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 Bloomfiel 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/ Contains More Aspirin	5% 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 477M; 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

1967-CX 451 1/		1967-CX 454 2/		1970-CX 452 3/		1970-CX 455/56 4/	
For Fast Relief		Relieves Pain Most Quickly		For Fast Relief		Gives Fast Acting Relief	
Anacin	Bayer	Anacin	Bayer	Anacin	Bayer	Anacin	Bayer
68%	55%	79%	65%	65%	57%	64%	65%
Gives Long Lasting Relief		Relieves Pain for Long Period		Long Lasting		Gives Longer Lasting Relief	
67%	53%	64%	44%	58%	57%	41%	35%
Good for Severe Headaches		Good for Severe Headaches		Good for Severe Headaches		Good for Severe Headaches	
75%	48%	84%	52%	86%	47%	45%	40%
		Very Strong Product		Extra Strength		Is Extra Strength	
		55%	37%	19%	21%	26%	12%
Strong				Strong			
31%	19%			16%	25%		
Gives Complete Relief				Gives Complete Relief			
58%	51%			57%	56%		

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 4547148, 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] 1967		CX-455/56[2] 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 1963 1/	CX-451 1963 2/	CX-452 1970 3/	CX 4[illegible]/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	
	13%	28%	
	A Heavy Dragging Feeling	A Heavy Dragging Feeling	
	27%	20%	

1/ CX 454Z14B; Rosa, Tr. 2217-18; Pamel, Tr. 1616-17.

2/ CX 1058A70, 2473, 2474, 2475; Rose, Tr. 2729-30. Dr. Rose's testimony reflected 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 1052189, 2192; Rose, Tr. 2728-29. (See n. 2, supra).

4/ CX 456Z22J; Rosel, 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: 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 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			Did Not Rate Both Products			
	Rated Anacin Higher Than Aspirin	Rated Anacin Equal to Aspirin	Rated Anacin Lower Than Aspirin	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 4571012, 1013, 1014 (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. 1582; Ross, Tr. 2207). This assumption is supported by the testimony of 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%	13.2%	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 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.

577. It is generally agreed that advertising, experience based on usage and word-of-mouth communications are the three major sources of images (Ross, Tr. 2239; Smith, Tr. 7732; Jacoby, Tr. 5487–88). However, experts recognize that word-of-mouth communications are essentially a derivative factor, dependent upon both advertising and prior product usage (Ross, Tr. 2238; Jacoby, Tr. 5490; Sen, Tr. 7327–28; Smith, Tr. 7732). Thus, advertising and product usage are the two most important sources of consumers' images of products (Ross, Tr. 2239).

578. Advertising also plays an important role in creating and helping to foster awareness of a brand, in creating expectations about how the product will perform and in generating initial trial of the product (Jacoby, Tr. 5292, 5406, 5489).

579. A consumer's initial trial of a product is often explained by the consumer's perception of how the product will perform; these expectations are often generated by advertising (Sen, Tr. 7330–31; Smith, Tr. 7735–36). Consequently, every time a consumer uses a product, that usage experience interacts with the expectations that were created by advertising (Ross, Tr. 2269–70, 2701–02; Jacoby, Tr. 5407; Smith, Tr. 7745). **[153]**

580. Over a period of time, specific claims contained in an advertisement tend to merge with a consumer's beliefs about the product. This proposition remains true even though the consumer may subsequently forget the specific content of those advertising claims (Ross, Tr. 2045, 2689–91; Smith, Tr. 7437). Thus, if a general theme of an advertising campaign is reiterated over time, the product image relating to that theme will endure despite the likelihood that consumers will have forgotten the specific content of previous advertisements directed to that product claim (Smith, Tr. 6108–09; Kuehn, Tr. 6681–82).

581. The importance of usage experience as a source of comparative product image becomes significantly lessened with respect to a product class such as OTC analgesics, where consumers are unable to make an objective evaluation of how the products perform. In this instance, the relative importance of advertising as a primary source of comparative product image is enhanced accordingly (Ross, Tr. 2246–49, 2255–57, 2613–17, 2703–05; Sen, Tr. 7330–31; Smith, Tr. 7745).

582. In the case of OTC analgesic products, a consumer's ability to objectively evaluate the products' pharmacological performance is greatly reduced by the consumer's expectations of performance resulting from exposure to advertising, the placebo effect, the subjective nature of pain in general and minor pain in particular,

and by the fact that each pain experience is different for the consumer at a given time and place. The consumer is, thus, unable to effectively evaluate the comparative pharmacological performance of OTC analgesic products when he or she knows the products being taken (*i.e.,* on an unblinded basis) (F. 210, 211, 218–20, 223 and 225).

583. The essential inability of consumers to evaluate the comparative pharmacological performance of analgesics must be distinguished from the fact that consumers continually form subjective judgments or perceptions concerning product performance. Consumers' subjective perceptions of superior performance, however, are unreliable due to the fact that consumers know the product that they are taking. Consequently, all their expectations about the performance of that product are called into play as they form their subjective perceptions of how the product is working for them. These expectations are continually fueled by advertising (Ross, Tr. 2239–41, 2271, 2276, 2278).

584. Usage experience with OTC analgesic products does not serve, in a true sense, to disconfirm consumers' expectations of how the products will perform. Therefore, **[154]**in the case of OTC analgesic products, usage, more often than not, tends to reinforce the initial product image induced by advertising (Ross, Tr. 2250, 2269–77; Jacoby, Tr. 5449, 5453–55; Blattberg, Tr. 7055–56; Smith, Tr. 7782).

585. The record shows that American Home spent approximately $210 million between 1960 and 1970, advertising Anacin to consumers as a product superior to aspirin in relieving pain and as a tension reliever. During the period 1968 to 1970, Anacin's advertising-to-sales ratio was approximately 37% (CX 611Z157).

586. American Home's presentation of Anacin in advertising as a more effective pain reliever has consistently emphasized speed, extra ingredients, more pain reliever and similar indicia of superior pain relieving performance. For example, respondents' witness, George DeMott, the President of Whitehall Laboratories, testified that American Home has been making an extra strength claim for Anacin since 1967 (DeMott, Tr. 4748; CX 306B; CX 314A).

587. Advertisements disseminated between 1963 and 1973 had consistently portrayed Anacin as effective for tension relief and for helping people cope with the ordinary stresses of everyday life (CX 611).

588. The record also shows that the public has perceived and understood American Home's superiority and tension relief claims in the advertisements for Anacin (F. 66–170, *supra*). The ASI copy tests in evidence confirm that a significant number of consumers

perceived superior efficacy claims and tension relief claims in the advertisements they viewed (F. 67, 86, 101, 110, 117, 133 and 157, *supra*). The advertising penetration studies show that superior efficacy and tension relief claims were being recalled by consumers off the top of their heads (F. 500, *supra*). The consumer image studies consistently show across time, method and sample that a significant number of consumers believe Anacin to be a more effective pain reliever than aspirin (F. 568–70, *supra*).

589. The consumer research comparing Anacin and aspirin has remained generally stable over the years (F. 502, 503, 569 and 570, *supra*). The record indicates that product usage, as a source of product image, is substantially influenced by advertising (F. 578–79 and 584, *supra*).

590. The record also indicates that the role of usage experience, as a source of product image, is significantly diminished in the case of OTC analgesic products (F. 581–82, *supra*). **[155]**

591. In light of these circumstances, it is concluded that advertising has played a substantial, and perhaps the most important, role in the creation and maintenance of consumers' beliefs and images of Anacin as a pain reliever superior to aspirin and as an effective tension reliever.

D. *The Duration Of Advertising Effects*

592. Experts for both parties testified that consumers' recall of specific copy points for advertising themes made in Anacin advertising (*i.e.*, penetration of advertising) will endure for a period of from three to nine months after those claims have been made (Ross, Tr. 2261–62; Smith, Tr. 6086–88; Blattberg, Tr. 7116–20; Sen, Tr. 7181). However, beliefs and images concerning attributes stressed in advertising for Anacin can endure long after the specific information that led to their formation has been forgotten (Ross, Tr. 2261–63; Jacoby, Tr. 5482; Kuehn, Tr. 6681–82; Smith, Tr. 7755; F. 580, *supra*).

593. The durability of consumers' beliefs and images of Anacin as a superior pain reliever and as an effective tension reliever depends upon various factors such as the types of beliefs and images, their importance or salience to consumers, whether they relate to a general favorable opinion of Anacin or to a narrow aspect of its performance and whether the consumers who hold these beliefs are users of Anacin (Ross, Tr. 2258–59, 2264–67; Jacoby, Tr. 5449–55, 5479–80; Smith, Tr. 6094–96, 7768, 7777–81).

594. The record contains evidence that, even if respondents were to cease disseminating advertising claims that Anacin is a more effective pain reliever than aspirin and that it is effective for the

relief of tension, images of Anacin on those attributes would persist in the minds of consumers who did not use the product for approximately one year after those claims ceased (Ross, Tr. 2258–59, 2266; Smith, Tr. 6088, 7774–75). The one year estimate of duration among non-users is based upon professional experience. Dr. Ross's opinion was based, in part, upon his review of literature showing that a substantial number of consumers still have images of some products 20 years after those products have gone off the market (Ross, Tr. 2260, 2265).

595. On the other hand, images of Anacin's superior efficacy and tension relieving efficacy will persist among Anacin users for a period longer than one year because such usage will continually reinforce their images (Ross, Tr. [**156**]2266–67; Jacoby, Tr. 5449–55; Smith, Tr. 6094–96, 7768, 7782, 7821; F. 584, *supra*).

596. Once a consumer has begun to perceive that Anacin is more effective than aspirin and that it relieves tension, and once these beliefs have become a part of the consumer's image of Anacin, these beliefs lose their functional connection with the information that originally generated them (Ross, Tr. 2267).

597. The record, as a whole, shows that until and unless new information is provided to consumers about Anacin that corrects or modifies these beliefs, the beliefs and images will endure for a long period of time because consumers' usage experience with Anacin will not serve to disconfirm the beliefs (Ross, Tr. 2267–71; F. 584, *supra*). On the contrary, each time consumers use Anacin, that usage tends to reinforce the expectations of consumers that advertising induced in the first place (Ross, Tr. 2269–70; Jacoby, Tr. 5453–55).

598. Respondents' expert witnesses, Drs. Blattberg and Sen, contended that a high degree of brand loyalty to Anacin among Anacin users (*i.e.*, a significant number of repeat purchases of the brand) was a prerequisite to a finding that usage reinforces consumers' images of the product, with those images having been substantially influenced by advertising (Blattberg, Tr. 6877, 6887–88; Sen, Tr. 7181–88). To shed light on this question, Drs. Blattberg and Sen prepared an analysis of the purchasing patterns in the analgesics market and the amount of brand switching that occurs (RX 176 through RX 185).

599. Their analysis of how consumers behave in the marketplace was based upon panel data, collected by means of consumer purchase diaries, which were supplied by NPD Research, Inc. ("NPD") (Johnson, Tr. 6136–40; Blattberg, Tr. 6823, 6830). One frequent use of such panel data is to examine brand switching behavior in given product categories (Johnson, Tr. 6151).

600. American Home purchased panels of data for two periods of time from NPD in 1977. One panel covered the period December 1970 to January 1973, with the exception of one missing month, May 1972. For the latter period, there were two panels which were not coterminous in length: one panel covered the period from July 1975 to May 1976, and the other panel covered the period from July 1975 to December 1976 (Johnson, Tr. 6149; Blattberg, Tr. 6831). [157]

601. Tod Johnson, president of NPD, testified that NPD collects data from two nationally representative panels which are demographically and geographically balanced through use of a stratified quota sample, and which consist of a minimum of 6500 reporting households per month (Johnson, Tr. 6140, 6143–45).

602. However, the sample selected by NPD is neither representative of the entire United States population nor a probability sample (Johnson, Tr. 6158–66). NPD contacts potential participants based upon lists compiled from telephone books or automobile registrations. Samples based on telephone books do not include unlisted numbers or people without telephones, while samples based on auto registrations do not include people without cars. Moreover, NPD's invitation to join a panel, which is mailed out to consumers, is rejected by 90% of those contacted. Of the 10% of the families contacted that do accept and respond, less than one-half actually become participants (Johnson, Tr. 6175–77).

603. RX 176 through RX 185 contain the results of Drs. Blattberg and Sen's analysis of two sets of NPD Panel Data on analgesics purchases by families. Neither these exhibits nor, therefore, the NPD data on which they are based include any information on the individuals who actually used the products purchased (Johnson, Tr. 6153–55; Blattberg, Tr. 6930).

604. RX 176 through RX 185 do not take into account several factors which can affect the conclusions which can be drawn about the purchase behavior of families participating in NPD's panels. Such factors, appropriate for analysis, include the size and composition of the participating families, the length of time that they participated, the sequence and mix of the brands purchased and the size of the purchase (Johnson, Tr. 6220; Sen, Tr. 7262, 7263–66; Blattberg, Tr. 6930–31).

605. In this proceeding, Drs. Blattberg and Sen adopted a stringent, narrow definition of brand loyalty: the exclusive, or virtually exclusive, usage of one brand over time (Blattberg, Tr. 6976; Sen, Tr. 7192, 7196). However, Dr. Blattberg also testified that there is much disagreement about the concept of loyalty to one brand versus multiple brand loyalty (Blattberg, Tr. 6978–79).

606. If the criterion for brand loyalty to a product were lowered from Drs. Blattberg and Sen's figure of 90% of consumer purchases being devoted to Anacin to 65%, for [158]instance, then 20% or more of the families who were heavy users of analgesics and who purchased Anacin would be deemed "loyal" to the product (RX 178 and RX 183. See also Sen, Tr. 7303–04, 7309–10; Blattberg, Tr. 6975, 7020, 7028–29).

607. Moreover, there is a category of consumers who may conveniently be called "national brand switchers." While these consumers are not loyal, in the conventional sense, to one brand, their purchase behavior is limited to switching among two or three national brands (Blattberg, Tr. 6959, 6978; Sen, Tr. 7266–70).

608. Dr. Blattberg testified that approximately one-third of those households on the panel who made more than one transaction during the panel period made two or three transactions (RX 180; Blattberg, Tr. 7024–25). Of those households with two or more transactions, and with Anacin representing at least one of those transactions, 67.5% purchased three or fewer brands during the 1970 to 1973 panel period (RX 180B) and 74.44% purchased three or fewer brands during the 1975 to 1976 panel period (RX 185B) (Blattberg, Tr. 7020–22). Of this same group of households, 10.17% were totally loyal to Anacin (*i.e.*, 100% of their purchases were of Anacin) during the 1970 to 1973 period (RX 180B), and 14.64% were totally loyal to Anacin during the 1975 to 1976 period (RX 185B) (Blattberg, Tr. 7028–29).

609. Given the tenuous worth of NPD data as well as the significant degree of brand loyalty either to Anacin or to a small, select group of national brands that would include Anacin, Drs. Blattberg and Sen's analysis of the panel data, presented in RX 176 through RX 185, does not materially weaken the conclusion that usage reinforces consumers' images of Anacin with those images having been substantially influenced by advertising (F. 584, 589 and 591, *supra*).

610. The evidence in the record shows that a pain reliever's attributes of efficacy, speed and strength are of central importance to users of OTC analgesic products. In CX 455, *A Study of Vanquish's Market Opportunities - 1970* , each of over one thousand consumers surveyed was asked to rate the desirability of 37 qualities in pain relievers (CX 455ZC25,Z123). The six qualities picked most often by the total sample of respondents as "extremely desirable" or "very desirable" were, in descending order, "Stops a headache," "Relieves pain," "Completely safe to take," "Provides quick relief," "Doesn't upset the stomach," and "Provides long [159]lasting relief" (CX

456Z058–Z060). A ranking of this kind is a method advocated by one of respondents' witnesses, Dr. Jacoby, to assess the importance or salience of beliefs (Jacoby, Tr. 5240–41, 5243–44). Four of the top six qualities relate to the pain relieving efficacy of analgesic products. Respondents' expert, Dr. Smith, agreed with this conclusion based on his analysis of responses to another question in CX 455 which asked respondents to list the reasons why they used their own brands most often. Those unaided responses confirm that the reasons associated with pain relieving efficacy, speed and strength are paramount in consumers' minds (Smith, Tr. 6026–28; CX 456Z344, Z345). For one OTC analgesic product to be regarded as superior to another along these important, yet general, dimensions strongly suggests that the belief will endure.

611. The record evidence also clearly shows that OTC analgesic users believe that tension relief is an important attribute of these products as a class. Over 50% of the group of regular analgesic users surveyed in CX 455 believed that "Relieves nervous tension" is an "extremely desirable" or "very desirable" attribute of an OTC analgesic product (CX 456Z059; Ross, Tr. 2223). Furthermore, an analysis of the heavy Anacin users surveyed in CX 451 and CX 452 discloses that substantial numbers of Anacin users felt that Anacin is useful for the treatment of nervousness, tension, depression and other mood related problems (Table XX, *infra.* See also RX 136, 137 and 138; Rossi, Tr. 1621).

TABLE XX

Percentage Of Anacin Users Who Feel Anacin Is Particularly Good For A Symptom

	1967*	1970**
Nervousness	58%	46%
Tension	72%	71%
Depression	33%	29%
Sleep Problems	39%	29%
A Heavy Dragging Feeling	30%	21%

* CX 1058Z470, Z473; Ross, Tr. 2229–30.
** CX 1059Z189, Z192; Ross, Tr. 2228–29. [160]

612. The record shows that Anacin's product image as an effective tension reliever is likely to endure for a long period of time

unless that image is corrected or modified by new advertising information (F. 596 and 597, *supra*).

E. *Conclusion*

613. "Corrective" information in advertising has been shown in experimental situations to be an effective means of altering or modifying consumer beliefs in performance attributes and images of products (Smith, Tr. 7770).

614. A general criticism of corrective advertising is that information disseminated in a corrective message will frequently have carryover, or spillover, effects. In other words, the corrective advertisement will invariably have an impact on images and beliefs other than those that are to be corrected and, perhaps, spread to other products of the manufacturer or to the general reputation of the manufacturer (Jacoby, Tr. 5310–13, 5458–62; Smith, Tr. 6102, 7773–74).

615. Respondents' expert witness, Dr. Jacoby, conceded that studies are divided on whether corrective advertising only affects the targeted belief or spreads beyond that belief to other, perhaps valid, beliefs (Jacoby, Tr. 5458–60, 5467).

616. In the setting of this proceeding, it is apparent that most consumers are not familiar with the name, American Home Products Corporation, and, thus, do not associate Anacin with American Home. However, the carryover effects of corrective advertising directed towards Anacin and APF may spread to other products that consumers perceive as associated with them (Smith, Tr. 6104–05).

617. The record as a whole supports the inference that a significant number of consumers believe APF to be a product which causes gastric discomfort less frequently than any other non-prescription internal analgesic (F. 572, *supra*), and that the existence of a substantial question regarding the scientific validity of this claim is a material fact to consumers.

618. Complaint counsel have established by a preponderance of credible evidence that Anacin has an image among a significant number of consumers as a product that is a more effective pain reliever than any other non-prescription internal analgesic and that this image will endure for a **[161]**long period of time (F. 568–70 and 597, *supra*). Complaint counsel, however, have not offered any evidence to show that consumers believe Anacin's superior efficacy is established by medical and scientific substantiation. In the absence of any direct evidence, complaint counsel's proposed corrective advertising provision directed towards Anacin's comparative efficacy claims must necessarily be based on the inference that the record

demonstrates the existence of an establishment image among consumers regarding Anacin's superior efficacy (F. 485, *supra*).

619. It is of course arguable that, since Anacin's comparative efficacy claims also carry implied establishment claims, the existence of Anacin's superior efficacy image among consumers is *ipso facto* a sufficient basis for the inference that there exists an establishment image among consumers and, further, that the establishment image is likely to endure unless altered or modified by corrective advertising. However, such a finding, in the absence of any direct evidence, is an inference based upon an inference (F. 574 and 575, *supra*).

620. The complaint in this proceeding does not allege that advertising claims of Anacin's superior efficacy and APF's superior safety lack a reasonable basis or are false (F. 15, *supra*). Rather, complaint counsel's proposed corrective advertising provision directed to Anacin's and APF's establishment images is based solely on the "substantial question" doctrine, a novel theory of Section 5 liability.

621. To require disclosure of the existence of a substantial question, a material fact, in future advertisements claiming the superior efficacy of Anacin or the superior safety of APF is one thing. To require corrective advertising grounded only upon the substantial question theory is another matter. It is the determination of the administrative law judge that, coupled with the considerations discussed in F. 619, *supra,* to impose such a radical form of relief as a corrective advertising requirement in this case would be fundamentally inequitable and inconsistent with administrative due process.

622. A corrective advertisement, for the purposes of this case, is a statement in an advertisement that will be understood by consumers to say that Anacin is not effective as a tension reliever. Consumers should be able to perceive the source of this new information to be at least as credible as the source of the original claims sought to be corrected (Ross, Tr. 2280–82). **[162]**

DISCUSSION

The Meaning Of Advertisements—General Considerations

It is well established that the Commission, and an administrative law judge, may determine the meaning of an advertisement solely from an examination of what is contained therein, without consumer testimony or survey data as to how an advertisement is perceived by the consumer. The test is whether, after reviewing an advertisement in its entirety, an interpretation is reasonable in light of the claims

made in the advertisement. An advertisement may convey more than one claim, and the same claim may be susceptible of more than one interpretation by the consumer. If an advertisement is capable of conveying more than one impression to the consumer and any one of them is false, the advertisement may be found to be misleading. From its own review of an advertisement, the Commission may find impressions which the advertisement is likely to convey to the public, and determine whether such impressions have a tendency or capacity to deceive the public, even in cases where a number of consumers may testify that they were not actually deceived.[11] In determining the tendency and capacity of an advertisement to mislead, the Commission looks to the impression an advertisement may make on the gullible and unthinking rather than on the trained and sophisticated.[12] Indeed, the central purpose of Section 5 is "to abolish the rule of *caveat emptor* which traditionally defined rights and responsibilities in the world of commerce." *FTC* v. *Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963).

In this connection, the unique impact of television commercials upon the audience deserves further discussion.

The revolutionary insight Marshall McLuhan has provided into contemporary mass communication is that "medium is the [163] message."[13] This epigram invites an understanding of the unique dimensions of today's mass-media communication. Today's printed and electronic mass communication does not aim to communicate classified data and fragments of information in the conventional sense as much as it stresses pattern recognition, in which visual and aural configurations serve as symbols. The "message" is not to be understood through the technical meaning of printed or spoken words or sounds as much as it is through recognition of the aural-visual pattern of the "medium" itself. At the risk of oversimplification, the message is recognized and understood through patterns of aural-visual symbols which are intended to evoke a desired imagery. A casual viewer of today's television commercials is struck by the element of essential truth in McLuhan's epigram. In my view, it is fair to say that, with respect to many television commercials that one encounters today, their evaluation is not complete when one stops at the meaning of their technical "content"—what the spoken words say. One needs to proceed to the "pattern" of symbols—what

[11] *E.g., Ford Motor Company*, 87 F.T.C. 756, 794–795 (1976), and the cases cited therein.

[12] *E.g., Charles of the Ritz Dist. Corp.* v. *FTC*, 143 F.2d 676 (2d Cir. 1944); *FTC* v. *Standard Education Society*, 302 U.S. 112, 116 (1937); *Exposition Press, Inc.* v. *FTC*, 295 F.2d 869, 872 (2d Cir. 1961), *cert. denied*, 370 U.S. 917 (1962); *National Bakers Services* v. *FTC*, 329 F.2d 365, 367 (7th Cir. 1964); *Rodale Press, Inc.*, 71 F.T.C. 1184, 1237 (1971).

[13] See Marshall McLuhan, *Understanding Media* (1964); *The Medium Is The Message* (1967).

the commercial (medium) in its totality symbolizes to the psychic and social consciousness of the audience-viewer. The key to true understanding is not classification and differentiation of the spoken words or sounds, but the imagery evoked by the patterned aural-visual symbols.[14]

This observation appears to have particular application to a television commercial which projects a distinct pattern of compressed, fluid pictorial and aural images, submerging its technical "content" and appealing directly to the viewer's psychic and social consciousness. In a very real sense, the viewer's critical faculties of classification and differentiation are drowned in patterns of imagery and symbols. Thus it is possible that, in skilled and practiced hands, the spoken words of a television commercial may appear to say one thing, while its pictorial and aural imagery conveys to the psyche of the viewer-audience something quite different. This observation is of some importance in evaluating many of the television commercials reviewed in this proceeding. In my view, in evaluating many of the advertisements challenged in this proceeding, the conventional **[164]** wisdom of the psychology of learning is inadequate and needs to be complemented by the McLuhanian perspective. For example, this approach is especially suited to the evaluation of the television commercials involving the "tension relief" claim, which clearly depict situational tensions of various kinds that are distinguished from pain-associated tension.

In evaluating the meaning of individual advertisements, I have primarily relied on my knowledge and experience to determine what impression or impressions an advertisement as a whole is likely to convey to a consumer. When my initial determination is confirmed by the expert testimony of complaint counsel or respondents, I rested. When my initial determination disagreed with that of expert testimony, which was often conflicting, I reexamined the advertisement in question, and further considered such record evidence as the ASI copy tests[15] and verbatim responses[16] before reaching a final determination. In this connection, my determinations agreed in most instances with those of Dr. Ross, complaint counsel's expert, and

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[14] Dr. Smith, respondents' consumer psychology expert, also noted the importance of the "symbolic" or "covert" message that is carried within an advertisement through color, environment and other devices (Smith, Tr. 7493–94).

[15] The ASI copy tests were conducted for and relied upon by American Home. (*E.g.*, CX 611Z155–Z156, CX 306, CX 327, CX 329; DeMott, Tr. 4755). In my view, although the test environment is somewhat artificial and does not purport to simulate the typical home-viewing environment, the ASI tests provide a valuable insight regarding the probable consumer perception of the copy points contained in test ads. See *American Home Products Corp.* v. *Johnson & Johnson*, 436 F. Supp. 785, 794 (S.D.N.Y. 1977), *aff'd* Nos. 77–7503, 7527 (2d Cir. May 1, 1978).

[16] The use of verbatim responses found in copy tests as an aid in determining the meaning of an advertisement is well established. *E.g.*, *Ford Motor Co.*, 87 F.T.C. 756, 779, 794 (1976); *Bristol-Myers Co.*, 85 F.T.C. 688, 706–12, 744–45 (1975).

disagreed with those of Dr. Smith in most instances. This is not surprising for a number of reasons.

First, Dr. Smith's focus was on what an advertisement claimed explicitly in its audio portion. Furthermore, Dr. Smith completely ignored what he calls a "symbolic" or "covert" message that may be carried within an advertisement through the depiction of an environment, the use of color and other non-verbal devices (Smith, Tr. 7493–94). **[165]**

Second, Dr. Smith's focus was further blurred by his seeming preoccupation with an advertiser's promotional campaign theme instead of evaluating each advertisement as a whole and individually (Smith, Tr. 7517–18). This is contrary to the law.[17]

Third, Dr. Smith's analysis was further flawed in that he attempted to gauge the message an advertisement may have carried to consumers in terms of the advertisements of American Home's competitors. (*E.g.*, Smith, Tr. 5649–51, 5703–06, 5775–78). This is contrary to the law.[18]

Fourth, before concluding that an advertisement contained an alleged claim, Dr. Smith appeared to require not only that the claim be perceived by consumers but also that it be retained by them for some definite period of time (Smith, Tr. 7437–39). However, "delayed recall measures consumer interest and advertising persuasiveness as well as message content."[19]

Fifth, Dr. Smith relied heavily on consumer research which did not focus on the question of whether a particular claim was perceived by consumers upon exposure (Smith, Tr. 5785, 7442–48, 7558). Indeed, Dr. Smith conceded that, if the issue was whether a particular advertisement made an alleged claim, he would have relied on his own judgment and on the ASI tests, in that order (Smith, Tr. 7518, 7562). This was what Dr. Ross, complaint counsel's expert, did and differs radically from what Dr. Smith did on his direct examination. (*E.g.*, Smith, Tr. 5785, 7517).

In any event, in determining the meaning of advertisements, in addition to relying on my own judgment as to what an advertisement as a whole can reasonably be interpreted to mean to a consumer, I have carefully considered all relevant record evidence on this issue. Now I shall turn to an examination of the challenged advertising claims. **[166]**

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[17] *E.g., Chrysler Corp.*, 87 F.T.C. 719, 751–52 (1976), *modified on other grounds*, 561 F.2d 357 (1977); *Ford Motor Co., supra*, 87 F.T.C. at 794–95.

[18] *E.g., Chrysler Corp., supra*, 87 F.T.C. at 751–52; Ford *Motor Co., supra*, 87 F.T.C. at 794–95.

[19] *American Home Products Corp.* v. *Johnson & Johnson*, Nos. 77–7503, 7527, Slip Opinion at 2887 n. 15 (2d Cir. May 1, 1978).

The Challenged Advertising Claims For Anacin

With respect to advertising claims for Anacin, all of the challenged claims can be viewed as representing a central claim, the claim of superior efficacy (Comp. ¶ 12(a)), with the exception of two groups. The two exceptions are those related to the so-called "tension relief" claim (Comp. ¶ 15) and the "22 seconds" claim (Comp. ¶ 8(A)(4)). Most of the other claims are related in some way to the central claim of superior efficacy and would be understood by consumers as variations of that central theme.[20] The so-called "establishment" claim (Comp. ¶ 10(A)) is implied as a matter of law from the superior efficacy claim.[21]

As Dr. Smith, respondents' expert, stressed, efficacy is the raison d'etre for OTC analgesic products. Such claims of specific product attributes as speed, strength or quantity of pain reliever will be associated with, and perceived as suggesting, efficacy by consumers (Ross, Tr. 1902–03; Smith, Tr. 5772–74, 5779, 7558–59). Thus, it is reasonable to view claims for such underlying product attributes in terms of superior efficacy.

1. *Representations That Anacin Has More Pain Reliever (Comp. ¶¶ 8(A)(1) and (3))*

It is my determination that a number of American Home's advertisements contained the claim that:

(1) Anacin has more pain relieving ingredients than any other OTC analgesic product (Comp. ¶ 8(A)(1)); and
(2) Anacin has more than twice as much of its pain relieving ingredient as any other OTC analgesic product (Comp. ¶ 8(A)(3)).

The claim that Anacin has more pain reliever is expressly made in many Anacin advertisements. For example, it is expressly claimed that Anacin provides "extra pain reliever" **[167]**(CX 50A through CX 53A) or that "Anacin tablets go further and add an extra slice 'by providing' all this extra pain reliever" (CX 30A). Some Anacin advertisements attempt to limit the comparison to more of a specific pain relieving ingredient. (*E.g.*, CX 13A, CX 14A, CX 23A, CX 164). For example, several advertisements state that:

> 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, CX 14A).

[20] More pain reliever claim (Comp. ¶¶ 8(A)(1), (3)); better or different pain reliever claim (Comp. ¶ 8(A)(2)); doctors' preference claim (Comp. ¶ 20); and as effective as the leading prescription drug claim (Comp. ¶ 17).

[21] See p. 175, *infra*.

However, the impression that consumers will get is simply that Anacin has more pain reliever and, therefore, will provide significantly more pain relief than any other OTC analgesic product. Consumers will not make the subtle and refined distinction between "more pain reliever" and "more of a pain reliever" for the simple reason that the distinction is not meaningful to them. Indeed, why talk about more pain reliever or more of a pain reliever unless it is to mean significantly greater pain relief? (Ross, Tr. 1851–53, 1855, 1857–58, 1862–64, 1902–03; Smith, Tr. 5772–74, 5779, 7502–03, 7558–59).

Furthermore, the "more pain relief" message is often driven home by a simple, dramatic visual presentation. For example, some of the Anacin advertisements visually equate two Anacin tablets with four of the other extra-strength tablets (*e.g.,* CX 9A, CX 21A, CX 22A), or graphically illustrate Anacin's extra amount of pain reliever (*e.g.,* CX 15A, CX 30A, CX 33A, CX 41A, CX 60A).

It is true that the advertisements in question expressly compare Anacin to the "other extra-strength tablets" (*e.g.,* CX 9A, CX 21A, CX 23A, CX 89, CX115), to the "other leading" tablets (*e.g.,* CX 13A, CX 20A, CX 25A, CX 153), or to a group of other products (plain aspirin, buffered aspirin and the other extra strength tablets) (*e.g.,* CX 1, CX 30, CX 50, CX 105). However, they convey to consumers the message that Anacin provides more pain relief than any other product. For, if Anacin contains more pain reliever than the "leading products" and "extra strength" product, as well as plain aspirin and buffered aspirin, then Anacin has more pain reliever than anything else on the market, and "more pain reliever" means "more pain relief." **[168]**

2. *Representation That Anacin's Pain Relieving Ingredient Is Unusual, Special And Stronger Than Aspirin (Comp. ¶ 8(A)(2))*

It is my determination that a number of Anacin advertisements contained the claim that Anacin is different from ordinary aspirin and that it is stronger than aspirin.

For example, CX 173 states that:

> Anacin isn't just like an ordinary aspirin tablet. It has more of the drug doctors themselves most often choose to relieve pain.

Clearly the message is that Anacin is not like aspirin and that the "drug" in Anacin is something different from, and superior to, aspirin. Another advertisement, CX 41, states:

Anacin starts with as much pain reliever as the leading aspirin tablet. Then adds a core of this specific fast acting ingredient against pain.[22]

Similarly, the message is that Anacin starts with aspirin and adds some fast acting pain reliever to it. This impression is further reinforced by the fact that these advertisements do not say anywhere that Anacin's pain relieving ingredient is aspirin (Ans. of American Home, ¶ 22). In fact, American Home deliberately avoided such a disclosure for fear that "aspirin" will be confused with "Bayer Aspirin" by consumers (DeMott, Tr. 4659).

Furthermore, some of the advertisements emphasized Anacin's special or unique "formula." (See, *e.g.*, CX 26A, CX 89, CX 115). A special formula of Anacin means a special pain relieving formula and more pain relief to consumers. Otherwise, why talk about it in advertisements of an analgesic product?

3. *Representation That A Recommended Dose Of Anacin Is More Effective Than A Recommended Dose Of Any Other OTC Analgesic Product (Comp. ¶ 12(A))*

It is my determination that a number of Anacin advertisements contained the message that a recommended dose of Anacin is more effective than a recommended dose of any other OTC **[169]**analgesic product. This is the "more is better" message, the central theme running through many Anacin advertisements.

From my discussion in the preceding subsections 1 and 2, it follows that the advertisements which claim that Anacin has more pain reliever than any other product or that Anacin's pain reliever is special and stronger than aspirin also impliedly claim that a recommended dose of Anacin (2 tablets) is more effective for the relief of pain than a recommended dose of aspirin, buffered aspirin, the other leading headache tablets, the other extra strength tablets and anything else on the market.

Furthermore, some Anacin advertisements explicitly claimed greater efficacy for Anacin. For example, some claimed that Anacin will "work better" (*e.g.*, CX 153; CX 156), provide "extraordinary relief" (CX 172), or provide "extra pain relief power" (CX 115). Finally, the Anacin advertisements which claimed that Anacin is "as effective as" or provides "the same complete relief as" the leading prescription product (*e.g.*, CX 126 through CX 128, CX 132) clearly mean that Anacin is superior to all other non-prescription products.

[22] Also see CX 42A through CX 45A, CX 59, CX 63.

4. *Representation That Within 22 Seconds After Taking Anacin One May Expect Relief From Headache Pain (Comp. ¶ 8(A)(4))*

Although this alleged claim presents a close question, I have determined that this claim was made in a number of Anacin advertisements.

For example, CX 1A (a television commercial) states in part:

> While you won't feel it for minutes, right now relief is racing to your headache. So quickly that in the short time it takes you to kiss a baby, in just 22 seconds after Anacin is in your blood stream, it's already starting to work on your headache . . . .

In the video portion, a woman with a headache is taking Anacin while the clock begins to tick away. She then goes into her child's room and kisses her baby. Her facial expression changes to smiles. At the same time, the title "twenty-two seconds" appears on the screen. Although the audio message starts with a qualifier that "you won't feel it for minutes," it goes on to talk about how "right now relief is racing to your headache," and "in just 22 seconds after Anacin is in **[170]**your blood stream, it's already starting to work on your headache." In these circumstances, it is of course arguable that the message is qualified, and that consumers know better than to believe that any tablet can relieve a headache in just 22 seconds. However, in my view, a viewer of this television commercial will relate "22 seconds" to "headache relief" or at least understand the commercial to mean that in 22 seconds something will happen that will start the relief action. Thus, in terms of the imagery or environment depicted by the audiovisual presentation as a whole, the commercial can be reasonably interpreted to mean that within 22 seconds one may expect some relief from a headache.

Likewise, CX 151, a print advertisement,[23] states in prominent part:

> In 22 seconds after entering the bloodstream, Anacin is speeding relief to your pain—bringing you remarkable "all-over" relief . . . .

Unlike the television commercial reviewed above (CX 1A), this print commercial does not contain any qualifier. In my view, consumers will understand that "22 seconds" is meant to refer to the time period between the taking of Anacin and the beginning of relief. Otherwise, why would a commercial talk about 22 seconds?

5. *Representation That Anacin Relieves Nervousness, Tension*

[23] Also see, *e.g.*, CX 142 through CX 144, CX 153.

And Depression And Will Enable A Person To Cope With The Ordinary Stresses Of Every Day Life (Comp. ¶ 15)

It is my determination that a number of Anacin advertisements made the so-called tension relief claim alleged in Paragraph 15 of the Complaint.

A number of Anacin advertisements not only contained a generous sprinkling of such words as "tension," "nerves," "stress," "fatigue" and "depression"[24] but also depicted a variety of situational tensions.[25] Indeed, in some **[171]**television commercials the dominant image is situational tension and pain relief is clearly a secondary message.[26]

In some of the advertisements, stress and tension are emphasized in terms of the advertising time and space. For example, in CX 5, a television commercial, the major portion of both the audio and visual presentation focuses on tension and stress rather than on pain. Similarly, in CX 155, a print commercial, the prominent headline in bold-faced type says that Anacin "Calms Anxiety and Tension." Although the smaller type below this headline goes on to say, "as it relieves headache pain," consumers are likely to perceive the claim in the headline and understand the message to be relief from tension and anxiety apart from headache pain.

A number of the so-called tension relief advertisements represent in my view a skillful use of the imagery or symbolic technique of communication made possible by the television medium. In these commercials, through effective use of aural-visual techniques (sound effects, music and camera), the verbal content of a commercial (tension associated with pain) is submerged and reduced to a faint background noise while the dominant aural-visual imagery (situational tension) comes through dramatically.[27] (*E.g.*, CX 5, 7A, 26A and 89). The overall impact of these advertisements upon a viewer is clearly that Anacin is not only a pain reliever but is also good for tension, nerves, stress, fatigue and depression and helps one to cope with the ordinary stresses of everyday life, as alleged in the Complaint.

Finally, the record shows that a substantial segment of consumers believe that OTC analgesic products are good for tension relief (F. 571). It is therefore reasonable to conclude that Anacin's tension relief advertisements contributed in a substantial measure to the

[24] *E.g.*, CX 3, 5, 7A, 8A, 15A, 17A, 21A, 25A, 26A, 27A, 39A, 40A, 44A, 46A, 89, 115 and 155.

[25] *E.g.*, CX 3, 5, 7A, 8A, 17A, 26A, 40A, 46A, 170 and 171.

[26] *E.g.*, CX 3, 5, 7A, 8A, 40A and 46A.

[27] See pp. 162–64, *supra*. The record also shows that American Home recognized the effectiveness of this technique. *E.g.*, CX 327, CX 329, CX 402D, CX 404E, CX 420N.

creation of this consumer image. See pp. 220–22, *infra.* In my view, it is also obvious that the tension relief advertisements found a receptive audience who readily recognized and understood the tension relief theme. This is confirmed by the [172]ASI verbatims which indicate that as many as 17 to 25% of the viewers perceived the claim that Anacin is good for tension. See CX 420, CX 404; Smith, Tr. 7633–35.

6. *Representation That Certain Tests Prove That Anacin Is As Effective As The Leading Prescription Analgesic Drug And More Effective Than Any Other OTC Product (Comp. ¶ 17)*

It is determined that the alleged representation was made in a number of Anacin advertisements.

American Home has admitted that it made the representation that the scientific tests referred to in certain advertisements prove that Anacin is as effective as the leading prescription analgesic product (Ans. of American Home, ¶ 17. Also see CX 126 through CX 137, CX 140–41, 173 and 179). From this admission, it follows that American Home also impliedly claimed that Anacin is more effective than any other non-prescription analgesic product since consumers will readily perceive the "leading prescription product" to be more effective than non-prescription products.

7. *Representations Concerning Doctors' Survey (Comp. ¶ 20)*

The complaint charges that American Home made the representations that:

(1) A doctors' survey showed that twice as many specialists in internal medicine prefer Anacin for the treatment of headache pain to any other non-prescription analgesic product;

(2) More doctors recommend Anacin than any other non-prescription analgesic product for the treatment of headache pain; and

(3) Such recommendation constitutes convincing proof that Anacin will relieve headache pain more effectively than any other non-prescription analgesic product.

It is determined that a number of Anacin advertisements contain the alleged claims. CX 81 through CX 84 and CX 176 expressly claim that a survey of specialists in internal [173]medicine showed that "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" and further that this is "convincing proof about Anacin."

In my view, these advertisements also contain implied claims that twice as many doctors prefer Anacin over any other OTC analgesic product[28] and that such recommendation constitutes convincing proof that Anacin relieves pain more effectively than any other OTC analgesic product.[29] With respect to CX 146 through CX 148, the comparison is expressly limited to "the two leading extra-strength pain relief formulas." However, consumers will perceive that since Anacin is chosen 2 to 1 over the other extra-strength product by doctors, Anacin is more effective than any other OTC analgesic product.

The Challenged Advertising Claims For Arthritis Pain Formula

1. *Representation That APF's Analgesic Ingredient Is Unusual, Special And Stronger Than Aspirin (Comp. ¶ 8(B)(1))*

It is my determination that a number of APF advertisements contained the alleged claim.

