

Percentages Based On Users Of Both Anacin And Aspirin Who Rated Both Products*

	Rated Anacin Higher	Rated Both The Same	Rated Aspirin Higher	Total
Effectiveness:	34.5%(38)	60% (66)	5.5%(6)	110=100%
Speed:	40.8%(42)	52.4%(54)	6.8%(7)	103=100%
Strength:	35.2%(37)	59.0%(62)	5.7%(6)	105=100%

* The figures in parentheses represent the absolute numbers of respondents who fall within each category.

Source: Table XVIII.

560. Another way to assess the comparative images of Anacin and aspirin is to analyze the date on an aggregate, rather than on an individual, basis. This mode of analysis is based on whether the distribution of all respondents' ratings of Anacin is higher than, equal to or lower than the distribution of all respondents' ratings of aspirin. This method leads to the conclusion that the sample on an aggregate basis believed that Anacin was superior, equal or inferior to aspirin (CX 457Z001, Z002, Z003; Rossi, Tr. 1577).

561. A most conservative application of this aggregate analysis involves comparing the distribution of ratings of Anacin and aspirin by the subsample of respondents who rated both products but who had not used Anacin for at least six months prior to the survey. Analysis of this subsample is conservative because it removes from the analysis those respondents who are most likely to have a favorable image of Anacin, while retaining those most likely to have a favorable image of aspirin (Ross, Tr. 2203–04; Smith, Tr. 5954–55, 5957–58). In examining this admittedly biased subsample (biased in favor of aspirin), Anacin is still rated as more effective than aspirin. This analysis confirms the essential conclusion that Anacin is believed to be superior to aspirin within the population of those who have an opinion about both (Ross, Tr. 2199–2201; CX 631; Smith, Tr. 7726–27). **[149]**

562. Another type of aggregate analysis of the comparative beliefs of respondents who rated, and therefore had an image of, both products is reflected in the combined average ratings presented by Dr. Leavitt in CX 457Z009. A combined average rating has the virtue of reducing the aggregate distribution of ratings to single numbers for each product, which can be compared statistically. Such a statistical comparison shows that Anacin's average rating on all three attributes is significantly higher than aspirin's, and confirms

once again the overall conclusion to be drawn from the study: significant numbers of consumers believe Anacin is a more effective pain reliever than aspirin (Leavitt, Tr. 1308–11; Rossi, Tr. 1576).

563. The comparison of combined average ratings does not provide an independent foundation for the conclusion that Anacin has a superior image to aspirin because the calculation and comparison of average ratings for both products is a "parametric" statistical technique predicated upon certain assumptions about the nature of the respondents' ratings (Leavitt, Tr. 1498–99; Rossi, Tr. 1652–53; Ross, Tr. 2209–10; Jacoby, Tr. 5260). The primary assumption is that respondents used the four-point scale as an "equal interval" scale (Ross, Tr. 2062). In other words, it is assumed that they believed not only that "Extremely" was higher than "Very," and so on (an "ordinal" relationship), but also that the difference between "extremely" and "very" was the same as that between "very" and "fairly" and between "fairly" and "not" (Leavitt, Tr. 1435–38). If the equal interval assumption is satisfied, then it is appropriate to assign equal numeric intervals (*e.g.,* 3, 2, 1, 0) to the verbal anchors on the four-point scale, which then permits an adding and averaging of the ratings. Satisfaction of the assumption of "equal intervals" depends on how respondents perceived the scale, a perception that was not investigated in *The Leavitt Study* (Leavitt, Tr. 1436). However, the conclusion that the "equal interval" assumption was satisfied is reasonable (F. 541, *supra*).

564. Given the substantial size of the sample that was analyzed in this statistical comparison of average ratings and the equal interval characteristics of the four-point scale, it is reasonable to conclude that Anacin received higher ratings than aspirin whether or not one compared the averages or simply compared the aggregate distributions (Ross, Tr. 2210).

