

IN THE MATTER OF
STERLING DRUG, INC., ET AL.

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

Docket 8919. Complaint, Feb. 23, 1973—Final Order, July 5, 1983

This order requires a New York City manufacturer of nonprescription drug products, among other things, to cease advertising that "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol" or any other nonprescription internal analgesic has been proven to be superior to other pain relieving products, unless such claim has been substantiated by two well-controlled clinical tests. The company must have a reasonable basis to support any claim that its pain relievers are therapeutically superior to others, as well as competent and reliable scientific evidence for representations that the comparative pharmaceutical qualities of its analgesics have been proven or established. The order further prohibits the manufacturer from advertising that its products contain any unusual or special ingredient, when in fact such ingredient is commonly used in similar products; or from making any claim which misrepresents the product's analgesic ingredient.

Appearances

For the Commission: *Joel N. Brewer, Randell C. Ogg, Teresa A. Hennessy, Leslie E. Rossen and Roberta Gross.*

For the respondents: *Lionel Kestenbaum, Norman G. Knopf, William D. Appler, Jeffrey L. Kestler, Amanda B. Pedersen and Susan S. Pecaro, Bergson, Borkland, Margolis & Adler, Washington, D.C.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Sterling Drug, Inc., a corporation, Dancer-Fitzgerald-Sample, Inc., a corporation, and Lois Holland Callaway, Inc., a corporation, 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 Sterling Drug, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at 90 Park Avenue in the City of New York, State of New York. [2]

Respondent Dancer-Fitzgerald-Sample, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at 347 Madison Avenue, in the City of New York, State of New York.

Respondent Lois Holland Callaway, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York with its office and principal place of business located at 745 Fifth Avenue, in the City of New York, State of New York.

PAR. 3. Respondent Sterling Drug, Inc., is now and has been for all times relevant to this complaint engaged in the manufacturing, advertising, offering for sale, sale and distribution of certain non-prescription internal analgesic preparations which come within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act. The designations, directions for use and active ingredients for some of these analgesic drugs are as follows:

1. Designation: "Bayer Aspirin"

Active ingredients:

Aspirin

Dosage: 1 or 2 tablets with water every
4 hours, as necessary, up to 12 tablets a day.

2. Designation: "Bayer Children's Aspirin"

Active Ingredients:

Aspirin

Dosage: Varies depending upon age of child.

3. Designation: "Cope"

Active Ingredients:

Aspirin

Caffeine [3]

Methapyrilene Fumarate

Magnesium Hydroxide

Aluminum Hydroxide (Dried Gel)

Dosage: 1 or 2 tablets every 4 hours, as needed, up to 9 tablets per day.

4. Designation: "Vanquish"

Active Ingredients:

Aspirin
Caffeine
Acetaminophen
Magnesium Hydroxide
Aluminum Hydroxide (Dried Gel)

Dosage: 2 caplets with water. Can be repeated every 4 hours if needed, up to 12 caplets per day.

5. Designation: "Midol"Active Ingredients:

Aspirin
Caffeine
Cinnamedrine HCL

Dosage: 2 Midol Tablets with water. Repeat 1 or 2 tablets every 4 hours as needed, up to 8 tablets per day.

PAR. 4. Respondent Dancer-Fitzgerald-Sample, Inc., is now and for all times relevant to this complaint has been an advertising agency of Sterling Drug, Inc., and for all times relevant to this complaint, has prepared and placed for publication, advertising material, including but not limited to the advertising referred to herein, to promote the sale of the said "Bayer Aspirin", "Bayer Children's Aspirin" and "Cope".

Respondent Lois Holland Callaway, Inc., for all time relevant to this complaint has been an advertising agency of Sterling Drug, Inc., and for all times relevant to this complaint, has prepared and placed for publication advertising material, including but not limited to the advertising referred to herein, to promote the sale [4] of the said "Vanquish".

PAR. 5. In the course and conduct of its aforesaid business, respondent Sterling Drug, Inc., causes the said analgesic drug preparations, when sold, to be transported from its places of business located 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 Sterling Drug, Inc., maintains and at all times relevant to this complaint has maintained, a substantial course of trade in said preparations in commerce. The volume of business in such commerce has been and is substantial.

PAR. 6. In the course and conduct of their businesses, respondents Sterling Drug, Inc., Dancer-Fitzgerald-Sample, Inc., and Lois Holland Callaway, Inc., have disseminated, and caused the dissemination of, certain advertisements concerning the said drugs by the United States mail and by various means in commerce, including but not limited to, advertisements inserted in magazines and newspapers,

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 drugs and have disseminated, and caused the dissemination of, advertisements concerning said drugs 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. Typical of the statements and representations made in the advertisements, but not all inclusive thereof, are the following:

A. For Bayer Aspirin:

(1) To relieve a headache fast Bayer Aspirin's got the best help there is. Of all the leading pain relievers you see advertised, only Bayer is 100% aspirin. And Aspirin is what doctors recommend. [5]

(2) I'm Ozzie Nelson. Here's something I'm passing along to *my* family. This booklet about pain relievers. Bayer tested its aspirin for quality against 220 other brands. The results? Bayer is superior. I also read about the latest report written by the American Medical Association Council on Drugs . . . Straight aspirin is preferred over other non-prescription pain relievers. Find out why . . . aspirin's the best pain reliever. And Bayer's the best aspirin.

(3) Has anyone ever improved on Bayer Aspirin? Made a faster Aspirin? A more effective Aspirin? Lots of people have tried. They took plain Aspirin. Made it bigger. Smaller. They buffered it. They added extra ingredients. They squeezed it. Squared it. Flavored it. Gummed it. Capsuled it. Fizzed it. Even tried spraying it . . . They did everything—but improve it. Today there is still nothing faster . . . nothing more effective . . . than good old genuine Bayer Aspirin. It's pure Aspirin . . . not part Aspirin. It works wonders for headache, muscle pain, aches and fever of a cold. For just about anything that hurts.

(4) Would you like to see the inside story on all the major pain relievers you see advertised? Inside every single leading pain reliever is the same major ingredient . . . Aspirin . . . every one of those products relies chiefly on Aspirin. Surprised? Don't be . . . after all, Aspirin is the only pain reliever doctors overwhelmingly recommend for nearly every type of ache or pain. And did you know that Bayer is the only one of those pain relievers that makes all its own Aspirin? With care and experience no one else can match? That's why pure Bayer Aspirin, without Bufferin or Caffeine or any other extra ingredient is the pain reliever for you.

(5) Deciding which pain reliever you should take can be like a game. Some talk about strength, some talk about speed, some talk about ingredients they don't name. But of all the leading pain relievers you see advertised, Bayer is the only one that is all Aspirin. And Aspirin is what doctors recommend. [6]

(6) Bayer wants you to *know* about pain relievers . . . did you know that two Bayer Aspirin tablets bring all the pain relief power a headache can use? Did you know that Bayer without any additives is every bit as fast and effective in relieving pain as those products that have additives?

(7) Confused by claims? By shapes and sizes? By strange sounding ingredients? When you need fast relief from headache pain, don't forget this fact . . . Bayer is 100% Aspirin

and Aspirin is the strongest pain reliever you can buy. No wonder Bayer works wonders.

(8) If you've ever heard that all aspirin's alike, here's something you should know. While it's true that the United States Pharmacopoeia does set standards for aspirin, Bayer surpasses these standards in many ways. For example, Bayer standards require complete tablet disintegration within thirty seconds. That's ten times faster than the accepted five-minute standard. It's one of the things that helps make Bayer fast and gentle.

(9) 1ST MAN: How come Bayer doesn't buffer its aspirin? BAYER MAN: There's really no need to. In relieving pain, buffered aspirin isn't any faster or gentler than Bayer. Yes.

(10) When hot weather makes you feel headachy, tense, irritable, two Bayer Aspirin and a short rest can help you feel better fast!

It happens to most of us on a hot, humid summer day, when the pressures of daily living mount up. By mid-afternoon we feel so headachy and edgy that the simplest chore, the smallest disturbance becomes an irritation. We're in no mood to enjoy life or the company of others.

Here's how to turn that mood around: just take two Bayer Aspirin for your headache, sit down for a few minutes and relax. You too will say, "Bayer works wonders." These few minutes can make a world of difference in the way you feel and act. You'll enjoy being with people, and they'll enjoy being with you. [7]

Whenever you get headachy, tense and out of sorts on a hot summer afternoon, set aside a few minutes for Bayer Aspirin and a brief rest. Bayer is *pure* aspirin, not just *part* aspirin. Ask your pharmacist.