For example, several advertisements explicitly contrasted APF's pain reliever with aspirin. CX 201A, a television commercial, stated that:

> I'm on something different . . . Arthritis Pain Formula . . . 50% more pain reliever than a regular aspirin. So strong that you don't need it as often.[30]

The message is clearly that APF has some special pain reliever that is different from, and stronger than, aspirin. Indeed, the name of the product itself, "Arthritis Pain Formula," [174]suggests that meaning. Other television commercials, such as CX 210A, CX 217A and CX 218A, clearly characterize APF's pain reliever as something special and strong. Moreover, none of the challenged APF advertisements tells the consumer that APF's analgesic ingredient is ordinary aspirin. In these circumstances, an interpretation of these advertisements as conveying the message that APF's analgesic ingredient is something other than aspirin and stronger than aspirin is eminently reasonable.

2. *Representation That APF Will Eliminate All Pain, Stiffness And Discomfort Experienced By Arthritics (Comp. ¶ 8(B)(2)*

I have determined that the challenged APF advertisements cannot be reasonably interpreted to convey the alleged claim to consumers. Although it is arguable that several television commercials (*e.g.*, CX

[28] See CX 424; Ross, Tr. 1930-32.
[29] See Smith, Tr. 5903, 7598.
[30] Also see CX 206A, CX 210A, CX 217A, CX 218A.

201A, 202A and 203A), especially in their video portions, are capable of conveying the alleged claim to the consumer, I am not persuaded that it is a reasonable interpretation. In my view, these advertisements are clearly targeted to arthritis sufferers, a group that knows that no OTC drug can be expected to give complete relief from arthritic pain. Any other conclusion would be contrary to common sense. Furthermore, such expressions as "get going without all that pain or stiffness" cannot reasonably be interpreted to mean complete and total relief. When I viewed the challenged television commercials, the thought of a promise of complete relief from all arthritic pain never occurred to me. Even when I went back to them to look for the alleged claim, I was unable to see them. The message of these commercials is that APF is something special for arthritis sufferers, that it is stronger than aspirin, and that it will relieve some of the pain and stiffness of arthritis and help you get going.

3. *Representation That APF Will Cause Gastric Discomfort Less Often Than Any Other OTC Product (Comp. ¶ 12(B))*

It is my determination that a number of APF advertisements conveyed the alleged claim.

The express claim that APF is gentle to the stomach because of its "double-buffering" or because it is "microfined" clearly convey the message that APF has a larger amount of buffering action than other buffered products and is finer than others and that, therefore, it is the **[175]**gentlest of all OTC analgesic or antirheumatic products on the market. See, *e.g.*, CX 203A, CX 204A, CX 205A, CX 206A, CX 210A.

The Challenged Advertising Claims That Certain Claims Have A Reasonable Basis Or Are Established

1. *Representation That Tension Relief Claim Has A Reasonable Basis (Comp. ¶ 16)*

Under *Pfizer*,[31] the affirmative product claim that Anacin relieves tension implies as a matter of law that American Home has a reasonable basis for that claim and that American Home relied on it for the marketing of Anacin.

2. *Representation That Certain Comparative Efficacy Or Safety Claims Have Been Established (Comp. ¶¶ 7, 10(A) and (B), 11 and 17)*

[31] *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

Based upon the reasons discussed in pp. 210–16, *infra*, I have determined that the comparative efficacy claims for Anacin and APF and the comparative safety claim for APF carry within them, as a matter of law and marketplace fairness, an implied representation that the claimed superior efficacy or safety is scientifically established and that the proposition is accepted as proven or as a medical-scientific fact by the vast majority of scientists who are by training and experience competent to evaluate the validity of such propositions.

Furthermore, a number of Anacin advertisements expressly represented that the claim is "medically proved," or that there is "convincing proof" that the claim is a scientifically established fact. *E.g.*, CX 50A through CX 53A, CX 105 through CX 107, CX 149. Some of the advertisements also conveyed this message through the presentation of technical graphs measuring blood levels (CX 50A through CX 56A), by reference to actual scientific or clinical tests (*e.g.*, CX 81, CX 105 through CX 107, CX 126 through CX 137, CX 140 through CX 141), or by the use of chemical formulas (*e.g.*, CX 15A). **[176]**

Pain And Aspirin Products—Some Preliminary Observations

Pain is said to be the most common symptom for which man seeks relief by medication. It is generally agreed that mild to moderate pain that is self-limited ("minor pain") may be treated symptomatically by self-medication.[32] Pain is a subjective condition of diverse and often obscure etiology and defies a precise definition. Beecher, a recognized authority in the study of pain and analgesia, has observed that:

> Pain is a subjective matter clearly "known to us by experience and described by illustration." [However,] lexicographers, philosophers and scientists have none of them succeeded in defining pain. Having said that it is the opposite of pleasure, or that it is different from other sensations (touch, pressure, heat, cold) or how it is mediated (through separate nerve structures), or what the kinds of it are (bright, dull, aching, pricking, cutting, burning), or what kinds of things will produce it (trauma to nerve endings or to nerves, electric shocks, intense stimulation of the sensations of touch, pressure, heat, cold), or what it comes from (injury, bodily derangements, or disease), or that certain types of mild stimulation can probably be stepped up to a painful level through conditioning or what some reaction patterns to it are (escape or avoidance), none of these individual statements, nor indeed their sum total, provides a definition of pain.[33]

"Minor pain" was defined by the FDA OTC Internal Analgesics

[32] CX 367F.
[33] CX 367F–G.

Panel as "pain that is self-limited and which requires no special treatment or prior diagnosis by a physician." Minor pain is usually described as pain "of mild to moderate intensity as opposed to sharp, severe and/or protracted pain."[34] [177]

It is not surprising that aspirin is by far the most widely used OTC drug in the United States. It is estimated that almost 19 billion dosage units are sold annually. This amounts to about 5 million daily dosage units for every man, woman and child. Since aspirin was introduced into the American market some 75 years ago, it has been discussed extensively in the medical-scientific literature.

Although such important aspects of aspirin's pharmacological profile as the specific mechanism of its action and the localization of the site of its chemical action in humans are yet to be definitively determined, a considerable amount of biopharmacological data has been published with respect to the relationship between the dosage of aspirin and its analgesic action and the mechanism of its metabolism in animals and humans. It is now generally agreed, primarily on the basis of historical data, that aspirin is safe and effective as a mild analgesic, antipyretic and antirheumatic agent for humans.

It is generally believed that aspirin alleviates pain by both a peripheral effect (*i.e.*, the blockade of pain impulse generation) and a central nervous system effect.[35]

Aspirin is also an effective antipyretic or fever reducer, and may be safely used for self-medication when fever is due to the common cold or flu. Aspirin lowers the temperature in patients with fever but has no effect on the body temperature when it is normal. Heat loss is increased by increased peripheral blood flow and sweating, which is caused by a central action of aspirin on the hypothalamus.[36]

Inflammation and many rheumatic diseases often are accompanied by pain and sometimes fever. Since, in many rheumatic conditions, the object of therapy is to stop the disease process which usually requires drug dosages higher than those recommended for OTC use, OTC drugs for the treatment of inflammatory conditions and rheumatic disease should be used only under the advice and supervision of a physician. Aspirin acts as an agent which reduces joint or muscle tenderness or swelling. The precise mechanism or mechanisms of [178]action by which aspirin exerts anti-inflammatory effects is not known.[37]

In recent years, the medical-scientific knowledge and understand-

[34] CX 367G.
[35] CX 367G, Z011.
[36] Lasagna, Tr. 4096–97; CX 367G-H.
[37] CX 367H.

ing of aspirin's other (side) effects have been substantially expanded, promising both new benefits (such as the use of aspirin in anticoagulant therapy) and risks (such as the problem of aspirin intolerance). Based upon an exhaustive review of available data in medical-scientific literature, the FDA OTC Internal Analgesics Panel concluded that the most appropriate label indications for pain for OTC analgesic agents including aspirin should state: "For the temporary relief of occasional minor aches, pains and headache." It is generally agreed that aspirin is effective in mild to moderate pain although of limited value in severe pain. Recurrent or chronic pain even of minor intensity, such as frequent headaches or joint pain which flares up periodically, may indicate pathologic condition and should not be treated with OTC analgesics except under the advice and supervision of a physician.[38]

Since one of the most prevalent uses of aspirin and aspirin-containing products is in the treatment of headache pain, it is important to have a general understanding of this all too common affliction.

Headache, or cephalalgia, is a unique symptom and an ambiguous term for pain having many different etiologies. The most common type of headache is occasional headache, which is transient (usually lasting less than one day) and may be secondary to many factors including fatigue, tension, eyestrain, fever or alcohol ingestion. The chronic or recurrent headache may be caused by more serious underlying diseases such as vascular disturbances, brain tumor or abscess, intracranial lesions or lesions of the eye, nose, ear or throat.[39]

Headaches can be differentiated into three major categories: vascular, psychogenic and traction-inflammatory headaches. Vascular headache is provoked by the tendency for vasodilation that accompanies physiological changes **[179]**in cranial blood vessels. Common types of vascular headaches are hypertensive, migraine and toxic. OTC analgesics are inappropriate for hypertensive or migraine headaches. Psychogenic headache, one of the most common types of headache, accounts for up to 90% of chronic headaches. It is accompanied by persistent contraction of the muscles of the head, neck, and face, and may even be described as a sense of pressure rather than a true pain. Apprehension, anxiety, post-traumatic experiences and depression, as well as the individual's life stresses and habits, can precipitate the symptoms. Psychogenic headaches

[38] Generally see CX 367F, G, Z011–Z013; Stevenson, JTr. 1481–88; Grossman, Tr. 841–43; Farr, JTr. 2566–70; Azarnoff, Tr. 618–20.

[39] CX 367H.

are often described by synonymous terms such as muscle contraction and tension headache. Self-medication utilizing OTC analgesic drugs is generally contraindicated for chronic psychogenic headache. Traction and inflammatory headache, evoked by organic disease, is associated with inflammatory disease of the meninges, and intracranial or extracranial arteries or phlebitis. Although the FDA OTC Internal Analgesics Panel concluded that the occasional headache is self-limited and requires no medication, it recognized OTC analgesics' usefulness for symptomatic treatment.[40]

One of the issues in this case, related to the claimed superior efficacy of Anacin and APF, is whether the aspirin dose-response relationship studies, using moderate to severe pain in terminal cancer patients and patients with post-partum pain or post-operative pain, are applicable to headache pain. There is a conflict in the testimony of experts on this issue. In my view, the record as a whole does not show that all pain is alike. The record does show that the precise shape of a dose-response curve for aspirin is not known, and that the applicability of aspirin dose-response studies using pain other than headache pain (such as post-operative, post-partum and cancer pain), and encompassing the pain intensity spectrum of mild to moderate to severe pain (or only severe pain), to headache pain remains to be demonstrated.

The Therapeutic Superiority Of Anacin Over Aspirin Has Not Been Scientifically Established

I have determined that complaint counsel have established, by a preponderance of probative and reliable evidence, the negative proposition that the therapeutic superiority in terms of efficacy or safety of Anacin or APF over aspirin has not [180]been established. The record as a whole clearly shows that in order for therapeutic superiority to be established there must be two or more well-controlled clinical demonstrations which show statistically and clinically significant superior performance and which will cause the proposition to be accepted as a medical-scientific fact, or as "established," by the vast majority of experts who are by their training and experience qualified to evaluate the validity of such propositions. In my view, the record contains substantial medical-scientific evidence tending to show that two tablets of Anacin may reasonably be expected to provide technically greater analgesia than two tablets of aspirin for some individuals. However, that evidence is insufficient

[40] Rickels, Tr. 1198–99; CX 367H-I.

to overcome complaint counsel's *prima facie* showing that the therapeutic superiority of Anacin over aspirin has not been established as a scientific proposition. More importantly, the record also provides a basis for concluding that the extra amount of analgesia posited for Anacin by some dose-response studies does not have clinical significance as a practical matter.[41]

First, respondents have failed to produce or point to two or more well-controlled clinical studies which demonstrate statistically significant difference in analgesia between the two test drugs. Such eminent experts in the field of comparative analgesics as Drs. Moertel, DeKornfeld, Forrest, and Azarnoff testified that nothing short of that can establish respondents' thesis as a medical-scientific proposition (F. 197 and 200). Respondents' experts, Drs. Lasagna, Kantor, Wallenstein, McMahon and Okun expressed an opinion that Anacin will provide greater analgesia than regular aspirin, but they agreed that the only way to *prove* a statistically significant difference in the analgesic effects of Anacin versus aspirin would be to conduct a well-controlled head-to-head clinical trial. (Lasagna, Tr. 4249, 4271–73; Kantor, Tr. 3647; Wallenstein, Tr. 3513; McMahon, Tr. 3981; Okun, Tr. 4475–76, 4493–94, 4522–23).

The requirements with respect to the parameters of a well-controlled clinical demonstration (F. 201–17) are not the whim of a handful of partisan pharmacologists. On the [181]contrary, they represent a crystallization of slow and deliberate evolution in the development of a scientific methodology in clinical pharmacology that began in the early 1950's (F. 199). By the early 1960's, clinical pharmacologists, including respondents' medical-scientific experts, lived by them. Any learned journal of any consequence would not accept for publication a clinical trial of therapeutic agents which purports to measure their efficacy unless the study satisfies all of the essential elements of those requirements (F. 197, 200–17). Indeed, since the advent of the 1962 Amendment to the Food, Drug and Cosmetic Act, the FDA has incorporated these requirements into its regulations governing new drug applications for both prescription and non-prescription drugs. In my view, *the importance of these requirements increases when the question becomes one of comparative efficacy rather than simple efficacy or lack of it.*

Respondents' experts do not dispute the essential validity of the scientific rationale for these requirements, including the principle of replication. (*E.g.*, Lasagna, Tr. 4119–30, 4142–45, 4897–98). Rather,

[41] Although the focus of our analysis will be on the question whether superior efficacy of Anacin over aspirin is scientifically established, what really matters to consumers is whether the difference, if any, is clinically and therapeutically significant. Otherwise, why pay a higher price for Anacin?

the recent disaffection of some clinical pharmacologists appears to be based on socio-medical policy grounds. For example, Dr. Lasagna, a long-time advocate of the application of the scientific method to pharmacological research (Okun, Tr. 4412), has become convinced in recent years that the FDA's "bureaucratic dogma" requiring pre-marketing tests of all new drugs in animals and humans, including two well-controlled clinical demonstrations in humans, is excessively rigorous, resulting in a diminishing number of significant new drug introductions in this country and exacting excessive social costs.[42] (*E.g.*, Lasagna, Tr. 4185-86). **[182]**

American Home argues that in order to establish the existence of a substantial question, complaint counsel must come forward with a substantial amount of clinical data which tends to refute the alleged claim (RB at 6). Although the existence of a substantial amount of contrary scientific data will clearly preclude a claim from being scientifically established, such a requirement would, in my view, go beyond what is necessary to show that a given medical-scientific proposition is not established and may go a long way towards refuting the existence of a reasonable basis for the proposition. This is clearly contrary to the very rationale of the establishment-substantial question theory as a basis of Section 5 liability and should be rejected.[43] **[183]**

The evidence that American Home relies on in support of superior efficacy claim consists primarily of the allegedly "positive" or "ascending" dose-response curve for aspirin. Upon a closer analysis, however, this argument consists of two related, yet distinct, proposi-

[42] It may well be that the FDA's new drug approval procedures could stand improvement in some respects in light of the regulatory experience since the 1960's. Also, a strong argument can be made against restricting the freedom of a practicing physician to prescribe the treatment best suited in his judgment for his patient's condition at a particular stage in the disease process. In the final analysis, however, none of these arguments addresses or refutes the scientific rational of the well-established research methodology in clinical pharmacology. The most that can be said in these circumstances may be that there are a number of respected clinical pharamacologists who will be satisfied by a single, well-controlled clinical demonstration, conducted by an experienced investigator of established repute, and showing statistically significant differences of a substantial magnitude. Be that as it may, it is entirely another matter to argue that the rigors of established research methodology in clinical pharmacology should be discarded in advertising regulation, especially when the question is, as here, the scientific validity of a claim of therapeutic superiority of a particular OTC formulation (800 mg. aspirin and 65 mg. caffeine) over another product (650 mg. aspirin) for a specific condition (relief of minor pain or headache pain). In any event, respondents in this case have failed to produce a single definitive study, of the kind that will satisfy the "revisionists," in support of its claim.

[43] See pp. 210–16, *infra*. However, the record also contains some "contrary" medical-scientific evidence. For example, one of Dr. Kantor's aspirin dose-response studies showed a reverse curve between 600 mg. and 1200 mg. aspirin (F. 254). Dr. Kantor carefully reviewed the test procedures and data and could not explain away the reverse response (Kantor, Tr. 3622–23). Dr. Kantor also admitted that he did not know at what point between 600 mg. and 1200 mg. aspirin reached a plateau (Kantor, Tr. 3596). One of Dr. Parkhouse's aspirin dose-response studies also showed a reverse curve (Lasagna, Tr. 4922). Furthermore, the record contains a substantial amount of "negative" data in that many aspirin dose-response studies failed to show any statistically significant differences between the graded dosages tested (F. 243–55). Dr. Lasagna, respondents' expert witness, agreed that if enough studies fail to show any statistically significant differences between two drugs, then one may conclude that the two drugs were equally effective and that a claim of superiority could not be made (Lasagna, Tr. 4249). In my view, this is such a case.

tions. First, it is argued that a statistically significant, positive dose-response curve for aspirin has been shown to exist. Second, from the first proposition, so it is argued, it may be inferred that 800 mg. aspirin provides greater analgesia than 650 mg. aspirin. In my view, each of the two propositions is open to serious doubt. First, *the precise shape of a dose-response curve for aspirin is far from being established.* Second, and more importantly, even accepting at face value the studies which purport to show a statistically significant positive dose-response curve for aspirin, *the particular proposition that 800 mg. aspirin provides more and statistically significant analgesia than 650 mg. aspirin is nothing but an inference,*[44] albeit one based on sound pharmacological reasoning, *and remains to be verified by direct clinical tests.*[45] **[i84]**

The concept of dose-response relationship is a pharmacological formulation of the common sense notion that there is a relationship between the amount of a drug and the intensity of the drug's effect. The dose-response studies are attempts to quantitate this relationship scientifically and are usually expressed graphically (by way of the dose-response curve). The dose-response curve is generally accepted as a useful statistical tool in estimating the efficacy of a drug in terms of its anticipated potency and also serves as a basis when gauging the risk-benefit ratio of the drug in terms of its toxicity and side effects (dose-finding function). As such, it is an expression of the drug's intensity of action for specific dosages and must be interpreted in terms of such variables as the weight of test subjects, the ratio of the rate of absorption and distribution to the rate of detoxification or excretion, the physical properties of the drug and other specific characteristics of the test subjects. These variables are capable of fairly precise measurements. On the other hand, because of the peculiarities of individuals, judgment factors are

[44] *E.g.*, Kantor, Tr. 3656; Lasagna, Tr. 4271–73.

[45] American Home asserts that "the inferential process is a fundamental principle of all fields of science." (RRB, at 17 n. 14). It is true that the inferential process of induction and deduction is at the heart of the scientific method. By observation of particular events and from established general principles, new hypothetical propositions are formulated; the hypothesis is empirically tested; as the test results satisfy the conditions of the hypothesis, laws are arrived at by induction; from these laws, future results may be determined by deduction. However, the validity of a deductive inference depends on the truth or universality of the original principle, while the validity of an inductive inference depends on the uniformity of the subject matter and attains at most a high degree of probability. To apply this process to aspirin dose-response studies, a comparison of the results obtained at a sufficient number of graded dosage points may provide a basis for an inductive inference that there is a high probability that more aspirin will provide greater analgesia than less aspirin. The validity of this inference, however, depends on the representativeness of the test population. Even in cases where the test subjects were randomized, they were not representative samples of any group. Even assuming the validity of the inductive inference in this example, the validity of the deductive inference that 800 mg. aspirin will provide greater analgesia than 650 mg. aspirin depends on the accuracy of two underlying assumptions: (1) that the line connecting the mean data points actually tested corresponds to the true aspirin dose-response curve; and (2) that all pain is the same. As discussed hereinbelow, the accuracy of these two assumptions is open to serious doubt. *Cf.*, Lasagna, Tr. 4271–73.

inevitably involved. The subjective pain response model studies are attempts to apply this concept to natural or spontaneous pain states.[46]

There appears to be substantial agreement among clinical pharmacologists that, for the relief of mild to moderate pain for which aspirin is indicated, aspirin's minimum effective dosage is in the neighborhood of 325 mg., the usual single dosage about 650 mg., the usual effective dosage range about 325 to 650 mg., the maximum single dosage about 1000 mg., and the maximum daily dosage about 4000 mg. (*e.g.*, CX 367M-N). Until the late 1960's, it was generally agreed that 10 grain (about 650 mg.) aspirin was the maximum effective dosage for headache pain (Friedman and Merrit, p. 40; Wolf, *Headaches: Their Nature and Treatment* (1955), p. 68; Murray, "Evaluation **[185]**of Acetaminophen-Salcyilamide Combinations In Treatment of Headache," *The Journal of Clinical Pharmacology*, 7:150–155, 1967 (discussed in CX 367Z012).[47]

In the early and middle 1970's, a number of studies of graded aspirin dosages using patients with cancer, post-partum or post-operative pain suggested a dose related increase in pain relief between 600 and 1200 mg. aspirin. However, *none of the studies showed statistically significant differences between 650 mg. and 800 mg. aspirin. Furthermore, no headache pain study showed a statistically significant difference beyond 600 mg. aspirin.* For example, in the second Bloomfield study of post-partum patients, the response curve became flat at about the 600 mg. level (F. 246). The 1965 Kantor study showed that the specific dose-response curves were different for uterine cramp pain and episiotomy pain, and for uterine cramp pain a plateau was observed somewhere between 600 and 1200 mg. aspirin (F. 248–55). In Parkhouse's five studies of post-operative patients at three hospitals in England with 600 mg. and 1200 mg. aspirin, two studies showed about the same level of analgesia for the two doses, and three showed somewhat greater analgesia for 1200 mg. aspirin. Although three studies showed generally positive dose-response relationships, no statistically significant difference was observed between the two doses (F. 247). Although Kantor's 1977 study of post-partum patients showed a

[46] See,*e.g.*, Lasagna, Tr. 4047, 4102, 4144–45, 4156–57, 4271–73, 4953–55; Kantor, Tr. 3571–72, 3582–83; Okun, Tr. 4487–4502; Forrest, Tr. 556–57; Azarnoff, Tr. 606–07, 618–20, 629–30, 640–42, 652–54.

[47] Murray concluded that about 53% of headache patients do not need medication, and that of 47% who do need medication, about one-half will experience relief from a standard dosage (650 mg.) of aspirin. Dr. Lasagna, however, is of the view that, although some headache patients may experience complete relief from 10 gr. aspirin, many would experience greater relief with larger dosages (Lasagna, Tr. 4153–56, 4158–59).

In this connection, American Home's argument that the FDA OTC Internal Analgesics Panel recognized the superior efficacy of dosages greater than 650 mg. when it set the maximum single dosage at 1000 mg. is without merit. The 1000 mg. dosage clearly refers to safety rather than to efficacy when viewed in context.

positive dose-response relationship with 300, 600 and 1200 mg. aspirin, one of his earlier studies showed a reverse curve between 600 and 1200 mg. aspirin (F. 252 and 254). **[186]**

American Home places great reliance upon the McMahon study it commissioned for use in this litigation (RX 31). The purpose of the McMahon study was to clinically demonstrate, in a study of uterine cramp pain and episiotomy pain, the superior analgesic efficacy of two tablets of Anacin over two tablets of plain aspirin. The first McMahon study showed that Anacin does not provide statistically significant superior analgesia for a mixed uterine cramp-episiotomy pain population with moderate to severe pain. The second McMahon study showed Anacin provides a statistically significant superior analgesia *for the subgroup of episiotomy patients with severe pain* and *only for hours two and three in two of the four scales used,* and not including the global scale (Lasagna, Tr. 4879–80). However, the second McMahon study is of very limited value because of its numerous and serious defects (See F. 293–311).

At the hearing, respondents' two most eminent experts, Drs. Kantor and Lasagna, suggested that the recent insights provided by pharmacokinetics that saturation of aspirin's metabolic pathway of excretion in humans occurs at well beyond the 1200 mg. aspirin level, in combination with the aspirin dose-response studies and the presence of caffeine in Anacin, provide sufficient scientific support for the proposition that two tablets of Anacin give significantly greater analgesia than two tablets of plain aspirin for all types of pain, including headache pain (Kantor, Tr. 3582–83; Lasagna, Tr. 4207–08). Several questions may be raised with respect to the Kantor-Lasagna thesis. *First,* the relevance of the pharmacokinetic insight to the relief of headache (mild to moderate) pain is not apparent. It may be that an effective analgesia of *headache pain* is attained well before the saturation point is reached. *Second,* the applicability of the dose-response study findings, as inconclusive as they are, to headache pain or to any mild-to-moderate pain is open to serious doubt. It may well be that an effective analgesia of headache (mild to moderate) pain is reached before or near the point where a plateau is reached and the curve becomes flat.[48] *Third,* the efficacy of caffeine in a combination like Anacin has not been proven (Lasagna, Tr. 4227, 4265). **[187]**

The 1969 Hill and Turner studies[49] are illuminating. In a double-

[48] Dr. Lasagna conceded that the effects of 650 mg. and 800 mg. aspirin for mild to moderate pain, including headache pain, may be virtually the same (Lasagna, Tr. 4866).

[49] Hill, R.C. and P. Turner, "Post-Operative Pain in the Assessment of Analgesics in Man," *Brit. J. of Pharmacology* 35:363–364, 1969; "Importance of Initial Pain in Post-Operative Assessment of Analgesic Drugs," *The Journal of Clinical Pharmacology,* 9:324–327, 1969, discussed in Panel report, CX 367Z013.

blinded study of post-operative pain comparing aspirin with meperidine (a narcotic agent), aspirin was preferred at milder pain levels while meperidine was preferred at the severe pain levels. In another double-blinded study with post-operative (gynecological) pain, they could not differentiate between the two drugs and placebo in the patient population as a whole, but could differentiate between them when the patients were classified according to the initial severity of their pain. In the FDA OTC Internal Analgesics Panel's words, the "latter study could have been insensitive if the pain intensity had not been considered and illustrates one of the inherent difficulties in analgesiometry." In my view, these studies strongly suggest that 650 mg. aspirin probably is as effective as 800 mg. aspirin for mild to moderate pain, but 800 mg. aspirin may be preferred for severe pain.

A more fundamental question may be raised about the scientific validity of applying to headache pain inferences drawn from extrapolations based on the subjective pain response model methodology using cancer, post-partum and post-operative patient populations.

First, American Home vigorously argues that pain is pain and that the aspirin dose-response studies using post-operative, post-partum and cancer pain resolve the question of comparative efficacy in its favor. However, *there is no scientific evidence that headache pain is the same as post-partum pain, or pain in terminal cancer patients.* Indeed, not only is there evidence to the contrary, but common experience also suggests a contrary conclusion.[50] Dr. Lasagna, respondents' expert, agreed that one should show the comparative efficacy of one analgesic drug over another in several different types of pain before generally assuming that the drug would be superior to another in other untested types of pain (Lasagna, Tr. 4968). Drs. Kantor, Lasagna and Okun, [188]all respondents' experts, agreed that uterine cramp pain responses differ from episiotomy pain.[51] Drs. Kantor and Lasagna agreed that pain accompanied by inflammation responds differently from pain unaccompanied by inflammation.[52] Dr. Lasagna also testified that migraine headache pain does not respond to aspirin because of its different etiology.[53] Dr. Kantor also criticized the dose-response studies using cancer pain (such as the studies by Moertel, Houde, Sunshine and Wallenstein).[54]

[50] Anyone who has undergone surgery or experienced toothaches will agree that post-operative pain or dental pain is not like headache pain. Common experience also shows that the threshold of pain might differ substantially among individuals, as might their interpretation of pain. Moreover, pain response has a strong emotional component.

[51] Kantor, Tr. 3559–60; Okun, Tr. 4537–39, 4547–48; Lasagna, Tr. 4883–84.

[52] Lasagna, Tr. 4069–70. Dr. Kantor's study with trauma pain produced a reverse response curve between 600 mg. and 1200 mg. aspirin (Kantor, Tr. 3616).

[53] Lasagna, Tr. 4069–70. See also CX 367H-I.

[54] Kantor, Tr. 3645–46.

Dr. Okun agreed that the relative efficacy of two drugs may differ depending upon the type of pain involved.[55]

Second, complaint counsel's experts testified almost without exception[56] that the appropriate pain model for the purpose of determining the comparative efficacy of two dosages of a drug or two drugs is one using patients suffering from the particular type of pain in question. Dr. DeKornfeld insisted that at least one of the two well-controlled clinical demonstrations must use the particular pain in question before the findings can be applied to that pain.[57]

Third, complaint counsel's expert witnesses, with impressive experience and reputation in the field of comparative study of analgesics, testified that owing to the [189]subjective nature of pain the aspirin dose-response studies require that the test data be conservatively interpreted. For example, Dr. DeKornfeld observed that, because the analgesic testing is generally more fuzzy and imprecise in the sense of reliable results, more rigorous methodological requirements are indicated for comparative efficacy studies of analgesic agents than for some other pharmacological agents.[58] Dr. Forrest testified that in dose-response studies, a 10% difference may mean something when a subjective element (such as pain) is not involved, but that in subjective pain response model studies, a 10% difference may not mean anything.[59]

Fourth, both complaint counsel's and respondents' experts generally agreed that, with specific reference to mild to moderate pain, or headache pain, the 150 mg. difference in the amount of aspirin between two tablets of Anacin and two tablets of regular aspirin may not be sufficient to produce a therapeutically significant difference in analgesia.[60]

It is true that American Home's experts expressed an opinion upon direct examination that pain is pain and suggested that the findings of the aspirin dose-response studies using post-partum, post-operative and cancer pain are equally applicable to all types of pain, including headache pain. However, the experts were addressing the applicability of these findings to totally undifferentiated pain without regard to its intensity. Dr. Lasagna conceded that, for the relief of minor pain (including headache pain), the relief obtained

[55] Okun, Tr. 4422.

[56] Dr. Moertel, who conducted a comparative analgesic study using cancer pain, is of the view that the perception of pain may be different between headache and cancer, because the underlying causes are different, even though the responses are comparable (Moertel, Tr. 937–40). However, Dr. Moertel indicated that superior efficacy of Anacin over aspirin can be established only by two or more well-controlled clinical demonstrations, one of which should use headache pain (Moertel, Tr. 959–60).

[57] DeKornfeld, Tr. 2778–80, 2785–86, 2802–03, 2832. See also Lasagna, Tr. 4968.

[58] DeKornfeld, Tr. 2831.

[59] Forrest, Tr. 567–69. See also Azarnoff, Tr. 653.

[60] *E.g.*, DeKornfeld, Tr. 2790–91; Lasagna, Tr. 4168, 4070, 4866.

from the two doses (650 mg. and 800 mg.) may be virtually the same (*e.g.*, Lasagna, Tr. 4866).[61]

The NAS/NRC Analgesic Review Committee recommendation on which American Home relies is not of much aid to respondents. That Committee simply felt that if an OTC drug is shown to work for one type of pain, it should be presumed to work for other types of pain as well and therefore should **[190]**be certified as a general-purpose analgesic product in the absence of contrary evidence. This was undoubtedly a sound, common sense expedience in the massive drug screening project, for which the Committee labored long and hard, *where the sole concern was efficacy, or lack of it, and not comparative efficacy.* Certainly that expedience cannot be transformed into a universal scientific proposition that study findings based on cancer pain, post-partum pain and post-operative pain apply to headache pain or other minor pain.[62] **[191]**

American Home's second proposition, that from a positive aspirin dose-response curve based on studies using various graded dosages (600, 900 and 1200 mg.) of aspirin it can be inferred that 800 mg. aspirin provides significantly superior analgesia than 650 mg. aspirin, is patently an inference and no more than an inference.[63] Although it may be based on rational and sound pharmacological reasoning and thus provide a reasonable basis for the claim, it certainly is not established as a scientific proposition. *This conclusion follows from the very function of dose-response curves and the way in which they are plotted.*

As discussed hereinabove, the function of any dose-response curve is to provide a convenient statistical basis for *guessing* the relative efficacy of dosages not actually studied. *Respondents' experts agree*

[61] See also Lasagna, Tr. 4249.

[62] Furthermore, to a layman at any rate, the subjective pain response model methodology suggests important inherent limitations. In view of the known difficulties attending the experimental pain study methodology (for example, using electric schocks on volunteer subjects), popularity of the subjective pain response model using such captive patient populations as terminal cancer, post-partum and post-operative patients is understandable from the standpoint of frequency and accessibility. However, it is useful to keep in mind that the patients studied are not representative samples of any group. Nor are the studies epidemiological studies. Moreover, pain relief does not lend itself to an objective and precise measurement by the use of uniform, standard units (as do blood pressure, pulse rate, blood count, etc.). Patients' subjective responses to any given pain impulse are bound to vary from one individual to the next. In addition, the eliciting and recording of patients' subjective responses require the intervention of nurses as observer-recorders, a human element of unknown reliability. The endemic problem of the high rate of placebo responders observed in those studies must be added to all this. They are generally in the 30% to 40% range, and can be as high as 57% (Lasagna, Tr. 4132). Despite the substantial scientific trappings in which it is clothed, it is fair to conclude that the subjective pain response model study is not an exact science. Granting its obvious utility for the purpose of setting a range for indicated dosage levels of an analgesic agent, it certainly falls far short of an objective, exact, scientific tool for the purpose of determining the *comparative* efficacy of drugs not tested. Indeed, several of respondents' experts suggested that a headache pain model study may not be sensitive enough to differentiate analgesia obtained by 650 mg. and 800 mg. aspirin (*e.g.*, McMahon, Tr. 3761; Lasagna, Tr. 4058–59). However, it is equally plausible to say that, for the relief of minor pain, there may not be any significant difference to be measured in the first place between 650 mg. and 800 mg. aspirin. See Lasagna, Tr. 4866.

[63] See p. 183 n. 45, *supra.*

that a dose-response curve is not designed to, and cannot, answer the question (1) whether the two dosages not tested will in fact perform differently or (2) whether, if they do, the differences will be statistically significant.[64]

The dose-response curve connecting the data points for graded dosages actually tested is simply a matter of connecting the two points representing statistically valid mean values at each data point tested. At each data point, the test data regarding individual test subjects ideally form a cluster. The degree of the spread of this cluster varies from one test to the next. It may be "sloppy" or "compact." Clinical pharmacologists then pick a mean point, based on a statistical analysis of the cluster, and connect it with another data point similarly arrived at (See F. 227 and 228). Thus, *if only two dosages are tested, the dose-response curve will be linear. However, if more than two are tested, the curve may not be linear* (Azarnoff, Tr. 665–66). In fact, the classical dose-response curve common to most active drugs is one that shows an increasing effect as the dosage is increased until a plateau is reached beyond which any increase in dosage does not produce an increase in effect (Lasagna, Tr. 4102). Furthermore, in many drugs, the "log dose" relationship is such that the dose effect is proportional to the logarithm of the dosage. In other words, a small **[192]**increase in dosage is not anticipated to produce any significant incremental increase in effect. This is believed to be the case with aspirin (Kantor, Tr. 3572–73, 3613–14; CX 367T). Therefore, *the precise shape of the aspirin dose-response curve must first be determined. Even then, it does not provide a scientific basis for claiming that the difference between any two dosage points not tested will be statistically significant. Only head-to-head clinical trials of the two points can provide that answer.* There is agreement on this point among both complaint counsel's and respondents' experts who testified in this proceeding.[65] The McMahon study, the only study which purports to provide an answer to that question, fell far short of its goal.

Thus, in a nutshell, even assuming the existence of a positive dose-response curve for aspirin, its precise shape is not known, and American Home has failed to overcome complaint counsel's *prima facie* showing that the superior efficacy of Anacin (800 mg. aspirin in two tablets) over regular aspirin (650 mg. in two tablets) is not established and that there exists a substantial question about that proposition.

[64] *E.g.,* Wallenstein, Tr. 3513; Kantor, Tr. 3647–49, 3565; Lasagna, Tr. 4271–73; Okun, Tr. 4475–76, 4493–94, 4522–23.

[65] *E.g.,* Forrest, Tr. 559–64; Azarnoff, Tr. 605–06; Wallenstein, Tr. 3513; McMahon, Tr. 3981; Lasagna, Tr. 4271–73; Okun, Tr. 4475–76, 4493–94, 4522–23.

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I am aware of the testimony of several practicing physicians suggesting that the findings of the aspirin dose-response studies, including the McMahon study, provide a sufficient basis for preferring 800 mg. aspirin over 650 mg. aspirin for the treatment of headache pain.[66] However, Dr. Lasagna, for example, admitted that the practice of medicine is not an exact science but an art, and that, as a clinician, he would form a professional judgment regarding the comparative efficacy of 650 and 800 mg. aspirin, based on the existing data, and would be willing to try 800 mg. instead of 650 mg. aspirin on his patients (Lasagna, Tr. 4172–76). This is as it should be in the practice of medicine. The application of clinical pharmacology to clinical medicine inevitably involves the professional judgment of the clinician and is a matter of trial and error based on long experience, insight and wisdom. However, this is not to say that the superior efficacy of 800 mg. aspirin over 650 mg. aspirin has been scientifically established.[67] **[193]**

In the final analysis, the record as a whole shows that, for the relief of mild to moderate pain, including headache pain, for which aspirin is indicated, 650 mg. and 800 mg. aspirin are about equally effective. The best that can be said for American Home is that the record evidence may provide a reasonable basis for a claim that 800 mg. aspirin may sometimes be expected to provide somewhat greater analgesia to some people than 650 mg. aspirin. However, that claim has not been scientifically established. This conclusion is in accord with the FDA OTC Internal Analgesics Panel's findings.[68] **[194]**

Finally, as a practical matter, the superior efficacy claim that consumers perceive from the challenged advertising representations

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[66] *E.g.*, Lasagna, Tr. 4893–95.

[67] Clinical pharmacologists generally demand that statistically significant differences be established first by well-controlled clinical demonstrations; they then determine according to their professional judgment, whether there is any clinical significance, taking into account such factors as the magnitude and duration of the observed difference, side effects, ease of administration and price (Forrest, Tr. 557–59, 568–69; Azarnoff, Tr. 650; DeKornfeld, Tr. 2825–27).

[68] The Panel answered the question as follows (CX 367T):

> . . . Dosages above 650 mg. [aspirin] do not result in a significantly greater incidence or degree of pain relief in most studies. In some studies, however, dosages of 975 mg. (four 325 [*sic*] mg. tablets) appeared to have a greater analgesic effect based on dose-response curves which appeared to be increasing above 650 mg. The difference between the larger dosages compared with 650 mg. generally could not be shown to be statistically significant but the apparent increase in the dose-response curve above 650 mg. dosages suggests that greater pain relief may be obtained in some individuals with some types of pain with single dosages of 975 mg. to 1300 mg.
>
> Although the dose-response curves in a few studies suggest that larger dosages may produce a slightly greater incidence of analgesia than 650 mg. dosages, there are important limitations in this assumption.
>
> First, the relationship of increased analgesia to increased dosage is not linear but, like many drugs, the effect is proportional to the logarithm of the dosage. Second, the increase is generally relatively small because the dose-response curve is relatively flat requiring large increases in the dosage to obtain a relatively small increase in analgesic response.
>
> A third consideration is that most studies of analgesic effects have involved only single dosages. There is relatively little information on the dose-response curves after multiple dosages.

See also *The Medical Letter*, CX 363; *The AMA Drug Evaluation*, CX 362.

is not that Anacin or APF provides a larger amount of pain relief than aspirin *in an absolute or technical sense,* but that the difference is *therapeutically significant* —that it makes a real difference which consumers can feel. Otherwise, why choose Anacin or APF and not aspirin, or pay a higher price for them? In this sense, the record evidence is convincing that the proposition that there is a *therapeutically* significant difference in pain relief between Anacin or APF on the one hand and aspirin on the other hand is far from being established. Indeed, on the basis of this record, one may arguably dispute the existence of any reasonable basis for that proposition.

More Aspirin Is Not Better But May Be Worse

The focus of analysis in this case has been upon whether or not the proposition "more is better"—specifically, the therapeutic superiority of 800 mg. aspirin over 650 mg. aspirin—is scientifically established. On the basis of the record evidence, I have reached a negative determination. The analysis in this respect compared the evidence of analgesic effects of graded, single aspirin dosages, totally ignoring the effect of multiple dosages or chronic use of aspirin. However, it should be pointed out that, in terms of chronic use, the record evidence strongly suggest that more aspirin may be worse than less aspirin. For example, aspirin-induced gastrointestinal lesions and mucosal erosions **[195]**have been endoscopically observed.[69] Aspirin's adverse effects on renal and hepatic functions, including salicylate hepatitis, are also well established.[70] So is aspirin's systemic effect on the blood, including its anticoagulant effect.[71] Some of these adverse effects can be serious indeed, especially for persons with certain predisposing conditions (F. 403, 411, 412 and 432). Indeed, the cumulative evidence related to the various adverse effects of aspirin (F. 403, 404, 406–20 and 426–52) compels the conclusion that aspirin is a potent drug and should not be taken in quantities larger than is effective for the condition for which it is indicated. Considered in conjunction with the remarkable popularity of OTC analgesic products among American consumers and their long-held faith in the products' efficacy and safety for the relief of ills,[72] not to mention

[69] *E.g.,* Grossman, Tr. 839–40; Shapiro, Tr. 2951–52. See also CX 367Z017–Z018.

[70] F. 450. It should also be noted that the side effects of aspirin on renal and hepatic functions are more closely tied with aspects of the disease activity rather than aspirin dosage and can result from small or normal doses (Plotz, Tr. 1083).

[71] F. 451 and 452.

[72] See, *e.g.,* CX 463 and CX 468. See also Rickels, Tr. 1196–97.

the substantial number of chronic users of aspirin including rheumatic persons,[73] the importance of the record evidence tending to show that "more may be worse" cannot be overemphasized.[74] **[196]**

Caffeine As An Active Agent Or An Adjuvant In OTC Analgesic Products

American Home contends that the presence of about 32.5 mg. caffeine in Anacin is another factor in support of its claim of Anacin's superior efficacy. However, the record evidence is persuasive that (1) there is no reliable medical-scientific evidence showing caffeine to be an effective analgesic agent in humans and (2) the medical-scientific evidence to show that an aspirin-caffeine combination is more effective than aspirin alone for analgesic purposes is insufficient.