565. The analyses of *The Leavitt Study* data that are presented in F. 550–64, *supra,* focus on those respondents who rated both Anacin and aspirin because only this group can unequivocally be said to have a comparative image of the two **[150]**products (F. 543, *supra*). For example, the 157 respondents who rated aspirin on effectiveness but who did not rate Anacin on effectiveness (Table XIV, *supra*) did not hold a comparative image of the two products on that attribute and, therefore, did not meet the essential criterion for Dr. Leavitt's analysis (Leavitt, Tr. 1311–12) nor for the analyses presented in F. 550–64, *supra.* The other respondents either rated only one product or rated neither product. Nevertheless, their ratings of aspirin can be examined (CX 629A, B, C). Similarly, the ratings of those who rated Anacin on any attribute, without regard to whether they rated

aspirin, can be examined (CX 629A, B, C). However, this is not a rational basis upon which to compare images because, by definition, it includes those who did not have a comparative image of the two products (Rossi, Tr. 1582; Ross, Tr. 2205–08).

566. Despite these limitations, the ratings of Anacin among all respondents who rated it (regardless of whether they rated aspirin) were compared to the ratings of aspirin among all respondents who rated it (regardless of whether they rated Anacin). Respondent's own expert, Dr. Smith, agreed that Anacin's ratings on this basis were higher than aspirin's (Smith, Tr. 7724–27). When those ratings were averaged, Anacin's average ratings still were higher than aspirin's (Rossi, Tr. 2148). Even when all the ratings of Anacin, by both users and non-users, were compared with all the ratings of aspirin, by both users and non-users, Anacin's ratings were higher (Ross, Tr. 2205–07).

567. *The Leavitt Study* (CX 457) shows that a significant number of American consumers believe that Anacin is a more effective pain reliever than aspirin.

3. *Conclusion*

568. The five consumer research studies, CX 451, 452, 454, 455 and 457, and the experts' testimony, demonstrate that it is reasonable to infer that a significant number of consumers have an image of Anacin as a product that is more effective for the relief of pain than aspirin.

569. When looked at as a whole, the studies carried out during the period 1967 to 1970 (CX 451, 452, 454 and 455), confirm this conclusion despite different methodologies and sampling designs. Respondents' expert, Dr. Joseph Smith, testified that the consistency in the findings of these studies adds considerably to the credibility of their results (Smith, Tr. 5950). **[151]**

570. However, none of the 1967 to 1970 commercial studies permits a conclusion as to whether the individual consumers surveyed believed that Anacin was more effective than aspirin (or Bayer). They merely permit an inference that some proportion of the sample surveyed had a specific image of Anacin and that some proportion had a specific image of aspirin (or Bayer). Thus, these studies provide a basis for an inference regarding the nature and the extent of the comparative images among the consumers surveyed

(Ross, Tr. 2059–60), and confirm the essential findings of *The Leavitt Study* (CX 457).[9]

571. A significant number of consumers have an image of Anacin as a product that will relieve nervousness, tension, stress, fatigue and depression and will enable persons to cope with the ordinary stresses of everyday life (F. 525–27, *supra*).

572. Although no specific evidence was introduced to show that consumers have an image of APF as a product that will cause gastric discomfort less frequently than aspirin, it is reasonable to infer from the representations made in the advertisements disseminated for APF and from consumers' understanding of those representations (F. 181–85, *supra*) that a significant number of consumers have an image of APF as a product that will cause gastric discomfort less frequently than aspirin.

573. No evidence was presented to show that either of the images consumers have of Anacin and APF (as stated in F. 568 and 572, *supra*) was also an establishment image (F. 485 and 487, *supra*).

574. It is not reasonable to infer from the record evidence that consumers held an image that:

(a) it has been established that Anacin is more effective for the relief of pain than aspirin; or that

(b) it has been established that Arthritis Pain Formula will cause gastric discomfort less frequently than aspirin. **[152]**

575. However, it is reasonable to infer from the representations made in advertisements disseminated for Anacin and APF, taken together with the inferential conclusions presented in F. 568 and 572, *supra,* that consumers held the images referred to in F. 483 (a) and (b), *supra.* These inferential conclusions are implied as a matter of law.[10]

C. *The Source Of Consumer Images Of Anacin*

576. The record enumerates some of the multitude of factors that play a role in the creation of consumer beliefs and images about a product. Some of these factors are advertising, experience based on prior product usage, word-of-mouth communications, recommendation by doctors, price, packaging, brand name and the store where the product is purchased (Ross, Tr. 2238–39, 2577–84; Smith, Tr. 6079–81; Jacoby, Tr. 5486–87; Sen, Tr. 7170).

[9] In this manner, it is suggested that consumers' images of Anacin have been stable through significant periods of time (See Section VII D).

[10] Therefore, the two establishment images will not be discussed in the two sections that follow (Sections VII C and D), dealing with source and duration of images, respectively.