(11) Bayer recently tested its aspirin against 220 other brands. For purity, stability, speed of disintegration, Bayer was consistently better.

(12) I read about recent Bayer tests on aspirin. They tested for *quality*, for purity, for *freshness* against 220 other brands. The tests showed that Bayer makes the superior aspirin.

B. Bayer Aspirin for Children:

... You don't settle for any children's aspirin. You want the best. You want Bayer because no one makes aspirin like Bayer. No one purifies aspirin like Bayer. No one protects Aspirin like Bayer.

C. For Cope:

(1) Important studies made at the world's leading headache clinic show that for relief of severe nervous tension headaches a combination of a pain reliever and a sedative provides greater relief than either medication alone. Of all the leading remedies you can buy for ordinary nervous tension headaches, only Cope combines a gentle relaxer with a powerful pain reliever for really effective relief. If you have chronic headaches, see your doctor. For the usual nervous tension headache get Cope.

(2) I get it on rainy days. I get it during rush hour. I get it when the boss looks over my shoulder. When the name of the pain is nervous tension headache, the name of the remedy is Cope. Because Cope gives you a powerful pain reliever plus a gentle relaxer. [8]

D. For Vanquish:

(1) (3 tablets are shown with 1 caplet of Vanquish)

For your headache pain, here are your major choices: This leading extra strength product has no buffers. This leading buffered product has no extra strength. This leading pain reliever has strength but no buffers. Of all the leading pain relievers you can buy, only Vanquish gives you extra strength and gentle buffers. Vanquish. The choice. (Sterling Drug, Inc.)

(2) When you get a headache we think you should take Vanquish. And we'll show you why in a head to head comparison. This is Vanquish. It gives you extra strength and gentle buffers. And its the only leading pain reliever that does. This is a leading extra strength product. It has no buffers. And there are no buffers in this other extra strength product either. This leading buffered product comes without extra strength. We think your headache deserves extra strength and you deserve gentle buffers. (Sterling Drug, Inc.)

(3) Vanquish is different. It gives you proven effectiveness of Aspirin as in this tablet plus extra medication as in these. But it also includes two gentle buffers . . . With Vanquish the only one. (Sterling Drug, Inc.)

(4) Her headache is killing me. When she gets a pain in the head, it can be a big pain to me, so I give her Vanquish. Vanquish is strong medicine. Vanquish contains more pain relievers than the largest selling extra strength tablet . . . and it has gentle buffers. How's your headache, dear? Dit Dit Dit Dah . . . Vanquish is strong medicine. (Sterling Drug, Inc., and Lois Holland Callaway, Inc.) [9]

E. For Midol:

(1) Live Your Life . . . Relieved of Menstrual Distress. In the modern life you lead, there come the calm times, too. Strolling hand in hand. Reading together. Talking together. These are the precious, serene moments. And you let nothing interfere. Not even functional menstrual distress. How? With Midol. Because MIDOL contains:

An exclusive anti-spasmodic that helps STOP CRAMPS

Medically-approved ingredients that RELIEVE HEADACHE, LOW BACKACHE
. . . CALM JUMPY NERVES . . .

Plus a special mood-brightener that gives you a real lift . . . gets you through the trying pre-menstrual period feeling calm and comfortable.

PAR. 8. Through the use of these advertisements, and others similar thereto not specifically set out herein, it was represented directly or by implication:

A. By respondents Sterling Drug, Inc., and Dancer-Fitzgerald-Sample, Inc., that it has been established that:

1. Bayer Aspirin is superior in terms of significant therapeutic effect to any other aspirin.
2. Bayer Children's Aspirin is superior in terms of significant therapeutic effect to any other children's aspirin.
3. A recommended dose of Cope is more effective for the relief of "nervous tension headache" pain than a recommended dose of any other non-prescription internal analgesic.

B. By respondent Sterling Drug, Inc., that it has been established that:

1. A recommended dose of Vanquish is more effective for the relief of pain than a recommended dose of aspirin or buffered aspirin.

2. Because Vanquish contains "gentle buffers" it will result in less gastric discomfort than any non-prescription internal analgesic not containing buffers. [10]

C. By respondents Sterling Drug, Inc. and Lois Holland Callaway, Inc., that a recommended dose of Vanquish is more effective for the relief of pain than the largest selling "extra strength" tablet.

PAR. 9. In truth and in fact, none of said representations 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 safety and efficacy of such drugs, as to the validity of all such representations.

PAR. 10. Through the use of these advertisements, and others similar thereto not specifically set out herein, it was represented directly or by implication by respondents Sterling Drug, Inc., and Dancer-Fitzgerald-Sample, Inc. that:

A. Bayer Aspirin is superior in terms of significant therapeutic effect to any other aspirin.

B. Bayer Children's Aspirin is superior in terms of significant therapeutic effect to any other children's aspirin.

PAR. 11. There existed, at the time of said representations, no reasonable basis for making the above representations, in that respondents lacked competent and reliable scientific evidence sufficient to support such representations.

PAR. 12. Through the use of these advertisements, and other similar thereto not specifically set out herein, it was represented directly or by implication:

A. By respondents Sterling Drug, Inc., and Dancer-Fitzgerald-Sample, Inc., that a recommended dose of Cope is more effective for the relief of "nervous tension headache" pain than a recommended dose of any other non-prescription internal analgesic.

B. By respondent Sterling Drug, Inc., that:

1. A recommended dose of Vanquish is more effective for the relief of pain than a recommended dose of aspirin or buffered aspirin.

2. Because Vanquish contains "gentle buffers" it will result in less gastric discomfort than any non-prescription internal analgesic not containing buffers. [11]

C. By respondents Sterling Drug, Inc. and Lois Holland Callaway,

Inc., that a recommended dose of Vanquish is more effective for the relief of pain than the largest selling "extra strength" tablet.

PAR. 13. There existed, at the time of said representations, a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drugs, as to the validity of such representations.

PAR. 14. Moreover, respondents made said representations without disclosing the existence of such a substantial question 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. Through the use of the aforesaid advertisements and others similar thereto not specifically set out herein, it was represented directly or by implication:

A. By respondents Sterling Drug, Inc. and Dancer-Fitzgerald-Sample, Inc. that a recommended dose of Bayer Aspirin relieves nervous tension, anxiety and irritability and improves the user's mood.

B. By respondents Sterling Drug, Inc., and Dancer-Fitzgerald-Sample, Inc. that a recommended dose of Cope relieves nervous tension, anxiety and irritability and will enable persons to cope with the ordinary stresses of everyday life.

C. By respondent Sterling Drug, Inc. that a recommended dose of Midol relieves nervous tension, stress, fatigue and depression and improves the user's mood.

PAR. 16. There existed at the time of said representations no reasonable basis for making the above representation in that respondents had no competent and reliable scientific evidence to support such representations.

PAR. 17. Through the use of the advertisements referred to in Paragraph Seven, sections (A) (2) (3) (4) (6) (7) and (9), (C), and (D) above it was represented directly or by implication: [12]

A. By respondents Sterling Drug, Inc., Dancer-Fitzgerald-Sample, Inc., that Bayer Aspirin is as effective for the relief of headache pain (including "nervous tension headache" pain) as, and will cause gastric discomfort no more frequently than, any other non-prescription internal analgesic, including Cope and Vanquish;

B. By respondents Sterling Drug, Inc., and Dancer-Fitzgerald-Sample, Inc., that Cope is more effective for the relief of "nervous tension headache" pain than any other non-prescription internal analgesic, including Bayer Aspirin and Vanquish;

C. By respondent Sterling Drug, Inc., that Vanquish is more effec-

tive for the relief of headache pain than any aspirin, including Bayer Aspirin, and will cause less gastric discomfort than any non-buffered internal analgesic, including Bayer Aspirin.

The representations referred to sections (A), (B), and (C) above are mutually inconsistent. Respondents have made claims for a product that are inconsistent with contemporaneous claims for other products made by the same firm.

PAR. 18. Furthermore, in advertisements for Cope, respondents Sterling Drug, Inc., and Dancer-Fitzgerald-Sample, Inc. referred to the results of tests or studies and represented, directly or by implication, that such tests or studies prove the claim that a recommended dose of Cope is more effective for the relief of "nervous tension headaches" than recommended doses of all other non-prescription internal analgesics.

PAR. 19. In truth and in fact, the tests or studies referred to do not prove the claim that a recommended dose of Cope is more effective for the relief of "nervous tension headaches" than recommended doses of all other non-prescription internal analgesics.