It is generally agreed that caffeine, commonly ingested in the form of coffee or tea beverages, is a mild central nervous system stimulant as well as a cardiac stimulant.[75] As such, it is useful in fighting fatigue or sleepiness. There is evidence that caffeine acts on the kidney to produce diuresis and relaxes stomach muscles. It has also been reported to cause increased gastric secretion in the stomach and possibly contribute to gastric bleeding.[76] Caffeine also inhibits platelet aggregation in vitro.[77] When used alone in an adult oral dosage of 65 mg. not to exceed 600 mg. in 24 hours, caffeine is safe but ineffective as an OTC analgesic, antipyretic and/or antirheumatic ingredient.[78]

OTC analgesic products which combine aspirin and caffeine have been widely available for many decades. Anacin and the so-called APC tablets are common examples.[79] In spite of the popularity of APC and other aspirin-caffeine combinations, the pharmacological rationale for their use as analgesics is not clearly understood. It is claimed that caffeine is an effective analgesic agent in animals and is useful for the treatment of certain headaches **[197]**due to the

[73] F. 403.

[74] In this connection, the FDA OTC Internal Analgesics Panel recommended that the standard dosage unit of aspirin be determined to be 325 mg., that products containing 325 mg. aspirin per dosage unit be clearly labeled "Contains the standard strength of 325 mg. (5 gr.) aspirin per dosage unit," and that products containing an amount of aspirin other than 325 mg. aspirin per dosage unit be clearly labeled "Contains non-standard strength of X mg. (X gr.) aspirin per dosage unit compared to the established standard of 325 mg. (5 gr.) aspirin per dosage unit." CX 367-O.

[75] Okun, Tr. 4354–55.

[76] Grossman, Tr. 855–56; Shapiro, Tr. 2969; Lasagna, Tr. 4194.

[77] CX 367Z114.

[78] CX 367Z112.

[79] APC is a combination of aspirin, phenacetin and caffeine. Until the early 1960's, Anacin was an APC formulation. Anacin has since dropped phenacetin from its formulation and slightly increased its caffeine content to about 32 mg. (Shaul, Tr. 3321).

constriction of blood vessels in humans. Despite some clinical evidence that an aspirin-caffeine combination appears to perform better for some individuals and the historical feeling among many clinicians that caffeine has a legitimate function in an OTC analgesic product formulation,[80] caffeine has not been established as an effective analgesic agent. Also, there is insufficient clinical data to show that caffeine is an effective adjuvant when used in combination with aspirin for analgesic purposes.[81] This is in accord with the FDA OTC Internal Analgesics Panel's conclusion on this subject.[82]

On the other hand, there is evidence to show that an aspirin-caffeine combination may be pharmacologically unsound. For example, it is known that caffeine stimulates secretion of gastric juices and, thus, an aspirin-caffeine combination would exacerbate aspirin's adverse side effects on the gastrointestinal tract. Also, there is a possibility that caffeine could heighten a person's awareness of pain (Lasagna, Tr. 4973). **[198]**

In sum, the record evidence is clear that the efficacy of caffeine, either as an active analgesic agent or an adjuvant in an aspirin-caffeine combination, has not been scientifically established.

Respondent Did Not Have A Reasonable Basis For Making The Tension Relief Claim For Anacin And Respondent's Tension Relief Claim Was Not Only Unfair But Also False

With respect to the tension relief claim for Anacin, American Home's defense is not that it had a reasonable basis for making such a claim but that it did not make such a claim, either directly or by implication. For the reasons discussed heretofore, I have determined that respondent's advertisements contained the alleged claim. See pp. 170–72, *supra.*

The record as a whole clearly shows that Anacin will not relieve tension. Dr. Rickels, an eminent authority in the study of psychopharmacologic drugs, testified that aspirin or Anacin will not relieve

[80] Dr. Okun, respondents' expert, suggested that caffeine liberates catecholamines, a group of hormones which cause analgesia in humans (Okun, Tr. 4358).

[81] In Dr. Moertel's clinical study of certain analgesic combinations using cancer pain, CX 361, an aspirin-caffeine combination was shown less effective than aspirin alone, although the difference was not statistically significant (Moertel, Tr. 968, 982).

Dr. DeKornfeld clinically compared aspirin, aspirin in combination with phenacetin, salicylamide with caffeine, and aspirin/phenacetin with caffeine. Although the combinations produced a mean pain relief score higher than aspirin alone, the difference was not statistically significant. See DeKornfeld, Tr. 2799–2803; CX 367Z113-Z114.

The Houde study using cancer pain, on which American Home relies, is inconclusive. Houde found that a combination of 210 mg. aspirin, 150 mg. acetominophen and 30 mg. caffeine gave somewhat better pain relief than either aspirin or acetaminophen alone. Houde, however, admitted that his data did not permit a conclusive statement that caffeine contributes to the efficacy of aspirin or acetominophen (Wallenstein, Tr. 3460–64, 3501–02, 3504–05, 3511–12; CX 367Z113-Z114).

[82] CX 367Z112-Z114.

tension or emotional anxiety (Rickels, Tr. 1205, 1209, 1236). Drs. Lasagna and Okun, respondents' experts, agreed with Dr. Rickels in this respect (Lasagna, Tr. 4100, 4198–99; Okun, Tr. 4437–38). In a well-controlled, double-blinded clinical trial evaluating the effects of aspirin on tension, aspirin was found not to be significantly superior to placebo in the relief of moderate tension (Rickels, Tr. 1194–98). Moreover, the study showed no difference in the results regardless of whether the study population was combined or broken down into those who also suffered moderate pain and those who did not.[83] (Rickels, Tr. 1197). The medical literature confirms that aspirin cannot be expected to relieve tension (Rickels, Tr. 1198, 1205). The FDA OTC Internal Analgesics Panel concluded that aspirin was "clearly ineffective" for "nervous tension" (CX 367K). Also, the FDA OTC Sedative Panel determined that aspirin was "ineffective" as a "day-time sedative" product, which was defined as one claiming "mood-modifying indications **[199]**such as 'for the relief of occasional simple nervous tension' " (CX 366E, Z002).

With respect to caffeine, Dr. Rickels testified that it would be "contraindicated" for a symptom of tension (Rickels, Tr. 1207, 1209). Although there is evidence that caffeine is a mild stimulant and relieves the feeling of fatigue to some extent, it does not provide any relief for tension.

However, American Home argues that Anacin is effective for pain-associated tension, a claim that it admits making. This claim refers to the so-called "tension-headache-tension" cycle, meaning a situation where headache pain is caused by underlying tension and the headache pain in turn causes further tension. Although aspirin or Anacin will relieve pain and thereby may cause some reduction in the irritability or tenseness resulting from pain, namely "secondary tension," this does not make aspirin or Anacin a tension relieving drug, a claim found to have been made by respondent. In this respect, Dr. Rickels explicitly testified that it "was not true" that "Anacin relieves headache pain and so its tension" or that Anacin "relieves tension as it relieves headache pain" (Rickels, Tr. 1236). Dr. Rickels' testimony stands undisputed. Since the claim is "not true," it follows that there can be no reasonable basis for the claim and that the claim is false.

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[83] Respondents' expert, Mr. Wallenstein, agreed that his study (RX 32) which compared two aspirin combinations, including an aspirin-acetominophen-caffeine combination, found that the caffeine combination data were "equivocal" (Wallenstein, Tr. 3501–02). Respondents' expert, Dr. Lasagna, agreed that RX 32's findings regarding the caffeine combination was inconclusive (Lasagna, Tr. 4217–18).

The Comparative Safety Of Micro-Fine And Buffered Aspirin Has Not Been Established

Also in issue in this case are two claims regarding Arthritis Pain Formula involving questions of drug formulations and comparative safety: the claims that APF will cause gastric discomfort less frequently than other OTC analgesic products (1) because APF is formulated with microfine aspirin particles and/or (2) because APF is formulated with two buffering agents (Paragraph 10(B) of the Complaint and 2(h) of Contested Issues of Fact). The subjective symptoms of gastric discomfort due to aspirin ingestion have been discussed in conjunction with other adverse effects of aspirin on the gastrointestinal tract (F. 363 and 406). The record evidence shows that the data in support of those claims of comparative safety are inconclusive at best and that the claims have not been established as medical-scientific propositions.

First, with respect to the first claim, although it is based on sound biopharmaceutical reasoning, it lacks supportive clinical data. It is of course theoretically plausible to hypothesize that the smaller the size of aspirin particles **[200]**the faster will be the rate of disintegration and absorption from the gastrointestinal tract and that, therefore, APF can reasonably be anticipated to cause less gastric discomfort than regular aspirin.[84] However, the crucial question is whether any statistically significant differences in terms of the incidence or severity of gastric discomfort have been established by well-controlled clinical demonstrations, and there is little scientific data one way or the other on this question.[85] Furthermore, it has been demonstrated that factors other than the size of the aspirin particles (for instance, the choice of excipient and the tablet compression during manufacture) may be important variables. The FDA OTC Internal Analgesics Panel, therefore, recommended a standardized dissolution test which can be used to detect preparations which will be so slowly absorbed as to potentially increase local adverse effects on the gastric mucosa or decrease efficacy due to decreased bioavailability.[86]

Second, with respect to the second claim that buffered aspirin causes less gastric discomfort than unbuffered or plain aspirin, the record shows a general consensus of a large number of studies which

[84] F. 362 and 364. See also Grossman, Tr. 851–52; Plotz, Tr. 1089–90; Sliwinski, Tr. 1136–37, 1165.

[85] F. 366, 368–70 and 378; CX 367Z006.

[86] See the Panel report, CX 367Z003-Z004.

Respondents' reliance on the blood level studies in support of the superior efficacy claims for Anacin and APF is not persuasive in that the record evidence is clear that no direct correlation between blood levels and analgesia has been shown with respect either to aspirin or to aspirin-caffeine combinations (F. 222 and 321–22).

demonstrate that buffered aspirin is more rapidly absorbed from the gastrointestinal tract.[87] The evidence also indicates that some persons who experience subjective symptoms of gastric distress may experience less gastric discomfort with some buffered aspirin than with unbuffered aspirin.[88] However, studies also indicate that simply adding buffers does not always increase the dissolution rate. The type and quantity of buffering [201]agents used, the tablet compression during manufacture, the choice of excipient and other pharmaceutical factors are also important variables. Therefore, actual testing of the dissolution rate is required to determine whether buffers present in APF actually affect the dissolution rate and, if so, to what extent. The totality of formulation and manufacturing variables of unbuffered and buffered aspirin products is crucial in determining their dissolution times.[89] Indeed, it has been shown that an adequately buffered aspirin may not have an advantage over a well-formulated unbuffered aspirin in terms of dissolution rate.[90] The discussions regarding the superior efficacy claim in terms of "establishment" in the preceding sections, apply here with equal force. See pp. 180–82, *supra.* In sum, in the absence of any well-controlled clinical study which demonstrates that APF tablets, with the two buffering agents in the quantities present in APF, cause gastric discomfort less often than unbuffered aspirin and show statistically significant differences between the two, the second comparative safety claim regarding APF has not been scientifically established.[91] This determination is in accord with the conclusion of the FDA OTC Internal Analgesics Panel.[92] [202]

The Studies Referred To In Certain Advertisements Do Not Prove That Anacin Is As Effective As The Leading Prescription Analgesic Product And More Effective Than Any Other OTC Analgesic Product

The two studies referred to in certain of the Anacin advertise-

[87] F. 373 and 374; CX 367Z005.

[88] F. 372–74.

[89] F. 362, 367 and 374; CX 367Z005.

[90] F. 373, 374 and 376; CX 367Z005.

[91] The only clinical study of APF conducted by American Home's Whitehall Laboratories (CX 304) failed to establish that APF causes a significantly less incidence of gastric discomfort than plain aspirin (Plotz, Tr. 1054–60; Sliwinski, Tr. 1138–47, 1162).

[92] CX 367Z099-Z100. See also *The Medical Letter,* CX 363; *AMA Drug Evaluations,* CX 362.

I am aware of the testimony in the record of some practicing physicians that their own clinical experience have convinced them that buffered aspirin causes subjective symptoms of gastric distress less often than unbuffered aspirin in some or many of their patients. This is generally consistent with the substantial amount of data reviewed by the FDA OTC Internal Analgesics Panel. However, I have determined that, with respect to a claim of *comparative* safety, as is involved herein, a greater degree of certainty is required and that nothing less than a well-controlled clinical demonstration satisfies this requirement.

ments (*e.g.,* CX 301 and CX 302) are the studies purporting to compare the analgesic efficacy of Anacin and Darvon Compound 65. Although the record shows that there is a general agreement among clinical pharmacologists that aspirin and aspirin-related products are as effective as Darvon Compound 65 for the relief of minor pain, the question in this case is whether the express or implied advertising representations that the two studies prove that Anacin is as effective as Darvon Compound 65 and more effective than any other OTC analgesic product have a reasonable basis.

The record clearly shows that neither CX 301 nor CX 302 proves the claim, let alone the implied claim that Anacin is more effective than any other OTC analgesic product. In order to prove the claimed parity with Darvon Compound 65, well-controlled clinical demonstrations are required. Neither CX 301 nor CX 302 can be reasonably said to qualify as a well-controlled study (F. 335–40). Similarly, neither study can be said to prove the implied claim of Anacin's superiority over other OTC analgesic products (F. 341–42).

Respondent's Survey Of Doctors Does Not Prove A Reasonable Basis For The Alleged Claims

It is my determination that the survey of doctors ("Doctors' Survey") referred to in some of the Anacin advertisements (*e.g.,* CX 81 through CX 84; CX 146 through CX 148; CX 176) and in Paragraph 21 of the Complaint does not provide a reasonable basis for the claims alleged in Paragraph 20 of the Complaint and found to have been made (F. 392–94).

The record clearly shows that the Doctors' Survey was so deficient in its design and execution that it could not provide any basis for the implied claim that more physicians recommended Anacin or that more specialists in internal medicine preferred it. The survey population was confined to physicians with a primary specialty in internal medicine who were in private practice and who were willing to receive promotional mail. The response rate was only about 10%. Obviously, such a mail survey does not provide any basis for the generalized claims found to have been made by American Home. Such a survey cannot be said to constitute reasonable substantiation for the alleged claims in any meaningful sense. **[203]**

Aspirin Disclosure Statements In Advertisements For Anacin And Arthritis Pain Formula Are Essential

An important issue in this case is whether the incidence and severity of adverse side effects of aspirin, either separately or

collectively, are of such magnitude as to make the presence of aspirin in Anacin and APF a material fact, within the meaning of Sections 5, 12 and 15 of the FTC Act, which should be affirmatively disclosed in future advertisements for the products. Section 15 of the Act provides in effect that a fact may become "material" in light of the "consequences which may result from the use of the commodity to which the advertisement relates" under "customary or usual" conditions. There is a vigorous dispute among the parties as to both the incidence and severity of adverse side effects and the utility of an advertising disclosure requirement, especially in view of the fact that the labels for Anacin and Arthritis Pain Formula list aspirin (or its chemical denomination "acetylsalicylic acid") as an ingredient, in accordance with FDA labeling regulations.

Aspirin is said to be the most popular OTC drug in this country. It is estimated that almost 19 billion dosage units are sold annually: this means over 5 million units a day. Without a doubt, aspirin is a highly effective and relatively safe analgesic agent. Its versatility and usefulness in terms of a risk-benefit ratio have been established over many decades. However, aspirin is also a potent drug and has a number of serious adverse side effects. Numerous expert witnesses in this case discussed the nature and extent of the principal side effects (F. 403, 404, 406–20, and 426–52). The FDA OTC Internal Analgesics Panel's report contains a handy compendium of aspirin side effects in eight major areas of concern (CX 367Z013-Z041). They include: effects on various organ systems such as the gastrointestinal tract, central nervous system, kidney, liver and the blood; specialized effects on hypersensitive persons, persons with certain disease states or during pregnancy; and effects when used with other drugs (See F. 406, 426, 444, 448 and 450–52). Some of these side effects are known to be serious and even life-threatening to many high risk subjects. The record shows that aspirin-induced or related hospital emergencies have reached alarming proportions. For example, in a recent survey, aspirin was found to be the second most frequent drug involved in adverse effects of drugs that were serious enough to require hospitalization. Two out of every 1,000 hospital admissions were attributed to aspirin (CX 367Z022). **[204]**

Consonant with its concern about the varied and substantial adverse effects of aspirin, the FDA OTC Internal Analgesics Panel recommended that appropriate warnings and cautionary statements be included on labels of all aspirin-containing OTC products (CX 367Z123-Z124). A number of these warnings and cautionary statements say that aspirin-containing products should not be taken under certain conditions or by certain persons without a prior

consultation with a physician. For the consumer to whom the warnings and cautions are intended, his knowledge that a given product contains aspirin is crucial. However, the record clearly shows that a large number of consumers are unaware of the fact that many OTC analgesic products, including Anacin, contain aspirin and that a large number of consumers neglect to read labels of such products (F. 402 and 457–64). These facts, involving important questions of public health, make aspirin ingredient disclosure highly desirable in all advertisements for aspirin-containing OTC products. In my view, the frequency and severity of two types of adverse effects, which can be life-threatening, make such advertising disclosure mandatory. They are aspirin-induced massive gastrointestinal bleeding and acute asthmatic attacks in aspirin-intolerant persons [93] (F. 410, 412–14, 426 and 428).

A. *Aspirin-Related Massive Gastrointestinal Bleeding*

Although the mechanism of action of aspirin upon the gastrointestinal tract resulting in sudden, massive bleeding is not definitively understood (F. 411), it is generally agreed that orally administered aspirin, as well as intravenously administered aspirin, can cause sudden, massive and life-threatening bleeding in the gastrointestinal tract, especially in persons with certain predisposed conditions such as dyspepsia, gastrointestinal lesions, peptic ulcers or other bleeding problems in the gastrointestinal tract (F. 413).

A recent survey showed aspirin to be the second most frequent drug involved in all hospitalizations due to the adverse effects of drugs. Two out of every 1,000 such **[205]**hospital admissions were attributed to aspirin. Massive gastrointestinal bleeding was second only to digitalis intoxication as the most frequent cause of drug-related hospitalization and aspirin and aspirin-containing products were involved in 60% of the cases.[94] Moreover, the mortality rate associated with this condition is high. Death occurs in 4 to 10% of all patients with massive gastrointestinal bleeding, including those associated with aspirin ingestion.[95] Even higher mortality rates are shown in those patients who require surgical intervention to stop the massive internal bleeding (CX 367Z022). Furthermore, there is evidence that aspirin can cause gastric ulcers when taken in large

[93] The record shows that a relatively small amount of aspirin (3 mg.) can cause a severe reaction, including anaphylactic shock, in aspirin-intolerant persons (F. 426 and 429).

[94] CX 367Z022. See also Dr. Grossman's discussion of Miller, "Hospital Admissions Due to Adverse Drug Reactions - A Report From The Boston Collaborative Drug Surveillance Program," *Clinical Pharmacology and Therapeutics*, 14:142–143, 1973 (Grossman, Tr. 877–80; CX 367Z022); F. 418.

[95] F. 414.

doses and aspirin may cause a specific kind of ulcer not seen in its absence.[96] Gastric ulcer is a serious disease with significant morbidity, and often requires surgery on the stomach.[97] By conservative estimate, aspirin ingestion results in 10 out of every 100,000 users developing a gastric ulcer, requiring hospitalization.[98] Levy's Boston Collaborative group study also estimated that one-eighth of all gastric ulcers were aspirin-related (CX 367Z020). Although these incidences are relatively small in terms of absolute numbers, they clearly present a serious public health problem. Therefore, the FDA OTC Internal Analgesics Panel recommended that all products containing aspirin should bear a warning: "*Caution*: Do not take this product if you have stomach distress, ulcers or bleeding problems except under the advice and supervision of a physician." (CX 367Z025). The aspirin-related gastrointestinal massive bleeding is compounded by aspirin's recently known anticoagulation effect (CX 367Z015). **[206]**

B. *Aspirin Intolerant Individuals*

Aspirin hypersensitivity reactions (or aspirin-intolerant reactions) are varied. They include: effects on the respiratory tract ranging from shortness of breath to severe asthmatic attacks; effects on the skin such as urticaria, angioedema, edema and rash; and anaphylactic shock involving laryngeal swelling, blockage of air pathways and a sudden drop in blood pressure which can result in death if not treated rapidly (F. 426 and 444). Although the incidence of aspirin intolerance in the general population is relatively small, it clearly presents a serious and substantial problem of public health. Therefore, the FDA OTC Internal Analgesics Panel recommended that labels for all products containing aspirin include the warning: "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). Dr. Moertel testified that the existence of aspirin in OTC analgesic products should be disclosed in advertising in order to protect persons with gastrointestinal bleeding or bleeding problems and aspirin-intolerant persons (Moertel, Tr. 1012).

In addition, in 1973 the American Academy of Allergy, a professional body composed of some 2,200 allergy specialists in the United States, adopted a resolution recommending that a "formulation containing aspirin and advertisements promoting the formulation

[96] F. 415.
[97] F. 416.
[98] F. 417.

should clearly indicate that the preparation contains aspirin and that aspirin can be harmful to some persons." (CX 367Z028; Farr, JTr. 2608–13). The FDA OTC Internal Analgesics Panel expressed its agreement with this resolution (CX 367Z028–Z029).[99] The 1973 resolution of the American College of Allergists, another professional body composed of allergy specialists, is also in accord with the 1973 resolution of the American Academy of Allergists (F. 446; Farr, Tr. 2613, 3650).

Against the unamimous judgment of two responsible professional organizations of specialists and the FDA OTC Internal Analgesics Panel, American Home argues that such advertising disclosure is totally unnecessary because **[207]**(1) the incidence of aspirin intolerance or massive gastrointestinal bleeding is small and (2) consumers can be counted on to read OTC drug labels. These arguments are unacceptable.

First, with respect to aspirin-intolerance, the incidence figures for asthmatics in the record varies from a low of 0.1% to a high of 28%.[100] Even if we were to take the low range, it represents close to one-quarter of a million persons who will suffer a severe adverse reaction from aspirin ingestion, which can be life-threatening. When we take into account the significant number of people who may suffer serious gastrointestinal side effects, the considerations for mandating advertising disclosure of aspirin content is overwhelming.

Respondents' argument that consumers know that Anacin and APF contain aspirin is unpersuasive. There is evidence that a substantial portion of consumers do not know that OTC analgesic products, such as Anacin, contain aspirin. This is not surprising in view of the long history of Anacin advertisements which carefully avoided any hint that it contains aspirin and suggested by implication that its analgesic ingredient is something special and that it is something other than aspirin.[101] Similarly unpersuasive is respondents' argument that those consumers who should not take aspirin are advised not to take aspirin and instructed to read labels by their physicians. First, many aspirin-intolerant persons are not aware of their condition in this respect until they experience a severe adverse reaction.[102] Second, the number of consumers who do not read labels

[99] The Panel also "strongly urges the Federal Trade Commission to require that cautionary language and warnings developed by the Panel be given emphasis in commercial advertising more so than is currently being done. . . ." (CX 367L).

[100] Stevenson, JTr. 1495. Dr. Stevenson testified that 10% is a conservative figure. The record as a whole supports the conclusion that 10% is probably the best estimate. On this basis, the number of persons who are aspirin intolerant reaches some 2.25 million.

[101] See the discussion of Anacin and APF advertisements, pp. 168, 173–74, *supra*.

[102] F. 455.

before they take an OTC product is as large as, if not larger than, those who read the labels.[103]

Finally, the presence of aspirin in Anacin and APF is a material fact from an economic point of view. The record shows that a substantial number of consumers do not know that [208]the analgesic ingredient in Anacin and APF is aspirin. Obviously, if this fact were known to consumers, that fact would be an important factor in making a choice between higher priced Anacin/APF and lower priced aspirin. In this sense as well, the presence of aspirin in Anacin and APF is a material fact which ought be disclosed in future advertisements.

Thus, the record evidence clearly establishes in my view the necessity of aspirin ingredient disclosure in Anacin and APF advertisements.

Caffeine Safety—Caffeine Disclosure Statements In Advertisements For Anacin Are Not Required

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. The recommended dosages of Anacin is within this range.[104] Although chronic caffeine toxicity has not been observed in humans, some resistance to caffeine is known to develop. Tolerance to caffeine is likely to develop with daily use. Caffeine is a cardiac stimulant. It is known to cause increased gastric secretion in the stomach and possibly contribute to gastric bleeding. It has been suggested that caffeine can cause peptic ulcers and should be avoided by patients with peptic ulcers.[105] Caffeine inhibits platelet aggregation in vitro and its use in patients with gastric bleeding is not recommended.[106] Caffeine also is associated with an increase in blood pressure and keeping users awake or jittery.[107]

Complaint counsel maintain that the public is seriously concerned with the effects of caffeine and desires to avoid ingestion of caffeine-containing products. They further argue that the public is entitled to a caffeine disclosure statement in all Anacin advertisements. However, the record does not show that the incidence and severity of adverse effects of caffeine are of such magnitude as to require an [209]advertising disclosure of the kind complaint counsel advocate. Although the record contains some evidence that a substantial

[103] F. 464.

[104] F. 424; Lasagna, Tr. 4098–99.

[105] Grossman, Tr. 872–75; Lasagna, Tr. 4194.

[106] Grossman, Tr. 866–67. See also CX 367Z114.

[107] Lasagna, Tr. 4194.

segment of the public may desire to avoid caffeine ingestion for one reason or another, the record as a whole does not support a conclusion that the adverse effects of caffeine are such as to present a serious public health problem.[108] After all, complaint counsel do not dispute that the amount of caffeine in two tablets of Anacin (about 65 mg.) is smaller than that present in a single cup of coffee. In my view, the record as a whole does not support a conclusion that the presence of caffeine in Anacin is a material fact of which the failure to disclose would make Anacin advertisements unfair or deceptive.

Furthermore, there is a practical problem of requiring an advertising disclosure for caffeine on top of a similar disclosure for aspirin. As a practical matter, television and radio commercials are usually of a short duration, lasting for 30 to 60 seconds. In my view, to add the caffeine disclosure requirement may have the undesirable effect of diluting the impact of aspirin disclosure, a much more important message, and blurring its focus. Also, there is a real practical problem in requiring multiple affirmative disclosures in a single, short commercial. Accommodation of the two ingredient disclosures in a short commercial may present difficult, if not insurmountable, technical problems.

Finally, an affirmative disclosure requirement is a form of prior restraint upon commercial speech and should not be lightly imposed in the absence of a clear showing that non-disclosure would make the advertisement unfair to the consumer or deceptive. The record as a whole fails to make out such a showing in my view. Therefore, complaint counsel's arguments for a caffeine disclosure requirement are rejected. **[210]**

The Unfairness Doctrine And The Substantial Question Theory

Complaint counsel argue that a comparative or superlative claim of efficacy or safety of an OTC analgesic product, made expressly or by implication, constitutes, as a matter of law, a representation that the claim is scientifically established. They further argue that, with respect to the comparative efficacy claim for Anacin and the comparative safety claim for APF, the claims are not established because there exists a substantial medical-scientific question about their validity among scientists who by their training and experience

[108] F. 421–25. The General Foods study (CX 471—received *in camera*) is less than persuasive on this point. In my view, there is a real question whether the study's findings can be transferred in a meaningful sense to a drug. While coffee is a beverage of refreshment nature, Anacin is a drug to be taken for specific physical conditions. The record contains scant evidence as to the extent of caffeine concern, if any, among consumers of OTC analgesic products or medical experts.

are competent to judge the validity of such claims. Complaint counsel finally argue that the existence of a substantial question is a material fact and that an advertisement which carries such a comparative claim without disclosing the existence of a substantial question is not only false within the meaning of Sections 12 and 5 of the FTC Act but also an unfair act or practice within the meaning of Section 5. At first blush, this theory of Section 5 liability is a novel one.

Upon reflection, however, I am persuaded that the substantial question theory outlined hereinabove is, in the particular factual context of this case, a reasonable and logical refinement of the "reasonable basis" doctrine, which has been judicially sanctioned. *Pfizer, Inc.*, 81 F.T.C. 23 (1972); *Firestone Tire & Rubber Co.*, 81 F.T.C. 398 (1972), *aff'd*, 481 F.2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 1112 (1973); *National Dynamics Corp.*, 82 F.T.C. 488 (1973), *aff'd*, 492 F.2d 1333 (2d Cir. 1974), *cert. denied*, 419 U.S. 993 (1974).

The basic rationale of *Pfizer* is that an affirmative product claim carries with it an implied representation that the advertiser possessed and relied on a reasonable basis for the claim when the claim was made and that such an advertising claim in the absence of a reasonable basis is an unfair act or practice in violation of Section 5 within the meaning of Section 5. See *FTC* v. *Sperry & Hutchison Co.*, 405 U.S. 233 234 (1972). The reasonable basis requirement applies even if an advertisement claim is in fact true. 81 F.T.C. at 63. Also see *id.* at 67–68.

In *Pfizer*, a case involving a simple efficacy claim for a topical OTC anesthesic preparation, the Commission reasoned that (81 F.T.C. at 62): **[211]**

> Given the imbalance of knowledge and resources between a business enterprise and each of its customers, economically it is more rational, and imposes far less cost on society, to require a manufacturer to confirm his affirmative product claims rather than impose a burden upon each individual consumer to test, investigate, or experiment for himself. The manufacturer has the ability, the knowhow, the equipment, the time and resources to undertake such information by testing or otherwise—the consumer usually does not.
>
> * * * Absent a reasonable basis for a vendor's affirmative product claims, a consumer's ability to make an economically rational product choice, and a competitor's ability to compete on the basis of price, quality, service or convenience, are materially impaired.

The Commission, therefore, concluded that as a matter of marketplace fairness, a consumer is entitled to rely upon the manufacturer to have a reasonable basis for making performance claims. *Id.*

In determining what constitutes "a reasonable basis," the Commis-

sion set forth a number of guidelines in *Pfizer*. First, the Commission made it clear that the requirement is not solely a "reasonable man" test. The reasonable basis requirement questions both the reasonableness of an advertiser's actions and the adequacy of evidence upon which such action is based.[109] The reasonable basis standard is essentially a fact issue to be determined on a case-by-case basis, and depends on such overlapping considerations as: (1) the type and specificity of the claim made (*e.g.*, safety, efficacy, dietary, health, medical); (2) the type of product (*e.g.*, food, drug, potentially hazardous products); (3) the possible consequences of a false claim (*e.g.*, personal injury); (4) the degree of reliance on the claim by consumers; and (5) the type and accessibility of evidence adequate to form a reasonable basis for the particular claim.[110] For some types of claims and for some types of products, the only reasonable basis "in fairness and in the expectation of the consumers" would be an adequate and well-controlled scientific test.[111] **[212]**

This proceeding involves comparative and superlative efficacy and safety claims for aspirin-based OTC internal analgesic products. Such drugs as a class is known to be the most popular OTC drug in this country. American consumers purchase some 19 billion dosage units annually (F. 14). Although they are generally safe and effective for the relief of minor pain and headache pain and for the reduction of inflammation and fever, they are potent drugs and have numerous adverse side effects, some of which are serious and can be life-threatening (F. 404 and 406–52). Anacin is the largest selling and most heavily advertised aspirin-based OTC internal analgesic product. Against this background, what is the reasonable level of substantiation required under the fairness doctrine for a claim that Anacin is more effective than aspirin because of the extra amount of aspirin (150 mg.) and caffeine (65 mg.) contained in two tablets of Anacin over two tablets of 5 gr. aspirin, or for a claim that Anacin is more effective than any other OTC analgesic product?

Consumers obviously have no means of verifying the truth of such a pharmacological-clinical superiority claim for themselves (See F. 210, 211, 218–20, 223, 225, 581 and 582). Moreover, consumers are willing to pay, and do pay, a significantly higher price for the alleged superior efficacy of the product. If the alleged superiority is not established, the consumer's evidently widespread self-medication with such higher-priced, "extra-strength" OTC analgesic products is not only pharmacologically superfluous and economically wasteful

[109] See *id.*at 64.
[110] *Id.*at 64.
[111] *Id.* at 64, 66–67.

but also is accompanied by significant health hazards (increased potential for adverse side effects) (See F. 403–52).

In my view, in the circumstances of this case, such a comparative or superlative claim constitutes, "in fairness and in the expectation of the consumers" and as a matter of law, an implied representation that the manufacturer has a sufficient kind and degree of substantiation for its claim. To state it another way, the consumers of OTC analgesic products are entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a sufficient kind and level of substantiation for the claim. In the circumstances of this case, the only sufficient substantiation for the claim is that the claim is accepted as established by the medical-scientific community. The record is clear that, with respect to OTC internal analgesic products, the medical-scientific community requires two or more well-controlled [213]clinical studies using appropriate pain models, one of which is a headache pain model (F. 197–225).

It is also clear that the absence of that kind and level of substantiation leaves a substantial question regarding a claim of comparative or superlative efficacy or safety, and that the existence of such a question is a material fact, of which the failure to disclose will render an advertisement deceptive (See pp. 216–17, *infra*). What then is a substantial question? A substantial question is a fact issue to be determined on a case-by-case basis. In this case, complaint counsel argue essentially that a substantial question exists because the comparative or superlative efficacy or safety claim is not accepted as true or as a proven scientific fact by the vast majority of medical scientists who are by their training and experience competent to judge the scientific validity of such claims. In this sense, a substantial question does not mean unanimity of medical-scientific opinions. Nor do occasional dissents make out a substantial question. It relates rather to the quality and quantum of medical-scientific evidence in support of a proposition. In the field of clinical pharmacology, it is generally agreed that two or more well-controlled clinical demonstrations showing statistically significant results are sufficient to establish a medical-scientific proposition. The record as a whole shows that in the absence of that level of supporting data, the medical scientists are unwilling to accept a proposition as true or proven. The expert witnesses who testified in his proceeding virtually without exception supported this view.

American Home, on the other hand, contends that the existence of substantial question requires more, that it requires a substantial mount of *negative* data from well-controlled clinical studies (RB at

6). However, this position is contrary to the weight of record evidence in this case[112] (See F. 195, 223, 225, 260–62, 276–78 and 318–20).

Furthermore, the rationale of the substantial question theory as applied to advertising claims for comparative or superlative efficacy or safety of OTC analgesic products is not only consistent with congressional policy of drug regulation embodied in the 1962 Amendment to the Food, Drug and Cosmetic Act and implemented by the FDA, but also is consonant with the findings and recommendations of the FDA OTC Internal Analgesics Panel. **[214]**

In Section 505(d) of the Food, Drug and Cosmetic Act, as amended (21 U.S.C. 355), Congress mandated a "substantial evidence" standard for granting a new drug application (NDA) with respect to all drugs, including new OTC drugs. Congress defined "substantial evidence" of drug efficacy in Section 505(d) as

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have . . . .

Under the HEW regulations promulgated to implement that congressional policy, the FDA has set forth several principles which, in its words,

> have been developed over a period of years and are recognized by the scientific community as essentials of adequate and well-controlled clinical investigations. They provide the basis for the determination whether there is "substantial evidence" to support the claims of effectiveness for "new drugs" . . . . 21 CFR 314.111(a)(5)(ii).

It should be pointed out that many of the FDA's "principles" closely parallel the very criteria testified to by the expert witnesses in this proceeding as important elements of a well-controlled clinical study. *Cf.* 21 CFR 314.111(a)(5)(ii)(a) through (c) and F. 201–17. Furthermore, these FDA requirements have been consistently upheld by courts. See *e.g., Weinberger* v. *Bentex Pharmaceutical, Inc.*, 412 U.S. 645 (1973); *Ciba Corp.* v. *Weinberger*, 412 U.S. 640 (1973); *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973); *United States* v. *Articles of Food and Drug Consisting of Coli-Trol 80, etc.*, 518 F.2d 743 (5th Cir. 1975); *Sterling Drug, Inc.* v. *Weinberger*, 503 F.2d 675 (2d Cir. 1974).

These well-established criteria for establishing the effectiveness of new prescription and non-prescription drugs have been recently reaffirmed by the FDA when it promulgated review procedures for

[112] With respect to aspirin's dose-response curve, the record contains a substantial amount of such negative clinical test data. *E.g.*, F. 243–57.

OTC drugs by various panels of experts, including the Panel on Analgesic, Antipyretic and Antirheumatic Products, and when the FDA initiated rulemaking proceedings **[215]**known as "monograph" proceedings. See 21 CFR 330.10(a)(4)(ii). Pursuant to this mandate, the FDA OTC Internal Analgesics Panel set forth specific criteria for well-controlled clinical studies required to establish the efficacy and safety of active agents used in OTC analgesic products. The Panel's criteria closely resemble the criteria extensively testified to by various experts, including American Home's, at trial in this proceeding.[113] More specifically, "to establish Category I status for a Category III compound,"[114] the Panel required "at least two studies by independent investigators" (CX 367Z075) which conformed to a number of specific criteria. These criteria are virtually identical to the ones testified to by expert witnesses in this proceeding. *Cf.* CX 367Z074–075 and F. 200–17.

Thus, the FDA, pursuant to congressional policy embodied in the Food, Drug and Cosmetic Act, requires at least two well-controlled clinical demonstrations of efficacy for both new prescription drugs and new OTC drugs. The FDA has reaffirmed the same standard in connection with its OTC drug review with respect to the issue of *simple* efficacy. The FDA OTC Internal Analgesics Panel recommended the same standard for OTC analgesic products for labeling with respect to the issue of *simple* efficacy and safety. It is eminently reasonable, therefore, for the Commission to apply the same standard to advertising claims of *comparative* or *superlative* **[216]** efficacy or safety for OTC analgesic products involved in this proceeding.[115]

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[113] Although the specific task of the Panel was to determine the effectiveness and safety of active ingredients used in OTC analgesic products for labeling purposes, the Panel dealt with issues of comparative efficacy or safety on several occasions, applying the same criteria. *E.g.*, CX 367Z110–Z111 ("faster to the bloodstream" issue); CX 367Z075 (greater analgesia postulated for aspirin-caffeine combination drugs).

[114] Category I was defined as "generally recognized as safe and effective," Category II as "not generally recognized as safe and effective," and Category III as "conditions for which the available data are inconsistent to permit final classification [either as Category I or II] at this time." (CX 367C-D).

[115] American Home argues that since Anacin and APF are effective and safe for the indicated conditions, it is not equitable to require a standard higher than a reasonable basis for comparative claims for these products (RRB, at 6–10). While this argument has some surface plausibility, it pales before the compelling rationale of the unfairness doctrine discussed hereinabove. On the contrary, in view of this record, it would be unthinkable for the Commission to allow a lesser standard for *comparative* claims in advertisements than what the FDA requires for *simple* (or absolute) claims in labels. To do so may tend to encourage OTC drug manufacturers to make unnecessary and therapeutically insignificant modifications to well known drugs, all having the same general actions or similar efficacy or safety factors, in order to achieve some marketing advantage as a result of advertising designed to emphasize the modifications and thereby imply superior product performance. In my view, this does not seem to be consistent with the basic purposes of Sections 5 and 12 of the FTC Act.

The Establishment Claims Related To Anacin And APF Will Be Deceptive Unless Qualified By An Affirmative Disclosure Of the Existence Of A Substantial Question

It is axiomatic that the Commission's power under Sections 5 and 12 to proscribe deceptive or misleading advertisements includes the power to require affirmative disclosure of a material fact in future advertisements of a product claim. In this sense, a fact is material if non-disclosure of that fact makes a claim patently deceptive and misleading. *E.g., ITT Continental Baking Co.,* 83 F.T.C. 865, 965 (1973), *rev'd in part,* 532 F.2d 207 (2d Cir. 1976); *FTC* v. *Royal Milling Co.*, 288 U.S. 212, 216–17 (1933); *Pep Boys-Manny Moe & Jack Co.* v. *FTC,* 22 F.2d 158, 161 (3rd Cir. 1941). *Cf., National Commission On Egg Nutrition,* 88 F.T.C. 89, 192–94 (1976), *modified,* 570 F.2d 157 (7th Cir. 1977). In this case, an establishment claim, express or implied, would clearly be misleading and deceptive unless qualified by disclosure of the fact that a substantial question exists regarding its scientific validity.

The record shows that the only scientifically established analgesic ingredient in Anacin and APF is aspirin. Respondents impliedly claimed that the propositions that Anacin and **[217]**APF are more effective or safer than aspirin have been scientifically established. These claims are based on the differences in formulation between Anacin/APF and aspirin. Respondents' unqualified claims in this regard imply that the difference in formulation, or rather the slight modification made to a regular aspirin tablet (150 mg. additional aspirin in Anacin), provides therapeutically superior analgesia. In the circumstances of this case, the fact that the implied claims have not been scientifically established, or that there is a substantial question among scientists who by training and experience are qualified to evaluate the validity of such claims, is a material fact which must be disclosed to consumers. The fact that there is a substantial scientific question is a vital factor for consumers in making their purchasing decisions.

The existence of a substantial question discussed above is even more material, indeed crucial, in this case because consumers cannot be expected to evaluate the validity of these establishment claims. Faced with an unqualified establishment claim, consumers are unable to make the intelligent and informed choice that is a paramount objective of Section 5. See p. 212, *supra.*

American Home's Constitutional Objections To The Substantial Question Theory Are Without Merit

American Home has raised two major objections to the substantial question theory on constitutional grounds. First, it argues that the establishment standard is vague and unpredictable and, thus, violative of due process. Second, it argues that the establishment standard is an invalid prior restraint on constitutionally protected commercial speech (RB 18–23). In my view, these arguments are without merit.

First, it is clear from the discussions in the preceding sections that the substantial question theory in the context of this case requires of American Home for advertising purposes nothing more than the quality and quantum of medical-scientific evidence long required by the FDA with respect to all new drugs (both prescription and non-prescription drugs) for labeling purposes. This standard is both well-established and clearly defined, and has been judicially reviewed and sanctioned. All American Home need do to meet the substantial question test is to have that kind and level of medical-scientific evidence (essentially two or more well-controlled [218]clinical demonstrations) which will establish its comparative or superlative claim when such claim is made.[116] There is nothing vague or unpredictable about this standard.

With respect to the fact that the performance claim challenged in this case is an implied claim rather than an express one, it clearly does not rise to the level of vagueness in the due process sense. Findings of Section 5 liability involving implied advertising claims have been upheld by the Supreme Court in numerous cases throughout the history of Section 5 jurisprudence. Therefore, American Home's vagueness argument is rejected.

Secondly, American Home's free speech argument is not well founded. It is well established that so-called commercial speech is entitled to the full protections of the First Amendment. *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Counsel,* 425 U.S. 748 (1976). However, it is also well established that commercial speech that is false or misleading forfeits that protection. *Id.* at 771 n. 24; *Warner-Lambert Co.* v. *FTC,* 562 F.2d 749 (D.C. Cir. 1977), *reversing in part, Warner-Lambert Co.,* 86 F.T.C. 1398 (1975), *cert. denied,* 46 U.S.L.W. 3616 (April 14, 1978); *National Commission on Egg Nutrition,* 88 F.T.C. 89, 195–99 (1976), *modified,* 570 F.2d 137 (7th Cir. 1977).

[116] During the oral argument, complaint counsel agreed that two or more well-controlled clinical studies supporting such claims when they are made will constitute an absolute defense in a substantial question action under Section 5. See Transcript of Oral Argument, Tr. 7842–46.

In the cases involving commercial speech, the important test is whether the proposed prior restraint will prohibit truthful speech or otherwise unduly tend to inhibit truthful speech. In this proceeding, it was found that respondents' comparative claims of superior efficacy and safety have not been established and that the existence of a substantial question with respect to these advertising claims is a material fact, of which the failure to disclose would render the advertising claim deceptive and misleading. In these circumstances, the requirement for affirmative disclosure of that material fact is well within the long established proscription against deceptive commercial speech.[117] American Home's argument [219]that such a requirement in the context of the substantial question theory would have the effect of chilling truthful speech is, therefore, without merit.

Finally, the constitutional challenge against the reasonable basis requirement is misdirected for the reason that the tension relief claim in this case not only lacked a reasonable basis but also is false.

Anacin's Product Image—Source And Duration And The Corrective Advertising Requirement

Complaint counsel contend that: (1) a substantial number of consumers believe that Anacin is a more effective pain reliever than aspirin and is a tension reliever; (2) these mistaken images are due in substantial part to American Home's misleading advertising claims made over a long period of time; (3) these consumer images will persist in the absence of corrective advertising designed to convey to consumers a corrective message that Anacin's superior efficacy is not established and that Anacin will not relieve tension. Respondent vigorously argues that: (1) the record evidence does not demonstrate consumers' belief that it has been established that Anacin is a more effective drug than aspirin or their belief that Anacin is a tension-relieving drug; (2) the record evidence does not show that the challenged advertising claims were the principal or significant source of such images, if such images were found to exist; and (3) the corrective advertising proposed by complaint counsel would have a punitive effect and is unjustified. It is my determination that: (1) the record as a whole does not support anything more than an inference that consumers have the establishment image alleged by complaint counsel; (2) the corrective advertising directed to the superior

[117] During the oral argument, respondents' counsel agreed that if the record supports a finding that the existence of a substantial question is a material fact, the requirement for affirmative disclosure of that fact would be consistent with the constitutionally sanctioned proscription against deceptive advertising under Section 5 of the FTC Act (Transcript of oral argument, Tr. 7896–97).

efficacy image is, thus, not justified; (3) the record as a whole supports the conclusion that consumers believe Anacin to be a tension reliever; and (4) the corrective advertising directed to the tension relief image is justified. **[220]**

A. *Product Images, Sources And Duration*

In my view, the mere fact that American Home has disseminated the challenged advertising claims for a long period of time (at least since 1963) supports a fair inference that consumers will believe that Anacin is a more effective analgesic drug than aspirin and that Anacin is a tension reliever.[118] This inference is further confirmed by some empirical data in this case, although such empirical evidence is less than overwhelming.

First, the record as a whole clearly supports the conclusion that consumers have for some time believed that Anacin is a more effective analgesic drug than aspirin and is a tension reliever. A number of commercial market research documents in evidence, including CX 451, 452, 454 and 455, support that conclusion. Although these market surveys were conducted at various times during the 1967 to 1970 period, for different clients, by different firms, using different methodologies and drawing upon different samples, they produced fairly consistent results. Although they were neither perfectly designed nor flawlessly executed, they were in general of the kind and quality normally used by business firms to help guide their marketing efforts (Smith, Tr. 5948–50). See also F. 502 and 503. An analysis of the data pertaining to efficacy-related product attributes shows that consumers believed that Anacin was a more effective drug than aspirin (F. 521, 523, 524 and 568–70).

Second, *The Leavitt Study* (CX 457), conducted for complaint counsel in 1975 for use in this litigation, provides further confirmation. Although *The Leavitt Study* suffers from a serious and major defect in that the completion rate was only about 50%, it nevertheless shows that more than one-half of the survey population (between 56 to 60%) had a comparative image of Anacin and aspirin, and that among them a significantly larger segment believed Anacin to be more effective than aspirin (F. 530 and 550–67).

The Leavitt Study is less impressive with respect to the tension relief image, but it produced spontaneous **[221]**responses from a not insignificant number of respondents, indicating that the tension relief image did exist in the fall of 1975 (F. 525). This is noteworthy

[118] *Cf. Warner-Lambert Co.*, 86 F.T.C. 1398, 1501–02, 1503 (1975), *rev'd in part*, 562 F.2d 749, 762 (D.C. Cir. 1977), *cert. denied*, 46 U.S.L.W. 3616 (U.S. April 14, 1978); *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157 (7th Cir. 1977, supp. opinion Jan. 28, 1978).

in view of the fact that tension relief advertisements had ceased about December 1973.

Thus, the penetration/image studies referred to above confirm what common sense and experience suggest, namely, that American Home's dissemination of the challenged advertising claims for a long period of time led to consumer images that Anacin is more effective than aspirin and that it relieves tension.

Next, respondents' sole-source argument is contrary to Commission precedent and should be rejected. The record as a whole clearly supports the inference that respondents' challenged advertising claims, made over a long period of time, played a substantial role in creating or reinforcing the misleading beliefs about Anacin among consumers.[119] Anacin has been advertised as a more effective pain reliever than aspirin and as a tension reliever. A substantial segment of consumers believe that Anacin is a more effective pain reliever than aspirin and is a tension reliever. This correspondence between advertising themes and consumer beliefs is a further indication that Anacin's advertising played a significant role in creating or reinforcing those beliefs.

With respect to the duration issue, the record as a whole supports the conclusion that the consumer beliefs about Anacin that have been found to exist will endure for some time and will tend to be reinforced either by subsequent advertising about Anacin or by subsequent use[120] (F. 579-84, 589–97 and 618). The duration of specific consumer beliefs and images generally depends on such factors as their importance to consumers, their specificity and the frequency with which they are reinforced by subsequent advertising or **[222]**by consumers' experience with Anacin that appear to them to be consistent with those beliefs (F. 584, 593 and 595–97). Clearly, efficacy is the *raison d'etre* of analgesics and is the most important product attribute for an analgesic product (F. 120). Tension relief is also an important attribute of an analgesic for a large segment of consumers of OTC analgesics (F. 495–500, 525–27 and 571). Respondents' expert, Dr. Smith, agreed that if a product is held in high esteem along the product dimensions that are important, it is likely that such beliefs will endure (Smith, Tr. 7776–77). The record evidence thus confirms what common sense and experience suggest, namely that product images about attributes important to consum-

[119] See *Warner-Lambert Co., supra*, 86 F.T.C. at 1501–02, 1503 (1975), 562 F.2d at 762; *Waltham Instrument Co.* 61 F.T.C. 1027, 1049 (1962), *aff'd*, 327 F.2d 427 (7th Cir. 1964), *cert. denied*, 377 U.S. 992 (1964).

[120] *Cf. Warner-Lambert Co., supra*, 86 F.T.C. at 1502–03, 562 F.2d at 762; *National Commission on Egg Nutrition* v. *FTC, supra.*

ers, once created, will endure for a long time and will tend to be reinforced by subsequent advertising or by subsequent use.[121]

B. *The Corrective Advertising Requirement*

The basic rationale of corrective advertising is that a misleading product image, once created, is likely to endure unless that image is unlearned by consumers through exposure to an appropriate corrective message for a sufficient time period. The Commission's Section 5 power to require corrective advertising in appropriate cases is not open to question. *Warner-Lambert Co., supra; National Commission on Egg Nutrition, supra.* Complaint counsel appear to argue that the finding that some of respondents' advertisements contained an implied establishment claim of superior efficacy for Anacin and the finding that some consumers believe that Anacin is more effective than aspirin *ipso facto* requires a corrective advertising requirement. I am of the view that the corrective advertising requirement is a discretionary remedy and that considerations of fundamental fairness and equity are relevant, although in all cases the elimination of mistaken consumer images is the paramount consideration.

In this case, although the finding of an implied establishment claim in certain advertisements is supported by the record and is a fair inference, I am not persuaded that the record supports an inference that consumers have an *establishment* image or that such an inference is fair in the circumstances of this case. In my view, to find an implied establishment claim in certain of respondents' **[223]** advertisements and to require in future advertisements containing such claims an affirmative disclosure of the material fact that a substantial question exists is one thing. To find an implied establishment claim, *which is not alleged to be false*, and to require corrective advertising in every future Anacin advertisement simply on the basis of consumer belief that Anacin is more effective than aspirin is another matter. The unfairness of the latter proposition is also compounded by the fact that complaint counsel's theory of liability, in this respect, is a novel one. Furthermore, if the finding of an establishment image among consumers is to be implied from consumers' image of Anacin's superior efficacy as a logical consequence of the implied establishment claim theory, the basis for doing so in this case is less than substantial since the evidentiary basis for finding a consumer belief that Anacin is superior than aspirin is itself less than overwhelming. Finally, as a practical matter, the aspirin disclosure requirement in the order will also have the further

[121] *Cf. Warner-Lambert Co., supra*, 86 F.T.C. at 1501–02.

effect of alerting consumers to the fact that the analgesic ingredient in Anacin is aspirin and may reasonably be expected to cause some consumers to modify their image of Anacin's superior efficacy to some extent. On balance, it is my determination that, on the basis of this record, corrective advertising directed to the superior efficacy image is not justified.

Corrective advertising directed to the tension relief image, however, stands on a different footing and is clearly required in my view. The tension relief claim was shown to be *false*. The evidentiary basis for the finding that American Home made that claim is solid as is the basis for concluding that consumers believe that Anacin is a tension reliever. Although the tension relief claim ceased by December 1973, it had been made for a long time. In view of the record evidence showing that consumers perceive tension relief as an important attribute of Anacin, it is reasonable to conclude that the tension relief image is likely to persist for some time to come in the absence of a corrective message. Therefore, it is my view that corrective advertising directed to the tension relief image is clearly justified.

The Liability Of Clyne, The Advertising Agency for APF

Complaint counsel and Clyne agree that an advertising agency may be held liable for false advertising if it actually participated in the deception and that it may be found to have participated in such deception if it knew or [224]had reason to know that the advertising was false. *Doherty, Clifford, Steers & Shenfield, Inc.*, v. *FTC*, 392 F.2d 921, 928 (6th Cir. 1968). Clyne was the advertising agency for APF since 1969 and does not deny that it participated generally in the preparation and dissemination of the APF advertisements containing the challenged claims. However, it vigorously contends that it did not know and had no reason to know that any of the challenged claims was false, that in fact it in good faith relied on the substantiation information furnished by American Home, and that under the law it had a right to do so. Complaint counsel agree that an advertising agency does not have the duty to conduct an independent scientific investigation or to retain medical scientists as expert consultants in order to insure that the medical-scientific claims contained in an advertisement are true or have been established. However, they argue that in this case Clyne knew or should have known that the substantiation material was patently inadequate and that, therefore, Clyne is equally liable. It is my determination that the record as a whole shows that: (1) Clyne either

knew or had reason to know that the uniqueness claim for APF was false; and (2) that Clyne's good faith reliance on the substantiation information obtained from American Home with respect to the comparative safety claim for APF was reasonable.

First, with respect to the uniqueness claim for APF (Comp. ¶8(B)(1)), there is no question that Clyne knew that the analgesic ingredient in APF is aspirin and that APF is essentially a buffered aspirin preparation. Therefore, the express and implied claims that APF's analgesic ingredient is unusual or special were patently false, and Clyne knew or should have known that they were false.

Second, with respect to the comparative safety claim for APF (Comp. ¶ 10(B)), the substantiation information furnished by American Home (CX 304) indicated that APF demonstrated less incidence of gastrointestinal irritation than buffered aspirin (CX 304S). Clyne should not be faulted for having equated "gastrointestinal irritation" with "stomach discomfort." Clyne had no reason to doubt the veracity or competency of American Home's medical-scientific research. Thus, it is reasonable to assume that Clyne relied in good faith upon this information. The key question is whether it was reasonable for Clyne to have relied on American Home with respect to the safety claim for APF. In my view, it was not unreasonable for Clyne to have done so. The Complaint does not allege that the claim is false; it merely alleges that the claim is not **[225]**established. This is not a case where the disparity between the advertising representations and the substantiation information is so great as to preclude a conclusion that the advertisements were conceived through reasonable reliance on the assurances of the manufacturer that the claim is true or has a reasonable basis. *Cf. Standard Oil Co. of California*, 84 F.T.C. 1401, 1474–75 (1974). Clyne cannot be reasonably charged with the duty to conduct an independent investigation that the claim is scientifically established in the sense that there existed two or more well-controlled clinical demonstrations in support of the claim. In these circumstances, Clyne's good faith reliance on American Home's assurances, as embodied in CX 304, was reasonable.

Relief

It is axiomatic that in Section 5 cases the Commission has the power and duty to fashion appropriate remedies which are reasonably calculated to prohibit the unlawful practices found to exist. *E.g.*, *Jacob Siegel Co.* v. *FTC*, 327 U.S. 608, 611–13 (1946); *FTC* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952); *FTC* v. *National Lead Co.*, 352 U.S. 419, 428–30 (1957). The remedy must have a reasonable relationship to

the unlawful practice and be no broader than is reasonably necessary to remedy the violation. *Jacob Siegel Co.* v. *FTC, supra,* at 613; *Beneficial Corp.* v. *FTC,* 542 F.2d 611, 619–20 (3d Cir. 1976). See also *Warner-Lambert Co.* v. *FTC,* 562 F.2d 749, 757–58 (D.C. Cir. 1977); *National Commission On Egg Nutrition* v. *FTC,* 570 F.2d 157, 164 (7th Cir. 1977).

A. *The Entry Of An Order Covering All Non-Prescription Drug Products Is Justified With Respect To American Home*

About a decade ago, the Commission had occasion to observe, in a case involving American Home, that:

> The law is clear that an order . . . need not be confined to the particular product or even the type of products sold by a respondent, particularly where the respondent has, by past conduct, demonstrated that the misrepresentations with which it has been charged are not isolated examples of its practices.[122] **[226]**

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> In the field of drug advertisements it is particularly important that the Commission's orders be sufficiently broad to ensure that the public will be fully protected against any future misrepresentations made by respondents with respect to the entire line of proprietary preparations which it sells and that it not be limited to just one type of preparation.[123]

In that case, the Commission ordered respondents not to "misrepresent . . . the efficacy of [any] drug." Although the reviewing court disagreed that respondents' past conduct justified the broad order in that case,[124] it is my view that now is the time to place American Home under a broad proscription with respect to all OTC drug products marketed by it. Furthermore, the proscription here is narrower and is related to the particular type of unlawful practice found to exist in this case.

B. *The Reasonable Basis Provision Is Justified*

Part II B of the Order would prohibit simple and non-comparative efficacy or safety claims that are not supported by a reasonable basis. This prohibition is based on the finding that respondent for a long period of time claimed that Anacin was a tension reliever without a reasonable basis therefor. Although the tension relief claim ceased about December 1973, the provision is necessary in order to prevent in the future the renewal of that claim as well as any other simple

[122] *American Home Products Corp.*, 70 F.T.C. 1524, 1625–26.
[123] *Id.* at 1627.
[124] *American Home Products Corp.* v. *FTC,* 402 F.2d 232, 237 (6th Cir. 1968).

and non-comparative efficacy or safety claim concerning any non-prescription drug product not supported by a reasonable basis.

C. *The Requirements For Affirmative Disclosure Are Appropriate*

Part III A and B of the Order would require disclosure of the presence of aspirin in future advertisements for aspirin-containing products. Part III D would prohibit [227]advertising claims of comparative efficacy or safety unless such claims are established. However, Part III E would permit comparative efficacy or safety claims whenever they are qualified by a disclosure statement that there exists a substantial question regarding the claims.

Part III D's requirement for two or more "adequate and well-controlled" clinical investigations are based on the FDA regulation which sets forth similar criteria necessary to provide "substantial evidence" of efficacy for new drugs (21 CFR 331.111(a)(5)(ii) and 330.10(a)(4)(ii)), with certain modifications. The FDA regulation has been modified to reflect the facts that (1) this case involves comparative efficacy and safety, and (2) this case involves only OTC drug products. In this respect, I have adopted complaint counsel's proposed order provisions and hereby subscribe to the reasons explained in complaint counsel's Memorandum (CB, 183–88).

D. *The Corrective Advertising Provision*

The Order requires American Home to include in every Anacin advertisement a statement that "Anacin is not a tension reliever." The duration of the corrective advertisement to be required is a difficult question. However, I am persuaded that it is reasonable to adopt for the purposes of this case the one-year formula used by the Commision in the *Warner-Lambert* case, which met the reviewing court's approval. *Warner-Lambert Co.*, D. 8891, Modified Order To Cease And Desist, July 20, 1978. The average should be based on the period 1968 through 1973, when the tension relief claim ceased.

E. *The Provisions Directed To Clyne*

The provisions directed to Clyne are based on its liability for the false uniqueness claim with respect to APF, and will be confined to advertisements of OTC internal analgesic products. Complaint counsel have not shown that a broader product coverage with respect to Clyne is justified in view of its past Section 5 violations.

CONCLUSIONS OF LAW

1. The Federal Trade Commission has jurisdiction over the advertising of Anacin and Arthritis Pain Formula under Section 5 of the Federal Trade Commission Act. [228]

2. Respondents' use of false and misleading advertising representations as found herein has had and now has the capacity and tendency to mislead consumers into the mistaken belief that the said representations are true and into purchasing substantial quantities of Anacin and Arthritis Pain Formula by reason of said mistaken belief. In the absence of an appropriate order, consumers are likely to continue to purchase substantial quantities of said products in the mistaken belief that respondents' past advertising representations regarding the comparative efficacy of said products were supported by evidence generally accepted by the scientific community as establishing such propositions, and that the tension relieving representations regarding Anacin had adequate substantiation.

3. The acts and practices of respondents as found herein were and are prejudicial and injurious to the public and constitute unfair methods of competition and unfair and deceptive acts in commerce in violation of Section 5 of the Federal Trade Commission Act.

4. The Complaint is hereby dismissed as to all respondents insofar as it relates to the advertising representations that Arthritis Pain Formula will eliminate all pain, stiffness and discomfort usually experienced by arthritis sufferers in the morning (Comp. 8(B)(2)). The complaint is dismissed as to the C.T. Clyne Company, Inc. except as relates to the advertising representations that Arthritis Pain Formula's analgesic ingredient is unusual and special (Comp. 8(B)(1) in part).

5. The accompanying order is necessary and proper for the purpose of prohibiting the continuation of the proscribed acts and remedying the injury and unfairness to the consuming public.

ORDER

I

It is ordered, That respondent American Home Products Corporation, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or [229]other device, in connection with the labeling, advertising, offering for sale, sale or distribution of "Anacin," in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist

from representing, directly or by implication, that Anacin relieves nervousness, tension, anxiety or depression or will enable persons to cope with the ordinary stresses of everyday life.

II

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing, directly or by implication:

1. That such product contains more of any ingredient than any other non-prescription internal analgesic product or products, or otherwise making a quantitative comparison with any other product or products, unless: **[230]**

a. The ingredient is named by its common, or usual, name;
b. The product, or products, used for comparison is, or are, named;
c. The ingredient is present in greater amount in such preparation than in the product, or products, used for comparison;

and unless each advertisement containing such representation also contains a clear and conspicuous disclosure stating that the comparative efficacy or safety claim "has not been scientifically proven." Such disclosure statement shall be further subject to the requirements of IV A 1 and 2 of this Order.

2. That such product contains any ingredient, or combination of ingredients, which is unusual, special or exclusive when such ingredient, or combination of ingredients, is available in other non-prescription internal analgesic products.

3. That such product will relieve headache pain in any period or amount of time; *provided, however,* that it shall be a defense in any enforcement proceeding instituted under this prohibition **[231]**for respondent affirmatively to establish that there is a reasonable probability that a great majority of consumers will obtain relief from headache pain within such period or amount of time.

B. Making any simple and non-comparative representations, directly or by implication, concerning the effectiveness or safety of such product unless, at the time such representation is made, respondent has a reasonable basis for such representation which shall consist of competent and reliable scientific evidence.

III

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula" or any other non-prescription drug product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Referring, directly or by implication, to aspirin, or to any commonly known ingredient, by any word or words without disclosing the common, or usual, name of such ingredient. **[232]**

B. Failing to disclose in the advertising of such product the presence of aspirin when such product contains such ingredient.

C. Misrepresenting, in any manner, any test, study or survey or any or all of the results thereof.

D. Representing, directly or by implication, that a claim concerning the comparative effectiveness or comparative freedom from side effects of such product has been established unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the effectiveness and comparative effectiveness or comparative safety of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness or safety that it is represented to have, and (2) that such comparative effectiveness or safety is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be **[233]**conducted on any disease or condition referred to, directly or by implication; or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. To provide the

basis for the determination whether any clinical investigation is "adequate and well-controlled," the plan or protocol for the investigation and the report of the results shall include the following:

1. A clear statement of the objective of the investigation.
2. A method of selection of the subjects that:

a. Provides adequate assurance that they are suitable for the purposes of the investigation, and diagnostic criteria of the condition to be treated (if any);

b. Assigns the subjects to the test groups in such a way as to minimize bias; and

c. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity, or duration of disease or condition (if any), and use of drugs other than the test drugs.

3. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment **[234]**of any subject's response and steps taken to minimize bias on the part of the subject and observer.

4. A comparison of the results of treatments or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. The investigation must be conducted double-blind, and methods of double blinding must be documented. In addition, the investigation shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

5. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

E. D. hereinabove shall not be construed to prohibit respondent from making any representation, directly or by implication, concerning the comparative efficacy or safety of such product when such representation or claim is not established by two or more well-controlled clinical investigations as specified in D. hereinabove, **[235]** provided each advertisement containing such representation also contains a clear and conspicuous disclosure stating that the comparative efficacy or safety claim "has not been proven." Such disclosure statement shall be further subject to the requirements of IV A 1 and 2 of this Order.

IV

A. *It is further ordered*, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, do forthwith cease and desist from disseminating or causing the dissemination of any advertisements for the product Anacin unless it is clearly and conspicuously stated in each such advertisement that "Anacin is not a tension reliever."

1. In print advertisements, the disclosure shall be displayed in type size which is at least the same size as that in which the principal portion of the text of the advertisement appears and shall be separated from the text so that it can be readily noticed.

2. In television advertisements, the disclosure shall be presented simultaneously in both the audio and video portions. During the audio portion of the disclosure in television and radio advertisements, no other sounds, including music, shall [236]occur. Each such disclosure shall be presented in the language, *e.g.*, English, Spanish, principally employed in the advertisement.

B. The aforesaid duty to disclose as provided in Paragraph IV A shall continue until respondent has expended on Anacin advertising a sum equal to the average annual Anacin advertising budget for the period of April 1968 to April 1973.

V

It is further ordered, That respondent the C.T. Clyne Company, Inc., a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising of "Arthritis Pain Formula" or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that such product contains any ingredient or combination of ingredients which is unusual or special when such ingredient or combination of ingredients is available in other non-prescription analgesic product or products.

VI

It is further ordered, That respondents American Home Products

Corporation and the C.T. Clyne Company, Inc. shall notify the Commission at least thirty (30) days prior to any [237]proposed change in their respective corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in their respective corporation which may affect compliance obligations under this Order.

VII

It is further ordered, That the respondents herein shall within sixty (60) days after service of this Order upon them, file with the Commission a written report setting forth in detail the manner and form in which they have complied or intend to comply with this Order.

Paragraph Eight B 2 of the Complaint is hereby dismissed as against American Home Product Corporation. The Complaint is dismissed as against the C.T. Clyne Company, Inc. except with respect to Paragraph Eight B 1 and related allegations.

APPENDIX I

A Description Of The Methodology Of The Image And Penetration Studies In Evidence

CX 451 – *A Study In-Depth Of Heavy Users Of Analgesics For Headache Relief*

Client: Whitehall Laboratories, division of American Home.

Purpose: To study consumer attitudes toward, and images[1] of analgesics with emphasis placed on the leading brands—Anacin, Bayer, Bufferin and Excedrin; to examine brand switching patterns; to aid in developing marketing strategies for the products involved (Weinberger, Tr. 683–84, 686; CX 451D–E).

Date of Study: Interviewing took place during the month of May 1967 (CX 451Z086).

Background of Researchers: The study was conducted by Oxtoby-

[1] See F. 486, *supra*, for the meaning attributed to the term, "consumer image," in this proceeding.

Smith, a consumer and market research organization, with Mr. Martin Weinberger bearing primary responsibility for the project (Weinberger, Tr. 682–83). Mr. Weinberger has had ample experience in the area of consumer research (Weinberger, Tr. 680–81).

Mr. Weinberger designed the research and the questionnaire, prepared the tabulation plan, analyzed the data and drafted the report (Weinberger, Tr. 684, 686, 702–03). Oxtoby–Smith's field director prepared written instructions for the interview supervisors (Weinberger, Tr. 689; CX 452Z090–Z092). These supervisors, who did not work exclusively for Oxtoby-Smith, often had been utilized in previous field work done for the firm; the supervisors selected the interviewers (Weinberger, Tr. 693).

In-house coding and keypunching allowed for close supervision by Oxtoby-Smith (Weinberger, Tr. 684, 697–98, 699). The tabulation of the data was done by an outside computer firm. CX 1058 contains the tabulations for this study (Weinberger, Tr. 701).

Methodology: The questionnaire was pretested (Weinberger, Tr. 687).

Interviews were conducted in 21 cities selected for geographic dispersion and intended to be representative of the national distribution of city populations (CX 451Z085; CX 452Z088). The study was conducted among 1,509 respondents, divided equally by sex (CX 451Z084). Quotas were set for the following groups: [2]

(1) Heavy users, defined as those who took six or more pain relievers for headache in the two-week period prior to the interview and representing users of each of the four leading brands (Anacin, Bayer, Bufferin and Excedrin) as well as a group to represent users of non-leading brands. Excluded from this heavy user group were those who took pills for problems other than headache; took more pills for arthritis than for headache; or use an effervescent tablet as their regular brand.

(2) Light users, defined as those who took at least one pain reliever for headache in the month preceding the interview.

(CX 451Z084; Weinberger, Tr. 687–89).

Interviews were conducted on a door-to-door basis (CX 451Z086; CX 452Z087) during days, evenings and Saturdays so as to find working persons and persons of both sexes at home (CX 452Z090). Interview supervisors developed routes that were assigned to the interviewers. If the appropriate person in a household were not available, the interviewer was instructed to proceed to the next household. Call-backs (in the event no one was home) were not

made (Weinberger, Tr. 695). Thus, the sample selection was not shown to have been based on principles of accepted statistical sampling that assure representativeness and projectability of the sample.

There is no indication of the interview refusal rate.

Interviewers utilized a written questionnaire, with detailed instructions, on which they recorded the responses of those interviewed (CX 452Z090–Z108).

The interview supervisors validated, by telephone, 15% of the interviews completed in their area. Oxtoby-Smith also validated 15% of the completed interviews, with 5% overlapping the 15% that had been validated by the interview supervisors. If validation revealed that an interview was not conducted, then all of that interviewer's work would be validated and possibly thrown out (Weinberger, Tr. 696–97; CX 451Z086). [3]

CX 452 – *A Follow-Up Study Of Attitudes Toward Headaches And Analgesics Among Heavy Users Of Leading Brands*

CX 452 was designed as a follow-up study to CX 451 and was developed to explore whether there had been significant shifts in public sentiment toward the leading analgesic products (CX 452D–E). The description and statement of methodology provided for CX 451 (Appendix I, pp. 1–2) are applicable to this study as well and are incorporated herein unless otherwise stated.

Date of Study: Interviewing took place during the week starting July 6, 1970 (CX 452Z088).

CX 1059 contains the tabulations for this study (Weinberger, Tr. 701).

Methodology: The study was conducted among 759 respondents, divided equally by sex (CX 452Z087–Z088).

In addition to the four leading brands included in CX 451 (Anacin, Bayer, Bufferin and Excedrin), users of Alka-Seltzer were also included in this study (CX 452Z087–Z088). The results for light users were tabulated for this study as well as for CX 451 (Weinberger, Tr. 691–92).

Approximately three-fourths of the items in each individual question in CX 451 were repeated in CX 452 (Weinberger, Tr. 706).

CX 453 – *Headache Remedy/Pain Reliever Product Usage And Advertising Penetration*

Client: Whitehall Laboratories division of American Home.

Purpose: To ascertain current advertising penetration[2] levels of Anacin, Bayer, Bufferin, Excedrin and Tylenol (CX 453C).

Date of Study: Interviewing was done between March 19 and April 9, 1973 (CX 453D).

Background of Researchers: The study was conducted by Sobel-Chaikin Research Associates, an independent market research organization, in cooperation with American Home [4](CX 453D). Mr. Charles Sobel had primary responsibility for the study (Sobel, JTr. 462). Mr. Sobel has had extensive experience in the design and execution of consumer research, with almost all of his work involving advertising penetration (Sobel, JTr. 448–53, 455).

Sobel-Chaikin selected the interview supervisors based on prior experience; the supervisors selected the actual interviewers. Both supervisors and interviewers were given detailed instructions (Sobel, JTr. 472).

In-house coding (Sobel, JTr. 483–85) and in-house data processing (Sobel, JTr. 485–86) allowed for supervision by Sobel-Chaikin.

Methodology: There was no pretesting of the questionnaire, but the questions had been used before (Sobel, JTr. 464).

The survey covered 10 market cities (Sobel, JTr. 465; CX 453C).

The 500-person sample, evenly divided by sex (Sobel, JTr. 465–66), is not statistically projectable (Sobel, JTr. 557–58). The survey population was randomly selected from listed telephone numbers (Sobel, JTr. 466–69).

Interviewers recorded responses from the phone interviews on call record sheets; no call-backs were made (Sobel, JTr. 469–70). The interview refusal rate was not tabulated.

The survey was limited to users of headache remedies or pain relievers who had taken such medications in the 30 days prior to the interview (Sobel, JTr. 474).

The survey only reports responses that were given by more than eight respondents (Sobel, JTr. 524–27).

Respondents were asked about their recall of brands on an unaided basis first and, then, on an aided basis (Sobel, JTr. 505).

Interview supervisors performed some of the validation and revalidation of the interviews; Sobel-Chaikin contracted with an outside research firm for 10 to 15% of the revalidation (Sobel, JTr. 477–81). This process served to reduce bias since the outside firm had

[2] See F. 488, *supra*, for the meaning attributed to the term, "advertising penetration," in this proceeding.

no interest in whether or not the interviews were properly conducted. [5]

CX 454 – *Assets And Liabilities Study Of Adult Analgesics*

Client: Glenbrook Laboratories, division of Sterling Drug.

Purpose: To provide assets and liabilities profiles for Bayer Aspirin and other leading analgesic products in the context of consumers' images of the products (CX 454C).

Date of Study: Interviewing took place during the first half of July 1967 (CX 454E).

Background of Researchers: The study was conducted by the research department of Dancer-Fitzgerald-Sample, Inc., an advertising and market research organization, with Mr. Lloyd C. Miller in charge (Miller, JTr. 209–10). Mr. Miller was responsible for the design and analysis of the study. The field work was subcontracted out to Crossley Surveys, an organization that designs and conducts surveys on consumer products, with Mr. Franklin B. Leonard in charge (Leonard, JTr. 83, 85–87). Mr. Leonard was responsible for selecting the sample, conducting the interviews and coding the results (Leonard, JTr. 89, 119–20). Both Mr. Leonard and Mr. Miller have extensive experience in consumer market research (Leonard, JTr. 83–86; Miller, JTr. 206–09).

The interview supervisors were carefully chosen by Crossley. They were constantly monitored, trained and provided with detailed instructions. The interviewers, selected by Crossley as well as by the supervisors, were also carefully trained and instructed (Leonard, JTr. 105–13). Crossley did the editing and coding, while the tabulations were farmed out to another organization (Leonard, JTr. 118).

Methodology: The questionnaire was not pretested inasmuch as many of questions, as well as the technique utilized, were taken from a 1963 study (Leonard, JTr. 94–95).

Personal in-home interviews were conducted of 605 analgesic users, geographically and economically dispersed throughout the country. A sex quota of an even distribution of males and females was imposed (CX 454E, Z156–Z157). The selection of the sample, termed a multistage stratified area sample, was done in several steps. It involved going from 35 primary sampling units to minor civil divisions, to blocks, to households and, finally, to one individual within a household. This systematic selection of the sample, intended

to be representative of the U.S. population in terms of 4 geographic regions and in terms of 3 sizes of standard metropolitan statistical areas and one size of all nonmetropolitan areas, resulted in about 15 to 20 interviews per sampling unit (Leonard, JTr. 95–99). The interviewers were instructed to proceed from a random starting point and travel in a specified direction; such instructions [6]were provided by Crossley, and removed as much discretion from the interviewers as possible (Leonard, JTr. 99–100). The sample, however, was not a straight probability sample and the results are not statistically projectable to the entire country (Leonard, JTr. 127–28; Miller, JTr. 261).

Call-backs were not made. The interval refusal rate was not tabulated (Leonard, JTr. 114; Miller, JTr. 260).

After a respondent was qualified as an analgesics user, a questionnaire and booklet technique was utilized to elicit the respondent's image of seven brands of analgesics (Leonard, JTr. 89–90; CX 454F). The respondents were given a notebook of 31 pages, each page containing a positive statement relating to an attribute associated with analgesics at the top and a negative statement at the bottom; they were asked to place a card for each of the seven brands into one of six pockets running from top to bottom and, thereby, to express an attitude about each brand for each attribute (Leonard, JTr. 90, 91; Miller, JTr. 215–16; CX 454D, Z155). There was an absence of a precise differentiation between the middle ranges of the six-point rating scale; whether such a middle rating indicated one or another meaning or no meaning at all could not be ascertained (Leonard, JTr. 139–41). Only the top and the two bottom gradations on the rating scale were used in the analysis with the other three ignored (Miller, JTr. 243–47, CX 454Z155). Persons who gave the same rating to all brands were classified as non-discriminators and were reported separately in the tabulations (CX 454Z155–Z156). Once the notebook part of the survey was completed, several questions relating to usage and awareness of analgesic brands were asked (CX 454D). The interviewers were required to carefully transfer the results of each interview from the notebook to a recording sheet (CX 454Z155; Leonard, JTr. 131–32).

Validation was done by the interview supervisors. Crossley also validated about 15% of the interviews, and Dancer-Fitzgerald-Sample validated an additional 10% on top of that (Leonard, JTr. 109, 115; Miller, JTr. 229–30).

CX 455 and 456 – *A Study of Vanquish's Market Opportunities*

Client: Glenbrook Laboratories, division of Sterling Drug (Pernica, JTr. 1893).

Purpose: To provide a market segmentation study, which divided consumers into groups based upon their motivations and needs with regard to analgesics; to assess the performance of Vanquish and to evaluate how it fitted into the analgesics market from a motivational perspective at the date of the study (Fishman, JTr. 1288; Pernica, JTr. 1891–92; CX 455E). [7]

Date of Study: November 1970 (CX 455B).

Background of Researchers: The study was conducted by Benton and Bowles, an advertising agency, with Mr. Joseph Pernica in charge (Pernica, JTr. 1891). Mr. Pernica was responsible for developing the methodology, study design, questionnaire, overseeing the execution of the study and reporting the results (Pernica, JTr. 1893, 1933–34). The field work was subcontracted to Lieberman Research, West, with Mr. Arnold Fishman, president of the firm, in charge (Fishman, JTr. 1281; Pernica, JTr. 1891). Mr. Fishman was responsible for carrying out the interviewing, coding and tabulations (Pernica, JTr. 1896). Both Mr. Fishman and Mr. Pernica have extensive experience in the area of consumer market research (Fishman, JTr. 1284–85; Pernica, JTr. 1887–90).

Area supervisors were selected by Mr. Fishman on the basis of past performance. The supervisors selected the interviewers. The supervisors and interviewers were provided with written instructions (Fishman, JTr. 1301–03).

Mr. Fishman's firm did the coding (Fishman, JTr. 1320–21), with Mr. Pernica involved in the approval of the codes used (Pernica, JTr. 1929). Mr. Fishman subcontracted out the keypunching and tabulations to Dataprobe (Fishman, JTr. 1321; Pernica, JTr. 1929–30).

Methodology: The questionnaire was pretested (Fishman, JTr. 1296; Pernica, JTr. 1898).

Personal in-home interviews of 827 analgesics users formed the basic sample, with an additional supplementary sample of 186 Vanquish users interviewed (CX 455F). Those respondents selected for the basic sample were from cities in "heavy-up advertising regions" of the Mid-Atlantic and West Coast; these were regions where the greatest amount of advertising dollars for Vanquish had been spent (CX 455F; Pernica, JTr. 1988–89). The basic sample was subject to a quota of 50% males/50% females. The supplementary sample came from high Vanquish share cities and was not subject to

a sex quota (CX 455F). The basic sample came from eight cities, with the intention of obtaining 100 respondents from each of the markets (Fishman, JTr. 1336, 1392; CX 455F). No weighting factors were used despite the fact that the same number of respondents was selected from cities of disparate populations (Fishman, JTr. 1397–99; Pernica, JTr. 1989).

The respondents had to be 18 years old or older (CX 455F). The sample was selected randomly. Telephone directories were used to generate initial street addresses; interviewers were instructed to go to the house next to that address and then around the block in sequence so as to control for unlisted telephone numbers (Fishman, JTr. 1298–1300; Pernica, JTr. 1926). [8]

Call-backs were not made in the event a suitable respondent were not at home (Fishman, JTr. 1392). The interview refusal rate was not tabulated.

The order of the brands was rotated in the questionnaire so as to reduce any bias that might be due to the order of presentation (Pernica, JTr. 1898).

The interviews were about 45 minutes in length (Fishman, JTr. 1294).

A six-point rating scale containing no neutral step was utilized. The sum of the two top ratings was reported so as to compress the data; the other four ratings were ignored (Pernica, JTr. 1915–18).

Validation of about 15% of the interviews was done by an outside validation service (Fishman, JTr. 1316–18, 1326).

The study contains a narrowly drawn sample and is not a national probability sample (Fishman, JTr. 1338; Pernica, JTr. 1926). Therefore, it is not statistically projectable to the entire nation (Fishman, JTr. 1357).

CX 457 – *Public Beliefs About Selected Analgesic Products*

Client: Federal Trade Commission (Leavitt, Tr. 1267; Crespi, JTr. 2267–68).

Purpose: To determine whether Anacin, Bufferin and Excedrin are each rated higher than aspirin on four attributes—effectiveness, speed, strength and gentleness (CX 457B and W; Leavitt, Tr. 1278). The study was conducted with the fore-knowledge that it would be used in litigation (Leavitt, Tr. 1270; Crespi, JTr. 2456).

Date of Study: Interviewing was conducted from December 5–10, 1975 (CX 457Q').

Background of Researchers: Dr. Clark Leavitt developed the

questionnaire and performed the analysis (Crespi, JTr. 2268). Dr. Leavitt also decided on the criteria that would be utilized in the field work (Leavitt, Tr. 1276–77). Dr. Irving Crespi, of the Gallup organization, had responsibility for the field work which consisted of conducting, recording, tabulating and coding the interviews as well as punching the results on computer cards and checking for internal consistency (Leavitt, Tr. 1290; Crespi, JTr. 2268). The sample was drawn by Gallup (Leavitt, Tr. 1288). Both Drs. Leavitt and Crespi have excellent academic [9]credentials and extensive experience in the design and execution of research surveys (Leavitt, Tr. 1245–55; Crespi, JTr. 2261–67; CX 507A–K; CX 508A–B). Dr. Leavitt was responsible for writing the report (Leavitt, Tr. 1315; CX 457).

The interviewers were regularly employed by Gallup and were given in-house training; they were provided with written instructions (Crespi, JTr. 2288–90).

The coding and keypunching were done by Gallup personnel (Crespi, JTr. 2296–2300).

Methodology: The questionnaire went through evaluation and pretesting stages by Gallup (Leavitt, Tr. 1287; Crespi, JTr. 2269–73).

Telephone interviews, approximately 10 minutes in length each, were completed for 786 persons (Crespi, JTr. 2277, 2296). Data from 780 interviews were sent to Dr. Leavitt (Crespi, JTr. 2387–88). Dr. Leavitt eliminated 17 interviews, leaving 763, because those 17 persons had not heard of one or more of the four brands (Leavitt, Tr. 1299; CX 457D).

The sample was drawn in two stages: first, utilizing current Census Bureau information and random mathematical selection procedures, a systematic sample from a random starting point with a probability of selection proportional to size was generated (Crespi, JTr. 2285–88; CX 457R–S); second, from telephone numbers arrived at in the first stage, and used as starting points, randomly selected digits were added onto the last digit of the telephone number in order to insure a representative proportion of residential listings as well as unlisted numbers (Crespi, JTr. 2282–85; CX 457Q').

The population surveyed was intended to be a national probability sample, representative of residential telephone numbers and projectable to persons 18 years of age or over with telephones (Leavitt, Tr. 1289; Crespi, JTr. 2288; CX 457D, Q').

If no one were at home, one call-back was made (Crespi, JTr. 2293). The interview refusal rate was 21.3%. From the initial sample of 2,020 telephone numbers, there were 445 invalid numbers, leaving 1,575. The interview completion rate was 49.9% (Crespi, JTr. 2294–

96; CX 1053). The interviews were conducted on weekday evenings and on the weekend in order to pick up working people (CX 457Q').