PAR. 20. Through the use of the advertisements referred to in Paragraph Seven, Sections A(11) and (12), and other similar thereto not specifically set out herein, respondents Sterling Drug, Inc. and Dancer-Fitzgerald-Sample, Inc. represented, directly or indirectly, that Bayer Aspirin has been tested against 200 other brands of aspirin for quality, purity, freshness, stability, and speed of disintegration, and that the results of the tests demonstrated that Bayer Aspirin is qualitatively superior to all of the other brands tested in all respects, and therapeutically superior to all of the other brands tested. [13]

PAR. 21. In truth and in fact, the tests referred to do not demonstrate that Bayer Aspirin is qualitatively superior in all respects, including speed of disintegration, to all other aspirins tested. Moreover, these tests do not demonstrate that Bayer is therapeutically superior to all other brands because at the time of such representations there existed a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug product, concerning the validity, significance or interpretation of such tests as related to such representation.

PAR. 22. Respondents Sterling Drug, Inc. and Dancer-Fitzgerald-Sample, Inc. represented directly or by implication that Cope contained a unique formula in that it alone among non-prescription headache remedies contained both a pain reliever and an ingredient with sedative properties. In truth and in fact the ingredients referred to are aspirin and methapyrilene, both of which were available for non-prescription use in Excedrin PM. Therefore, the advertisements re-

ferred to in Paragraph Seven (C)(1) were and are misleading in a material respect.

PAR. 23. Respondents Sterling Drug, Inc. and Lois Holland Callaway, Inc., marketed and advertised Vanquish without disclosing in the advertising for this product that it contains aspirin and caffeine. Aspirin and caffeine are well-known commonplace substances widely available in a variety of non-prescription products. Moreover, the use of aspirin or caffeine can be injurious to health and may cause undesirable side effects. Thus, respondents have failed to disclose in advertising a material fact, which if known to certain consumers would be likely to affect their consideration of whether or not to purchase such products.

PAR. 24. Furthermore, respondents Sterling Drug, Inc. and Dancer-Fitzgerald-Sample, Inc. marketed and advertised Cope without disclosing in the advertising for this product that it contains aspirin and caffeine. Aspirin and caffeine are well-known commonplace substances widely available in a variety of non-prescription products. Moreover, the use of aspirin or caffeine can be injurious to health and may cause undesirable side effects. Thus, respondents have failed to disclose in advertising a material fact, which if known to certain consumers would be likely to affect their consideration of whether or not to purchase such products. [14]

PAR. 25. Furthermore, respondent Sterling Drug, Inc. marketed and advertised Midol without disclosing in the advertising for this product that it contains aspirin and caffeine. Aspirin and caffeine are well-known commonplace substances widely available in a variety of non-prescription products. Moreover, the use of aspirin or caffeine can be injurious to health and may cause undesirable side effects. Thus, respondent has failed to disclose in advertising a material fact, which if known to certain consumers would be likely to affect their consideration of whether or not to purchase such products.

PAR. 26. Furthermore, in advertisements for Midol, respondents Sterling Drug, Inc. and Thompson-Koch Company represented directly or by implication that the analgesic ingredients in Midol are other than ordinary aspirin and that the stimulant in Midol is other than caffeine.

PAR. 27. In truth and in fact, the analgesic ingredient in Midol is ordinary aspirin, and the stimulant in Midol is caffeine.

PAR. 28. The advertisements referred to in Paragraph Eight above were, and are, misleading in material respects, as alleged in Paragraphs Nine, Thirteen, Fourteen, Nineteen, Twenty-one, Twenty-two, Twenty-three, Twenty-four, Twenty-five, and Twenty-seven and constitute and now constitute false advertisements.

PAR. 29. The making of claims for a product that are inconsistent

with contemporaneous claims for other products made by the same firm, as alleged in Paragraph Seventeen above, and the making of representations as alleged in Paragraphs Eleven, Thirteen, Fourteen, and Sixteen, constituted and now constitute unfair or deceptive acts or practices in commerce.

PAR. 30. The use by respondents of the aforesaid deceptive statements, representations, or claims, and the dissemination of the aforesaid false advertisements has had and now has, the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said statements, representations, or claims were and are true and into the purchase of substantial quantities of said drugs of respondent Sterling Drug, Inc. by reason of said erroneous and mistaken belief. [15]

PAR. 31. In the course and conduct of its aforesaid business, and at all times mentioned herein, respondent Sterling Drug, Inc. has been and now is in substantial competition in commerce, with corporations, firms and individuals in the sale of drug products of the general kind and nature as those sold by respondent.

In the course and conduct of its aforesaid business, and at all times mentioned herein, respondent Dancer-Fitzgerald-Sample, Inc. has been, and now is in substantial competition in commerce with other advertising agencies.

In the course and conduct of its aforesaid business, and at all times mentioned herein, respondent Lois Holland Callaway, Inc. has been, and now is in substantial competition in commerce with other advertising agencies.

PAR. 32. The aforesaid acts and practices of respondents, as herein alleged, including the dissemination of 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

JANUARY 30, 1981

PRELIMINARY STATEMENT

On February 23, 1973, the Federal Trade Commission ("Commission") issued a complaint charging Sterling Drug Inc. ("Sterling"),

Dancer-Fitzgerald-Sample, Inc. ("DFS") and Lois Holland Callaway, Inc. ("LHC") with violations of Sections 5 and 12 of the Federal Trade Commission Act, as amended (15 U.S.C. 45 and 52) in connection with certain advertisements for Bayer Aspirin ("Bayer"), Bayer Children's Aspirin ("BCA"), Vanquish, Cope and Midol, all over-the-counter ("OTC") internal analgesic products. Similar complaints were issued on the same date against *Bristol-Myers Company et al.* (Docket No. 8917) [102 F.T.C. 21] and *American [2] Home Products Corporation* (Docket No. 8918) [98 F.T.C. 136], in connection with certain advertisements for certain OTC internal analgesic products marketed by these firms.

On May 9, 1973, respondents Sterling & DFS filed their respective answers and LHC filed its answer on May 19, 1973, each denying that it violated the Federal Trade Commission Act. Administrative Law Judge William K. Jackson, originally assigned to this proceeding, entered a Prehearing Order, dated October 3, 1973, setting forth the issues of fact and law to govern the adjudicatory proceeding. This case, along with the two analgesic cases referred to above, was assigned to me upon Judge Jackson's retirement, effective January 1, 1975.

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 in this case.

Joint hearings in the three analgesic cases were held from June 6 through August 1, 1977. A number of complaint counsel's witnesses common to the three cases testified as to the design and execution of various surveys and studies upon which complaint counsel sought to rely. Some 66 exhibits were received in evidence and the transcript of the joint hearings comprised some 2850 pages. The joint hearings were followed by separate trials in Docket 8918 and Docket 8917 and an Initial Decision in each of the two cases has been filed on September 1, 1978 and September 28, 1979, respectively.

The separate trial in this case began in October 1979 and the record was closed on August 26, 1980. The record testimony covers over 18,000 pages of transcript. Some forty witnesses testified, including a large number of expert witnesses, and some 410 exhibits were received in evidence. In addition, a large volume of scientific publications and material was discussed by expert witnesses. By order dated September 12, 1980, the Commission extended the date within which to file the initial decision through January 30, 1981.

Neither advertising agency is defending this action at the present time. Lois Holland Callaway, Inc. is now insolvent and its creditor's committee is not defending the action (CX 690). Dancer-Fitzgerald-

Sample, Inc. was discharged by Sterling Drug Inc. in June 1976, and has had no responsibility nor interest in respondent's products since that time. Dancer-Fitzgerald-Sample entered into a consent order agreement with complaint counsel which was signed on December 8, 1977, and made final by the Commission on July 1, 1980 (45 FR 26,344-47, April 18, 1980; 45 FR 48,606, July 21, 1980) [96 F.T.C. 1 (1980)]. [3]

Based on the Complaint, Answers and Prehearing Orders, the following issues are matters for determination in this proceeding:

1. With respect to advertising representations for Bayer:

(a) That "it was represented, directly or by implication . . . , that it has been established that . . . Bayer Aspirin is superior in terms of significant therapeutic effect to any other aspirin." (Complaint ¶ 8; *see* Contested Issues of Fact ¶ 2(a), September 25, 1973, adopted by Prehearing Order, October 3, 1973 [hereinafter "Contested Issues of Fact"])

(b) That the above representation was not 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 safety and efficacy of such drugs, as to the validity of all such representations." (Complaint ¶ 9; *see* Contested Issues of Fact ¶ 3, Contested Legal Issues ¶¶ 3, 4, September 25, 1973, adopted by prehearing order, October 3, 1973 [hereinafter "Contested Legal Issues"])

(c) That "it was represented directly or by implication . . . [that] Bayer Aspirin is superior in terms of significant therapeutic effect to any other aspirin." (Complaint ¶ 10; *see* Contested Issues of Fact ¶ 4(a))

(d) That there existed "no reasonable basis" for making the above representation at the time it was made, "in that respondents lacked competent and reliable scientific evidence sufficient to support such representations." (Complaint ¶ 11; *see* Contested Issues of Fact ¶ 5; *see* Contested Legal Issues ¶¶ 1, 2)

(e) That "it was represented directly or by implication . . . that a recommended dose of Bayer Aspirin relieves nervous tension, anxiety and irritability and improves the user's mood." (Complaint ¶ 15; *see* Contested Issues of Fact ¶ 9(a))

(f) That there existed "no reasonable basis" for making the above representation at the time it was made, "in that respondents had no competent and reliable scientific evidence to support such representations." (Complaint ¶ 16; *see* Contested Issues of Fact ¶ 10; Contested Legal Issues ¶¶ 1, 2)

(g) That "it was represented, directly or indirectly, that Bayer Aspirin has been tested against [4] 220 other brands of aspirin for quality,

purity, freshness, stability, and speed of disintegration, and that the results of the tests ["223 test"] demonstrated that Bayer Aspirin is qualitatively superior to all of the other brands tested in all respects." This was interpreted by respondent as meaning overall pharmaceutical superiority. It was interpreted by complaint counsel as meaning superiority in each tested respect. On October 2, 1975, the Administrative Law Judge adopted complaint counsel's interpretation. (Complaint ¶ 20; Contested Issues of Fact ¶ 15) This position was later explained as referring to the respects enumerated in ¶ 20 of the Complaint: quality, freshness, stability, and speed of disintegration (Order Denying Complaint Counsel's Motion for Summary Judgment, October 24, 1975, note page 6; Oral Argument on Motion for Partial Summary Judgment, October 22, 1975, pp. 24-25).

(h) That the so-called "223 test" does "not demonstrate that Bayer Aspirin is qualitatively superior in all respects, including speed of disintegration, to all other aspirins tested." (Complaint ¶ 21; *see* Contested Issues of Fact ¶ 16; Contested Legal Issues ¶¶ 3, 4)

(i) That it was represented that the "223 test" "demonstrated that Bayer Aspirin is . . . therapeutically superior to all of the other brands tested." (Complaint ¶ 20; *see* Contested Issues of Fact ¶ 17)

(j) That the "223 test" does "not demonstrate that Bayer is therapeutically superior to all other brands because at the time of such representations there existed a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug product, concerning the validity, significance or interpretation of such tests as related to such representation." (Complaint ¶ 21; *see* Contested Issues of Fact ¶ 18; Contested Legal Issues ¶¶ 3, 4)

2. With respect to advertising representations for BCA:

(a) That "it was represented, directly or by implication . . . , that it has been established that . . . Bayer Children's Aspirin is superior in terms of significant therapeutic effect to any other children's aspirin." (Complaint ¶ 8; *see* Contested Issues of Fact ¶ 2(b))

(b) That the above representation was not established "for reasons including, but not limited to, the existence of a substantial question, recognized by [5] experts qualified by scientific training and experience to evaluate the safety and efficacy of such drugs as to the validity of all such representations." (Complaint ¶ 9; *see* Contested Issues of Fact ¶ 3; Contested Legal Issues ¶¶ 3, 4)

(c) That "it was represented directly or by implication . . . [that] Bayer Children's Aspirin is superior in terms of significant therapeutic effect to any other children's aspirin." (Complaint ¶ 10; *see* Contested Issues of Fact ¶ 4(b))

(d) That there existed “no reasonable basis” for making the above representation at the time it was made, “in that respondents lacked competent and reliable scientific evidence sufficient to support such representations.” (Complaint ¶ 11; *see* Contested Issues of Fact ¶ 5; Contested Legal Issues ¶¶ 1, 2)

3. With respect to advertising representations for *Vanquish*:

(a) That “it was represented directly or by implication . . . that it has been established that:

(i) A recommended dose of *Vanquish* is more effective for the relief of pain than a recommended dose of aspirin or buffered aspirin;

(ii) Because *Vanquish* contains ‘gentle buffers’ it will result in less gastric discomfort than any nonprescription internal analgesic not containing buffers; and that

(iii) A recommended dose of *Vanquish* is more effective for the relief of pain than the largest selling ‘extra strength’ tablet.” (Complaint ¶ 8; *see* Contested Issues of Fact ¶¶ 2(d), 2(e), 2(f))

(b) That the above representations have not 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 safety and efficacy of such drugs, as to the validity of all such representations.” (Complaint ¶ 9; *see* Contested Issues of Fact ¶ 3; Contested Legal Issues ¶¶ 3, 4)

(c) That “it was represented directly or by implication . . . that: [6]

(i) A recommended dose of *Vanquish* is more effective for the relief of pain than a recommended dose of aspirin or buffered aspirin;

(ii) Because *Vanquish* contains ‘gentle buffers’ it will result in less gastric discomfort than any nonprescription internal analgesic not containing buffers; and that

(iii) A recommended dose of *Vanquish* is more effective for the relief of pain than the largest selling ‘extra strength’ tablet.” (Complaint ¶ 12; *see* Contested Issues of Fact ¶¶ 6(b), 6(c), 6(d))

(d) That at the time of the above representations regarding *Vanquish* there existed “a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drugs, as to the validity of such representations” (Complaint ¶ 13; *see* Contested Issues of Fact ¶ 7; Contested Legal Issues ¶¶ 4, 5)

(e) That these representations were made “without disclosing the existence of such a substantial question 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." (Complaint ¶ 4; *see* Contested Issues of Fact ¶ 8; Contested Legal Issues ¶¶ 4, 6, 7)

(f) That respondent "marketed and advertised Vanquish without disclosing in the advertising for this product that it contains aspirin. . . .¹ Aspirin . . . [is a] well-known commonplace [substance] widely available in a variety of non-prescription products. Moreover, the use of aspirin . . . can be injurious to health and may cause undesirable side effects. Thus, [7] respondents have failed to disclose in advertising a material fact, which if known to certain consumers would be likely to affect their consideration of whether or not to purchase such products." (Complaint ¶ 23; *see* Contested Issues of Fact ¶¶ 20, 21; Contested Legal Issues ¶¶ 6, 8)

4. With respect to advertising representations for *Cope*:

(a) That "it was represented, directly or by implication . . . that it has been established that a recommended dose of *Cope* is more effective for the relief of 'nervous tension headache' pain than a recommended dose of any other non-prescription internal analgesic." (Complaint ¶ 8; *see* Contested Issues of Fact ¶ 2(c))

(b) That the above representation was not 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 safety and efficacy of such drugs, as to the validity of all such representations." (Complaint ¶ 9; *see* Contested Issues of Fact ¶ 3; Contested Legal Issues ¶¶ 3, 4)

(c) That "it was represented directly or by implication . . . that a recommended dose of *Cope* is more effective for the relief of 'nervous tension headache' pain than a recommended dose of any other non-prescription internal analgesic." (Complaint ¶ 12; *see* Contested Issues of Fact ¶ 6(a))

(d) That at the time the above representation was made, there existed "a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drugs, as to the validity of such representations." (Complaint ¶ 13; *see* Contested Issues of Fact ¶ 7; Contested Legal Issues ¶¶ 4, 5)

(e) That these representations were made "without disclosing the existence of such a substantial question. . . . 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,

¹ Paragraph 23 of the Complaint also alleged that failure to disclose that caffeine is an ingredient of Vanquish was a failure to disclose a material fact which, if known to certain consumers, would be likely to affect their consideration of whether or not to purchase the product. However, complaint counsel stated that they were not pursuing the caffeine disclosure issue (Prehearing Conference Order, October 22, 1979).

respondents have failed to disclose material facts.” (Complaint ¶ 14; see Contested Issues of Fact ¶ 8; Contested Legal Issues ¶¶ 4, 6, 7)

(f) That “it was represented directly or by implication . . . that a recommended dose of Cope [8] relieves nervous tension, anxiety and irritability and will enable persons to cope with the ordinary stresses of everyday life.” (Complaint ¶ 15; see Contested Issues of Fact ¶ 9(b))

(g) That there existed “no reasonable basis” for making the above representation at the time it was made, “in that respondents had no competent and reliable scientific evidence to support such representations.” (Complaint ¶ 16; see Contested Issues of Fact ¶ 10; Contested Legal Issues ¶¶ 1, 2)