The order of the presentation of the four products (Anacin, Bufferin, Excedrin and Aspirin) was rotated so as to reduce position bias (Crespi, JTr. 2274, 2276; CX 457H). **[10]**

A four-point rating scale, with three positive steps ("extremely," "very" and "fairly") and one negative step ("not"), was used (CX 457D–F). Absolute, rather than comparative, questions were asked (CX 457F–G). There was no pretest regarding the validity of the assumption that the four attributes—effectiveness, speed, strength and gentleness—were important to consumers (Leavitt, Tr. 1333–34, 1337–40).

Approximately 8% of the interviews were validated by the interview supervisors (Crespi, JTr. 2293–94).

CX 462 – *The 1969 Excedrin Study*

Client: Bristol-Myers.

Purpose: To study primary and secondary users of Excedrin, brand image, brand switching, occasions for usage, awareness and advertising penetration, all within the context of Excedrin compared to other analgesics (Rosenbluth, JTr. 2863–64; Randall, JTr. 2986; CX 462J–L).

Date of Study: The field work was conducted from June 6, 1969 through July 20, 1969 (CX 462L).

Background of Researchers: The study was conducted by the research department of Young and Rubicam, an advertising agency, with Mr. Leon Rosenbluth in charge (Rosenbluth, JTr. 2856, 2864). Mr. Rosenbluth engaged Mr. Stanley Randall to analyze the data and write the report (Rosenbluth, JTr. 2870–71; Randall, JTr. 2981). Mr. Randall was the principal author (Randall, JTr. 2983). Grudin Appel, a market research firm, was chosen to conduct the interviews, draw the sample, and do the coding and tabulating (Rosenbluth, JTr. 2865, 2868; Nudorf, JTr. 2901); Mr. H. William Nudorf was in charge (Nudorf, JTr. 2900, 2902). Each of these individuals, and their respective companies, has extensive experience in the consumer market research field (Rosenbluth, JTr. 2855–62, 2868, 2871–73; Nudorf, JTr. 2900–01; Randall, JTr. 2978–80).

Mr. Nudorf personally selected the interview supervisors on the basis of experience. The supervisors selected the interviewers (Nudorf, JTr. 2946–47). Detailed written instructions were provided for the interviewers (Nudorf, JTr. 2906–07, 2913, 2922–31).

Grudin Appel did the coding (Nudorf, JTr. 2951). They subcontracted the tabulation to Donovan Data, a well-qualified data processing firm (Rosenbluth, JTr. 2868–69; Nudorf, JTr. 2952). [11]

Methodology: The questionnaire was put through limited pretesting to assure its utility for field work (Nudorf, JTr. 2909).

Personal, in-home interviews of 1,045 male and female analgesic users, 18 years of age or older, were conducted (CX 462L). The sample was arrived at through the use of Census Bureau information, telephone directories to generate initial addresses and mathematical and random selection of households to be interviewed (Nudorf, JTr. 2932–44, 2963–65). The study was conducted in Nielsen A and B counties which were where Excedrin had its highest market shares; these are urbanized, major metropolitan areas and make up about 66% of the country (Nudorf, JTr. 2932; Randall, JTr. 2986). Sixty geographically dispersed sampling points were used (CX 462L). In order to obtain a sufficient base of Excedrin primary and secondary users for analysis, other analgesic users were intentionally undersampled. Subsequently, the sample was statistically weighted so as to represent the population of A and B counties, yielding a total weighted sample of 1926 interviews (Randall, JTr. 2987–89; CX 462L). The resultant sample of 1926 respondents is projectable to A and B counties (that is, to urbanized metropolitan areas) (Nudorf, JTr. 2944–45; Randall, JTr. 2988, 3024, 3026–27).

Each interview ran about 50 minutes (Nudorf, JTr. 2931). The responses were recorded by the interviewers on worksheets that allowed for validation as to whether the interviewer was following the prescribed sampling procedure (Nudorf, JTr. 2943). Anyone in a household, 18 years of age or older, qualified as a respondent (Nudorf, JTr. 2966). Interviewers worked evenings and on weekends so as to pick up working people (Nudorf, JTr. 2967). There was provision for call-backs in the event no one was at home (Randall, JTr. 2987). The interview refusal rate was not tabulated.

The four brands—Anacin, Bayer, Bufferin and Excedrin—had their order of presentation rotated so as to reduce position bias (Nudorf, JTr. 2928–29).

The interview supervisors validated a portion of the interviews (Nudorf, JTr. 2948–49). Grudin Appel checked the sampling points against maps. If a discrepancy arose, then 5–20% of that interviewer's work was validated (Nudorf, JTr. 2949–50). Mr. Randall spot-checked some questionnaires, coding and tabulations (Randall, JTr. 2991–93); he excluded any data that he felt was unreliable (Randall, JTr. 2996–97). [12]

CX 467 – *Consumer Use of Headache Remedies And Knowledge Of Their Ingredients*

Client: Bristol-Myers.

Purpose: As stated in title, for Anacin, Bayer and Bufferin (CX 467C).

Date of Study: Interviewing was conducted in May 1964 (CX 467D).

Background of Researchers: The study was conducted by the Gallup Organization, with Dr. Irving Crespi in charge (Crespi, JTr. 2314, 2316–20). Dr. Crespi has excellent academic credentials and extensive experience in the design and execution of research surveys (Crespi, JTr. 2261–67; CX 508A–B).

The interviewers were regularly employed and directly supervised by Gallup; they were provided with written instructions (Crespi, JTr. 2327–29).

The coding and keypunching were done by Gallup; checking and verification were done by Gallup supervisors (Crespi, JTr. 2296–2300, 2330). The tabulation of the data was done by an outside computer service (Crespi, JTr. 2331–32).

Methodology: The questionnaire was pretested (Crespi, JTr. 2324).

Personal interviews of 1607 persons were conducted (Crespi, JTr. 2327; CX 467D). Allowance for persons not at home was made by incorporating a "times-at-home" weighting to all results, rather than by call-backs (CX 467R). The interview refusal rate was not tabulated.

The interviewers recorded respondents' answers in check boxes for closed-ended questions (Crespi, JTr. 2329). Five questions out of nine were open-ended, requiring the interviewers to record verbatim answers (CX 467C–D; Crespi, JTr. 2329–30).

Twenty to thirty percent of the interviews were validated by sending postcards to respondents (Crespi, JTr. 2330–31).

The order of questioning about each of the brands was rotated to control for any bias that might be due to the order of presentation (CX 467C–D).

The sample was intended to be a national probability sample down to the block level in urban areas and down to segments of townships in rural areas. Based upon Census Bureau data and random mathematical selection procedures, 150 different sampling areas were selected—technically, this is known as a systematic sample from a random starting point with probability proportional **[13]**to size. This sampling procedure should produce a sample representa-

tive of the adult population, 21 years of age or older, living in private households in the United States. The sample is designed to be statistically projectable to that portion of the total population (Crespi, JTr. 2326–27, 2285–88; CX 467S).

CX 468 – *Pain Reliever Telephone Study*

Client: Bristol-Myers.

Purpose: Unstated; presumably, to assess usage of and awareness of ingredients in non-prescription analgesics, focusing on users of Bufferin and Excedrin (*See* questionnaire at CX 468Z019–Z021).

Date of Study: Interviewing was conducted during the week of July 10, 1972 (CX 468C).

Background of Researchers: The study was conducted by Edward Blank Research, Inc., a market research firm (Blank, JTr. 2657–58, 2664). Mr. Edward Blank, president of the firm (Blank, JTr. 2657), has had ample experience in conducting market research surveys (Blank, JTr. 2658–63).

The field work was conducted by local interviewers who were selected by interview supervisors. The supervisors were chosen by Mr. Blank on the basis of past performance or recommendations (Blank, JTr. 2670). Both the supervisors and interviewers were provided with rudimentary written instructions (Blank, JTr. 2671–73. *See* also questionnaire at CX 468Z019–021).

Mr. Blank's firm did the coding (Blank, JTr. 2676–77). The processing and tabulations of the data were subcontracted out to Datatab. Datatab checked the coding for errors (Blank, JTr. 2678–80).

There was no analysis done of the data in CX 468 (Blank, JTr. 2681).

Methodology: The questionnaire was not pretested (Blank, JTr. 2668).

The interviews were conducted by telephone (Blank, JTr. 2666). No call-backs were made if a suitable respondent were not home. The interview completion rate was not tabulated (Blank, JTr. 2673).

The sample size was 500 interviews, 100 in each of five markets (New York, Atlanta, Chicago, Denver and San Francisco), with a quota of 40% males/60% females, regardless of their use of analgesics. 499 interviews were completed (Blank, JTr. 2665; CX 468C). The sample was systematically selected in a random [14] fashion from telephone directories (Blank, JTr. 2668–70); only listed

telephone numbers were called (Blank, JTr. 2689). The respondents had to be 18 years of age or older (Blank, JTr. 2673). The survey population is not statistically projectable to the entire country nor, in the case of the New York market, is it projectable to that entire city (Blank, JTr. 2685–86).

The interviewers and supervisors were responsible for selecting the sample (Blank, JTr. 2671–73).

There was rotation of the order of the brands in the questionnaire so as to reduce position bias (Blank, JTr. 2667).

Validation of approximately 15% of the interviews was done by an independent Watts company. Validation was done by telephone and was limited to verifying that an interview had taken place (Blank, JTr. 2674–76).

CX 477 – *Advertising Penetration Study*

Client: Bristol-Myers.

Purpose: To assess the penetration of two ideas in the "Glass Men" advertising campaign (for Bufferin)—"faster to your headache" and "gentler to your stomach" (Weitz, JTr. 911; CX 477C).

Date of Study: Interviewing was conducted in April 1971 (CX 477C).

Background of Researchers: The study was conducted by the research department of Ted Bates and Co., utilizing the services of Valley Forge Information Services ("Valley Forge"). Both Mr. Kenneth Frato, for Valley Forge, and Ms. Anne Weitz, for Ted Bates, have had extensive experience in working with consumer surveys (Frato, JTr. 717–18; Weitz, JTr. 807, 810).

The interviewers were employees of Valley Forge, thereby assuring a degree of control and supervision over the manner in which the interviews were conducted (Frato, JTr. 723). The coding and tabulation were done by Ted Bates (Weitz, JTr. 823, 826; CX 477C).

Methodology: The questionnaire was pretested (Frato, JTr. 727).

The interviews took place over the telephone (Frato, JTr. 721). As each telephone interview was taking place it could be monitored by a supervisor (Frato, JTr. 742), thereby eliminating the need for validation (Frato, JTr. 746). **[15]**

The interviewers recorded responses on call record sheets (Frato, JTr. 753). There was provision for up to two call-backs to be made (Frato, JTr. 744). The interview refusal rate was not tabulated.

Where respondents gave general answers to a question, the

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interviewer would follow-up with questions of a probing nature which tended to elicit responses (Frato, JTr. 729–31).

The survey population was intended to represent a national probability sample. Telephone numbers were randomly selected on a systematic basis from United States phone books; there were 100 sampling points across the country (Frato, JTr. 736–39, 750, 753–54; CX 477Z004). The sample was 70% female, 30% male, according to the assigned quota (Weitz, JTr. 887–89). The respondents had to be 18 years of age or older (CX 477Z004). The sample consisted of 1,004 individuals, but 125 West Coast residents were excluded (resulting in a sample of 879) because that part of the country was a test area for Bufferin and Excedrin (CX 477C). Thus, the projectability of the survey was limited to persons over 18 years of age, with listed telephone numbers, who did not reside on the West Coast (Frato, JTr. 755; Weitz, JTr. 931–32).

Opinion of the Commission

By Pertschuk, *Commissioner:*

Aspirin: homey, familiar, time-tested aspirin has long been an honored staple in the American family's arsenal against common maladies. So homey is this ingredient that it evokes no aura of mystery or magic, though indeed its therapeutic properties are significant; so familiar that the firm that pioneered its development was stripped of its trademark in private litigation 60 years ago;[1] so commonplace that a maker of one aspirin-based pain reliever seeking to differentiate its product from the rest faces a formidable marketing task. What better way to meet this challenge than to establish a new identity for the product, dissociated from ordinary aspirin, and then to represent it as special and more effective than its competitors? That effort may solve the marketer's marketing problem—but if the representations of specialness and superiority are not adequately supported, they can be, simply put, deceptive. That is the heart of the case before us.

At issue is the lawfulness of advertising claims made for Anacin and Arthritis Pain Formula (APF), two over-the-counter (nonprescription, or "OTC") aspirin-based analgesic (pain relief) products.[2] The Commission's complaint, issued on February 23, 1973 [2]against American Home Products Corporation (AHP) and Clyne Maxon, Inc. (Clyne), AHP's advertising agency for APF, charged that the respondents had violated Sections 5 and 12 of the Federal Trade

[1] *Bayer Co.* v. *United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921).

[2] Anacin's active ingredients are aspirin and caffeine; APF's are aspirin and two antacids. See *infra*, p. 5.

Commission Act (15 U.S.C. 45, 52) in making certain advertising claims as to the efficacy, freedom from side effects, and analgesic content of Anacin and APF. In particular, the complaint alleged that AHP advertised Anacin and APF without disclosing that the analgesic ingredient in these products is ordinary aspirin (Complaint ¶ 22), and that AHP had, directly or by implication, made the following claims, which were alleged to be false, deceptive or unfair:

(1) the analgesic ingredient in Anacin and APF is unusual, special, and stronger than aspirin (Comp. ¶ 8(A)(2) and 8(B)(1));

(2) Anacin contains more pain-relieving ingredients per tablet than any other over-the-counter internal analgesic (Comp. ¶ 8(A)(1)), and more than twice as much of its analgesic ingredient as any other analgesic product (Comp. ¶ 8(A)(3));

(3) a recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other OTC internal analgesic (Comp. ¶ 12(A));

(4) it has been established, or proved by scientific tests or studies by experts qualified by scientific training, that Anacin is more effective than any other OTC analgesic for the relief of headache pain (Comp. ¶ 10(A)), and as effective for the relief of such pain as the leading prescription analgesic (Comp. ¶ 17);

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

(6) Anacin relieves nervousness, tension, stress, fatigue, and depression and will enable persons to cope with the ordinary stresses of life (Comp. ¶ 15);

(7) doctors prefer and recommend Anacin for the treatment of headache pain over any other OTC internal analgesic (Comp.¶ 20);

(8) APF causes gastric discomfort less frequently than any other OTC internal analgesic (Comp. ¶ 10(B)); and its freedom from such side effects has been established (Comp. ¶ 12(B)); and

(9) APF will eliminate all pain, stiffness, and discomfort usually experienced by arthritis sufferers in the morning (Comp. ¶ 8(B)(2)). **[3]**

AHP's advertising agency, Clyne, was charged with responsibility only for the claims relating to APF.

Hearings were held before Administrative Law Judge (ALJ) Montgomery K. Hyun, who rendered an initial decision finding against respondent AHP on all allegations of the complaint except that concerning the noncomparative efficacy claim for APF (Comp. ¶8(B)(2)). The charges against Clyne were dismissed with the

exception of that relating to APF's unusual ingredient claim (Comp. ¶8(B)(1)).

Judge Hyun's order would require AHP to disclose the presence of aspirin in any OTC drug advertisement, and to disclose the presence of any commonly known ingredient in Anacin, APF or any other OTC drug product when an advertisement refers to common ingredients directly or by implication. It would also prohibit false claims that an ingredient is unusual. The order would set certain standards for comparative efficacy or side effects claims for OTC drug products: claims that the superiority of such a product has been established would be required to be supported by at least two adequate clinical tests, and other comparative ads would be required to disclose that the claims have not been proven. Misrepresentations of test or survey results would be prohibited.

The order would also bar AHP from making tension relief claims for Anacin, unsubstantiated claims that AHP's products will relieve headache pain in any period of time, and any other noncomparative efficacy or safety claim for an OTC analgesic without reliable scientific evidence. The ALJ's order would also require AHP to include in all Anacin advertising the statement "Anacin is not a tension reliever" until a sum equal to the average annual Anacin advertising budget for a certain period of years has been spent. Finally, it would prohibit Clyne from falsely representing that APF, or any other OTC analgesic, contains an unusual ingredient.

The matter is before the Commission on the appeals of respondents and complaint counsel from the initial decision and order. Respondents' principal contentions on appeal are that (1) the ALJ erred in finding that certain of the representations alleged in the complaint were made in AHP's advertising; (2) the clinical testing standard imposed by the ALJ's order for comparative claims is without support in the record; (3) the principal advertising claims are supported by adequate medical and scientific evidence; and (4) the provisions of the order are overbroad, unsupported by the record, or in violation of respondents' First Amendment rights. Complaint counsel take exception to the ALJ's failure to order corrective advertising to remedy asserted lingering effects of AHP's comparative efficacy claims for Anacin, as well as his decision not to impose liability on Clyne for all APF claims. In all other respects, complaint counsel argue in support of the ALJ's findings and conclusions. [4]

As this overview indicates, the allegations in this case primarily charge respondents with conveying the superiority of Anacin and APF over competing analgesics through a variety of allegedly misleading techniques. They are alleged to have used false claims,

deceptive omissions of material fact, and claims which were neither substantiated by the methods of proof required in the relevant scientific community nor adequately qualified to reveal the lack of such proof. In our discussion below, we will review each alleged claim or omission in turn, to determine first whether the alleged representation was made and then whether it is false, deceptive or unfair within the meaning of the FTC Act. The comparative claims will be discussed first, and then the noncomparative claims which were also challenged in the complaint.[3] **[5]**

I. *"Unusual Ingredient" Claims; Failure To Disclose Aspirin*[4]

The ALJ sustained the allegations of the complaint charging respondents with claiming falsely that the analgesic ingredient in Anacin and APF is unusual, special and stronger than aspirin (Comp. ¶ 8(A)(2) and 8(B)(1)), and with failing to disclose that the analgesic ingredient in these products is ordinary aspirin (¶ 22). AHP appeals these findings.

We note first the relevant factual background. The only analgesic ingredient in either Anacin or APF is aspirin. F.F. 387, 391. The active ingredients in Anacin are aspirin (400 mg. per tablet) and caffeine (32.5 mg.). The active ingredients in APF are microfine (micronized) aspirin (486 mg. per tablet) and two antacids (dried aluminum hydroxide gel (20.14 mg.) and magnesium hydroxide (60.42 mg.). F.F. 11, 14. Aspirin is a commonplace substance, available in many products. F. 387. Indeed, with almost 19 billion dosage units sold annually, it is the most widely used analgesic in the United States. F. 14. There can thus be no doubt about the falsity of any advertisements representing the analgesic ingredient in Anacin or APF to be unusual, special, or stronger than aspirin.[5]

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

F.	–	Initial Decision, Finding No.
I.D. p.	–	Initial Decision, Page No.
CX	–	Complaint Counsel's Exhibit No.
RX	–	Respondent's Exhibit No.
Tr.	–	Transcript of Testimony, Page No.
TROA	–	Transcript of Oral Argument Before Commission
R.A.B.	–	Respondent's (AHP's) Appeal Brief
C.C.A.B.	–	Complaint Counsel's Appeal Brief

[4] Respondents presented several arguments on appeal concerning the ALJ's methods of determining the meanings conveyed by the challenged advertisements. We have addressed those arguments fully in the Appendix attached to this opinion.

[5] As a federal court has commented, "A claim of superior analgesia for Anacin compared to [aspirin] would be nonsensical since the only analgesic ingredient in Anacin is [aspirin]." *American Home Products Corp.* v. *Johnson & Johnson*, 436 F. Supp. 785, 801 (S.D.N.Y. 1977), *aff'd*, 577 F.2d 160 (2d Cir. 1978).

While respondents do not contest the finding that such claims are false, AHP argues on appeal that its advertising did not represent Anacin's and APF's analgesic ingredient to be unusual, special, and stronger than regular aspirin. We believe the ALJ's finding that these claims were made is amply supported by the advertisements themselves as well as by expert testimony (F.F. 85–98, 171–77).

The advertising campaign for these products consisted of an attempt to differentiate them from ordinary aspirin, as respondents' witness testified (Smith, Tr. 7550–51). Indeed, that was the company's objective, according to Mr. DeMott, the president of AHP's Whitehall Laboratories Division, who had responsibility **[6]**for advertising and marketing of Anacin (DeMott, Tr. 4659). On the basis of the small actual differences in formulation between the Anacin (and APF) compounds and plain aspirin, respondents' advertisements have created an impression that the products are based on some special, unusually strong pain reliever entirely different from and superior to aspirin. Whenever aspirin is named in the Anacin ads, it is used in such a way to contrast it with Anacin and associate it with Anacin's competitors. None of the challenged Anacin advertisements discloses that the analgesic ingredient in Anacin itself is, in fact, aspirin; instead, the identity of Anacin's ingredient is in every single instance obscured with phrases like "the pain reliever doctors recommend most" and "this specific fast acting ingredient against pain."

For example, in one series of advertisements it is claimed:

> 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-45A).

In this series a scale is shown, with one side labeled "ANACIN TABLET" and the other "ASPIRIN TABLET." Other advertisements claim:

> ● Anacin isn't just like an ordinary aspirin tablet. It has more of the drug doctors themselves most choose to relieve pain (CX 173);
>
> ● anacin rushes to your head more pain reliever than the leading aspirin tablet * * * more than the leading buffered aspirin tablet * * * more of the pain reliever doctors recommend most (CX 46A);
>
> ● 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 buffered aspirin * * *. The big difference in Anacin makes a difference in the way you feel (CX 151).

The strained syntax of many of the advertisements (*e.g.*, CX 41–45A)—in which the references to Anacin's analgesic ingredient do

not appear to relate back to the word "aspirin"—fosters the impression that Anacin contains something other than [7]aspirin (Ross, Tr. 1891–92). The clear import of these advertisements is that the analgesic ingredient in Anacin is something other than aspirin (Ross, Tr. 1880, 1882, 1896).[6]

In addition, in many of the advertisements, Anacin is described as an "exceptional" (CX 26A, 28A) or "special fortified" formula (CX 89, 93–94, 115–17, 142–44, 146, 154–56), or as containing "an extra active ingredient not found in leading aspirin or buffered aspirin tablets" (CX 151). The record shows that consumers would reasonably have understood such claims to refer to an analgesic ingredient, and therefore to mean either that Anacin contains no aspirin, or that it contains something in addition to aspirin which significantly contributes to the analgesic function of the product (Ross, Tr. 1892–96; CX 404 at p. 37).

The challenged APF advertisements (CX 201–07, 210, 217–18) make similar claims by the same techniques. Through statements specifically contrasting APF's analgesic ingredient with aspirin (*e.g.*, CX 201, 203–07, 210), and representations about the "specialness" of its formulation, (*e.g.*, CX 210, 217–18,), respondents' advertising suggested that the analgesic ingredient in APF was something other than aspirin (Ross, Tr. 2303–05).

The combination of affirmative misrepresentations and consistent failure to identify the actual analgesic ingredient in Anacin and APF not only implies that something other than aspirin distinguishes AHP's products, but also has a capacity to cause consumers to believe the products do not contain any aspirin. Expert testimony in the record indicates that respondents' ads are likely to mislead consumers in this manner (*e.g.*, Ross, Tr. 1880–83, 1892–3, 1896, 2303–5). Other evidence, including testimony of experts on both sides as well as several consumer surveys, shows that a significant proportion of consumers is in fact unaware that Anacin contains aspirin. (See generally F. 402, 457–464, and CX 451, CX 452, CX 468, Shapiro, Tr. 2989–5; Moertel, Tr. 985; Stevenson Tr. 1509.) [8]

In light of these findings, we conclude that respondents' representations about the analgesic ingredient in Anacin and APF, and, in

[6] Dr. Smith, respondents' expert on advertising interpretation, stated that some consumers would have understood ads such as CX 41 and CX 173 to mean that Anacin's analgesic ingredient is something other than aspirin (Smith, Tr. 7551–53, 7557–58), although in his view the image and penetration data and the ASI studies tend to show that the representation alleged was not conveyed. As we discuss in the Appendix to this opinion, the image and penetration data provide little guidance on the meaning of the specific ads we have before us. Moreover, in our view, ASI copy tests conducted on the "extra core" ads provide confirmatory evidence of the ALJ's findings. See CX 421 at pp. 28, 30–33, 35–36, CX 422 at pp. 27, 29–30, 33, 34.

the context of these representations the failure to disclose the presence of aspirin, had a capacity to mislead consumers.[7] A misleading claim or omission in advertising will violate Section 5 or Section 12, however, only if the omitted information would be a material factor in the consumer's decision to purchase the product. *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965). Section 15 provides that an omission may be material "in the light of representations made or suggested . . . or material with respect to consequences which may result from the use" of the product.

There can be little doubt about the materiality to buyers of Anacin and APF of the fact that the unnamed analgesic ingredient is ordinary aspirin, in light of the representations made and suggested in the ads that the substance is unusual and special, described above. The very fact that AHP sought to distinguish its products from aspirin strongly implies that knowledge of the true ingredients of those products would be material to purchasers. In addition, the actual identity of the ingredient takes on particular significance due to the potentially serious consequences which may result from aspirin consumption, demonstrated by the record here. Aspirin may cause adverse side effects such as dyspepsia for some individuals (Grossman, Tr. 828; Plotz, Tr. 1044). For others, including asthmatics, a dangerous allergic reaction to aspirin is possible. (Falliers, Tr. 3187; Moertel, Tr. 1012; Stevenson, Tr. 1474). The Report for OTC Internal Analgesics (CX 367) of the Food and Drug Administration's (FDA) advisory review panel (a panel of outside experts established by FDA to review the safety and efficacy of OTC drugs)[8] summarizes the possible adverse side effects of aspirin, which range from massive gastrointestinal bleeding (which may be fatal) to hepatic (liver) [9] dysfunctions (CX 367014).[9] For example, aspirin may interfere with

[7] It has long been held that deception can occur by material omission as well as affirmative statement. See, *e.g.*, *Porter & Dietsch, Inc.* v. *FTC*, 605 F.2d 294 (7th Cir. 1979), *cert. denied* 445 U.S. 950 (1980); *Simeon Management Corp.* v. *FTC*, 579 F.2d 1137, 1146 (9th Cir. 1978); *J.B. Williams Co.* v. *FTC*, 381 F.2d 884 (6th Cir. 1967). Section 15 of the FTC Act, 15 U.S.C. 55, specifically provides that a drug advertisement may be false under Section 12 for a misleading failure to reveal material facts.

[8] For a more complete discussion of FDA's regulatory scheme, see *infra* at 20–24.

[9] Respondents' objections to the admission into evidence of the FDA Panel Reports (CX 366 and CX 367), R.A.B. at 25 n.**, are without merit. AHP contends that the reports are inadmissible because they are hearsay and are preliminary documents subject to revision. It has long been acknowledged, however, that "administrative agencies like the Federal Trade Commission have never been restricted by the rigid rules of evidence." *FTC* v. *Cement Institute*, 333 U.S. 683, 706 (1948). Under the Commission's Rules of Practice, all relevant and material evidence—whether it is hearsay or not—is admissible, as long as it is reliable. 16 C.F.R. 3.43(b). The information contained in the panel reports is unquestionably material and relevant, and we believe scientific reports prepared by groups of experts for the FDA pursuant to its regulations to be presumptively reliable. Respondent has given us no reason to doubt the trustworthiness of the findings and conclusions of the panels.

Our determination of reliability is bolstered when the exceptions to the hearsay rule are considered. The reports would fall under the well-recognized exception for public records and reports, codified in the Federal Rules of Evidence at Rule 803(8). This exception is premised both on necessity and on the inherent trustworthiness of official records. 4 *Weinstein's Evidence* ¶ 803(8)[01], at 803–189 (1979). Under this exception, and under case law developed prior to the codification of the Federal Rules, records of administrative proceedings have been admitted

(Continued)

normal blood clotting, increase internal bleeding, cause peptic ulcers, increase the incidence of neonatal deaths, depress the central nervous system, and cause anemia. For individuals with aspirin allergies, according to the Report, ingestion of aspirin may result in shortness of breath, laryngeal swelling from anaphylactic shock, blocking of air pathways, and a sudden drop in blood pressure (*id.*). **[10]**

Respondents argue that only a small number of individuals suffer these adverse side effects from aspirin consumption (R.A.B. at 65–67). The ALJ found, however, and we agree, that the number of individuals who may be adversely affected by aspirin is significant. F. 453.[10] We note that the FDA's Internal Analgesics Panel considered the problems associated with aspirin great enough to recommend that the labeling of all products containing aspirin carry an aspirin disclosure.[11] The FDA Panel also stated its agreement with the 1973 resolution of the American Academy of Allergy recommending that advertisements promoting formulations containing aspirin clearly indicate that they contain aspirin. CX 367Z028–29.[12] In addition, the Panel expressed its view that the consumer "needs to be correctly and fully informed" about OTC analgesics, and that advertising of OTC analgesics may not provide adequate warnings about their potential hazards. CX 367L. In this context, the Panel noted that the FDA does not regulate the advertising of OTC drugs, and thus requested that "the proper authority, *i.e.*, the Federal Trade Commission * * * more effectively regulate the commercial advertising of internal analgesic[s] * * * on the basis of the labeling recommendations contained in this document [the Panel's Report]." *Id.*

The ALJ also stated that the presence of aspirin is material "from an economic point of view" (I.D. at pp. 207–08), and complaint counsel argue in support of this proposition on appeal (*e.g.*, Complaint Counsel's Ans. Br. at 65). If the record contained evidence of a significant disparity between the prices of Anacin and plain aspirin, it would form a further basis for a finding of materiality. That is, there is reason to believe consumers are willing to pay a premium for

into evidence by the courts. See Weinstein, *supra* Section 803(8)[03] at 803–202. Moreover, submissions to an administrative agency from an outside person that have become part of the agency's official file have also been admitted. See *Sternberg Dredging Co.* v. *Moran Towing & Transp. Co.*, 196 F.2d 1002, 1004–05 (2d Cir. 1952); Weinstein, *supra*, ¶ 803(8), at 803–197.

[10] For example, two out of every 1,000 hospital admissions were caused by aspirin-related problems (CX 367Z022) and approximately one-eighth of all gastric ulcers are related to aspirin (CX 367Z021).

[11] The recommended disclosure would read, "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. See also CX 367(0).

[12] The American College of Allergists passed a similar resolution. Farr, JTr. 2608–12.

a product believed to contain a special analgesic ingredient, but not for a product [11]whose analgesic is ordinary aspirin.[13] The record contains no evidence on comparative prices, however,[14] and our finding of materiality is not based on the suggested economic effects.

Respondents also suggest that the labeling of OTC drugs with their active ingredients provides sufficient notice to the consumer that a product contains aspirin (R.A.B. at 64 n.**). We note first, however, that when the first contact between a seller and buyer occurs through a deceptive advertisement, the law is violated even if the truth is subsequently made known to the purchaser through information on the label. *Carter Products, Inc.* v. *FTC*, 186 F.2d 821 (7th Cir. 1951). The record is replete with evidence, moreover, including the testimony of respondents' own witnesses, that in spite of the fact that aspirin is listed on the label, many consumers are unaware of the aspirin content of Anacin, APF and other OTC drugs (F.464; Shapiro, Tr. 2984–85; Falliers, Tr. 3264; Lasagna, Tr. 4194; Moertel, Tr. 985, 1019). It is for this very reason that the FDA Panel recommended that the FTC regulate advertising of OTC drugs in accordance with the Panel's labeling recommendations (CX 367L). Finally, given that respondents' Anacin and APF advertising implied by omission and affirmative misrepresentations that the products did *not* contain aspirin, it is even less likely that labeling disclosures can be adequate in this context to alert people to the presence of aspirin in the products.

For all of these reasons, we hold that respondents' misrepresentations about the analgesic ingredient in its products, and the related failure to disclose the presence of aspirin, constitute a violation of Sections 5 and 12 of the FTC Act. [12]

II. *Comparative Efficacy and Side Effects Claims*

A. Introduction

The complaint contains two sets of allegations challenging respondents' comparative claims, discussed separately in Parts B and C below. First, Paragraphs 10 and 11 of the complaint charged that

[13] We also suspect, based on common experience in the marketplace, that a sizable price disparity between Anacin or APF and plain aspirin could in fact be shown. A comment by respondent's counsel, on oral argument before the ALJ, lends some support to this suspicion:

> Judge Hyun: You don't deny the fact that Anacin is more expensive than plain aspirin?
>
> Mr. Murphy: Than some aspirin. I have no knowledge, Judge. I know that I can buy A&P aspirin for less than I can buy Bayer aspirin. And I presume I can buy it for less than I can pay for Anacin.

Tr. 7916.

[14] An article in "The Medical Letter" which includes data purporting to show a difference between the price of Anacin and that of other aspirin-based products, including generic aspirin, was admitted into evidence. CX 363C. However, the remarks of Judge Hyun and complaint counsel at the time the article was admitted make clear that it was not received for the purpose of establishing the relative prices of the products. JTr. 2841–43.

respondents represented falsely that Anacin's superior efficacy for pain relief and APF's superior freedom from side effects (gastric discomfort) have been "established." In Part B, we consider the alleged representations of establishment (proof), the scientific view of the meaning of proof in this context, and the existence of the requisite proof.

Paragraphs 12, 13 and 14 of the complaint charged that respondents represented that Anacin is more effective, and that APF will cause less gastric discomfort, than any other OTC analgesic, without disclosing that at the time these claims were made there existed a substantial question recognized by qualified scientific experts concerning the validity of such representations. Under these charges, claims representing the superiority of AHP's products even without the use of direct references to scientific proof, research, tests or the like were alleged to be unfair or deceptive due to the existence of and failure to disclose a "substantial question." Part C below reviews this set of allegations.

Before addressing the "established superiority" and "failure to disclose a substantial question" allegations in turn, however, we must consider two arguments AHP has raised concerning exactly what comparative representations were made, as they relate to both the sets of allegations covered in Part B and Part C. Respondents contend, first, that the advertisements stating that Anacin contains more analgesic ingredient than competing products[15] did not represent that Anacin is more effective (R.A.B. at 38–39). In our view, however, there is little room to doubt the ALJ's conclusion that the references in those ads to the amount of "pain-reliever" or "pain-relieving ingredient" would reasonably have been understood by consumers as meaning that the product is more effective for relief of headache pain. See generally F.F. 71–73, and I.D. at 166–67. [13]

Respondents argue more strenuously that the ALJ erred in concluding (F.F. 66–84, 116–47, 181–89) that any claims were made for the superiority of its products over *all other* OTC analgesic products, and assert that its advertising in fact made only limited comparisons to specific products. R.A.B. at 35–39. In support of its contention, AHP cites chiefly the results of image and penetration studies. Yet as we explain more fully in the Appendix, such studies provide only limited guidance on the meaning consumers take from specific ads, and they cannot in any event establish the negative: that an individual ad did *not* convey a particular meaning.

We find that the ALJ's conclusion was correct. First, some of the

[15] See F. 66.

ads make sweeping comparisons expressly. For example, in CX 9 and CX 164 the audio portion begins as follows: "With all of the pain relievers in the world to choose from . . ."[16] The record shows that consumers could reasonably have understood this language to refer generally to all analgesics on the market. See, *e.g.*, Ross, Tr. 1879.

In other advertisements, Anacin or a characteristic of Anacin is compared favorably with "aspirin, buffered aspirin or the so-called extra-strength tablet."[17] Respondents' own expert conceded that at the time the advertisements were disseminated, all of the major OTC analgesic products fell into one of those three categories. Consequently, consumers could reasonably have interpreted the enumerated categories as an exhaustive listing of all OTC analgesics (Smith, Tr. 7503–04). [14]

In addition, in some ads Anacin's efficacy is compared with "the other leading extra-strength tablets"[18] or "any other leading headache tablet."[19] We believe that consumers could reasonably interpret these claims to mean that Anacin is better than what are otherwise the best products in the category. See Ross, Tr. 1870. While respondents' expert Dr. Smith stated that in his view it was unlikely that a significant number of consumers would understand "the other leading products" to refer to all other OTC analgesics, he nevertheless conceded that "some not insignificant number of consumers" would interpret that language to mean the best products in that product category (Tr. 7505–07). He later testified that products perceived to be "better than the best" are also necessarily perceived to be "better than all the others" (Tr. 7516).

Finally, in still other advertisements respondents claimed that tests have proven that Anacin is as effective as the leading *prescription* analgesic. CX 81–84, 105–07, 126–37, 141, 173–77, and 179. AHP has admitted that certain ads represented that tests and studies show Anacin is as effective for the treatment of headache pain as the leading prescription product. Ans. of AHP ¶ 17; Tr. 406–07. There is testimony in the record indicating that because

[16] See also CX 13A, 14A.

[17] In CX 152, for example, it is claimed:

> EXTRA POWER * * * Anacin contains the pain reliever doctors recommend most. And Anacin gives you more of this pain reliever than 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.

The same or similar language is used in, *e.g.*, CX 105, 107.

[18] For example, in CX 21A–22A it is claimed as follows:

> Two Anacin tablets have more of the one pain reliever doctors recommend most than 4 of the other leading extra-strength tablets * * *. Anacin contains more of the specific pain reliever than 4 of the others.

Substantially the same language is found in CX 1A, 9, 23A, 163–64, 170–71.

[19] In CX 20A, for example, it is claimed: "Anacin tablets have more of the one strong pain reliever doctors specify most. More than any other leading headache tablet." CX 13A–14A, 25A, 39A–40A, 142A–44A and 153A contain the same or similar language.

prescription drugs are generally perceived to be stronger and more effective than non-prescription products, consumers could reasonably understand these representations to mean that Anacin is more effective than all other OTC analgesics (Ross, Tr. 1933–34, 1937–40, 1941; Smith, Tr. 7576).

For all of these reasons, we affirm the ALJ's conclusion as to the breadth of respondents' comparative claims for Anacin.[20] In addition, the challenged advertising made claims for APF's comparative freedom from side effects (gastric discomfort) [15]using statements to the effect that its "double-buffering" makes APF gentle on the stomach. See, *e.g.*, CX 203A, 204A–206A. Consumers could reasonably have understood "double-buffering" to mean that APF has twice as much buffering as the otherwise most buffered brand in the product category (Ross, Tr. 2306–08). As even Dr. Smith conceded, many consumers (especially those suffering from arthritis) believe that buffered products are more gentle to the stomach than regular, unbuffered aspirin (Smith, Tr. 7645); the "double buffering" representation therefore suggests that APF is less likely to cause discomfort than any other OTC analgesic.

B. Proven ("Established") Superiority (Complaint ¶¶ 10 and 11)

We must determine next whether any of respondents' ads represented that the products' superiority is proven (or "established") as alleged, and, if so, what type and degree of support constitutes such proof and whether the record demonstrates that such proof exists.

1. Claims of Scientific Proof

The ALJ found that respondents represented that Anacin's superior efficacy for pain relief and APF's superior freedom from side effects (gastric discomfort) are proven or established, and that these representations were conveyed through a variety of statements referring to scientific studies and expert opinion in conjunction with references to the superiority of Anacin and APF (F.F. 132–47, 186–89). Respondents deny that any of their advertisements conveyed the alleged representations of proof (R.A.B. at pp. 34–35).

The Commission finds that many of the challenged Anacin

[20] There is no dispute that the claims of more pain relieving ingredients per tablet than any other OTC analgesic, and more than twice as much analgesic ingredient as any other OTC analgesic, are both false as alleged in the Complaint, ¶¶ 8(A)(1) and 8(A)(3). See Noncontested Issues of Fact 11 and 12 (F.F. 194, 193).

advertisements, when viewed in their entirety, did convey the message that the superiority of this product has been proven.[21] It is immaterial that the word "established," which was used in the complaint, generally did not appear in the ads; the important consideration is the net impression conveyed to the public. See *Carter Products Inc.* v. *FTC*, 323 F.2d 523, 528 (5th Cir. 1963). Many of the ads do make explicit reference to underlying medical or scientific proof.[22] For example, CX 154 claims **[16]**in pertinent part: "*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 * * * " (emphasis added). Claims such as "medically-proven Anacin" were used repeatedly.[23] This language could reasonably be understood by consumers to mean that Anacin's superior efficacy has been established as a matter of medical or scientific fact (Ross, Tr. 1926). In addition, many of the challenged advertisements cite the results of "doctors' tests," "medical reports," "scientific research," or "clinical tests," specifically announcing that the studies were performed by physicians and in some instances that the results appeared in medical journals.[24]

Each of the advertisements in this latter group also contains an express claim that the specified study or test "proves" "substantiates," "shows," or even (CX 107) proves "beyond a doubt" that Anacin is as effective as the leading prescription analgesic. As we noted *supra* at 14, consumers may reasonably understand that prescription drugs are stronger and more effective than OTC products, and therefore would reasonably understand such representations to signify that Anacin was also proven by scientific tests to be more effective than any other OTC analgesic.

Finally, the express claims are in some instances coupled with a description of the controls purportedly used in conducting the tests,[25] or references to the results of doctors' surveys,[26] **[17]**which are asserted to demonstrate a preference for Anacin's pain relieving

[21] The ALJ also found, citing only CX 204 (and 204A), that respondents made similar claims of proof for APF's comparative freedom from side effects (F.F. 186–89). The Commission does not believe that such representation can reasonably be found in these or any other APF ads in the record.

[22] See, *e.g.*, CX 81–84, 105–07, 115–17, 126–37, 141–44, 154, 176–79.

[23] *E.g.*, CX 115–17, 142–44, 149.

[24] See CX 81–84, 105–07, 126–37, 141, 173–77, 179.

[25] CX 128–30, for example, describes how the tests were performed:

> These tests were conducted by physicians who specialize in scientific research. The tests were done in a clinic of one of the nation's largest electronic plants on hundreds of men and women who often get headaches from the exacting precision work they do. Half the patients were given Anacin and the other half given the prescription. Neither the patients nor the doctor knew which tablet was given until the results were reviewed.

See also CX 141 ("clinical evidence in a double blind randomized study").

[26] CX 81–84, 176–77, 179.

ingredient. The net result in each case is an implicit suggestion that the superior efficacy claims for Anacin had been proved to the satisfaction of the medical-scientific community.

In addition to the explicit references to medical or scientific proof, AHP also used depiction of technical graphs and chemical formulas to convey the suggestion that the claimed superior efficacy claims for Anacin are supported by scientific proof.[27] For example, the video portion of CX 15A shows a series of benzene rings representing the chemical structure of aspirin. These are used in the challenged advertisement to contrast the amount of pain-reliever contained in Anacin with that contained in the "other well-known extra-strength tablet."[28] The prominent display of medical reference texts in some ads (CX 14A) reinforced the suggestion that the claims rest on medical evidence or authority. Respondents' own expert testified that consumers believe that medical treatises are based on scientific evidence (Smith, Tr. 7589–90).