(h) That respondents “referred to the results of tests or studies and represented, directly or by implication, that such tests or studies prove the claim that a recommended dose of Cope is more effective for the relief of ‘nervous tension headaches’ than recommended doses of all other non-prescription internal analgesics.” (Complaint ¶ 18; see Contested Issues of Fact ¶ 13)

(i) That “the tests or studies referred to do not prove the claim that a recommended dose of Cope is more effective for the relief of ‘nervous tension headaches’ than recommended dose of all other non-prescription internal analgesics.” (Complaint ¶ 19; see Contested Issues of Fact ¶ 14)

(j) That it was “represented directly or by implication that Cope contained a unique formula in that it alone among non-prescription headache remedies contained both a pain reliever and an ingredient with sedative properties . . . [and that] the ingredients referred to are aspirin and methapyrilene, both of which were available for non-prescription use in Excedrin PM. Therefore, the advertisements . . . were misleading in a material respect.” (Complaint ¶ 22; see Contested Issues of Fact ¶ 19)

(k) That respondent “marketed and advertised Cope without disclosing in the advertising for this product that it contains aspirin. . . .² Aspirin . . . [is a] well-known commonplace [substance] widely available in a variety of non-prescription products. Moreover, the use of aspirin . . . can be injurious to health and [9] may cause undesirable side effects. Thus, respondents have failed to disclose in advertising a material fact, which if known to certain consumers would be likely to affect their consideration of whether or not to purchase such products.” (Complaint ¶ 24; see Contested Issues of Fact ¶¶ 20, 21; Contested Legal Issues ¶¶ 6, 8)

5. With respect to advertising representations for *Midol*:

² Paragraph 24 of the Complaint also contained allegations regarding a failure to disclose the ingredient caffeine. This issue has been abandoned. See n. 1, *supra*.

(a) That "it was represented directly or by implication . . . that a recommended dose of Midol relieves nervous tension, stress, fatigue and depression and improves the user's mood." (Complaint ¶ 15; *see* Contested Issues of Fact ¶ 9(c))

(b) That there existed "no reasonable basis" for making the above representation at the time it was made, "in that respondents had no competent and reliable scientific evidence to support such representations." (Complaint ¶ 16; *see* Contested Issues of Fact ¶ 10; Contested Legal Issues ¶¶ 1, 2)

(c) That respondent "marketed and advertised Midol without disclosing in the advertising for this product that it contains aspirin. . . .³ Aspirin . . . [is a] well-known commonplace [substance] widely available in a variety of non-prescription products. Moreover, the use of aspirin . . . can be injurious to health and may cause undesirable side effects. Thus, respondent has failed to disclose in advertising a material fact, which if known to certain consumers would be likely to affect their consideration of whether or not to purchase such products." (Complaint ¶ 25; *see* Contested Issues of Fact ¶¶ 20, 21; Contested Legal Issues ¶¶ 6, 8)

(d) That it was "represented directly or by implication that the analgesic ingredients in Midol are other than ordinary aspirin and that the stimulant in Midol is other than caffeine." (Complaint ¶ 26; *see* Contested Issues of Fact ¶ 22)

(e) That the "analgesic ingredient in Midol is ordinary aspirin, and the stimulant in Midol is caffeine." (Complaint ¶ 27) [10]

6. The Complaint further made the following allegations with regard to inconsistent representations:

(a) That "it was represented directly or by implication . . . that Bayer Aspirin is as effective for the relief of headache pain (including 'nervous tension headache' pain) as, and will cause gastric discomfort no more frequently than, any other non-prescription internal analgesic, including Cope and Vanquish." (Complaint ¶ 17; *see* Contested Issues of Fact ¶ 11(a))

(b) That "it was represented directly or by implication . . . that Vanquish is more effective for the relief of headache pain than any aspirin, including Bayer Aspirin, and will cause less gastric discomfort than any non-buffered internal analgesic, including Bayer Aspirin." (Complaint ¶ 17; *see* Contested Issues of Fact ¶ 11(c))

(c) That "it was represented directly or by implication . . . that Cope is more effective for the relief of 'nervous tension headache' pain than any other non-prescription internal analgesic, including Bayer Aspi-

³ Paragraph 25 of the Complaint also contained allegations regarding a failure to disclose the ingredient caffeine. This issue has been abandoned. *See* n. 1, *supra*.

rin and Vanquish.” (Complaint ¶ 17; *see* Contested Issues of Fact ¶ 11(b))

(d) That respondents have “made claims for a product that are inconsistent with contemporaneous claims for other products made by the same firm.” (Complaint ¶ 17; *see* Contested Issues of Fact ¶¶ 11, 12)

(e) That these representations are “mutually inconsistent.” (Complaint ¶ 17; *see* Contested Issues of Fact ¶ 12; Contested Legal Issues ¶¶ 9, 10)

7. The Complaint made the following general allegations:

(a) That the excerpts from advertisements for Bayer Aspirin, Bayer Children’s Aspirin, Vanquish, Cope and Midol listed in paragraph 7 of the Complaint were typical of the statements and representations made in the advertising. (Complaint ¶ 7; *see* Contested Issues of Fact ¶ 1)

(b) That the advertisements referred to in paragraph 8 of the Complaint were misleading in material respects, as alleged in Complaint ¶¶ 9, 13, 14, 15, 16, [11] 19, 20, 21, 22, 24 and 27 and constituted false advertisements. (Complaint ¶ 28; *see* Contested Legal Issues ¶ 11)

(c) That the making of claims for a product that are inconsistent with contemporaneous claims for other products made by the same firm, as alleged in Complaint ¶ 17 and the making of representations as alleged in Complaint ¶¶ 11, 13, 14 and 16, constituted and now constitute unfair or deceptive acts or practices in commerce. (Complaint ¶ 29; *see* Contested Legal Issues ¶¶ 9, 10)

(d) That “[t]he use by respondents of the aforesaid deceptive statements, representations, or claims, and the dissemination of the aforesaid false advertisements has had and now has, the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said statements, representations, or claims were and are true and into the purchase of substantial quantities of said drugs of respondent Sterling Drug, Inc. by reason of said erroneous and mistaken belief.” (Complaint ¶ 30)

(e) That “[t]he aforesaid acts and practices of respondents, as herein alleged, including the dissemination of 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.” (Complaint ¶ 32)

The proposed findings and conclusions submitted by the parties and their arguments in support thereof have been given careful consideration by me and to the extent not adopted by this Initial Decision in

the form proposed or in substance, are rejected as not supported by the evidence or as immaterial. Any motion appearing on the record not heretofore or hereby specifically ruled upon either directly or by the necessary effect of the conclusions in this Initial Decision are hereby denied.

Upon consideration of the entire record in this proceeding and having considered the demeanor of the witnesses, I make the [12] following findings of fact and conclusions of law and order based on the record considered as a whole.⁴

FINDINGS OF FACT

I. INTRODUCTION

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

1. Sterling Drug Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at 90 Park Avenue, New York, New York (Statement of Noncontested Issues, ¶ 1).

2. Dancer-Fitzgerald-Sample, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at 347 Madison Avenue, New York, New York (*Id.* ¶ 2). On December 8, 1977, DFS agreed to an Order to Cease and Desist in this matter conforming to the requirements of Section 2.32 of the Commission Rules. The Decision and Order with respect to DFS was issued July 1, 1980 [96 F.T.C. 1 (1980)].

3. Lois Holland Callaway, Inc. is a corporation organized, existing under and by virtue of the laws of the State of New York with its office and principal place of business [13] located at 745 Fifth Avenue, New York, New York (Answer of LHC, ¶ 2). On or about September 1978, LHC ceased doing business because of its insolvency. Its affairs are presently managed by an informal creditors committee. On October 24, 1979, co-counsel to the creditors committee notified complaint

⁴ 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 - Sterling's Proposed Findings.
RB - Sterling's Post-Trial Memorandum.
RRB - Sterling's Post-Trial Reply Memorandum.
Tr - Transcript of hearings, sometimes preceded by the name of the witness.
CX - Complaint counsel's documentary exhibit.
RX - Sterling's documentary exhibit.
Comp. - Complaint.
Ans. - Answer.

counsel that neither stockholders nor former officers of LHC intended to present any defense in the instant proceeding (CX 680A-D).

4. Thompson-Koch is an unincorporated division of Sterling, which at all times pertinent to this action has acted *inter alia* as an in-house advertising agency for Midol (CX 678, admission 220; Hartman, Tr. 9135). Glenbrook Laboratories ("Glenbrook") is an unincorporated division of Sterling, which at all times pertinent to this proceeding has had responsibility for marketing all the products involved in this proceeding (CX 678, admission 38). The Sterling-Winthrop Research Institute ("SWRI") was at all times pertinent to this proceeding, an unincorporated research division of Sterling (CX 678, admission 39).

5. Sterling is now and has been engaged in the manufacturing, offering for sale, sale and distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Midol," "Cope," and "Vanquish" (Statement of Noncontested Issues, ¶ 4). In the course and conduct of its business, Sterling causes these products, when sold, to be transported from its places of business located in various States of the United States to purchasers located in various States of the United States and in the District of Columbia. Sterling maintains and at all times relevant to the proceeding has maintained a substantial course of trade in these products in commerce. The volume of such business has been substantial (Answer of Sterling, ¶ 5).

6. From 1969 through 1973 annual consumer sales for Bayer Aspirin, Bayer Children's Aspirin, Midol, Vanquish and Cope averaged \$52.6 million, \$9.38 million, \$3.9 million, \$4.9 million and \$2.57 million, respectively (CX 575A-E). In 1969, the average retail price for 100-tablet bottles of Bayer Aspirin was \$1.01; the average wholesale price for a 36-tablet package of Bayer Children's Aspirin was \$.22; the average wholesale price for a 60-tablet package of Cope was \$.71; and the average wholesale price for a 30-tablet package of Midol was \$.59 (CX 575A-B, D-E).

7. Bayer Aspirin, Bayer Children's Aspirin, Cope, Midol and Vanquish are nonprescription analgesic products which come within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act (Answer of Sterling, ¶ 3).

8. The designation, active ingredients and directions for use of these nonprescription analgesic drugs is set forth in paragraph 3 of the Complaint, and is adopted and incorporated by reference at Statement of Non-Contested Issues, paragraph 7 and admissions 965-68 of CX 678, as follows: [14]

Bayer Aspirin (per tablet):

324 milligrams (mg) aspirin.

Dosage: 1 or 2 tablets with water every 4 hours, as necessary, up to 12 tablets a day.

Bayer Children's Aspirin (per tablet):

Aspirin 81 mg

Dosage: Varies with age of child.Cope (per tablet):

Aspirin 421.2 mg

Caffeine 32 mg

Methapyrilene fumarate 12.5 mg

Buffers:

Aluminum hydroxide 25.0 mg

Magnesium hydroxide 50 mg

Dosage: 1 or 2 tablets every 4 hours as needed, up to 9 tablets per day.Midol (per tablet):

Aspirin 453.6 mg

Caffeine 32.4 mg

Cinnamedrine hydrochloride 149 mg

Dosage: 2 Midol tablets with water. Repeat 1-2 tablets every 4 hours as needed, up to 9 tablets per day.Vanquish (per tablet):

Aspirin 227 mg

Acetaminophen 994 mg

Caffeine 33 mg

Buffers:

Aluminum hydroxide 25 mg

Magnesium hydroxide 50 mg

Dosage: 2caplets with water. Can be repeated every 4 hours if needed, up to 12 caplets per day.

9. In the course and conduct of its business, Sterling disseminated, and caused to be disseminated, certain advertise[15]ments concerning Bayer Aspirin, Bayer Children's Aspirin, Cope, Midol and Vanquish, by United States mail and by various means in commerce, including, but not limited to, advertisements inserted in magazines and newspapers, 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 or which were likely to induce, directly or indirectly, the purchase of these drugs in commerce (Answer of Sterling ¶ 6). These activities have included the dissemination of the advertising representations challenged in this proceeding.

10. In promoting these products by advertising from 1969 through 1973 Sterling spent at least \$86.5 million for Bayer and \$15.5 million for Vanquish; for advertising from 1969 through 1972, \$11.4 million for Bayer Children's Aspirin; for advertising from 1969 through 1970, \$5 million for Cope and \$2.1 million for Midol (CX 575A-E). Thus annual advertising expenditures from 1969 through 1973 have averaged approximately \$17.3 million for Bayer and \$3.1 million for Vanquish; from 1969 through 1972, \$2.8 million for Bayer Children's Aspirin; and from 1969 through 1970, \$2.5 million for Cope and \$1 million for Midol. Average ad to sales ratio for Bayer for the 1969-1973 period amounted to 33% (17.3/52.6) (F. 6, *supra*).

11. In 1969 the average retail price per tablet was \$.0044 for non-Bayer plain 5-grain aspirin, as compared with \$.0101 for Bayer; the average 100-tablet bottle price was \$.44 for non-Bayer aspirin, compared with \$1.01 for Bayer (CX 575A, F). These figures show that in 1969 consumers were paying nearly two and a half times more for Bayer than for non-Bayer plain 5-grain aspirin.

12. Bayer Aspirin competes in the over-the-counter internal analgesic market. The prime competitors in that category are Anacin, Bufferin, Excedrin, Tylenol (nonaspirin product), and a large group of plain 5-grain aspirin brands (Alberts, Tr. 8918; Miles, Tr. 9360).

13. Bayer is the only 5-grain aspirin nationally advertised on television (Alberts, Tr. 8919; Miles, Tr. 9360). Advertising for all other 5-grain aspirins is limited to in-store promotions at the retail level, print advertising, and a very small amount of spot television (Alberts, Tr. 8919; Mattimore, Tr. 15384-85). Bayer Aspirin is the only 5-grain aspirin with 100% distribution in food and drug outlets. The other 5-grain aspirin brands have regional or limited distribution (Alberts, Tr. 8919-20; Miles, Tr. 9360).

14. Sterling regularly purchased and used Nielsen data on the analgesic market. Nielsen marketing data for the analgesic [16] market reports upon the principal brands in the market and upon a category of "All Other Adult Aspirin." This category consists of all straight aspirin brands in the market apart from Bayer: branded aspirin such as Squibb, McKesson, Norwich, St. Joseph and store brands or private-label aspirin (Alberts, Tr. 8988; Mattimore, Tr. 15383-85).

15. Bayer Aspirin's market share has declined relative to the other major analgesic brands in the last 30 years (Alberts, Tr. 8995-96). In the early 1950's, Bayer's share of the analgesic market (in dollar sales) was 25%, Anacin 20%, Bufferin 2%. In 1957, the market shares were Bayer 16%, Anacin 18%, Bufferin 15-18% (Alberts, Tr. 8995; Miles, Tr. 9362). In 1960, the market shares were Bayer 15%, Anacin 17%, Bufferin 12%, Excedrin 8-9% (Alberts, Tr. 8995-96; Miles, Tr. 9362).

16. RX 291 presents Nielsen marketing data for Anacin, Bayer, Bufferin, Excedrin, Vanquish, Cope, Tylenol and All Other Adult Aspirin for the period from 1968 through 1979, showing market shares in dollar and tablet sales (RX 291; Alberts, Tr. 8968). From 1968 to 1979, Tylenol went from virtually no share to being the market leader with more than 25% of the dollar market, which is more than twice the share of its closest competitor, Anacin (RX 291A; Alberts, Tr. 8967-68). From 1968 to 1979, there was a downtrend in market share of Bayer Aspirin in both dollars and tablets (RX 291A, C; Alberts, Tr. 8974). In 1968, Bayer had 16.5% of the market in dollar sales, 27.2% in tablet sales. In 1979, Bayer had dropped to 9.9% of the market in dollar sales, 17.8% of the market in tablet sales (RX 291B, D).

17. Tablet sales data demonstrates that Bayer Aspirin, the traditional leader among 5-grain aspirin brands, has lost its leadership to the All Other Aspirin group. In 1968, Bayer had 27.2% of the tablet market compared to 23.8% for All Other Aspirin. In 1979, Bayer had 17.8% of the tablet market compared to 20.6% for All Other Adult Aspirin. Over the decade, its decline was almost three times that of the All Other Aspirin group (RX 291D; Alberts, Tr. 8974-75).

18. The store brands and private-label brands of aspirin, which number in the hundreds, are manufactured by a relatively small number of tableting companies, about 20-25 (Alberts, Tr. 9046; Mattimore, Tr. 15352-53). These brands are purchased by stores and private-label distributors on a price basis, annually or periodically, so that purchases of the same brand can be from a number of different manufacturing sources over time (Alberts, Tr. 8954; Mattimore, Tr. 15348-49; *see* Miller, Tr. 6980).