Similar advertising techniques have previously been held to imply the existence of scientific proof. For example, in *Porter & Dietsch, supra*, 90 F.T.C. at 865, we found that explicit references to clinical tests were used to convey [18]the suggestion that claims of weight loss for users of the diet tablets at issue in that case were substantiated by "competent scientific proof." On the other hand, in *Pfizer, Inc.*, 81 F.T.C. 23 (1972), complaint counsel argued that certain advertising claims for "Unburn" contained implied representations of scientific proof, but we upheld the ALJ's finding that the implied representations of scientific testing had not been made. In that case, however, we noted specifically the respondents' argument that "the total setting of the ad, the frivolous nature of the dialogue, the use of a bikinied model, and the general 'aura of sexiness' prevent the ad, taken as a whole, from carrying the scientific overtones argued by complaint counsel." *Pfizer, Inc., supra*, 81 F.T.C. at 59. AHP's advertising of Anacin is easily distinguished. As we described above, some of AHP's ads expressly referred to scientific or medical proof, and others used imagery strongly suggesting scientific

[27] Nonverbal images such as pictorial elements and graphics are capable of conveying deceptive advertising messages. *ITT Continental Baking Co.*, 83 F.T.C. 865, 959–60 (1973), *modified on other grounds*, 532 F.2d 207 (2d Cir. 1976).

[28] Other advertisements, aired after the complaint issued (CX 50A–54A, CX 56A–58A, and CX 61), display a form of graph superimposed on a profile of the headache sufferer, which purports to measure levels of aspirin in the blood and to reflect the comparative efficacy, in terms of speed and strength, of Anacin, buffered aspirin, and plain aspirin. The record shows that at least some consumers would understand the claim regarding the differences among pain relievers in the bloodstream to be based on authoritative medical opinion (Ross Tr. 1924–25) or scientific tests (Smith, Tr. 7588–89). In some of these advertisements, a figure dressed as a doctor or pharmacist, or seated in what appears to be a professional office, uses the graph or formulas to explain why Anacin is more effective than its competitors. Verbatim comments recorded in one ASI copy test document the tendency of consumers to perceive the spokesperson in such an ad as a doctor or pharmacist (see CX 425 at p.27).

or medical support. Reading these ads, as we must, for their total or general message to the consuming public, we conclude they contain a claim that Anacin's superior efficacy is proven by competent scientific evidence.

2. Requisites of Scientific Proof

The record reflects no real dispute as to the type of evidence scientists require before they regard it as having been proven (established) that one drug is more effective than another. Complaint counsel and respondent called numerous expert witnesses on the issues related to medical and scientific substantiation of the claims made in the advertisements. From their testimony, it is clear that at least since the early 1950's well-controlled clinical testing (*i.e.*, the observation and analysis of pain and relief in patients suffering actual pain) conforming in design and execution to generally recognized criteria have been required to establish or prove absolute or relative drug efficacy (Azarnoff, Tr. 600–01; Moertel, Tr. 942–43, 956–57, 1021–25, 1028; DeKornfeld, Tr. 2777–78, 2780–81, 2785–86; Lasagna, Tr. 4119, 4142-44, 4177–78; Forrest, Tr. 447, 449–50, 472–73; Rickels, Tr. 1228–29; Wallenstein, Tr. 3490). The use of generally recognized standards serves to reduce the chance of systematic bias entering into clinical studies (Moertel, Tr. 943–44; DeKornfeld, Tr. 2778–79; Lasagna, Tr. 4142).

Experts in the field of clinical testing of analgesics are generally agreed on the requisites of a well-designed clinical study (Azarnoff, Tr. 463). Pre-existing bias toward the tested product on the part of the subjects or those involved in the execution of the study must be eliminated. To this end, the well-designed clinical study should be double-blinded—that is, neither the subjects nor those conducting the study should be able to identify the test drugs until preliminary analysis of the data is complete [19](Forrest, Tr. 444, 457–58; Moertel, Tr. 948; DeKornfeld, Tr. 2778–82; Wallenstein, Tr. 3488; Lasagna, Tr. 4123, 4126, 4128).[29] The record shows that the expectations of both subjects and observers can affect the amount of relief obtained from the tested drug, and that this is a major source of bias in clinical testing (DeKornfeld, Tr. 2782). Pre-existing bias toward the tested product is a particularly significant factor in working with OTC analgesics, which are readily identifiable by color, shape, or other distinctive attributes (DeKornfeld, Tr. 2782). Random distribution of the subject population among treatment groups

[29] In some instances (*e.g.*, a study of acupuncture), a double-blinded study may not be possible. It is critical, however, in comparative studies involving subjective response information (Forrest, Tr. 554–55).

further balances out variables and biases not otherwise controlled for (Forrest, Tr. 444; Azarnoff, Tr. 601; Wallenstein, Tr. 3488; Lasagna, Tr. 4123). The development of a written protocol, which sets out in advance the purposes of the study, the number and types of patients to be studied, the parameters to be evaluated, and the analytic techniques to be used in evaluating the results, protects against biases which might develop during the course of execution or analysis through manipulation of the data (Azarnoff, Tr. 604–05, 605–09, 643; Moertel, Tr. 947–48, 952; DeKornfeld, Tr. 2778–2783; Lasagna, Tr. 4124, 4858–59).

The record also shows that the customary practice in drug comparison studies is to require a pharmacologically inactive treatment (placebo control) as a direct measure of test sensitivity. Placebo control is particularly important in the case of analgesic studies because a subjective response like pain relief is highly susceptible to influence by the subject's expectations (Okun, Tr. 4419). In clinical studies of mild to moderate pain, the rate of positive response to a pharmacologically inactive rate has been as high as 60% (Forrest, Tr. 496; Lasagna, Tr. 431–33). The inert substance serves as a control for perceived pain relief based on expectations alone, or attributable to the self-limiting nature of mild to moderate pain (Forrest, Tr. 444, 446, 459–61; Azarnoff, Tr. 605–06; Moertel, Tr. 950; DeKornfeld, Tr. 2785; Lasagna, Tr. 4128, 4130, 4134).[30]

In addition, if the objective is to determine comparative drug efficacy, the tested products should be evaluated in the same study (together with a placebo). Without such head-to-head studies, the investigator is unable to determine whether products vary from each other to a significant degree (Azarnoff, Tr. 605–06). Finally, scientists have historically required the results of clinical studies showing a difference among drugs to be statistically significant to the 95% level of confidence. This insures that the likelihood of the results being attributable to chance will not be greater than 5% (Forrest, Tr. 456; Azarnoff, Tr. 608; Moertel, Tr. 954–55; DeKornfeld, Tr. 2784; Lasagna, Tr. 4136–37; Okun, Tr. 4420). **[20]**

The record shows that a minimum of two clinical trials conforming in design to the aforementioned criteria and reaching the same conclusions and statistical significance is required to establish comparative drug efficacy. (Forrest, Tr. 449–50; Azarnoff, Tr. 601, 609–10; Moertel, Tr. 942, 956–57; DeKornfeld, Tr. 2778, 2780–81; Lasagna, Tr. 4142–44). The two-test minimum further reduces the

[30] The potential impact of the placebo effect and the self-limiting nature of some ailments have been previously recognized by the Commission. *Warner-Lambert Co.*, 86 F.T.C. 1398, 1495–96 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

chance that any observed therapeutic value is attributable to factors other than the pharmacologic activity of the tested drug. Even in the most meticulously planned study, unknown factors that the investigator simply could not have recognized could be operative (Moertel, Tr. 956–57). Dr. Azarnoff, explained:

> One reason is to reduce the chance that there was any systematic bias in the study. That is, if you do a study in Los Angeles in a certain group of subjects, there may be something inherent in those subjects either because of the region in which they live, genetic background, environmental factors, a variety of other things, which would not be picked up because it is systematically occurring throughout all subjects. [Tr. 610–11.]

Finally, since ultimately the test of analgesic efficacy is established by the subject's response, at least one of the required studies should be conducted on the type of pain for which the superior efficacy claim is being made. Because scientists do not fully understand the mechanism by which trauma evokes pain, they are not comfortable about extrapolating from one pain situation to another, or from experimental pain models, which employ artifically induced pain, to a clinical situation (Forrest, Tr. 443–44, 447–49; Azarnoff, Tr. 610–11; DeKornfeld, Tr. 2778–80; Lasagna, Tr. 4144–45).

The criteria testified to by the expert witnesses in this proceeding are fully consistent with and reflected in regulations adopted by the Food and Drug Administration (FDA) to implement the congressional policy of drug regulation that was mandated in the 1962 amendments to the Food, Drug, and Cosmetic Act of 1938 (52 Stat. 1040).[31] The Drug Amendments of 1962 (Harris-Kefauver Act) **[21]** (Pub. Law No. 87–781, 76 Stat. 780), modified the 1938 Act to prohibit the introduction into commerce of "new drugs" not generally recognized by qualified experts to be effective (as well as safe) for their indicated uses.[32] (See 21 U.S.C. 321 (p)(1).) The Act requires that a new drug application (NDA) be filed with the FDA before a new drug is marketed, and the FDA is now directed to refuse approval of an NDA in the absence of "substantial evidence" that the drug is effective for its indicated uses. (21 U.S.C. 355(d) and (e)). "Substantial evidence" is defined in the Act to mean:

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[31] The FDA and the FTC of course share authority over representations about the efficacy of drugs. Although it is often stated that the FDA has authority to regulate drug labeling and the FTC has authority to regulate drug advertising, the jurisdiction in fact overlaps. The FTC has authority to challenge false or misleading labeling (*Houbigant* v. *FTC*, 139 F.2d 1019 (2d Cir.), *cert. denied*, 323 U.S. 763 (1944)), and under certain circumstances the FDA may challenge representations made in advertising (*Alberty Food Products Co.* v. *United States*, 185 F.2d 321 (D.C. Cir. 1950)). In practice, however, pursuant to a liaison agreement between the two agencies, the FTC has assumed primary responsibility for advertising and the FDA for labeling. 36 FR 18539 (1971).

[32] The Act does not define what constitutes "general recognition" among experts, but it has been held to require "substantial evidence," the meaning of which is discussed in the text. See also n.[59] at p. 35, *infra*.

evidence consisting of *adequate and well-controlled investigations, including clinical investigations*, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling thereof.

Section 505, 21 U.S.C. 355(d)(1976) (emphasis added).[33] **[22]**

The legislative history of the 1962 Amendments, fully reviewed in *Pharmaceutical Manufacturers Assn.* v. *Richardson*, 318 F. Supp. 301 (D. Del. 1970), demonstrates Congress' judgment that it was imperative to require an objective determination—based on reliable scientific evaluation, not anecdote or uncontrolled study—not only that a drug is "safe" but that it produces the results claimed for it. One concern, for example, was that ineffectual treatment can lead to delays in receiving proper medical care.[34] As summarized by the Supreme Court, "The hearings underlying the 1962 Act show a marked concern that impressions or beliefs of physicians [about the efficacy of a drug], no matter how fervently held, are treacherous." *Weinberger* v. *Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 619 (1973).

To implement the congressional policy, the FDA has promulgated regulations which embody the essential principles of "adequate and well-controlled clinical investigations," and provide the basis for the statutory determination whether there is "substantial evidence" to support drug efficacy claims. In the FDA's own words, the criteria established by the regulations "have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations." 21 C.F.R. 314.111(a)(5)(ii). They include: (1) a clear statement of the objectives of the study; (2) a method of subject selection which minimizes bias, assures suitability of subjects, and assures comparability of pertinent variables; (3) an explanation of observation and

[33] The Act contains grandfather clauses that exempt certain drugs which were subject to the Food and Drug Act of June 30, 1906, and certain drugs which were in use prior to the 1962 Amendments, from the premarket clearance requirement. (21 U.S.C. 321 (p)(1)(1976); 21 U.S.C. 321 note (1976)). As AHP points out (R.A.B. at 22), the principal ingredient in Anacin and APF (aspirin) is an "old drug" which is not subject to the efficacy requirements of the Food and Drug Act. However, to fall under the first grandfather clause AHP would have to show that as to the drug marketed earlier the "labeling contained the same representations concerning the conditions of its use" as Anacin's, 21 U.S.C. 321 (p)(1), and to fall under the second grandfather clause Anacin would have to be "intended solely for use under conditions prescribed, recommended or suggested in [the] labeling" of the earlier drug, 21 U.S.C. 321 note. Moreover, aspirin combination drugs such as Anacin and APF have been subject to the OTC drug review procedures under FDA regulations. See *infra* at p. 28.

In any event, our use of the Food and Drug Act standards here as a benchmark against which to measure the adequacy of AHP's proof of efficacy does not require a determination that Anacin and APF are subject to the efficacy requirements of that Act.

[34] See, *e.g.*, comments of Sen. Kefauver (chief sponsor of the 1962 Amendments) regarding the dangers of using a drug that does not produce its purported therapeutic effects. 107 Cong. Rec. 5640 (1961). See also *United States* v. *Rutherford*, 441 U.S. 903 (1979).

recording methods, including steps taken to minimize bias on the part of the subject or observer; (4) a comparison of results with a control, in such a way as to permit quantitative evaluation; and (5) a summary of methods of analysis and an evaluation of data, including any appropriate statistical methods. (21 C.F.R. 314.111(a)(5)(ii)(a).)[35]

The requirement that at least two adequate tests be conducted is also consistent with FDA standards. Ordinarily, reports from more than one independent investigator are required to establish "substantial evidence" of drug efficacy. The applicable regulation provides in pertinent part: [23]

> b. An application may be refused unless it includes substantial evidence consisting of adequate and well-controlled investigations including *clinical investigations*, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved * * *.
>
> * * * * * * *
>
> c. Ordinarily, the reports of clinical studies will not be regarded as adequate unless they include reports *from more than one independent, competent investigator* who maintains adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated and comparable records on any individuals employed as controls.

21 C.F.R. 314.1(b)(1980) (emphasis added).

The criteria for establishing efficacy were reaffirmed in the FDA procedures adopted in 1972 for reviewing the safety and efficacy of OTC drugs already on the market (21 C.F.R. 330 (1979)). The FDA established a drug review program, utilizing advisory review panels of outside experts to evaluate the safety and efficacy of OTC drugs, to review OTC drug labeling and to propose monographs establishing conditions under which OTC drugs are generally recognized as safe and effective (21 C.F.R. 330.10(a)(I)). The FDA issued general safety, efficacy, and labeling standards to be used by the panels in evaluating the data. The FDA-mandated standard of efficacy for panel review of OTC drugs provides:

> *Proof of effectiveness shall consist of controlled clinical investigations as defined in ¶314.111(a)(5)(ii) of this chapter*, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. [24]

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[35] A petition for waiver of any or all of these criteria may be filed under 21 C.F.R. 314.111(a). See discussion *infra* at p. 52.

Effective December 26, 1979, the same standards—requiring substantial evidence of drug efficacy and safety based on adequate and well-controlled studies as defined in Section 314.111 (a)(5)(ii)(a)—were made applicable to indication-for-use claims in labeling for prescription drugs and also to comparative safety and efficacy claims made in prescription drug advertising (44 FR 37434, 37466–67 (June 26, 1979)).

21 C.F.R. 330.10(a)(4)(1980) (emphasis added).[36]

The advisory panel on OTC internal analgesics has specifically commented on the design of clinical studies used to evaluate analgesic drugs, and the criteria are substantially the same as those recognized by the expert witnesses in this proceeding. CX 367Z074-75. Significantly, establishment of "Category I" status (generally recognized as safe and effective) for a "Category III" compound (drugs for which the available data are insufficient to permit final classification), requires at least two studies by independent investigators conforming in design to the standards previously described. CX 367Z075.[37] **[25]**

3. Existence of Scientific Proof

To summarize, we have found that AHP made claims in its advertisements that Anacin's superiority over other OTC analgesics for pain relief has been proven or established by evidence considered adequate in the relevant medical and scientific community. We have also found that the scientific community requires at least two adequate, well-controlled clinical studies, meeting certain specific criteria, for proof of OTC drug claims, and that these standards are reflected in the statute and regulations under which the FDA reviews OTC drug claims. We must next determine whether Anacin's purported proven superiority has in fact been established by the requisite clinical tests.

Respondents first contend that the two studies performed by Dr. Gilbert McMahon (RX 31) "satisfy even the 'establishment' theory of substantiation," because they are two "adequate and well-controlled [clinical studies] demonstrating Anacin's superior efficacy to regular aspirin tablets" (R.A.B. at 48). We disagree, and affirm the ALJ's conclusion that the studies were so seriously flawed that they did not establish Anacin's superiority.

The McMahon studies purported to be head-on comparisons of the

[36] The FDA's statutory and regulatory requirements outlined here have been judicially upheld, as constituting an expression of well-established principles of scientific investigation." *Weinberger* v. *Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 617-19 (1973). There is no basis, moreover, for AHP's assertion that FDA's substantiation requirements for OTC drugs are in any respect lower than its requirements for prescription drugs (R.A.B. at 23). (The statements of former FDA Commissioner Edwards cited by respondent appear to reflect mainly his views that evaluation of prescription drugs should have a higher priority within FDA, and that a drug-by-drug approach to OTC drugs—as opposed to the type of review undertaken by the panels—appeared impractical. If Commissioner Edwards did believe the substantiation standards for the two classes of drugs should differ, that view is not reflected in any statute or regulation.)

[37] The portion of the FDA regulations that permits Category III drugs to be marketed (21 C.F.R. 330.10(a)(13)) was declared to be unlawful in 1979 because it was in conflict with the provisions of the Food and Drug Act. *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The FDA has published a proposed revision to its regulations in response to this decision, which would delete Category III from the regulatory scheme (45 FR 31422 (1980)). The revision, which is not yet final, would not affect the standards for proof of efficacy. *Id.*

efficacy of Anacin and generic aspirin (RX 31A). The first study compared the effects of an aspirin-caffeine preparation similar to Anacin with those of generic aspirin on two types of moderate to severe post-partum pain: uterine and episiotomy pain (RX 31B). The second made the same comparison for severe uterine or episiotomy pain (*id.*). The ALJ did not credit the testimony of Dr. McMahon (McMahon, Tr. 3771) and other experts (Lasagna, Tr. 4938; Okun, Tr. 4352), that the studies demonstrated Anacin's superiority to aspirin (F. 318–20).

Several defects in the McMahon studies prevent them from providing adequate substantiation for claims of Anacin's established superiority.[38] First, neither study reached statistical significance for the entire group tested (F. 318–19). The first test did not produce statistically significant results for patients suffering from *either* type of pain, and the second did not do so for those afflicted with uterine cramping pain (*id*; McMahon, [26]Tr. 3752, 3887; Okun, Tr. 4525).[39] Second, the aspirin-caffeine combination tested against aspirin was not shown to be equivalent to Anacin in its commercial form (McMahon, Tr. 3838–39; F. 296). It is thus not clear that a test of Anacin itself would achieve similar results, since a different compound could behave differently.

Third, the effects of a particular analgesic on one type of pain are not necessarily the same as its effects on another kind of pain (F. 314). The record establishes that the particular pain for which an analgesic is intended should be used as a model in at least one of the studies conducted to establish the analgesic's efficacy (*e.g.*, Forrest, Tr. 44344; Azarnoff, Tr. 610–11; F. 204),[40] and respondents' witnesses admitted that headache pain is different from other kinds of pain (*e.g.*, Lasagna, Tr. 4148). For example, because headache pain is ordinarily self-limiting (McMahon, Tr. 3823), relief of headache pain may or may not be due to consumption of an analgesic. In addition, it is not known whether headache pain is a cramping pain (similar to

[38] In addition, we note that these tests could not show that respondents possessed and relied upon a "reasonable basis" for their claims, as respondent has asserted (*e.g.*, R.A.B. at 42), because they were conducted well after the claims had begun to be disseminated (indeed, after the commencement of this litigation). See *infra* at 40, n.[63].

[39] Even the statistically significant results for severe episiotomy pain of the second test are questionable. The study was terminated as soon as statistical significance was reached; if the study had been permitted to continue for the full length of time specified in its protocol, the results might have been different. Although Dr. McMahon testified that terminating a study when statistical significance is achieved is a commonly accepted practice (McMahon, Tr. 3843), Dr. Lasagna (one of respondent's own experts) did not agree (Lasagna, Tr. 4863).

[40] Respondents' witness, Dr. Lasagna, testified that post-partum pain is a valid model for the study of oral analgesics (Lasagna, Tr. 4055), but later stated that certain kinds of drugs may be better for certain kinds of pain than for others (Lasagna, Tr. 4068). Even assuming that results from tests involving post-partum pain can be extrapolated to headache pain (*id.*), such extrapolation remains an inference, and not established scientific fact. (See F. 317.)

uterine cramping pain) or a constant pain (like epistiotomy pain) (Lasagna, Tr. 4883).

For all these reasons, the studies did not establish Anacin's superiority over aspirin for relief of headache pain. Nor is there any basis in the record for finding Anacin to be more effective than other OTC analgesics, as the ads represented, as no clinical studies were conducted to support such a claim.

Respondents also assert, however, that "the aspirin dose response curve" proves that Anacin is more effective than regular aspirin tablets (R.A.B. at 43). A dose response curve is established by plotting points on a graph representing the average degree of pain relief (according to data from clinical studies) corresponding to different dosages of a drug, and drawing a line through the points. F.F. 226–27. Respondents argue that because the ascending shape of the dose response curve for aspirin indicates that more aspirin produces greater pain relief at some dosages, and because Anacin (with 800 mg. of aspirin) contains [27]150 mg. more aspirin per dose than common five-grain aspirin, Anacin is shown to produce more pain relief than aspirin. We believe, however, that while the dose response curve is recognized by most clinicians as useful for predicting the efficacy of a particular dosage (F. 229), for several reasons it cannot be said to establish scientifically Anacin's superiority over aspirin.

First, every point on the curve has not been scientifically established; rather, the curve is created by a series of inferences. Most of the points on the curve are in fact estimates, which are extrapolated from the few points that have been established by clinical studies (Kantor, Tr. 3572; Lasagna, Tr. 4273; DeKornfeld, Tr. 2816–17). Thus, a given dosage may or may not relieve pain to the extent indicated by the curve.[41] Even respondents' experts testified that points on the curve that have not been placed by actual studies cannot be said to have been established in a manner that is statistically significant (McMahon, Tr. 3933; Okun, Tr. 4475–76).

But more significant for our purposes is the fact that even assuming that the curve as a whole has been established, the evidence indicates that above 600 mg. the curve is either very shallow or levels off to a plateau (Kantor, Tr. 3573; Lasagna, Tr. 4881).[42] In other words, a substantial increase in dosage is necessary to produce even a small increase in pain relief (Kantor, Tr. 3573; Azarnoff, Tr. 642; F. 257), yet Anacin contains only 150 mg. more aspirin than common aspirin. Indeed, several dose-response studies

[41] F. 228–342.

[42] See F. 244–256.

showed *no* statistically significant differences in pain relief for dosages greater than 600 mg. (F. 246–55). Thus, the aspirin dose response curve cannot establish the superiority of 800 mg. of aspirin over 650 mg.,[43] or, consequently, the superiority of Anacin over aspirin (or other analgesic products).[44] **[28]**

Finally, we have determined (*supra* at p. 14) that respondents' claim of established superiority was also made implicitly through a claim that Anacin is as effective as the leading prescription pain reliever, which was Darvon Compound 65. Respondents offer as substantiation the results of two studies conducted by Dr. Lay (CX 301) and Dr. Teschner (CX 302). Neither of these studies, however, is adequate to establish that Anacin is as effective as Darvon Compound 65. The Lay study was flawed because it was not properly double-blinded (CX 301G; see Forrest, Tr. 508). The Teschner study was not double blinded (CX 302C), and did not include a placebo (Lasagna, Tr. 4200–01; DeKornfeld, Tr. 2792). Expert witnesses for both complaint counsel (Moertel, Tr. 970, 972; DeKornfeld, Tr. 2792–92; Forrest Tr. 508) and respondents (Lasagna, Tr. 4200–01; Okun, Tr. 4431) concluded that both studies had significant drawbacks.[45]

In sum, in view of the absence of adequate testing, Anacin's superiority has not been established. Where advertising representations reasonably lead consumers to understand that the claims are supported by adequate scientific testing, the claims must be documented by scientific tests. *Porter & Dietsch* v. *FTC*, 90 F.T.C. 770, 865–72 (1977), *aff'd*, 605 F. 2d 294 (7th Cir. 1979), *cert. denied* 445 U.S. 950 (1980); *National Dynamics Corp.*, 82 F.T.C. 488, 560–61 (1973), *aff'd in part, remanded on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974). AHP's advertisements conveying an unmistakable claim of proven or established superiority for Anacin are therefore false and deceptive, and constitute a violation of Sections 5 and 12 of the FTC Act. **[29]**

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[43] It is of course possible that for some individuals, an 800 mg. dosage of aspirin may provide greater relief than 650 mg. (see F. 258), but this proposition has not been established for the population as a whole, or even the average individual.

[44] As the ALJ pointed out, the fact that Anacin also contains caffeine could conceivably affect Anacin's dose response curve as compared to that of aspirin (F. 261), but there is no reason to expect the caffeine to improve pain relief since caffeine is not an analgesic (CX 367Z112).

[45] Moreover, even if Anacin were proven to be as effective as Darvon Compound 65, that would not necessarily establish Anacin's superior efficacy over other OTC drugs (Lasagna, Tr. 4202; Okun, Tr. 4436; DeKornfeld, Tr. 2794; Moertel, Tr. 978). There is some evidence indicating that regular aspirin is actually as effective as Darvon Compound 65 (*e.g.*, CX 360A (Moertel study published in *New England Journal of Medicine*); DeKornfeld, Tr. 2820). The American Medical Association's *Drug Evaluations* (a reference book for doctors with current information on drug uses and effects, CX 362N; see also Moertel, Tr. 990) states that Darvon is probably no more effective than aspirin (CX 362P). Thus, it is not clear that Anacin, even if it worked as well as this Darvon compound, would necessarily perform better than its aspirin-based competitors.

C. Failure To Disclose Existence of a Substantial Question (Complaint ¶¶ 12, 13, 14)

As we noted earlier, a second category of allegations is contained in Paragraphs 12, 13 and 14 of the complaint. The complaint alleges that in some advertisements respondents made affirmative and unqualified representations of Anacin's superior efficacy or APF's freedom from side effects[46] which, unlike the advertisements discussed in Part B above, are unembellished with specific references to underlying scientific proof or tests, or other clear indicia of scientific or medical evidence (graphs, charts, treatises, etc). See, *e.g.*, CX 1A, 9A, 20A–25A, 38A, 39A, 89A, 90A, 92A–97A, 99A, 100A, 121–24A, 160A–64A.[47] It is alleged that such advertisements are deceptive or unfair because of their failure to disclose that the claims are open to substantial question (Comp. ¶ 25). The ALJ sustained these allegations. For the reasons given below, we find that such advertisements have a capacity to deceive.

When an analgesic advertiser claims its product to be superior in performance, even without the additional explicit claim that it has been so proven, it is reasonable for consumers to construe that claim to be the assertion of a fact that is generally accepted, within the scientific community, as established. By their nature, therapeutic drug products raise special public health concerns, in light of the [30] risks associated with their use.[48] Harmful side effects present the most obvious danger. Other risks attending inappropriate consumption of drugs include the possibility that the consumer will forego other, necessary treatment for a medical condition, or will consume in unsafe doses an otherwise harmless product.[49] It is these latter concerns that underlay the passage in 1962 of the amendments to

[46] We explained above in Part A why we concluded that respondents' claims about the quantity of analgesic ingredient in Anacin and APF did constitute comparative efficacy claims, and that respondents' claims did compare its products to all other OTC analgesic products.

[47] Many of the ads in this category do mention briefly that "doctors recommend" or "doctors specify" Anacin's pain reliever, without any other references to or symbols of medicine, science or proof. While we believe that these indications of medical approbation can contribute somewhat to an aura of scientific authority, they do not, standing alone, constitute quite the same sort of direct, forceful representation of scientific proof as is conveyed by the techniques described *supra* at pp. 15–18. See Smith, Tr. 7587–88.

[48] See Sections 12, 13(a) and 15 of the FTC Act, under which the Commission has specific authority to seek to enjoin the dissemination of false drug advertising, and the legislative history attending passage of those provisions. Senator Wheeler commented, for example, "We are more strict with the advertising of foods, drugs, devices and cosmetics because their effect is direct and their use might endanger life." 83 Cong. Rec. 4435–36 (1938). The enactment and legislative history of the Federal Food, Drug, and Cosmetic Act, as amended, 52 stat. 1040, and the regulatory scheme that Act imposes on the marketing of OTC as well as prescription drugs, also establishes unequivocally the Congressional concern in this area. See, *e.g.*, Hearings on S. 1552 before Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong. We note, further, that in a recent judicial decision involving AHP and its representations of the superiority of Maximum Strength Anacin, the court took into account the fact that the claims had a bearing on matters of public health. *McNeilab, Inc.* v. *American Home Products Corp.*, 79 Civ. 3973, slip op. at 30 (S.D.N.Y., filed July 21, 1980).

[49] See discussion of the evidence adduced in this proceeding concerning the risks associated with aspirin, *supra* at pp. 8–10.

the Federal Food, Drug and Cosmetic Act requiring "substantial evidence" to demonstrate drug effectiveness claims, as we have described *supra* at 22. When the nature of a product is such that it gives rise to a serious safety concern, advertisers are held to a high standard of care, in order to assure to the greatest extent possible that their claims will not be misunderstood by the public. See *Firestone Tire and Rubber Co.*, 81 F.T.C. 398, 456 (1972), *aff'd* 481 F. 2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 112 (1974).[50]

In addition, the effects of many drugs, including analgesics, are such that while it is possible to verify objectively the consequences of their use, the ability to do so lies peculiarly within the power of the manufacturer; that is, the producer is uniquely equipped with the facilities and expertise necessary to ascertain reliably the drug's effects, or the comparative effects of two drugs, by controlling for the placebo effect and other spurious factors. (See discussion *supra* at pp. 18–24 concerning the requisites of meaningful scientific substantiation of claims that one analgesic is superior to another.) [31]

Under these circumstances, we find that when an advertiser has made unequivocal, unqualified claims about a drug product's effects, particularly in an intensive, long-running campaign,[51] consumers may be led to expect, quite reasonably, that the claims are supported by meaningful evidence, of the sort that would be likely to satisfy the relevant scientific community.[52] While some consumers may be skeptical, and treat all objectively verifiable representations in advertisements as mere expressions of the advertiser's opinion rather than as generally accepted facts upon which a rational purchasing decision may confidently be based, we doubt that advertising could long remain the powerful method of communication that it is were such an attitude common to the large majority of consumers.[53] In short, advertisements are an important source of decision-guiding information because many consumers assume that when advertisements make unqualified assertions of fact, those

[50] We note that in *Firestone* some of the claims directly involved the safety of the respondent's tires while others did not, and the Commission's order required cessation of any "safety or performance" claims unless "fully and completely substantiated by competent scientific tests." 81 F.T.C. at 475.

[51] See discussion *infra* at 58–60 concerning the evidence indicating that the extensive promotion of Anacin as a stronger, faster and otherwise better pain reliever has created a widespread belief in the product's superiority over other brands. See also *infra* at 48 for reference to the ALJ's findings on the extent of dissemination of the claims.

[52] In addition, consumers may reasonably believe that the marketing of therapeutic drugs is closely regulated by the government, and that scientific standards of substantiation are thereby imposed. See *Simeon Management Corp.*, 87 F.T.C. 1184, 1230 (1976), *aff'd*, 579 F.2d 1137 (9th Cir. 1978). We note that the same scheme of regulation to which both the Commission and the court referred in *Simeon* applies to the over-the-counter drugs at issue in the present case. See *supra* at 24, n.[36].

[53] Respondent conceded in its brief on appeal that consumers may infer from a "straight and unembellished comparative performance claim" that the advertiser's evidence "would be acceptable to responsible medical experts." R.A.B. at 35. Moreover, respondent's expert witness testified that consumers are likely to expect a higher level of support for claims about drug products than for claims about other products. Smith, Tr. 7586.

assertions are, indeed, not open to substantial question. *National Comm'n on Egg Nutrition*, 88 F.T.C. 89, 197–98 (1976), *aff'd and ordered enforced as modified*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Sears, Roebuck & Co.*, Docket No. 9104 (April, 1980), slip op. p. 16, *appeal pending*, No. 80–7368 (9th Cir.).

Thus, AHP's advertising representations have a capacity to lead consumers to believe that the superiority of Anacin and APF has been established in the manner customarily [32]required by the scientific community.[54] And it follows that if such an unequivocal assertion is in fact open to substantial question—a matter to which we will turn in a moment—then the failure to disclose as much constitutes the misleading omission of a material fact.[55]

That the fact omitted is material, and its omission misleading, is evident from consideration of the difference in persuasive impact between the following two claims:

1. Anacin is more effective than aspirin in the relief of pain.
2. Although the matter is still open to question, we believe that Anacin is more effective than aspirin in the relief of pain. [33]

The first claim, like claims made in the advertising challenged here, assures the consumer that there is simply no question: Anacin is better than aspirin, and the consumer can thus rely, in purchasing Anacin, upon the fact he or she will be doing more thereby to relieve pain symptoms than were he or she to purchase plain aspirin. The second claim leaves the matter in some doubt: the advertiser certainly believes its product is better than aspirin, perhaps based on some evidence, but a prudent consumer could decide that inasmuch as the matter remains open to substantial question, he or she is better off buying aspirin, or buying neither product in the event the

[54] Advertisements having the capacity to deceive are deceptive within the meaning of the FTC Act; actual deception need not be shown. See, *e.g.*, *Murray Space Shoe Corp.* v. *FTC*, 304 F.2d 270, 272 (2d Cir. 1962); *U.S. Retail Credit Ass'n* v. *FTC*, 300 F.2d 212, 221 (4th Cir. 1962); *Rhodes Pharmacal Co. Inc.* v. *FTC*, 208 F.2d 382, 387 (7th Cir. 1953), *aff'd*, 348 U.S. 940 (1955). It is well settled that the Commission has the expertise to determine whether advertisements have the capacity to mislead the public. Consumer testimony or survey data, although sometimes helpful, is not essential. *Resort Car Rental System, Inc.* v. *FTC*, 518 F.2d 962, 964 (9th Cir. 1965); see *FTC* v. *Colgate Palmolive*, 380 U.S. 374, 391–2 (1965).

[55] The conclusions set forth herein are merely an elaboration, in the specific context of drug products, upon well-established principles of advertising law requiring that advertisers possess and rely upon a reasonable basis for affirmative product claims. *Pfizer, Inc.*, 81 F.T.C. 23, 60–65 (1972). It has repeatedly been held that failure to possess a reasonable basis for advertising claims is a deceptive practice, *e.g.*, *Porter & Dietsch*, 90 F.T.C. 751, 866 (1978), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980); *Jay Norris, Inc.*, 91 F.T.C. 751, 854 (1978), *aff'd*, 598 F.2d 1244 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979); *National Dynamics Corp.*, 82 F.T.C. 488, 550 n. 10 (1973), *aff'd in part and remanded in part on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974). Deception derives from the failure to disclose to consumers the material fact that an affirmative product claim lacks the support that would be presumed absent some qualification of it. The appropriate measure for such support is, of course, to be determined in light of the particular claims made and the products for which they are made. For reasons noted in the text, we believe that such support in the case of drugs consists of the two or more well-controlled clinical studies deemed necessary by a broad spectrum of relevant experts to justify assertions as to drug performance.

consumer has already decided that aspirin is not a suitable palliative. The first claim may make better copy, but the second claim comes much closer to the truth.

There is a substantial question, recognized by the qualified experts, about the superiority of Anacin and APF over aspirin and other OTC analgesics. The record demonstrates the relevant scientific community to be unanimous in its view that the superiority of one analgesic product over another (or a class of others) cannot be established unless more than one adequate, well-controlled clinical test has been conducted. See discussion *supra* at pp. 18–24. Thus, in the absence of such tests, there necessarily exists scientific doubt, characterized in the complaint as a "substantial question," about the validity of the claims.[56] **[34]**

We have already concluded that Anacin's superior efficacy for headache relief has not been demonstrated by the requisite tests. Moreover, additional evidence of doubt within the relevant scientific community is supplied by the unanimous testimony of complaint counsel's witnesses, who stated that Anacin's superior efficacy has *not* been established (Forrest, Tr. 465; Azarnoff, Tr. 611–12; DeKornfeld, Tr. 2788; Moertel, Tr. 959). Indeed, some of these witnesses testified to their belief that Anacin is in fact no better than aspirin (Forrest, Tr. 520; Moertel, Tr. 959). While some of respondent's witnesses said that they believe that Anacin *is* better than aspirin (*e.g.*, Lasagna, Tr. 4938; Okun, Tr. 4352), it is clear from the record that there are, overall, significant doubts in the scientific community.

Nor has APF been proven to the satisfaction of the scientific and medical community to cause less gastric discomfort than other analgesics.[57] Respondents base their claim on inferences drawn from the product's composition, arguing that the formulation of APF—486 mg. of micronized aspirin (aspirin with a smaller particle size) combined with "two recognized buffering agents" (both of which are

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[56] This reasoning, we note, parallels the approach of the Food and Drug Administration. When the FDA reviews OTC drug claims, it presumes a lack of general expert recognition of the validity of the claims if adequate controlled clinical tests have not been performed, and this approach has been upheld by the Supreme Court. In *Weinberger* v. *Hynson, Wescott & Dunning, Inc.* 412 U.S. 609, 629–32, (1973), the Court noted that the Federal Food, Drug and Cosmetic Act defines a new drug as one "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective ***" 21 U.S.C. 321(p), but that the Act nowhere defines "general recognition among experts." The Court reasoned that "general recognition" of effectiveness must require at least "substantial evidence," which is required under Section 505(d) of the Act for approval of a new drug application (21 U.S.C. 355(d)). "Substantial evidence," as we discussed *supra* at pp. 20–24, must consist of adequate controlled clinical tests. (The Court also commented, in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652 (1973), that whether a drug is a "new drug" depends on "the expert knowledge and expertise of scientists based on controlled clinical experimentation and backed by substantial support in scientific literature.")

[57] We have determined that AHP did not make a direct "establishment" claim with regard to APF (see *supra* at 15, n.[21]), but it did claim that APF causes less gastric discomfort than other analgesics. This claim is open to substantial question, as explained in the text.

antacids (RX 96B))—reduces the amount of gastric discomfort caused by its consumption (R.A.B. at 59).[58] **[35]**

While there is some testimony in the record that buffered aspirin may cause less gastric discomfort than regular aspirin (*e.g.*, Shapiro, Tr. 3041; CX 367Z100; see RX 96B),[59] even respondents' experts were not convinced that the use of buffers necessarily reduced gastric discomfort (*e.g.*, Lasagna, Tr. 4192–93). Complaint counsel's experts testified that substantial evidence that the addition of buffers results in less gastric discomfort does not exist (Sliwinski, Tr. 1149; Plotz, Tr. 1063; Grossman, Tr. 862; F. 383).[60] In fact, the American Medical Association's *Drug Evaluations* [61] states that the available evidence does not indicate that buffered aspirin is any better than ordinary aspirin (CX 362W). **[36]**

It is also open to question whether the substitution of microfine (micronized) aspirin for regular aspirin reduces the incidence of gastric discomfort. There is some evidence that micronized particles may be absorbed more quickly and thus cause less irritation (*e.g.*, RX 96B). Complaint counsel's experts testified, however, that it has not been established that microfine aspirin causes less gastric discomfort (Sliwinski, Tr. 1149; Plotz, Tr. 1061; F. 369). Indeed, Dr. Grossman stated that it is unlikely that microfine aspirin makes any difference at all (Grossman, Tr. 850–51). The fact that these medical experts did not agree that micronized aspirin reduced gastric discomfort demonstrates the existence of doubt in the medical community.

Thus, APF's claimed superiority in terms of gastric discomfort, like Anacin's purported superior efficacy for pain relief, has not been established, and is open to substantial question in the scientific community. Respondent has, then, advertised the superiority of its analgesic products without either demonstrating that superiority adequately or qualifying the claims by disclosure of the existence of a

[58] The only study of APF in the record is one that compared its efficacy to that of buffered aspirin (CX 304). Since the only data from that study concerning gastric discomfort was generated incidentally, in the course of the efficacy comparisons (CX 304Z023; see Plotz, Tr. 1054), it is not sufficient to show APF's superior freedom from side effects. (See discussion *infra* at 43–44.) Respondent quite properly does not rely on CX 304 for substantiation of the freedom from gastric discomfort claim.

[59] RX 96 is a letter written by Dr. Arthur Grollman, a professor of experimental medicine at the University of Texas Medical School, reciting his views on the safety and efficacy of a drug formulated in the same manner as APF. The letter states Dr. Grollman's opinion that micronized particles are "less apt to cause gastric irritation" and that the antacids "give additional protection against gastric irritation" (RX 96A). This letter is evidence of only one physician's opinion as to the freedom from side effects of a drug like APF and it is refuted by complaint counsel's showing that APF's comparative freedom from gastric discomfort is open to substantial question in the scientific and medical community.

[60] Respondents quote the FDA panel report which concludes that buffered products "can be expected" to reduce gastric discomfort (R.A.B. at 60, quoting CX 367Z100). The panel report, however, speaks of only *some* of the persons who suffer gastric discomfort from consumption of regular aspirin, and goes on to conclude that "the evidence is insufficient to substantiate the claims that buffered * * * aspirin * * * is safe for use in patients who should not take regular * * * aspirin" (CX 367Z101).