19. The analgesic market is a heavily advertised product category (Alberts, Tr. 8959-60; Miles, Tr. 9359-60; RX 292, RX 413B). From 1967 through 1973, the national television advertisers in the analgesic product category were Anacin, [17] Bufferin, Excedrin and Bayer Aspirin. Advertising expenditures were:

	Bayer (millions)	[Combined] Anacin, Bufferin, Excedrin (millions)
1967	\$15.7	\$37.1
1968	16.3	39.4
1969	17.9	45.3
1970	17.8	48.5
1971	18.0	53.1
1972	18.1	49.3
1973	14.7	45.9

(RX 292)

20. The combination products have made and continue to make claims of superiority to plain aspirin—Bufferin that it is faster and gentler, Excedrin that it is stronger, Anacin that it is stronger. In the past several years, with the growth of comparative advertising, more advertising has been directed against Bayer by name, rather than against aspirin (Alberts, Tr. 8988–89; RX 413C-P; Complaint Counsel's Admission Nos. 100–129; *see* Ross, Tr. 6092–94).

21. Bayer advertising is the only national advertising that defends plain 5-grain aspirin against the anti-aspirin advertising of buffered and combination aspirin products (Alberts, Tr. 8993–94; RX 402G-H; *see* Ross, Tr. 6099–6101).

22. In the early 1950's, respondent Sterling complained to the Federal Trade Commission about advertising for Bufferin, at that time a rather recent entrant. It contended that Bufferin advertising improperly represented that it was safer than aspirin, faster-acting than aspirin and that it was other than aspirin. Documents relating to this complaint are in the record as CX 371, RX 407 and RX 156.

23. Until the early 1970's, the Federal Trade Commission failed to take any action against Bufferin. After years of correspondence and a meeting with officials of the FTC, Sterling was led to believe that, in FTC staff's view, there was no basis for challenging the Bufferin claims under the FTC Act (CX 371, RX 156, RX 407). The FTC's failure to take any action and the inroads made by Bufferin (and later Excedrin) were among the factors considered and relied upon by respondent in developing the combination products which it introduced in the 1960's, Vanquish and Cope (Alberts, Tr. 8961; Tainter, RX 284R-S; Trout, Tr. 16104; RX 407A-H). Vanquish was introduced as an "extra-strength" product in the analgesic market segment promoted and defined as such by Excedrin (Alberts, Tr. 9012). Cope was introduced as a formulation designed for nervous tension headache (Tr. 15401–05). [18]

24. Vanquish and Cope have been minor factors in the analgesic market. During the period in which Vanquish advertisements challenged in this case were disseminated, the products accounted for 1.4% to 1.6% of the analgesic market. Since 1974, Vanquish's market share has steadily declined and in 1979 accounted for 1.1% of the analgesic market (RX 291B; CX 633). Cope's market share was 1% in 1969 to .7% in 1971; thereafter, Nielsen data was not collected for Cope (RX 291).

25. Vanquish advertising terminated in 1977. According to Sterling, there are no plans now or in the future to resume Vanquish advertising (Alberts, Tr. 9013).

26. During the period in which the challenged Cope advertisements were disseminated, Cope's market share ranged from 1% (in 1969) to

0.7% (in 1971) (RX 291B). Cope advertising terminated in 1971. According to Sterling, there are no plans to resume such advertising (Alberts, Tr. 9013). Indeed, the product in the form sold in 1969-71 is no longer on the market; it has been reformulated as a result of FDA action.

27. Midol is a specialized product, designed and promoted for the relief of menstrual symptoms. It is one of two products in the menstrual remedies category of the analgesic market (Hartman, Tr. 9136, 9142).

28. LHC has been an advertising agency for Sterling and has prepared, placed for publication and disseminated advertising material for "Vanquish" for all purposes of this proceeding after April 1971 (LHC Answer, ¶¶ 4, 6).

29. Sterling is now and has been engaged in substantial competition in commerce with other firms in the sale of drug products of the general kind and nature as those sold by Sterling, and LHC has been in substantial competition in commerce with other advertising agencies (Statement of Non-Contested Issues, ¶ 13).

II. THE BACKGROUNDS AND QUALIFICATIONS OF CERTAIN WITNESSES WHO TESTIFIED IN THIS PROCEEDING

A. *For Complaint Counsel*

Timothy C. Brock, Ph.D.

30. Dr. Timothy C. Brock is a Professor of Psychology at Ohio State University and is a licensed psychologist. Dr. Brock holds a Ph.D. from Yale University in psychology with a specialization in social psychology. In 1955 he joined the Yale Communication and Attitude Change Program and began a career in [19] the field of persuasion and communication. Since that time Dr. Brock has had extensive experience in evaluating the formation, reinforcement and endurance of beliefs and attitudes. This experience includes extensive experience in conducting and evaluating research in this area, including research regarding the formation of attitudes about consumer goods and services (Brock, Tr. 5043-44, CX 605).

31. Since 1957, Dr. Brock has contributed extensively to the body of literature regarding the role of communication in attitude formation and change. His numerous publications include research and analyses of persuasion techniques, measurement of attitude change, and identification of public opinion and attitudes (CX 605). Dr. Brock's research has also included studies on the endurance of beliefs and attitudes (Brock, Tr. 5051-52). Dr. Brock has performed two studies that address the role of persuasive communications on consumer perceptions of the performance of drugs (Brock, Tr. 5054-55).

32. Dr. Brock is a member of many professional associations in the fields of psychology and consumer psychology, including the American Psychological Association, the American Sociological Association, the Society of Experimental Social Psychology and the American Association for the Advancement of Science. He is a Fellow in the American Psychological Association, the American Sociological Association and the American Association for the Advancement of Science, and has been elected Secretary-Treasurer of the Evaluation Research Society, a national society of professionals concerned with the measurement and assessment of the long-term efficacy of various social and educational programs (Brock, Tr. 5045-47). Dr. Brock has also served on the editorial boards of several professional journals and has frequently reviewed articles submitted for publication to a number of other professional journals relating to the formation and persistence of attitudes. The research includes work in the field of belief formation and change, the measurement of beliefs and attitudes, and the effectiveness of various types of communication to induce attitude change (Brock, Tr. 5049).

33. Dr. Brock is a well-qualified expert in social psychology, with special expertise in the techniques of persuasion and the source and duration of consumer beliefs and attitudes, including the design and analysis of research addressing those areas.

Thomas J. DeKornfeld, M.D.

34. Dr. Thomas J. DeKornfeld, a Professor of Anesthesiology at the University of Michigan Medical School, is a recognized authority in the field of analgesic testing (DeKornfeld, Tr. 8325). His involvement in the clinical testing of analgesics dates back to the late 1950's when he began working with [20] Dr. Louis Lasagna (DeKornfeld, Tr. 8369). Since that initial involvement, Dr. DeKornfeld has conducted between 30 and 40 clinical studies on a variety of drugs, with the majority of these studies being performed with analgesics (DeKornfeld, Tr. 8330-31). Included within these clinical studies have been tests using over-the-counter analgesics. In a major study conducted in the late 1950's, Drs. DeKornfeld and Lasagna examined the comparative efficacy of over-the-counter analgesics and placebos. The results of this study were published in the *Journal of the American Medical Association* (DeKornfeld, Tr. 8332; CX 615E). Before joining the faculty of the University of Michigan Medical School, he was the Director of Therapeutic Research for Parke, Davis and Company, a major pharmaceutical corporation, and supervised all of the clinical research activities of the firm in the United States and Canada (DeKornfeld, Tr. 8326; CX 615A).

35. For the last 14 years Dr. DeKornfeld has served as Secretary of

the University of Michigan Medical School's Committee to Review Grants for Clinical Research and Investigation Involving Human Beings. In this capacity, he, along with other committee members, reviews all research protocols for studies involving human subjects conducted under the auspices of the University's Medical School (DeKornfeld, Tr. 8334; CX 615C). Dr. DeKornfeld has also participated in the evaluation of the designs of analgesic clinical tests as a member of the Consulting Board to the U.S. Veterans Administration Cooperative Analgesic Study (DeKornfeld, Tr. 8334). Dr. DeKornfeld has also published many articles in recognized medical journals involving analgesics and analgesic testing (CX 615D-H). Dr. DeKornfeld has also served as consultant to some of his medical colleagues who have had problems with patients relating to pain and the use of analgesics. In his medical practice, Dr. DeKornfeld has used analgesic drugs in clinical situations (DeKornfeld, Tr. 8337-38). Dr. DeKornfeld is eminently qualified to give expert testimony regarding analgesics, clinical testing, and clinical analgesic testing.

Richard S. Farr, M.D.

36. Dr. Richard S. Farr is Chairman of the Department of Medicine of the National Jewish Hospital in Denver. Dr. Farr, who is widely recognized as a preeminent researcher in immunology, has had extensive clinical training in the diagnosis and management of bronchial asthma and allergy, including the asthma and allergic effects associated with 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 (Farr, Tr. 2541-50). [21]

37. 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 the National Jewish Hospital. Dr. Farr has had extensive experience in the design, execution and analysis of clinical tests of the side effects of aspirin, and has published widely on the topic. His experience extends to the clinical management of asthmatic and allergic patients and he has widely lectured and taught on this topic.