[61] See *supra* at 28, n.[45].

substantial question. The advertisements in question are therefore deceptive within the meaning of Section 5 of the FTC Act.[62]

There remains for our consideration, however, respondents' contention that they were denied notice and a fair opportunity to be heard on the "substantial question theory" of liability. R.A.B. at 7–10. Respondent's argument appears to consist of three separate assertions. First, AHP contends that the "substantial question theory" pleaded in the complaint is a "novel theory," in that it challenges neither the truthfulness nor the lack of a "reasonable basis" for the claims made. R.A.B. at 8. But the fact that the "substantial question" phrasing used in this complaint may not have appeared in Commission cases previously would not constitute any violation of AHPs' rights. As we have explained, respondents' liability for their failure to disclose the existence of a substantial question rests on principles of deception in advertising that are established under Section 5. Respondents cite no legal authority for the proposition that a violation of due process may arise from an interpretation of the law which, although not previously articulated, flows directly from existing precedent. **[37]**

Indeed, it is settled that "there is . . . a very definite place for the case-by-case evolution of statutory standards," *SEC* v. *Chenery Corp.*, 332 U.S. 194, 203 (1947). See also *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). The Supreme Court has specifically confirmed the Commission's authority to interpret Section 5 of the FTC Act in a case-by-case manner. See, *e.g.*, *FTC* v. *R.F. Keppel & Bros.*, 291 U.S. 304 (1934). A problem only arises if the retroactive effect of applying a new standard causes a detriment to the respondent which outweighs the need for administrative flexibility. *NLRB* v. *Bell Aerospace Co., supra.* That is not the case here, where respondent will only be required to cease deceptive advertising practices, and will not be subject to fines, damages, or other immediate penalties.

Second, AHP argues that this theory of liability is "vague." R.A.B. at 8. We take this to mean that respondents believe it was denied notice and an opportunity to defend itself on the allegation of failure to disclose the existence of a substantial question. We believe, however, that the issue this allegation raised—*i.e.*, the question of what level of substantiation the scientific community would require to support the validity of respondents' claims such that no substantial question would remain—was hardly one which AHP could not perceive from the complaint and progress of the proceedings. *NLRB*

[62] In light of this conclusion, we do not reach the question whether the advertisements are also unfair under Section 5.

v. *Mackay Radio & Tel. Co.*, 304 U.S. 333, 349–50 (1930); cf. *NLRB* v. *Johnson*, 322 F.2d 216, 219–20 (6th Cir. 1963).

The complaint charged, in Paragraph 13, that at the time respondents made the comparative claims alleged in Paragraph 12, "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," and in Paragraph 14, that respondents failed to disclose the existence of a substantial question. In Paragraph 25, the complaint charged that this failure to disclose constituted an unfair or deceptive act or practice.

The pretrial proceedings made clear that to establish liability under this standard, complaint counsel would have to demonstrate the existence of a substantial question about the validity of the claims on the basis of the entire state of medical knowledge and opinion. Statement of Complaint Counsel on Certain Issues in Response to the Order of the Administrative Law Judge, filed July 27, 1973 ("Statement on Certain Issues") at 1–2; Pre-Trial Conference Transcript of Feb. 20, 1974, at 52, 64 (remarks of Judge Jackson), of Feb. 9, 1976, at 13–14 (remarks of Judge Hyun), and at 49 (remarks of Mr. Donegan). As complaint counsel repeatedly explained before trial, and as the ALJ confirmed, the issue of whether there is in the scientific community a substantial question **[38]**about a given proposition is a factual determination to be made on the basis of expert testimony and other evidence on the record. Statement on Certain Issues at 3; Pre-Trial Conference Transcript of March 4, 1976, at 74–6. Respondents were not deprived of an opportunity to rebut complaint counsel's showing of a substantial scientific question; indeed, the ALJ specifically announced at a Prehearing Conference, "I will allow both sides to put on evidence which conforms to any statement of their version of substantial question." Pre-Trial Conference Transcript of Feb. 20, 1974, at 48, 55–6. As we discussed above, the record ultimately demonstrated that the scientific community retains doubts about the validity of comparative analgesics claims if those claims have not been established by more than one adequate controlled clinical test, and that a substantial question did in fact exist as to Anacin's and APF's superiority.

Finally, respondents contend that the ALJ resolved this aspect of the case under the "reasonable basis" standard notwithstanding respondents' understanding throughout the trial that that was not the relevant legal standard. R.A.B. at 10. The ALJ, in applying the substantial question standard, stated that this standard "is, in the

particular factual context of this case, a reasonable and logical refinement of the 'reasonable basis' doctrine . . . ." I.D. at 210 (emphasis added). In our view, Judge Hyun was correct. The Commission's formulation of the substantial question allegations in this complaint constituted an assertion that a specific type of substantiation is required for the OTC analgesics claims challenged—*i.e.*, that the existence of a substantial question among the qualified scientists concerning these analgesic claims renders them deceptive, unless the existence of a substantial question is disclosed in the ads. Our reasoning in support of this interpretation of Section 5 is provided above. Respondents were on notice that this standard is not precisely the same as "reasonable basis," but is an extension of it, insofar as it requires that we look beyond the reasonableness of the supporting evidence in a respondent's possession when its claims were made, to the universe of relevant scientific knowledge and opinion.

For all the foregoing reasons we find unpersuasive respondents' assertions of a denial of due process arising from the application of the substantial question standard of liability.

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In sum, we have examined two categories of comparative efficacy and side effects claims made by respondents, and found each to be deceptive under the appropriate legal standard. The first category of claims, covered by Paragraphs 10 and 11 of the complaint (and discussed in Part B above), consists of direct representations that the superiority of AHP's drug products has been *proven*. Where those claims are made, they must, based on the testimony in this case (and consistent with FDA's standards), find support in more than one adequate clinical test. We found further that AHP failed to meet this standard here, and that its claims of proof were therefore false and deceptive. **[39]**

Advertising claims in the second category, covered by Paragraphs 12, 13 and 14 of the complaint (and discussed in Part C above), represent that AHP's products are better than its competitors', but do not rely on affirmative indicia of "proof." We have held that in the context of drug products, consumers may reasonably expect such claims to be supported by evidence sufficient to satisfy the scientific community, which this record shows to be more than one adequate clinical test. Because respondents' claims were neither supported by the requisite evidence nor accompanied by a disclosure of the absence of proof or existence of doubt, we found them to be deceptive.

III. *Other Alleged Claims*

A. Tension relief

Respondents are alleged to have claimed in numerous advertisements "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" (Comp. ¶ 15). AHP argues that the advertisements at issue promised relief from tension and related mood effects only when those effects are caused by headache pain (R.A.B. at 40–41).

We agree with the ALJ that many of respondents' advertisements convey the message that Anacin is not only a pain reliever, but is also independently effective for relief of tension, nervousness, and stress. F.F. 156–170; I.D. at 170–72. These advertisements emphasize the "mood" effects that could be achieved by taking Anacin, and give far less attention to the secondary message that Anacin relieves headache pain.

One scene repeatedly depicted, for example, is a household situation in which one family member, feeling tense or pressured by some minor irritation, takes Anacin, with the result that the irritation is removed and harmony in the home restored. See, *e.g.*, CX 39–46. See also the "Housewife Headache" series of print ads, CX 92–95, stressing the "nervous tension and fatigue" that can result from housework ("a mild form of torture"). Another variation on this theme is CX–160, a radio ad in which the announcer, against a background that includes a baby crying and a dog barking, cites "fatigue" (twice), "stress" (twice), "nerves" (twice), "tension" and "headache pain," concluding, "Yes, there can be more to a headache than just pain."

Other advertisements are based on the tension associated with stressful jobs. For example, CX 31A shows a bank teller handling a long line of customers on payday, the teller's tension headache dissolving into a smile after Anacin is taken. In still other ads we see an individual in a hurry (CX 22A) or pressured by a variety of burdensome tasks (CX 8A), and witness the tension "relaxed" by Anacin (as it relieves pain, we are told). **[40]**

Another technique used to create a sense of tension is to remind viewers of typically stressful situations that they might have encountered in the past. For example, one advertisement shows a man anxiously waiting in an employment office (CX 38); another shows a young couple looking for an apartment (CX 26). In the apartment advertisement, the tension is depicted by outward signs of stress on the part of the young woman: in one frame she is biting her

lip, in another she appears to be biting her nails. After Anacin is taken, the couple finds an apartment, and the tension is relieved.

The ASI copy test for this commercial (CX 418) shows that "tension/nervous tension" was the symptom most often identified by viewers. Twenty-two percent identified tension/nervous tension as a symptom relieved by Anacin, while only three percent named "tension headache" (CX 418J). Dr. Ross pointed out that relief by Anacin of tension *per se* was perceived by more consumers than relief of a tension-caused headache (Ross, Tr. 1997). Indeed, Dr. Ross testified that in viewing these Anacin advertisements, particularly the family scenes, the consumer perceives that "the dominant benefit that is being promised by Anacin is the relief of fatigue, stress and nerves, not dominantly pain or headache" (Ross, Tr. 1953). Referring to CX 26 (apartment commercial), Dr. Ross stated that the primary theme of the advertisement is that nerves and stress (rather than pain) are relieved by Anacin (Ross, Tr. 1995). Dr. Ross also testified that the print advertisements (*e.g.*, CX 89) were devoid of references to pain and that the headache to be relieved by Anacin ("Housewife's Headache") was characterized as being composed of tension and fatigue, not of pain (Tr. 2004–05).

These ads, considered in their totality, convey a strong message that Anacin relieves anxiety, stress and other mood problems entirely apart from its function as a pain reliever.

Having found that respondents' advertisements made the tension relief claims as alleged, we must consider whether respondents had a reasonable basis for making such claims.[63] AHP argues only [41]that it had a reasonable basis for its claim "that Anacin will relieve *tension-associated pain*," (R.A.B. at 59 (emphasis added)). This is essentially a repetition of its argument that the Anacin advertisements made representations only about tension caused by headache pain, an argument which we have already rejected. Respondents do not claim to have had a reasonable basis for the representations that Anacin will relieve tension and stress apart from its pain-relieving properties. The record is clear and uncontradicted that Anacin does not possess such properties (DeMott, Tr. 4765; Rickels, Tr. 1236–37; F.F. 343–57).

[63] As to this noncomparative claim, the complaint charged respondents with lack of a reasonable basis, "in that respondent had no competent and reliable scientific evidence to support such representations" (Comp. ¶ 16), rather than failure to disclose the existence of a substantial question. The Commission is aware that the application of these two different standards (see *supra* at 38 for discussion of the difference) to noncomparative and comparative advertising claims could create an appearance that comparative claims will be burdened hereafter by more stringent substantiation requirements, and that comparisons—which when truthful and nondeceptive may be useful to consumers—will be thereby disadvantaged. The Commission does not intend any such result, nor does it believe such a result necessarily flows from this case. We note that the FDA statute and regulations discussed earlier directly apply the "substantial evidence" standard to noncomparative claims on OTC drug labels (and to noncomparative and comparative claims in prescription drug labeling and advertising).

B. Relief in 22 Seconds

The complaint (¶8(A)(4)) also alleged that AHP's advertising represented "that within approximately 22 seconds after taking Anacin a person may expect relief from headache pain." Unlike the ALJ, we find it improbable that consumers would believe, based on the advertisements in the record, that Anacin can relieve headache pain only 22 seconds after it is taken. The print advertisements (CX 142–44, 151, 153) all stated that Anacin would provide relief 22 seconds "after entering your bloodstream," not after it is taken. Moreover, the one television ad that used this theme (CX 1) specifically qualified the 22-second claim with the comment, "[w]hile you won't feel it for minutes * * *." Therefore, we do not adopt F.F. 148–55.

C. Survey Claims

Paragraph 20 of the complaint alleges, and the ALJ found, that AHP's advertisements also contained claims representing that physicians or specialists prefer and recommend Anacin more than other OTC analgesics, as demonstrated by surveys. See F.F. 109–12. The ALJ found that the mail survey on which these representations were based was inadequate to substantiate them. Respondent has not appealed these findings. We agree with the ALJ that the claims were made and that there was no adequate basis for them, in light of the response rate in the survey of only 10%. See F. 393.

IV. *Liability of C. T. Clyne Company*[64]

The ALJ concluded that respondent Clyne, AHP's advertising agency for APF, was liable for the false claim that APF's analgesic ingredient is unusual or special, but not for the claim that it is established by medical or scientific proof that APF causes less gastric discomfort than other OTC internal analgesics (I.D. at 224). The ALJ's order thus requires that Clyne cease and desist from representing, with respect to any OTC internal analgesics, that such products contain any ingredient or combination of ingredients that is unusual or special, when that ingredient or combination of ingredients is contained in other OTC analgesics. [42]

Complaint counsel appeal from the limitation of Clyne's liability to the ingredient content claim and assert that Clyne should be held liable for the gastric discomfort comparative claim as well (C.C.A.B.

[64] The C. T. Clyne Company, Inc. is the corporate successor to Clyne Maxon, Inc., the advertising agency named in the complaint (CX 610B (Stip. 1)).

at 26). They argue that the order should be expanded to apply to Clyne requirements for comparative efficacy claims comparable to those applied to AHP (C.C.A.B. at 40). Respondent Clyne does not appeal directly from the findings of the ALJ, although in its answering brief it contends that it is entitled to a clause in the order precluding liability unless Clyne knew or had reason to know that the representations at issue were false or deceptive (Clyne Ans. Br. at 26–27), and a clause that expressly provides that Clyne is permitted to rely on its client for any substantiation required by the order (Clyne Ans. Br. at 27).

The liability of advertising agencies for violations of Section 5 is governed by two general principles. First, in order for the agency to be held liable, it must have been an active participant in the preparation of the advertisements at issue. *Doherty, Clifford, Steers & Shenfield, Inc.* v. *FTC*, 392 F.2d 921, 927 (6th Cir. 1968); *Carter Products, Inc.* v. *FTC*, 323 F.2d 523, 534 (5th Cir. 1963); *ITT Continental Baking Co., Inc.*, 83 F.T.C. 865, 967 (1973), *aff'd and modified*, 532 F.2d 207 (2d Cir. 1976). Second, it must have known or have had reason to know that the advertisements were false or deceptive. *Doherty, supra*, 392 F.2d at 927; *Standard Oil Co.* 84 F.T.C. 1401, 1475 (1974); *aff'd and modified*, 577 F.2d 653 (9th Cir. 1978).[65]

The record demonstrates that Clyne was a sufficiently active participant in the creation of the Arthritis Pain Formula advertisements at issue[66] to satisfy the first criterion for advertising agency liability (Ans. of Clyne, ¶ 4; CX 610B (Stip. 3, 5, 6); CX 611Z165; F.9, 467 (I.D. at 9, 116)).[67] It is evident, moreover, that Clyne was aware of both the aspirin content of APF (Noncontested Facts ¶ 13) and the fact that aspirin is available in many OTC drug products (Noncontested Facts ¶ 14). Clyne, therefore, not only had reason to know that APF's analgesic ingredient was not unusual, but the ALJ correctly found that Clyne actually knew that the unusualness representations were false (I.D. at 224). We sustain the ALJ's finding of Clyne's liability for these claims. **[43]**

We have found that the claim that it is established that APF causes less gastric discomfort than other internal OTC analgesics was not made by means of the same techniques conveying proof that AHP used for Anacin (*supra* at 15, n.[21]). We have also found,

[65] Although as we discuss *infra* complaint counsel have affirmatively established that Clyne knew or should have known that the ads were deceptive, we note that it has been held that the burden of proof rests in the first instance on the advertising agency: "An agency is clearly liable for the advertising it has created, produced or assisted in producing unless it can be shown that it did not know or could not know that the challenged advertising was false." *ITT Continental, supra*, 83 F.T.C. at 968.

[66] The only allegations in the complaint relating to Clyne are those that deal with the advertising of Arthritis Pain Formula (*e.g.*, Comp. ¶¶ 4, 8B, 9B, 10B, 12B and 22).

[67] Moreover, Clyne's active participation is undisputed on appeal.

however, that AHP and Clyne did make the unqualified claim that APF will cause gastric discomfort less frequently than other internal OTC analgesics, without disclosing that this claim is open to substantial question in the medical community. We must therefore decide whether Clyne knew or had reason to know that this unqualified claim was deceptive.

Clyne argues that an advertising agency has no responsibility to conduct an independent examination of the relevant scientific evidence before participating in the creation of its clients' advertising programs (Clyne Ans. Br. at 4–5). Nevertheless, under the circumstances presented, Clyne should have inquired further than it did into the state of the medical evidence supporting the comparative efficacy claim.

Clyne admits that the only evidence it had before it that the claim was true was CX 304, a study conducted by the research division of AHP (CX 611Z144), and that no experts other than those employed by AHP were consulted (CX 611Z169). CX 304 (entitled "Arthritis Pain Formula Evaluation") consists of a study conducted by AHP to compare the efficacy of APF and buffered aspirin for relief of the symptoms of arthritis. Although the purpose of the study was not to compare the gastric effects of the two formulations, and data on such effects were gathered only incidentally, the study concluded that "[i]t was established that Arthritis Pain Formula demonstrated significantly less evidence of gastrointestinal irritation and bleeding than did the buffered aspirin formula" (CX 304S).[68]

The ALJ found that Clyne's reliance on the AHP study was not unreasonable, and that a contrary finding would impose a duty on the advertising agency, unwarranted by the facts of the case, to conduct an independent investigation of its clients' substantiation for their claims (I.D. 224–25).

An advertising agency may, of course, rely on a *reliable* study provided by its client to substantiate advertising claims. If a study is on its face defective, however, such reliance cannot be considered reasonable. The APF evaluation here at issue is so clearly inadequate to support the claim that APF's freedom from gastric discomfort is superior to that of other analgesics that Clyne cannot be said to have been reasonable in its reliance. **[44]**

It should have been clear, even to the untrained eye, that the data on gastric discomfort generated by the study were collateral to its main purposes. A glance at the study's protocol (which was provided

[68] Complaint counsel point out that "gastrointestinal irritation" is not necessarily the same as "gastric discomfort" (C.C.A.B. at 29 n. 73). That proposition, however, is not self-evident, and Clyne's assumption that the two terms were synonymous is understandable. We agree with the ALJ that "Clyne should not be faulted for having equated 'gastrointestinal irritation' with 'stomach discomfort' " (I.D. 224).

to Clyne along with the study (CX 304A021–27)) demonstrates that only those side effects that happened to be volunteered by the patients were to be recorded (CX 304Z023). The data tables show that very few patients did volunteer that information (CX 304Z019). Such uncorroborated data are patently insufficient to prove scientifically APF's relative freedom from gastric discomfort. Thus, it should have been obvious to Clyne that there was a disparity between the type of substantiation provided and the unqualified representations made for the superiority claim. Under these circumstances, Clyne should have inquired further into AHP's substantiation.

We hold, then, that Clyne could not have reasonably relied on the AHP study as support for the claim that APF's freedom from gastric discomfort is superior to that of other internal OTC analgesics, and that Clyne is therefore liable for the deception caused by the claim.[69] This holding does not, as Clyne suggests, burden advertising agencies with a duty to conduct independent scientific investigations in order to substantiate their clients' claims (Clyne Ans. Br. at 5). Clyne could easily have fulfilled its responsibility here by insisting that its client provide further substantiation or by disclosing the lack of proof or existence of a substantial question. We hold only that when presented with a facially inadequate study as substantiation, an advertising agency may not ignore the study's defects. **[45]**

V. *Relief*

A. Overview

The attached order encompasses the acts and practices of respondents which we have found to violate Sections 5 and 12, as described in the foregoing discussion, and, where we believe it to be necessary, circumscribes potential closely-related violations under the Commission's well-established authority to close off all avenues to prohibited conduct. *FTC* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952). See also *Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 468 (1972), *aff'd* 481 F.2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 1112 (1973); *Carter Products, Inc.* v. *FTC*, 268 F.2d 461, 498 (9th Cir.), *cert. denied*, 361 U.S. 884 (1959).

The order diverges in several important respects from that proposed by the ALJ (described above at p. 3). For example, the ALJ's order would have applied a clinical testing requirement to

[69] For the sake of clarity we have included a "know or reason to know" clause in Part V.A of the order. Although such a clause is not required (*ITT Continental Baking Co.* v. *FTC, supra*, 532 F.2d at 224), complaint counsel do not object to its inclusion (C.C.A.B. at 31 n. 78). In part V.B, we have included "know or reason to believe," because we can assume that Clyne does not itself have the expertise to evaluate thoroughly the validity of these studies, and must to a certain extent rely on its client for expert evaluation.

advertising by respondent of any OTC drug, whereas the attached order applies such requirements only to advertisements for OTC internal analgesic drugs, for reasons to be explained below. Under this order, in all such advertisements, AHP must cease any claim of proven superior effectiveness or proven superior freedom from side effects unless the claim is proven by adequate clinical studies, and cease any other claim of superior effectiveness or superior freedom from side effects unless it is either proven by adequate clinical studies or qualified by disclosure of the existence of a substantial question or the absence of scientific proof.

In addition, the attached order requires that along with ceasing false "unusual ingredient" claims for any OTC drug, AHP must disclose the presence of aspirin in any Anacin or APF ad making any performance claim. We have deleted the provision in the ALJ's order requiring disclosure of the presence of aspirin in any advertisement for an OTC drug containing aspirin.

Under our order AHP must also cease misrepresentations of test or survey results, and false representations about the quantity of any active ingredient in comparison to the quantity in competing products. Finally, AHP is ordered to cease tension relief claims for Anacin, and other non-comparative claims for Anacin, APF, or any other OTC drug product for which a reasonable basis, consisting of reliable scientific evidence, is lacking. **[46]**

Respondent C.T. Clyne is ordered to cease unusualness claims for APF and other OTC analgesics which it knows or has reason to know are false, and with respect to claims of comparative freedom from side effects of APF or other OTC analgesics, Clyne must either know or have reason to believe that a product's superiority has been established, or make the necessary disclosure. The latter provision was not imposed under the ALJ's order.

We find it unnecessary to order corrective advertising to remedy previous claims of Anacin's superior efficacy. In addition, we reverse the ALJ and decline to order a corrective remedy for the tension relief claims. Finally, our order, unlike the ALJ's, does not cover labeling, but is limited to advertising claims.

B. Comparative Efficacy and Side Effects Claims

Under Part I.A. of the order, claims by AHP representing that the superior effectiveness or freedom from side effects of any OTC internal analgesic has been proven are prohibited unless they are supported by at least two adequate well-controlled clinical studies. The criteria shown by the record to be necessary to ensure that the clinical studies are adequate and well-controlled are set forth in the

order. Advertisements will trigger this testing requirement if they expressly claim that the product's superiority is proven or established; refer to medical or scientific research, tests or reports; or imply the existence of scientific or medical support through any of the sorts of techniques AHP has used, including references to or visual depiction of scientific graphs, formulas or diagrams, or a scientific or medical setting, conveyed *e.g.*, by the use of medical reference texts. See discussion *supra* at 15–18.

Part I.B. of the order provides that any other comparative claim by AHP for an OTC analgesic must be either supported by the same type of clinical testing set forth in Part I.A., or qualified by a disclosure that the claim has not been proven or that there is a substantial question about its validity.[70] A similar provision applies to analgesic advertising by Clyne, under Part V. As we have said, this record shows that any comparative analgesic claim not supported by adequate clinical tests cannot be considered to have been proven, and is necessarily open to a substantial question. We have also explained why the Commission believes that when such proof is lacking, it is deceptive to make a superiority [47]claim unless the existence of a substantial question or the absence of proof is disclosed.[71]

If respondents' advertising triggers the disclosure provision of Part I.B, the necessary disclosure must be made clearly and conspicuously in the ads. To eliminate uncertainty on respondents' part, the order permits them to use one of the forms of disclosure specified in the order itself.[72] In the alternative, they may design a disclosure of their own choosing. If respondents use language other than that specified in the order, they must maintain records that will be adequate to demonstrate that the required message will be or has been effectively conveyed to the advertisement's intended audience. Such records may consist of the copy tests performed in the routine course of respondents' business.

These provisions of the order apply to advertising of Anacin and

[70] False claims about the comparative quantity of analgesic or other active ingredients in respondent's OTC drug products are specifically prohibited under Part II.B.

[71] Affirmative disclosure requirements have been included in Commission cease and desist orders on numerous occasions where advertisements would otherwise be misleading (*e.g., National Comm'n on Egg Nutrition*, 88 F.T.C. 89 (1976), *aff'd and ordered enforced as modified*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Keele Hair & Scalp Specialists, Inc.*, 55 F.T.C. 1840 (1959), *aff'd*, 275 F.2d 18 (5th Cir. 1960), and the Commission's authority to order such disclosures is no longer open to question. *Warner-Lambert Co.* v. *FTC*, 562 F.2d 749, 759 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

[72] The disclosures specified are that the claim is "open to substantial question" or that the claim "has not been proven." Because this language constitutes precisely that message necessary to remedy what we have found to be otherwise misleading superiority claims, we have included it, rather than language proposed by complaint counsel, in the order. Complaint counsel proposed a disclosure that "it is not known whether . . ." or that "there is a real question whether . . . ." C.C.A.B. at 23. If those or other forms of disclosure can be shown to convey the required message, they would of course be acceptable under Part I.B.2.

APF, and of any other OTC internal analgesic product as well. While the case law makes clear that we are not required to restrict our order to the particular products at issue,[73] we [48]believe that some discussion of this issue is appropriate in light of the judicial modification of an earlier order against AHP. *American Home Products Corp*, v. *FTC*, 402 F.2d 232 (6th Cir. 1968).[74] As summarized recently in *Sears Roebuck & Co.*, Docket No. 9104 (April 28, 1980), slip op. p. 11, *appeal pending* No. 80–7368 (9th Cir.), "The appropriate scope of an order necessarily depends upon a rough evaluation of the extent to which a practice is likely to be repeated", as measured by factors including the transferability of the practice to other contexts, extent of the violation, state of mind of respondent, and past history of respondent.

Respondent could, with no difficulty, make unsubstantiated and unqualified assertions of superiority in advertising for other analgesic products as it has done in its promotion of Anacin and APF.[75] We turn, then, to consideration of those factors indicating whether AHP is likely to do so.

The advertising challenged in this proceeding was widely disseminated, in print and broadcast media, over a period of many years and at a cost of millions of dollars annually. F.F. 4, 5, 585, 586.[76] A reading of those advertisements demonstrates that respondent consistently made the deceptive claims. Moreover, as we stated in a previous opinion, "respondent is hardly a stranger to Commission proceedings." *American Home Products Corp.*, 70 F.T.C. 1524, 1625 (1966). This case represents the fourth time that we have entered a litigated cease and desist order against respondent on the basis of misleading advertising [49]claims for OTC drug products.[77] As we

[73] See, *e.g.*, *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 394–5 (1965); *Jay Norris* v. *FTC*, 598 F.2d 1244, 1250 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979); *ITT Continental Baking Co*, v. *FTC*, 532 F.2d 207 (2d Cir. 1976); *Sears Roebuck Co.*, Docket 9104 (April 28, 1980), appeal docketed No. 80–7368 (9th Cir.). Other court decisions sustaining Commission orders prohibiting specified deceptions as to a category of products, based upon findings of deception in the sale of one product, include *Porter & Dietsch, Inc.* v. *FTC*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (order prohibiting unsubstantiated efficacy claims for any "food, drug, cosmetic, or device" sustained on basis of findings that efficacy of one product was misrepresented); *National Dynamics Corp.* v. *FTC*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974) (order prohibiting certain unsubstantiated performance claims for *all* products sustained on basis of findings of deceptive advertising for one product).

[74] That case involved a hemorrhoid treatment product ("Preparation H") and the original order would have prohibited respondent from misrepresenting the efficacy of any drug. The court limited the order to the specific product at issue.

[75] This situation thus differs from that in *Standard Oil Co. of Calif.* v. *FTC*, 577 F.2d 653 (9th Cir. 1978), where the court found that "the petitioners' violations involved use of a visual image which was misleading because of the specific subject matter of the advertising. The violations were not a technique of deception that easily could be transferred to an advertising campaign for some other product." 577 F.2d at 663.

[76] In *FTC* v. *Colgate-Palmolive Co.*, *supra*, three commercials were found sufficient to support an "all products" order; in *ITT Continental Baking Co., Inc.* v. *FTC*, *supra*, "numerous advertisements comprising two large campaigns over a number of years" were found to support an order relating to growth properties of any food product.

[77] Our previous orders concerned: false representations of the drug "Freezone" to remove corns by respondent's wholly-owned subsidiary, *Wyeth Chemical Co.*, 29 F.T.C. 281 (1939); misrepresentations concerning

(Continued)

have stated, those previous Commission proceedings all concerned "the making of misleading exaggerations and misstatements in advertisements with respect to the efficacy of the drugs which [it] was selling." 70 F.T.C. 1524, 1625. There is simply no room left to doubt that respondent is "a habitual violator of the Federal Trade Commission Act," *American Home Products Corp.* v. *FTC, supra,* 402 F.2d at 237,[78] and that in order to protect the public adequately against future deception of the same sort, these provisions of our order must cover claims for more than the two products misrepresented.

We have, however, extended this section of the order only to OTC internal analgesics rather than all OTC drugs as the ALJ proposed,[79] in recognition of the possibility that comparative claims for other OTC drug products may be adequately substantiated, at least in some instances, by evidence other than two clinical tests meeting the criteria outlined above. Respondent has argued that a single standard of proof is inappropriate for assessing the comparative efficacy of different types of drugs. Resp. Reply Br. at 20–23. **[50]**

The record establishes that the standard requiring at least two tests, with placebo controls, is required for substantiation of analgesics claims, due to the likelihood that a subject's expectations will influence a subjective response like pain relief. But while the requirement for two such studies to support OTC drug claims in general has been widely accepted, we note that the FDA regulation for new drug approvals, which is expressly based on this standard, does provide that the testing criteria may be waived in whole or in part where a waiver petition demonstrates that "some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be, or have been, followed, the results of which will or have yielded [sic] data that can and should be accepted

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"Outgro" for restoring ingrown toenails, *American Home Products Corp.*, 63 F.T.C. 933 (1963); and misrepresentations about its hemorrhoid treatment product "Preparation H." *American Home Products Corp.*, 70 F.T.C. 1524 (1966).

[78] We also take notice of the fact that respondent has elsewhere been found to have made false and misleading representations concerning the properties of Anacin and "Maximum Strength Anacin." *American Home Products Corp.* v. *Johnson and Johnson,* 436 F. Supp. 785, 803 (S.D.N.Y. 1977), *aff'd,* 577 F.2d 160 (2d Cir. 1978) (representations concerning superiority of Anacin to Tylenol generally and for inflammation); *McNeilab, Inc.* v. *American Home Products Corp.*, 79 Civ. 3973 (S.D.N.Y., filed July 21, 1980) (representations that Maximum Strength Anacin is a stronger analgesic than Extra Strength Tylenol, and has the maximum strength allowed without a prescription).

[79] The ALJ subsequently stated in his decision in *Bristol-Myers Co.*, Docket No. 8917 (Sept. 18, 1979), that he has modified his views concerning the scope of this provision (see Initial Decision in that proceeding, at 254–55), and he would presumably agree with the product coverage of our order. In light of our resolution of this issue, we deny AHP's motion of Feb. 13, 1981 for remand and reopening of proceedings, which respondent bases on the ALJ's proposed orders in *Bristol-Myers* and in *Sterling Drug,* Docket 8919.

as substantial evidence of the drug's effectiveness." 21 C.F.R. 314.111 (a)(5)(ii)(a).[80] Therefore, although complaint counsel assert that this waiver has been applied to date by FDA's advisory panels only in "extremely unusual instances," none of which involved comparative drug claims (C.C.A.B. at 71–3), we cannot assume that a similar allowance for exceptions would be unwarranted for comparative OTC drug claims far afield from the scope of this litigation.[81]

AHP argues, however, that the testing standard applied by the ALJ violates its First Amendment rights. Relying on political speech cases, it contends that the requirement of two well-controlled clinical studies for comparative claims is an impermissible prior restraint, and that the alternative offered (disclosing that the representations made have not been proven) is similarly prohibited. R.A.B. at 19. Respondent also claims that the order provision infringes the First Amendment by chilling "truthful" comparative claims because of the expense of substantiating such claims. We find these arguments to be without merit. **[51]**

The order provision challenged by respondent does no more than prohibit advertising that is deceptive, by stating or implying that the superiority of respondent's analgesic products has been established by scientific or medical evidence, without disclosing the absence of scientific proof, or the existence of substantial scientific doubt. As the Supreme Court has only recently reiterated, there is no constitutional protection for deceptive advertising:

> There can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it . . . .

Central Hudson Gas & Electric Corp. v. *Public Service Comm'n*, 100 S. Ct. 2343, 2346 (1980).[82]

Where deceptive advertising occurs, the First Amendment does not prevent the imposition of such relief as is needed to prevent recurrence of the deception, *National Soc. of Professional Engineers* v. *United States*, 435 U.S. 679, 697–98 (1978); and the specific remedial requirement that advertising be substantiated has been judicially sustained in the face of First Amendment challenge, *Jay*

[80] See also 21 C.F.R. 330.10(a)(4)(ii), which incorporates the waiver provision quoted above in establishing procedures for FDA advisory review panels to follow in classifying OTC drugs as safe and effective and in promulgating monographs specifying conditions of use for each category of drugs.

[81] If in the future respondent discovers changed conditions of law or fact which would dictate that even comparative analgesic claims be subject to requirements different from those in this order, it is of course free to file a request for modification of the order under the Commission's Rules of Practice.

[82] Other cases establishing this point include, *e.g.*, *Friedman* v. *Rogers*, 440 U.S. 1, 13, 15–16 (1979); *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 383–4 (1977); *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 771–2, n. 24 (1976).

Norris Corp. v. *FTC*, 598 F.2d 1244, 1252 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979).

In *Jay Norris*, as here, respondent argued that an order (much broader than here) requiring that certain claims be substantiated would chill advertising. As the Commission noted, however, a substantiation requirement fosters rather than impairs First Amendment objectives, because substantiation by an advertiser is the only way to insure that claims are reliable. *Jay Norris Corp.*, 91 F.T.C. 751, 851–855 (1978), *aff'd*, 598 F.2d 1244 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979).[83] Moreover, the dissemination of advertising claims for which the advertiser lacks appropriate **[52]**support is itself a deceptive practice[84] and prohibition of such claims amounts, therefore, to no more than a constitutionally unobjectionable ban on deceptive advertising.

AHP argues more particularly that even if a requirement of prior substantiation is appropriate, the requirement that AHP possess at least two clinical tests in support of analgesic efficacy claims is overly restrictive. The order, however, does not prevent AHP from suggesting that its analgesic products possess certain properties, even absent two clinical tests, provided that AHP reveals that its claim remains open to question.[85] Given that the record shows that at least two clinical tests are required to establish claims of analgesic efficacy, any attempt to make an unequivocal claim of efficacy without that level of support would clearly be misleading. The testing requirement, therefore, constitutes a necessary and proper restraint on the precise type of misleading advertising that gave rise to this case.

C. Ingredient Claims and Omissions

We have described above, at pp. 5–8, the ways in which respondents conveyed a false representation of the unusualness or specialness of the analgesic ingredient in Anacin and APF. The

[83] The requirement that advertisements be substantiated has been repeatedly sustained. See, *e.g.*, *Porter & Dietsch, Inc.*, 90 F.T.C. 770 (1977), *aff'd* 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980); *Fedders Corp.*, 85 F.T.C. 38, 69 (1975), *aff'd*, 529 F.2d 1398 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976); *Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 475 (1972), *aff'd*, 481 F.2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 1112 (1973). We note that in *Central Hudson, supra*, the Supreme Court reaffirmed a major premise underlying the requirements of advertising substantiation when it stated that one reason the content of commercial speech may be regulated is that "commerical speakers have extensive knowledge of both the market and their products. Thus, they are well-situated to evaluate the accuracy of their messages . . . ." 100 S. Ct. at 2350, n. 6.

[84] *E.g.*, *National Comm'n on Egg Nutrition*, 88 F.T.C. 84, 191 (1976), *aff'd and ordered enforced as modified*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *National Dynamics Corp.*, 83 F.T.C. 488, 549–550 (1973), *remanded in part on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974).

[85] Requirements that commercial messages include "additional information, warnings and disclaimers" have been recognized as permissible under the First Amendment as a means of preventing deception. *Virginia State Bd. of Pharmacy, supra*, at 772, n. 24. See also, *Warner-Lambert Co.* v. *FTC*, 562 F.2d 749, 769–70 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

advertisements emphasized the purported difference between AHP's aspirin-based competitors and its own products, associating the competitors with aspirin but never identifying the analgesic ingredient in AHP's own products as aspirin. Under Part II.A of the order, the misleading affirmative claims may not henceforth be made by AHP in any OTC drug advertising when the ingredient represented as special is in fact commonly used in other products intended for the same purpose.[86] Under Part V, Clyne may not make such claims in any analgesic advertising when it has reason to know of the falsity of the claim. **[53]**

We believe it essential that Part II.A encompass all OTC drug advertising by AHP, and bar misrepresentations of the specialness of common ingredients other than aspirin. The effort to misrepresent the nature of a quite ordinary ingredient—whether it is aspirin, caffeine, or some other substance[87]—is a technique that could easily be applied to advertising of OTC drug products other than Anacin or APF. And as we have described above in detail, this respondent's history of misleading advertising raises a serious concern that the order imposed here be carefully drawn if it is to succeed in preventing future violations.[88]

In addition, Part III of the order requires that in Anacin and APF ads[89] making any performance claims (such as strength, ability to relieve pain, or freedom from side effects), the analgesic ingredient must be clearly and conspicuously disclosed **[54]**as aspirin (when it is aspirin). Part III will ensure that all Anacin and APF ads, save those that merely identify the product without any representation about performance, will reveal the analgesic ingredient to be aspirin; thus, advertisements for the two specific products which this record shows to have been promoted heavily by misleading statement and omission about their analgesic content will no longer create an erroneous impression that the ingredient is something different from and better than aspirin. Without this specific aspirin disclosure requirement, we are concerned that this respondent—with its

[86] Of course, a claim of the unusualness or specialness of an ingredient is likely also to convey a claim of superior effectiveness (or freedom from side effects), and thus be subject to the requirements of Parts I.A, I.B and V.B.

[87] Caffeine, like aspirin, is a common substance available in many products (F. 387; Ans of AHP, ¶ 23). Thus, if caffeine is commonly used in products intended for the same purpose as the advertised product (as aspirin is used in many products intended for pain relief other than Anacin), the advertisement may not state or imply that it is an unusual or special ingredient. The fact that the ALJ found that caffeine has not been shown to pose a serious public health problem is irrelevant, since the basis for this disclosure requirement is the need to prevent misleading representations about the ingredient.

[88] Because the advertising agency does not bring to this litigation the same history of advertising violations as AHP, we believe that an order covering only OTC internal analgesics will suffice as to Clyne. Nor does the order require Clyne to make affirmative ingredient disclosures.

[89] The order also covers advertisements for any product that includes "Anacin" or "Arthritis Pain Formula" in its name, such as "Maximum Strength Anacin."

striking history of related advertising violations—will devise ways to continue misrepresenting the nature of its product.

D. Tests and Surveys

Part II.C of the order prohibits respondent from misrepresenting any test, study or survey or the results thereof, concerning the efficacy or freedom from side effects of its OTC drug products. In light of the findings that respondent made misleading representations involving tests comparing Anacin with other analgesics (see *supra* at 15–17), as well as a survey of doctors (see *supra* at 41), a prohibition on future misrepresentations of this sort is necessary. Such a prohibition is particularly warranted in light of the order's other provisions requiring tests to substantiate certain claims, to ensure that any tests performed thereunder will not form the basis for further misrepresentations. We are limiting this provision, however, to conform to the types of misrepresentations that respondent made: namely, efficacy and freedom from side effects claims. See *Fedders Corp.*, 85 F.T.C. 38, 74 (1975), *aff'd*, 529 F.2d 1398, 1403 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976).

E. Tension Relief and Other Unsubstantiated Noncomparative Claims

Respondent argues that a cease-and-desist order relating to its unsubstantiated tension relief claims is unwarranted because such claims were abandoned in 1973. It is well established that the Commission has authority to enter an order even where the challenged practices have been voluntarily **[55]**abandoned or revised. See, *e.g.*, *American Medical Ass'n* v. *FTC*, 1980–2 (CCH) TRADE CAS. ¶ 63,569 at 77,028 (2d Cir.) (1980); *Giant Food Inc.* v. *FTC*, 322 F.2d 977 (D.C. Cir. 1963), *cert. denied*, 376 U.S. 967 (1964); *Fedders Corp.* v. *FTC*, 529 F.2d 1398 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976). Here, moreover, respondent ceased its tension relief advertising only after the complaint was issued. As the court stated in *Oregon-Washington Plywood Co.* v. *FTC*, 194 F.2d 48, 50 (9th Cir. 1952), "Parties who have abandoned their challenged practices only after proceedings are brought against them are in no position to complain of a cease-and-desist order. In such a case the discontinuance can hardly be thought to be voluntary." In these circumstances we believe that Part IV of the order, prohibiting tension relief claims for Anacin, is necessary to prevent future recurrence of past practices.

In addition, Part II.D of the order requires respondent to have a reasonable basis, consisting of competent and reliable scientific

evidence, for any other noncomparative representations concerning the effectiveness or freedom from side effects of its OTC drug products. In light of the overall history of advertising violations by AHP, described above, we believe this provision is necessary as a fencing-in measure to prevent respondent from making other unsubstantiated noncomparative claims.[90]

F. Corrective Advertising

This case also raises the question of when corrective advertising is appropriate to dissipate the lingering effects of false or deceptive advertisements. The order entered by the ALJ would include some of the corrective advertising proposed in the notice order accompanying the complaint: a disclosure in future advertising to correct a tension relief image would be required, but a disclosure to correct an "established superiority" image would not. AHP appeals **[56]**from the order to correct the tension relief image (R.A.B. at 73–83), while complaint counsel appeal from the failure to order a correction for the comparative efficacy and side effects claims (C.C.A.B. at 7).

It is well settled that the Commission may order prospective disclosures to correct misleading lingering impressions created or reinforced by previous advertising. *National Comm'n on Egg Nutrition* v. *FTC*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Warner-Lambert Co.* 86 F.T.C. 1398 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978). Once the Commission has determined that a false or deceptive image of a product exists in the minds of consumers, it may order the image corrected if it finds that advertising of the product is the primary source of the image, and that, absent correction, the image is likely to endure even after the advertising has ceased. *Warner-Lambert Co.*, *supra*, 86 F.T.C. at 1503 (1975); *Firestone Tire and Rubber Co.*, 61 F.T.C. 398, 429 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973) (separate statement of Commissioner Jones). In recognition of the nature and purpose of advertising, which is aimed at creating enduring product images, the Commission may in appropriate cases presume a lingering effect on consumers. *Warner-Lambert*, *supra*, 562 F.2d at 762; see also the Commission's Statement in Regard to Corrective Advertising, Trade Reg. Rep. (CCH) ¶ 39,046 (1979). See also *Note, Federal Trade Commission Authority to Order Corrective Advertising*, 1978 Wisc. L. Rev. 605, 624–25 (1978).

We must now apply these principles to the case before us.

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[90] See discussion *supra* at 47–49.

1. Tension Relief

Although consumer image and penetration studies in the record show that a significant number of consumers perceived Anacin to be effective for relief of tension (see, *e.g.*, CX 455Z027; CX 452Z024), we are not convinced that these images will persist.[91] [57]The studies reveal that consumers did not recall the tension relief theme as readily as other efficacy claims made by AHP. In the 1971 Bates (CX 477) and 1973 Sobel-Chaikin (CX 453) studies, for example, recall of the Anacin tension relief claim was much lower than recall of the pain relief claims (CX 477W (6%); CX 453035 (2%); Smith, Tr. 5876; I.D. at 122). Tension relief seems to have been a secondary image. When compared with other analgesics in the 1967 Glenbrook study, consumers preferred Anacin to other products much more often because of an image of superior efficacy for pain relief than because of an image of tension relief (CX 454Z022, Z029). In the 1969 Excedrin study (CX 462), only 10% of the respondents who stated that they used analgesics to relieve nervous tension used Anacin, as compared to 21% for Bayer (CX 452Z048), and there was little evidence of recall of the tension claim (Ross, Tr. 2216).[92]

There are two possible, related reasons why the evidence of lasting consumer recall of Anacin's tension relief message seems to be relatively weak.[93] First, tension relief appears to be a less important attribute of an analgesic to consumers than the relief of pain. Consumers tend to retain images of attributes that are most important to them, and their purchasing decisions are affected accordingly (Ross, Tr. 2083–84). Although the perceived ability of an analgesic to relieve tension may be significant to those consumers who seek such relief, the record demonstrates that most consumers consider analgesics most effective for pain relief. For example, the 1969 Excedrin study discussed above (CX 462) shows that strength claims penetrate to a far greater degree than other kinds of messages (CX 462Z070) and the 1967 Glenbrook Analgesics study (CX 454) found that speed (34%), strength (26%), and length (28%) of pain

[91] This conclusion does not conflict with our finding above that consumers did perceive such a message in the ads, or suggest that these claims should be allowed to continue if false or misleading. See generally F. 489 for discussion of the difference between evidence of perception of an advertising claim and evidence of retention of a lasting product image.

[92] In the 1975 Leavitt study (CX 457), only 1.4% of the population surveyed held a tension relief image (CX 457M). We do not rely on this study to assess consumer images, however, because of its serious flaws. See F.F. 528–563.

[93] We emphasize that we do not believe corrective advertising may only be imposed where there is an evidentiary basis like that in *Warner-Lambert, supra*. See *National Cmm'n on Egg Nutrition* v. *FTC*, *supra* at 165; Statement in Regard to Corrective Advertising, Trade Reg. Rep. (CCH) ¶ 39,046 (1979). For example, the Commission may, absent probative evidence one way or the other, infer that a deceptive advertisement will leave a lingering deceptive impression in consumers' minds. Here, however, for the reasons given, we decline to draw such an inference.

relief were far more significant to consumers than tension relief (19%). [58]

Second, the tension relief theme has not been the primary focus of AHP's advertising campaigns; the central theme has been effectiveness of its products for pain relief (CX 454; 462). Indeed, the ALJ found that the dissemination of advertisements containing tension relief claims ceased altogether in 1973 (F. 525). While the cessation of offending claims does not excuse respondent from liability for those claims, see *supra* at 55, the absence of those claims from the media over a period of several years is relevant to the likelihood that consumers have retained the erroneous product image and thus to the need for corrective advertising.

Since we are not convinced on this record that the tension relief claims are likely to endure in consumers' memories, we reverse the ALJ's decision to order correction of the tension relief message.

2. Comparative Claims

Complaint counsel argue on appeal that corrective advertising is necessary to remedy a false consumer belief that Anacin's superiority has been proven or "established," a belief instilled, they assert, by both advertisements expressly claiming proof and other comparative advertisements failing to disclose the existence of a substantial question. C.C.A.B. at 9, 12–13.[94] They ask the Commission to presume that unless corrected the belief in the proof of Anacin's superiority is one which will linger in consumers' minds beyond the life of the advertising which produced it, despite the absence of direct evidence on this claim's endurance (F. 573).

The record does provide considerable evidence indicating the existence, at least at the time the surveys were conducted (1967–70), of a widespread consumer belief in Anacin's superior efficacy. The 1970 Vanquish study (CX 455) shows that an image of extra strength "dominates brand perceptions" and "is highly correlated with market behavior" (CX 455I). The record demonstrates that a substantial number of consumers consider Anacin to be superior to other OTC analgesics for this characteristic; as complaint counsel's experts testified, several studies show that a superior efficacy image exists (Ross, Tr. 2080, 2184, 2193; Rossi, Tr. 1602, 1615). The 1969 Excedrin study (CX 462), for example, found that 53% of analgesics users described Anacin as "speedy" and 34% described it as "long-lasting" (CX 46Z004), as compared to other brands. The percentages

[94] Complaint counsel do not appear to seek a corrective remedy for advertising of APF. In light of our finding that APF ads did not make the "establishment" claim directly, (*supra* at 15 n *), we agree that a correction for APF ads would be less appropriate than one for Anacin ads.

for Anacin users were even higher (73% and 50%) (CX 46Z005). The 1967 Glenbrook study demonstrates similar results (CX 454N). Dr. Ross and **[59]**Dr. Rossi thus both concluded that a substantial number of consumers believe Anacin to be more efficacious than aspirin (Ross, Tr. 2048; Rossi, Tr. 1570).[95]

We are also convinced that the primary source of this consumer belief in Anacin's superiority is the advertising of the product. F.F. 576–84. Respondent argues that this image may just as easily have been created by product usage (Resp. Ans. Br. at 26), and therefore that corrective advertising would be inappropriate (Resp. Ans. Br. at 24). Product usage, however, can be a primary source of a product image only if the consumer has the ability to discriminate objectively between various similar products (Ross, Tr. 2250). Where no objective test is performed, a consumer who believes before use that there is a difference between products is likely to experience a placebo effect, whereby such a difference is perceived when the products are used (Ross, Tr. 2253). Thus if a consumer is unable to evaluate objectively a product's actual efficacy, the role of advertising as a cause of the consumer image is enhanced (Ross, Tr. 2255). The record demonstrates that many consumers cannot determine the efficacy of OTC analgesics through actual usage, due to the possibility of such a placebo effect (Azarnoff, Tr. 626; DeKornfeld, Tr. 2785; see discussion *supra* at 19). And if product usage is not the cause of the consumer's image of these products, the primary source of the image is likely to be the advertising.[96]

We have already concluded that many of respondent's advertisements claiming Anacin's superior efficacy represented expressly and by clear implication that the product's superiority has been proven, and that other superior efficacy claims, when not qualified by a disclosure of the existence of a substantial question, also had a capacity to mislead consumers as to the existence of proof. Therefore, if we were to conclude that **[60]**the image of Anacin's superiority will endure unless corrected, we could logically presume that an image of proven superiority is also likely to linger in consumers' minds, and order the relief sought by complaint counsel.

There is some basis in this record for concluding that the superiority image, and thus the implicit proven superiority image,

[95] Respondent argues that a study of data gathered by NPD Research, Inc. (RX 176–185) shows that any image consumers hold of Anacin's superior efficacy does not result in loyalty to the Anacin brand. Resp. Ans. Br. at 30. As the ALJ found, however, these data form a weak basis for conclusions about enduring consumer beliefs. F.F. 602–606, 609.

[96] We also reject respondent's theory that corrective advertising may only be required when advertising is the *sole* source of product images (Resp. Ans. Br. at 24). We need only find that the advertising played "a substantial role in creating *or reinforcing* in the public's mind a false belief about the product * * *." *Warner-Lambert, supra* 562 F.2d at 762 (emphasis added).

will endure. For example, the survey results appear to have been stable over several years, F.F. 503, 521, 568–9; and expert witnesses testified that the superiority image would last, F.F. 594–5. The Commission can also reasonably draw inferences about the endurance of the image from factors including the salience of the claim to consumers, the extent of dissemination, the forcefulness of the persuasive techniques used, and the likelihood that product usage will affect the image held. See F.F. 585–6, 590, 593, 597.

Corrective advertising need only be ordered, however, if we determine that it is the only way to ensure that the image of established superiority will not persist. Here, we believe that other remedial provisions in our order will do the job. A belief in the proven superiority of Anacin is most likely to continue if comparative claims continue to be made in Anacin advertising. But under this order, any future comparative efficacy or side effects claims must be effectively qualified—*i.e.*, corrected as to the lack of proof—unless the requisite proof actually exists, in which case there will be no further deception. Moreover, the order will prevent respondent from conveying an erroneous impression of the product's superiority (proven or not) by means of claims about the unusualness of the ingredient in the product, in that it will prohibit false unusualness claims and will require the disclosure, in many Anacin ads, of the familiar name of aspirin.

We believe that in the face of all of these measures, there is little likelihood that a false or unsubstantiated image of proven superiority will survive. Therefore, we affirm the ALJ's rejection of a corrective advertising provision for comparative efficacy claims.

G. Labeling

The ALJ's order would apply to the labeling as well as the advertising of respondent's products. Respondent argues that this requirement is unwarranted because its labeling practices were not at issue during the proceeding and because **[61]**the FDA has jurisdiction over labeling. While we believe that an order relating to labeling could properly be entered as a fencing-in provision, we do not believe that this is an appropriate instance for such an order. Our liaison agreement with the FDA recognizes that primary responsibility for labeling rests with the FDA, 36 FR 18539 (1971), and that agency is currently engaged in reviewing labeling claims for OTC drugs. In view of these circumstances, the attached order does not cover labeling.

H. Competitive Impact

AHP has requested in motions filed throughout this proceeding that the three cases instituted by the Commission involving advertising claims for OTC analgesic products should be a matter for a joint decision.[97] (*Bristol-Myers*, Docket No. 8917, involves claims for Bufferin and other products; *Sterling Drug*, Docket No. 8919, involves claims for Bayer Aspirin and other products.) AHP has argued that issuance of any Commission order adverse to it would cause it severe competitive injury, and that, at the very least, any such order entered prior to disposition of the other analgesics cases should take effect only upon the entry of final orders in the other cases. We find that the arguments offered by AHP in these motions do not justify the requested relief.

In several cases, respondents have sought to stay prosecution of Commission cases on the grounds that they will suffer competitive harm if prohibited from engaging in practices that are open to their competitors. The courts have held in such cases that the Commission has the discretionary authority to enter an order against one firm, even when its competitors are alleged to be engaged in the same practices and the **[62]**Commission has not similarly proceeded against any of them. See *FTC* v. *Universal Rundle Corp.*, 387 U.S. 244 (1967); *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411 (1958). The Commission's discretion in this area is limited only to the extent that it cannot institute proceedings which will arbitrarily destroy one of many alleged law violators in an industry. See *FTC* v. *Universal-Rundle Corp.*, *supra*, 387 U.S. at 251.

These principles are certainly applicable here, where proceedings against AHP's competitors are already pending before the Commission[98]—though of course there is no certainty whether or to what extent those proceedings will result in orders covering AHP's competitors, as any such orders will depend solely on the evidence adduced therein. We note, moreover, that AHP's allegations of competitive harm were based in substantial part on the assumption that the Commission would adopt the corrective advertising provision of the ALJ's order[99]—a provision which we have rejected. In these circumstances, we believe that the public interest will be best

[97] See Motion of American Home Products Corporation For Stay of this Proceeding Pending Consolidation of All Three Pending Analgesic Cases on Appeal (Dec. 19, 1979); Response of American Home Products To Complaint Counsel's Motion Requesting Expedited Decision (March 14, 1979); Motion of American Home Products Corporation to Stay the Appeal For the Purpose of Consolidating on Appeal All the Analgesic Proceedings (Sept. 29, 1978); Motion of American Home Products Corporation to Dismiss the Complaint or in the Alternative Suspend the Proceeding Due to Changed Circumstances (April 29, 1977).

[98] The Commission heard oral argument in *Bristol-Myers* in April, 1980; an initial decision was filed in January, 1981 in *Sterling Drug*.

[99] Motion of American Home Products Corporation to Stay the Appeal for the Purpose of Consolidating on Appeal All the Analgesic Proceedings, at p. 8 (Sept. 29, 1978).

served by issuing the cease and desist order in this proceeding for immediate effect.

APPENDIX

ALJ's Interpretation of the Advertisements

Respondent AHP contends that the ALJ's findings on the meaning of the challenged advertisements were based on an improper analysis of the record evidence (R.A.B. at 30–33).[1] Administrative law judge is authorized to use his own accumulated expertise in determining the meaning of advertisements (R.A.B. at 30). AHP urges, however, that the law judge erroneously failed to consider certain extrinsic evidence on the meaning of the challenged advertisements, and that he based his interpretations on a one-sided, selective use of the record (R.A.B. at 30–33). For the reasons stated below, we conclude that the ALJ properly considered the record evidence and determined the weight to be accorded the evidence with respect to each of the challenged advertising claims.

A. Relevance of Extrinsic Evidence in General

The legal test for determining whether advertising has violated Section 5 is whether the challenged representations have the capacity and tendency to deceive.[2] The Commission (and its ALJ) is authorized to make that determination without resort to expert testimony or consumer survey data, which constitutes a "surrogate form of direct consumer testimony."[3] Consistent with that standard, the ALJ primarily relied on his own experience and expertise in determining what direct or indirect representations were contained in the challenged advertising, but he [2]also considered the relevant extrinsic evidence in the record[4] (I.D. p. 165; F. 45), and properly

[1] The specific representations disputed on appeal by AHP are the alleged claims that: (1) AHP's products are superior to *all other* OTC analgesics; (2) the superiority of AHP's products has been established; (3) the analgesic ingredient in Anacin or APF is unusual, special, or stronger than aspirin; (4) Anacin relieves tension; and (5) within 22 seconds after taking Anacin a person may expect relief from headache pain. We have evaluated each of these alleged representations in turn, *supra.*

[2] See, *e.g., Murray Space Shoe Corp.* v. *FTC,* 304 F. 2d 270, 272 (2d Cir. 1962); *United States Retail Credit Ass'n* v. *FTC,* 300 F.2d 212, 221 (4th Cir. 1962); *Rhodes Pharmacal Co.* v. *FTC,* 208 F.2d 382, 387 (7th Cir. 1953), *rev'd on other grounds* 348 U.S. 940 (1955).

[3] *Ford Motor Co.,* 87 F.T.C. 756, 794 (1976); See *FTC* v. *Colgate-Palmolive Co.,* 380 U.S. 374, 391–92 (1965); *Standard Oil Co.*v. *FTC,* 577 F.2d 653, 659 (9th Cir. 1978); *J.B. Williams & Co.*v. *FTC,* 381 F.2d 884, 890 (6th Cir. 1967); *Firestone Tire & Rubber Co.,* 81 F.T.C. 398, 454 (1972), *aff'd,* 481 F.2d 246 (6th Cir.), *cert. denied,* 414 U.S. 112 (1974); *Carter Products, Inc.* v. *FTC,* 323 F.2d 523, 528 (5th Cir. 1963).

[4] In addition to the advertisements themselves, the evidence consists of (a) the testimony of experts in the

(Continued)

determined its probity and weight based on a number of factors, including the qualifications and experience of respondents' expert and the format, methodology, and relevance of the consumer research upon which respondents' expert relied.[5] F. 46–48, 50, 59, 62–65, 486, 488–90, 492–93, 500, 525, 588; I.D. pp. 164–65.

B. Testimony of Dr. Smith

Among the extrinsic evidence considered by the ALJ was the testimony of respondents' expert witness, Dr. Joseph Smith, and certain consumer survey data upon which his conclusions were based. I.D. pp. 164–65. The ALJ specifically considered the mode of analysis used by Dr. Smith; determined the relevance and weight of his testimony based on established legal standards; and, on that basis, rejected his conclusions [3]on the meaning of the challenged advertisements. F.F. 47–48; I.D. pp. 164–66. Respondent claims, however, that the ALJ erroneously failed to credit Dr. Smith's testimony (*e.g.*, Tr. 5664–67; 5755–58) relating to the representations conveyed in the challenged advertising.

We find that the ALJ's decision not to credit Dr. Smith's testimony was entirely proper, and consistent with established principles of advertising interpretation. Dr. Smith's analysis of the challenged advertisements relied heavily on consumer survey data—"penetration" and "image" studies (Smith, Tr. 7442–49, 7454–58, 7518, 7562). These studies, however, do not address the question of whether or not a particular advertisement conveyed a particular claim.[6] Yet it is

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fields of consumer psychology and behavior, marketing, and marketing research; (b) AHP internal memoranda relating to AHP's awareness that certain advertising techniques were effective; (c) copy tests on Anacin television commercials, including the verbatim comments of consumers; (d) consumer studies relating to consumer perceptions of certain attributes of OTC analgesics; (e) "image" studies of consumer attitudes and beliefs about the Anacin brand and its competitors; and (f) "penetration" studies designed to evaluate consumers' ability to recall Anacin advertising themes. The only evidence bearing on the meaning of APF advertising is expert testimony and the APF advertisements themselves.

[5] Thus, the ALJ's use of such extrinsic evidence as exists in the record was consistent with our observation in *ITT Continental Baking Co.*, 83 F.T.C. 865, 954 (1973), *modified on other grounds*, 532 F.2d 207 (2d Cir. 1976), that while extrinsic evidence should be taken into consideration, its probity or weight will depend on the "qualification and experience of the particular expert involved and the validity and soundness of methodology utilized in the survey." Similarily, in *Cinderella Career & Finishing Schools, Inc.*v. *FTC*, 425 F.2d 583, 588–9 (D.C. Cir. 1970), and *Universal Camera Corp.*v. *NLRB*, 340 U.S. 474, 494–96 (1951), both cited in respondents' brief (R.A.B. at 36), the courts merely indicated that the Commissioners and the Board could not disregard entirely the examiner's findings of fact and conclusions of law and the evidence upon which they were based. In *Giant Food, Inc.* v. *FTC*, 322 F.2d 977, 982 (D.C. Cir. 1963), *appeal dismissed* 376 U.S. 967 (1964), the court held only that such extrinsic evidence as existed in the record supported the Commission's conclusion on the meaning of the term "manufacturer's list price."

[6] Dr. Smith himself testified that "penetration" studies are designed to test consumers' recollection, over a period of time, of an advertiser's promotional themes rather than consumer understanding of particular advertisements (Smith, Tr. 7443–45). The recollection of consumers over time, as measured by a penetration study, inevitably takes into account a myriad of factors other than the message content of individual ads, including the extent of dissemination and the memorability and pertinence of the various advertising themes (Smith, Tr. 7445). Dr. Smith also observed that "image" studies, which evaluate consumer beliefs and attitudes (*e.g.*, quality, price) about a particular product and its competitive profile without regard to the source of such views, are not designed

(Continued)

beyond dispute that effective Section 5 enforcement requires that advertisers be held accountable for each advertisement on an individual basis.[7]

Moreover, Dr. Smith considered competitors' advertising claims to be relevant to an understanding of the representations contained in the challenged advertisements for Anacin and APF. He stated, for example, that the use of similar words or themes by competitors would either reduce substantially [4]the likelihood that the alleged message about Anacin would be perceived in the Anacin ads, or enhance the likelihood that if the message were perceived it would be "displaced" quickly (Smith, Tr. 5650–51). The ALJ properly determined that this testimony was entitled to little weight.[8] As we stated above, each challenged advertisement must be evaluated individually. Moreover, even if the meaning of Anacin ads as perceived by some consumers could have been affected by claims made in ads for competitors' products, *every* consumer perception of the Anacin messages alleged in the complaint would not have been "displaced" in the manner suggested.[9]

Dr. Smith also largely disregarded the nonverbal components of the challenged advertising in formulating his conclusions on their meaning (Smith, Tr. 7493–94). The ALJ correctly observed that this failure to assess the net impression of the advertisements diminished the probative value of the testimony. I.D. p. 164. [5]

C. ASI Copy Tests

Other extrinsic evidence considered by the ALJ consisted of the results of twenty copy tests conducted by Audience Studies, Inc. (ASI) that were placed into evidence by complaint counsel. CX 402, 404–07, 409, 412, 414, 415. These studies designed to elicit data from

to provide evidence on all of the possible meanings consumers take from specific advertisements of the product whose image is being studied (Smith, Tr. 5549–52; see also Sen, Tr. 7178–79, 7327–28).

[7] Thus, the legal determination as to whether an advertisement is deceptive is not based on its effectiveness relative to truthful ads in selling products (*Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 450 (1972), *aff'd* 481 F.2d 246 (6th Cir. 1973) *cert. denied*, 414 U.S. 112 (1974)), and the fact that nondeceptive ads may be part of an ad compaign is no basis for ignoring the ads which are deceptive (*Chrysler Corp.*, 87 F.T.C. 719, 751–52 (1976)).

[8] Respondent also claims that the ALJ erred in refusing to admit certain competitors' advertisements and in limiting the testimony of both Dr. Smith and Mr. DeMott (an AHP executive) addressing such advertisements (R.A.B. at 29). For the reasons given in the text, we believe the ALJ's actions were correct. Respondent misconstrues certain statements of complaint counsel in the Joint Hearings, which, respondent argues, constituted a concession that a competitor's advertising is relevant. The question discussed was whether a consumer survey reporting recall figures for Anacin, Excedrin and Bufferin should be admitted in the Bayer Aspirin portions (Joint Tr. 956–60) of *Sterling Drug*, Docket No. 8919. Complaint counsel stated that the data would serve as a basis for comparison for similar studies of Bayer advertising and specifically added: "I am not saying that you have to look at the advertisements of other products to understand the advertisement of Bayer * * *" (Joint Tr. 960).

[9] Advertisements frequently convey more than one meaning, but if one of them is misleading, the advertiser is liable for the misleading variation. See *e.g., National Comm'n on Egg Nutrition* v. *FTC*, 570 F.2d 157, 161 n. 4 (7th Cir. 1977); *cert. denied*, 439 U.S. 821 (1978) *Murray Space Shoe Corp.* v. *FTC*, 304 F.2d 270, 272 (2d Cir. 1962).

representative samples of consumers on the meanings conveyed by individual advertisements.[10] Respondents urge that the ALJ improperly failed to credit Dr. Smith's analyses of the verbatim responses elicited in the ASI tests. One of these analyses (RX 123–26) was performed in an attempt to determine whether the challenged advertising claims caused consumers to switch their purchasing preference or intent (Smith Tr. 7476). To prove that a deceptive claim has been made, however, complaint counsel need not show that it would have been likely to cause consumers to buy a product which they otherwise would not have purchased. *Firestone Tire & Rubber Co., supra,* 81 F.T.C. at 451. Dr. Smith himself conceded that his "switching" analysis shed no light on the question whether the advertisements conveyed the representations alleged (Smith, Tr. 7476).[11]

Respondent points also to Dr. Smith's analysis of the verbatim responses (RX 271) as conclusive proof that the claims alleged were not conveyed in the challenged advertising (R.A.B. at 31–32). That analysis is flawed, however, because Dr. Smith's approach was to code a response as a "directly-related recall" only if it recited the precise language of the alleged representation. See, *e.g,* Smith, Tr. 7541. We believe this to be an overly restrictive use of copy test results. Other expert testimony in the record shows, moreover, that a low response rate of verbatims falling into a particular category is meaningless without an assessment of the advertisement tested and all surrounding circumstances, and that even after such analysis it may be impossible to determine **[6]**conclusively that a given message was not communicated. (Lukeman, Tr. 241–44, 247–48; Seltzer, Tr. 367–68). In addition, the open-ended questioning technique used by ASI does not elicit an exhaustive playback from consumers of all the representations that may be perceived in the tested advertising. In sum, while such surveys can be a useful aid in advertising interpretation, and the ALJ used them for such assistance (I.D. p. 164), their limitations tend to diminish the significance of the absolute response rate for each advertising claim.

D. Other Objections

[10] In the copy tests involved here, audience members filled out their responses to a page of questions about their comprehension of the advertisements immediately after viewing the films. Approximately 30 to 40 minutes later, the audience members were presented with a recall document which asked them to write down all that they could remember about the advertisements. These "verbatim" responses were then tabulated and coded. Only twenty of the television advertisements, and none that appeared in print or were broadcast on radio, were subjected to ASI testing.

[11] Of course, the likelihood that consumers would alter their purchasing decisions on the basis of a claim or omission in advertising is relevant in determining the materiality of the claim, after it has been found to be deceptive or to have a capacity to deceive. See *supra* at 8–11 and 32–33.

AHP also urges that the ALJ erroneously precluded testimony of AHP's Whitehall Laboratories Division president, George DeMott, relating to the meaning of the challenged advertisements. (R.A.B. at 29). The ALJ's action in this instance was entirely correct because while Mr. DeMott was allowed to testify as to the general objectives of the company in designing its advertising strategies,[12] he was not offered as an expert qualified in advertising interpretation (Tr. 4689).

Finally, AHP contends that the ALJ committed reversible error by looking to certain post-complaint advertisements, which were admitted only for the purpose of assessing the appropriateness of any remedy and the currency of the advertising claims challenged in the complaint (Tr. 162–63, 674–77), to determine whether the alleged representations were made (R.A.B. at 30). The ALJ could not have used the post-complaint advertisements for assessment of the remedy, however, without first determining what representations they conveyed. In addition, most of the ALJ's findings cited by respondent rely on ads disseminated before the complaint issued, along with some disseminated later. In any event, there is no prejudice to respondent, because none of our conclusions with respect to claims made by respondents' advertising relies primarily on advertisements aired or printed after the complaint issued.

Thus, we hold that the ALJ engaged in a proper evaluation of the representations alleged to have been made in respondents' advertising.

SEPARATE STATEMENT OF COMMISSIONER CLANTON CONCURRING IN PART AND DISSENTING IN PART

I concur in the Commission's order and opinion except for the portion that deals with the substantial question issue. On that point, I dissent.

The majority holds that American Home Products violated Section 5 of the FTC Act by failing to state in its advertisements that there was a substantial question in the scientific community as to the veracity of its comparative performance claims for Anacin and APF. The majority's holding is based on the conclusion that consumers reasonably believe that any comparative drug performance claim is

[12] Tr. 4651–59. See *supra* at 5–6.

backed, not merely by reasonable substantiation, but by data that will be accepted as proof within the scientific community. Unfortunately, the majority can cite practically nothing in the record that indicates what consumers are likely to believe is adequate substantiation for comparative drug claims. It is one thing to infer consumer beliefs where advertising expressly claims, or clearly implies, that scientific proof exists. But it is something else entirely to decide that consumers believe such proof exists where the advertisements are silent on the issue.

A brief review of complaint counsel's theory concerning the substantial question disclosure will explain the dearth of relevant evidence on consumer perceptions; it may also illuminate the majority's own, different approach to this issue. In brief, complaint counsel have argued that it is unfair for a drug advertiser to make a comparative performance claim with anything less than scientific proof as substantiation. In making this assertion, complaint counsel state candidly that they are not relying on the reasonable basis test set forth in *Pfizer*, 81 F.T.C. 156 (1972). They observe, in fact, that this case was tried differently from a reasonable basis case. CCAB at 48 n. 104. Specifically, the trial did not focus on whether respondent's substantiating evidence was reasonable under the criteria listed in *Pfizer*. Instead, complaint counsel have urged that the Commission move beyond the reasonable basis test and develop a new standard that is more appropriate to "the specific problems encountered in a particular market." CCAB at 47. Citing the FDA's standards for determining the efficacy and safety of drugs, complaint counsel arrive at the conclusion that fairness requires that comparative drug performance claims should be substantiated by two well-controlled, clinical tests. [2]

Complaint counsel then suggest that *National Dynamics*, 82 F.T.C. 488, 546 (1973), *aff'd* 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974), and its progeny have established that if an advertiser's performance claims are unfair because they are not adequately substantiated, they are also deceptive because a performance claim must, as a matter of law, imply exactly the same level of substantiation that fairness requires. Under complaint counsel's approach, extrinsic evidence as to consumer assumptions about an advertiser's level of support appears to be wholly irrelevant; the implied claim of substantiation is legally determined by the standard necessary to avoid unfairness.

The ALJ evidently accepted complaint counsel's reasoning:

[T]he consumers of OTC analgesic products are entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a sufficient kind and level of

substantiation for the claim. In the circumstances of this case, the only sufficient substantiation for the claim is that the claim is accepted by the medical-scientific community . . . .

It is also clear that the absence of that kind and level of substantiation leaves a substantial question regarding a claim of comparative or superlative efficacy or safety, and that the existence of such a question is a material fact, of which the failure to disclose will render an advertisement deceptive . . . . (I.D. p. 212–13.)

Although the ALJ's analysis of marketplace fairness seemingly is derived, at least in part, from *Pfizer* (*see* I.D. pp. 210–16), complaint counsel disavowed reliance on *Pfizer* and it is clear that respondent was given no opportunity to address the "reasonableness" of its substantiating data.

In my view, the approach taken by complaint counsel and the ALJ is deficient in several respects and the majority has properly declined to follow it. As articulated, the deception (or material omission) theory advanced by complaint counsel is not dependent upon actual or probable consumer beliefs; rather, it depends entirely upon some independent notion of fairness that is distinct from the reasonable basis doctrine of *Pfizer*. Such an approach does violence to the legal concepts of both deception and unfairness. [3]

To be sure, the substantiation doctrine is predicated upon both a deception and an unfairness rationale. *Jay Norris Corp.*, 91 F.T.C. 751, 854 (1978), *aff'd*, 598 F.2d 1244 (2d Cir. 1979). Thus the Commission has indicated that it is reasonable for consumers to assume that objective product or service claims are backed by some kind of substantiation and that merchants are in a better position than consumers to verify the claims made on behalf of their products or services. That analysis also recognizes that substantiation requirements may vary, depending on a variety of factors which are set forth in *Pfizer*. But that kind of approach hardly warrants use of an abbreviated unfairness test to justify inferences about specific consumer beliefs concerning the level of substantiation that the Commission feels is appropriate in a given case. Such an exercise produces an artificial deception standard that is divorced from the reality of reasonable consumer expectations; it also misperceives the nature of our unfairness jurisdiction, which requires that challenged practices be analyzed in terms of both public policy and consumer injury. *See Commission Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction* in letter to Senators Danforth and Ford, December 17, 1980.

With respect to the unfairness issues, the problem with complaint counsel's arguments and the ALJ's reasoning is that they fail to balance the factors relevant to an unfairness case. Mention is made

in complaint counsel's answer brief and in the ALJ's initial decision that FDA regulations endorse the standard of two well-controlled clinical tests for safety and efficacy claims; this fact evidently provides some public policy justification for requiring similar proof in drug advertising. But the analysis cannot stop there. Regard must also be given to other relevant issues, such as the type and accessibility of data sufficient to constitute proof, or the type of consumer injury that would be risked if the advertiser possessed some lesser basis for its claims than scientific proof. It is thus impossible to declare that the substantiation the respondent did have on hand for its comparative advertisements was inadequate under an unfairness rationale.

The majority has not followed complaint counsel's approach. Rather, it attempts to imply a proof claim simply because the advertising at issue involves drugs. It is true, of course, that the Commission need not refer to consumer surveys or similar extrinsic evidence to interpret the meaning of an advertisement. *FTC* v. *Colgate Palmolive Co.*, 380 U.S. 374 (1965). Similarly, actual deception need not be shown by complaint counsel to carry its burden of proof. It is necessary only that the advertisement have the tendency or capacity to deceive. *Charles of the Ritz Dist. Corp.* v. *FTC*, 143 F.2d 676, 680 (2d Cir. 1944); *Firestone Tire and Rubber Co.*, 81 F.T.C. 398, 441 (1972), *aff'd* 481 F.2d 246 (6th Cir. 1973), *cert. denied* 414 U.S. 112 (1974). Still, [4]these precedents do not give the Commission a carte blanche to assume that an advertisement makes every claim that it might theoretically imply. Nor do they give the Commission the expertise to define, without the aid of extrinsic evidence, the particular expectations that consumers bring to a challenged advertisement. Rather, the Commission's interpretation of an advertising claim must be reasonably grounded on the expressions in, and format of, the advertisement. *National Dynamics*, *supra* at 548; *see Standard Oil Co. of California* v. *FTC*, 577 F.2d 653 (9th Cir. 1978).[1]

In this case, however, the majority has decided that a proof claim is implied by *any* comparative drug advertisement, regardless of the wording or format involved. Moreover, on closer analysis of the majority's opinion, one finds that the majority does not even cite the comparative nature of the advertising to support its conclusion that consumers believe drug performance claims are supported by proof.

[1] In *Simeon Management Corp.* v. *FTC*, 579 F.2d 1137 (9th Cir. 1978), the Ninth Circuit upheld a Commission determination that some consumers would reasonably believe that the government exercised control over the promotion and use of prescription drugs. *Id.* at 1146. This determination was evidently made without the benefit of extrinsic evidence. However, there is an obvious difference between prescription drugs and such commonplace medicines as aspirin. It can hardly be assumed that consumer beliefs regarding prescription drugs also apply to aspirin. Furthermore, the Commission did not reach any conclusions in *Simeon Management Corp.* concerning the *type* of substantiation that might be required before an advertiser claimed that its drugs were safe and effective.

Instead, the majority opinion suggests that consumers are entitled to believe that the drug advertiser has proof simply because the sale of drugs raises safety and health issues.

This assumption about consumer beliefs is not clearly implied by drug advertising in general. Neither is it supported by previous Commission determinations on the meaning of advertisements. The Commission has, of course, held on several occasions that consumers would reasonably believe that an advertiser had conducted scientific tests or surveys to support its claims. *Standard Oil Co. of California* v. *FTC, supra*; *Litton Industries*, Dkt. No. 9123 (filed January 5, 1981); *Crown Central Petroleum Corp.*, 84 F.T.C. 1493 (1974). Those cases are readily distinguishable, however. The proof and testing claims in *Standard Oil, Crown Central* and *Litton* were made explicitly. Better analogues to the advertising in this case may perhaps be found in the comparative claims at issue in *Firestone Tire and Rubber Co., supra.* The advertisements there claimed the Firestone tires "stopped 25% quicker" than competing brands. [5]We held that this assertion implied that scientific tests had been conducted to support the claim. In so ruling, we noted that a specific percentage was used to make the superiority claim and that the claim directly addressed significant safety concerns. By contrast, in this case, product performance was typically not compared in specific objective terms. Furthermore, the comparative claims did not raise safety issues. In the absence of such considerations or more direct evidence of consumer beliefs, I think the Commission should be loath to speculate as to what consumers may independently think about a product or the type of data needed to support claims concerning it.[2]

I am also concerned that the majority's attempt to limit its substantial question analysis to comparative drug advertising will prove untenable in the future. There is nothing in the majority's reasoning to suggest that proof-type substantiation would not also be required for noncomparative drug claims. Furthermore, there are many comparative performance claims outside the drug area that, if the majority's reasoning is followed, consumers would have equal reason to believe are substantiated by scientific proof. For example, if consumers believe that there are scientifically acceptable tests to

[2] Of course, if surveys or expert testimony showed that consumers actually believed, or were likely to believe, that the advertising made proof claims, some type of action might be appropriate. Here, however, the majority can point to no such evidence. The majority opinion notes that respondent conceded that a simple comparative performance claim for drugs would suggest that the underlying substantiation should be acceptable to responsible medical experts. The majority also notes that Dr. Smith, respondent's expert, admitted that consumers are likely to expect that drug product claims will have greater substantiation than other types of claims. See note 53 on page 31 of majority opinion. But these admissions fall far short of accepting the argument that consumers would assume that any comparative drug claim must be proven scientifically before it is advertised.

support the claim that one aspirin is better than another, it would be reasonable to assume that they believe similarly rigorous evidence supports any comparative claim that touches on health or safety issues. It is not clear where the line should be drawn under the proposed substantial question doctrine, which is a good reason why this test should not be used at all.

Finally, it should be obvious that a substantial question analysis is an ungainly tool for measuring deception in the instant case. The situation here is quite dissimilar from that in *National Commission on Egg Nutrition*, 88 F.T.C. 89 (1976), *modified in part*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978), where the respondent made affirmative claims that no scientific evidence linked the [6]consumption of eggs with increased risk of heart attack. The existence of just such a diet-health link was, in fact, the subject of lively debate among interested doctors, nutritionists, and researchers. In those circumstances, it was entirely appropriate to require that the fact of that debate be disclosed. Here, the notion of a substantial question regarding Anacin's and APF's superiority is more artificial. There is no actual debate in the medical and scientific communities about the relative efficacy of different analgesics. Rather, the record suggests that most researchers would simply dismiss a respondent's purported substantiation as inadequate to establish anything scientifically. Thus, ironically, to allow respondent to say even that there is a substantial question regarding its proof may actually countenance deception.

The most sensible manner of analyzing the substantiation for comparative drug advertisements that do not make establishment claims is simply to ask whether there is a reasonable basis to support them. It does not assume much, I think, to believe that consumers generally regard product performance claims to have some reasonable support. The Commission is then in a position to identify the precise level of support that is reasonable in each instance by referring to the criteria set forth in *Pfizer*. This analytical approach is flexible enough to permit respondents an opportunity to submit evidence on the feasibility of conducting scientific tests or research. As *Pfizer* suggests, however, in some circumstances the only reasonable basis may be medical or scientific proof. We might very well have reached that conclusion here. Unfortunately, we cannot resolve that question because the case was not tried on the theory that respondent's comparative claims lacked any reasonable basis. That omission may have been unfortunate, but we should not cure the problem by seeking to ground liability on a theory that has

inadequate record support and by ordering a remedial disclosure that is inappropriate to the circumstances of this case.

FINAL ORDER

This matter has been heard by the Commission upon the appeal of counsel for respondents and complaint counsel and upon briefs and oral argument in support of and in opposition to the appeals. The Commission, for the reasons stated in the accompanying Opinion, has granted each appeal in part, and denied each in part. Therefore,

It is ordered, That the initial decision of the administrative law judge be adopted as the Findings of Fact and Conclusions of Law of the Commission except as is otherwise inconsistent with the attached opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered, That the following Order to Cease and Desist be entered:

ORDER

I

It is ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or [2]through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that a claim concerning the superior effectiveness or superior freedom from side effects of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness or comparative freedom from side effects of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness or freedom from side effects that it is represented to have, and (2) that such comparative effectiveness or

freedom from side effects is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. The investigations shall be conducted in accordance with the procedures set forth below:

At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be conducted on any disease or condition referred to, directly or by implication; or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

1. The subjects must be selected by a method that:

a. Provides adequate assurance that they are suitable for the purposes of the investigation, and diagnostic criteria of the condition to be treated (if any); **[3]**

b. Assigns the subjects to the test groups in such a way as to minimize bias; and

c. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity or duration of disease or condition (if any), and use of drugs other than the test drugs.

2. The investigations must be conducted double-blind, and methods of double-blinding must be documented. In addition, the investigations shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

3. The plan or protocol for the investigations and the report of the results shall include the following:

a. A clear statement of the objective of the investigation;

b. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subject's response and steps taken to minimize bias on the part of subject and observer;

c. A comparison of the results of treatments or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data.

d. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

B. Making any representation, directly or by implication, of superior effectiveness or freedom from side effects of such product unless:

1. The superior effectiveness or superior freedom from side effects so represented has been established according to the terms set forth in paragraph I.A. of this Order, *or* [4]

2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the comparative efficacy or side effects claim, or that the claim has not been proven. Such a disclosure may consist of a clear and conspicuous statement that the claim is "open to substantial question," or that the claim "has not been proven." If other language is used by respondent to convey the required message, respondent shall maintain, for a period of three (3) years after the dissemination of any advertisement containing such disclosure, records sufficient to demonstrate that the required message is effectively conveyed to the advertisement's intended audience.

II

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription drug product, in or affecting commerce, as "commerce" and "drug" are defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that such product contains any unusual or special ingredient when such ingredient is commonly used in other non-prescription drug products intended for the same use or uses as the product advertised by respondent.

B. Making any false representation that such product has more of an active ingredient than any class of competing products.

C. Misrepresenting in any manner any test, study or survey or any of the results thereof, concerning the comparative effectiveness or freedom from side effects of such product.

D. Making any noncomparative representation, directly or by implication, concerning the effectiveness or freedom from side

effects of such product unless, at the time such representation is made, respondent has a reasonable basis for such representation which shall consist of competent and reliable scientific evidence. **[5]**

III

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any products in which "Anacin" or "Arthritis Pain Formula" is used in the name, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from failing to disclose clearly and conspicuously that the analgesic ingredient in such product is aspirin, when such is the case and when the advertisement makes any performance claim for the product.

IV

It is further ordered, That respondent American Home Products Corporation, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, that Anacin relieves nervousness, tension, anxiety or depression or will enable persons to cope with the ordinary stresses of everyday life.

V

It is further ordered, That respondent the C.T. Clyne Company, Inc., a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising of "Arthritis Pain Formula" or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that

such product contains any unusual or special ingredient when respondent knows or has reason to know that such ingredient is commonly used in other non-prescription internal analgesic products for the same use or uses as the product advertised by respondent. [6]

B. Making any representation, directly or by implication, of superior freedom from side effects of such product, unless:

1. Respondent knows or has reason to believe that the superior freedom from side effects so represented has been established according to the terms set forth in paragraph I.A. of this Order, *or*

2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the claim, or that the claim has not been proven. Such a disclosure may consist of a clear and conspicuous statement that the claim is "open to substantial question," or that the claim "has not been proven." If other language is used by respondent to convey the required message, respondent shall maintain, for a period of three (3) years after the dissemination of any advertisement containing such disclosure, records sufficient to demonstrate that the required message is effectively conveyed to the advertisement's intended audience.

VI

It is further ordered, That respondents American Home Products Corporation and the C.T. Clyne Company, Inc. shall notify the Commission at least thirty (30) days prior to any proposed change in their respective corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in their respective corporation which may affect compliance obligations under this Order. [7]

VII

It is further ordered, That the respondents herein shall within sixty (60) days after service of this Order upon them, and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which they have complied or intend to comply with this Order.

Paragraphs Eight A.4, Eight B.2, and Ten B. of the Complaint are hereby dismissed.