38. Dr. Farr served as the president of the American Academy of Allergy and has been associated with many other professional associations with particular interest in asthma and allergy. Dr. Farr is also a Distinguished Service Professor of the University of Chicago and is the recipient of the Borden Award for his outstanding work in the area of immunology (Farr, Tr. 2541-62).

39. Based on his background and experience, Dr. Farr is eminently

qualified to speak regarding asthma and allergy in general, and particularly about the asthmatic and allergic effects of aspirin and aspirin containing drugs.

Morton I. Grossman, M.D.

40. Dr. Morton I. Grossman's qualifications as an expert in gastroenterology, specifically with respect to the side effects of aspirin and antacid drugs and buffers, have been stipulated to by counsel (Grossman, Tr. 7448).

41. Dr. Grossman is recognized as one of the preeminent researchers and practitioners of gastroenterology in the world. Dr. Grossman, who currently directs the Center for Ulcer Research and Education in Los Angeles, is a Senior Medical Investigator in the Veterans Administration Wadsworth Hospital in Los Angeles, and has been Chief of the Gastrointestinal Section at the Veterans Administration Hospital in Los Angeles. Dr. Grossman 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 Committee of the FDA (Grossman, Tr. 7452-53; CX 612A-C).

42. 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. Dr. Grossman has done research on the mechanism and effects of aspirin ingestion on the gastrointestinal tract and has published many articles on this subject in learned journals. Dr. Grossman has also served on various editorial boards of scientific journals, such as the [22] *American Journal of Physiology*, and has chaired the editorial board of *Gastroenterology*, the official journal of the American Gastroenterological Association. He currently serves as a member of the editorial board of *Clinical Trials* which publishes articles dealing with problems that arise in designing and conducting clinical trials. Dr. Grossman has published over 350 articles in journals, contributed to scores of textbooks and other resource works on gastroenterology (Grossman, Tr. 7452-57; CX 612A-Z014).

43. Dr. Grossman has also been the recipient of major awards and honors in his field, including the Friedenwald medal of the American Gastroenterological Association which is its highest award. He also has held high offices with many of the professional societies concerned with problems of gastroenterology (Grossman, Tr. 7457-58; CX 612C).

44. Based on his education and training, as well as his wealth of research and clinical experience, Dr. Grossman is eminently qualified to speak to gastroenterology generally and specifically to gastrointestinal effects of aspirin and aspirin-containing products, including the effect of buffers in such products.

Robert John, M.D.

45. Dr. Robert John was Medical Director of Glenbrook Laboratories, a Division of Sterling, from June 1971 through October 1974 (John, Tr. 5486; CX 678, admission 106). He received his M.D. degree from the University of London King's College Hospital Medical School, was an intern at the Metropolitan Hospital in London, England, and recently was a resident at the New York Medical College (John, Tr. 5484-85; CX 624A). From 1960 through 1975, Dr. John worked in the pharmaceutical industry. From 1960 to 1962, Dr. John was Assistant Medical Director of Bristol-Myers' Products and International Divisions; from 1962 to 1965, he was Senior Clinical Research Associate at Warner-Lambert Research Institute, U.S.A.; from 1965 to 1967, he was Associate Medical Director of E.R. Squibb and Sons; from 1967 to 1968, he was Medical Director at Squibb Products Company; from 1968 to 1970, he was Medical Director at Squibb Beech-Nut, Inc.; and from 1970 through June 1971, he was Associate Medical Director of Winthrop Laboratories (John, Tr. 5486-87; CX 624C, D). In these positions, his responsibilities included clinical research into the safety and efficacy of drugs, including OTC analgesics, and review of advertising (John, Tr. 5487-88).

46. As Medical Director of Glenbrook Laboratories, Dr. John's responsibilities included reviewing advertisements and promotional materials with respect to medical claims, recommending clinical investigations, and keeping current with the medical literature concerning OTC analgesic agents (John, Tr. 5490, 5495). As part of his responsibility concerning the [23] review of advertising, Dr. John met with representatives of the advertising agency to insure that any medical claims appearing in proposed advertisements were substantiated (John, Tr. 5495-96). He also reviewed completed advertisements for all Glenbrook Laboratories products (John, Tr. 5504-06). According to Dr. John, he was the only Glenbrook Laboratories official to review advertisements for Bayer Aspirin, Bayer Children's Aspirin, Midol, Cope, and Vanquish from the viewpoint of medical substantiation, although he consulted occasionally with his superior, Dr. Monroe Trout, Vice President and Director of Medical Affairs for Sterling (John, Tr. 5490-92, 5495-96, 5504-05, 5578-80).

47. From time to time, Dr. John made presentations concerning the medical aspects of Glenbrook products to Sterling's Board of Directors

and other corporate executives (John, Tr. 5496-98). Dr. John also served on Glenbrook Laboratories' Executive Management Committee which reviewed Glenbrook's marketing strategy (John, Tr. 5491-94). This committee also included the President of Glenbrook, the Executive Vice President and the Group Product Managers. Similarly, Dr. John served on the corporate Aspirin Committee which reviewed developments in aspirin research (John, Tr. 5490-92, 5495).

48. Dr. John was chosen to represent Sterling before government and industry committees. He represented Sterling before the FDA's OTC Internal Analgesic Panel on the matter of aspirin warnings. He was also chosen to represent Sterling on the Proprietary Association Task Force on Special Analgesic Products (John, Tr. 5498-5503). By virtue of his personal involvement and opportunity to observe salient events at Sterling during the time when many of the challenged advertising claims were allegedly made, Dr. John is in a unique position to give evidence on the nature and quality of Sterling's advertising substantiation, with respect to aspirin products.

Orville H. Miller, Ph.D.

49. Dr. Orville H. Miller is a Professor of Pharmacy at the University of Southern California, School of Pharmacy, in Los Angeles, California. For over thirty years he has taught in the areas of pharmacy practice, industrial pharmacy, quality control and product development, which include the study of product formulation and pharmaceutical analysis (Miller, Tr. 6674). Dr. Miller has been chosen as a Fulbright Professor and taught at the University of Cairo for one year (Miller, Tr. 6677).

50. Dr. Miller has extensive experience in the area of pharmaceutical chemistry. He has served as a pharmaceutical consultant to numerous laboratories, hospitals, and committees since 1952, consulting in the areas of pharmaceutical quality, disintegration, bioavailability, pharmaceutical analysis and product formulation. Dr. Miller worked as a consultant to [24] Robinson Laboratories for eight years. His work there in part involved insuring compliance with the FDA's Good Manufacturing Practice Regulations. Specifically, he performed disintegration tests on a large variety of aspirin and aspirin-containing products. He has done similar consulting work concerning aspirin with other laboratories. In his consulting work, Dr. Miller has examined well over one hundred samples of aspirin and aspirin-containing products for pharmaceutical elegance, disintegration, dissolution, stability and bioavailability (Miller, Tr. 6686-99; CX 623A, B).

51. Dr. Miller was elected and served for ten years, from 1960-1970, as a member of the United States Pharmacopoeia Revision Committee, which establishes standards to insure the pharmaceutical quality

of drug products. These standards are officially recognized by the Food and Drug Administration. Dr. Miller reviewed or developed over thirty-six monographs which establish standards for the analytical procedures and purity tests for drugs. He has also served for three years on the Committee on Physiological Availability of Drugs, a joint committee of the United States Pharmacopoeia and the National Formulary, which was concerned with developing testing procedures to insure dissolution of drug products (Miller, Tr. 6677-84).

52. Dr. Miller has been a member of a number of professional societies in the fields of pharmacology, and has held several offices, including president of the American College of Pharmacists and chairman of the Practical Pharmacy Section of the American Pharmaceutical Association (Miller, Tr. 6684-85). He has served on a number of committees for professional societies, such as the Formulary Task Force of the California Pharmaceutical Association and a committee of the Academy of Pharmaceutical Science, which investigated potential problems concerning the bioavailability of drugs (Miller, Tr. 6685).

53. Based on his background, training, and experience, Dr. Miller is an expert well qualified to speak to the pharmaceutical quality of aspirin, specifically in the areas of pharmaceutical chemistry, pharmaceutical analysis, dissolution and bioavailability.

Charles G. Moertel, M.D.

54. Dr. Charles G. Moertel, who presently serves as the Director of the Mayo Clinic's Comprehensive Cancer Center, Chairman of its Department of Oncology, and Professor of Medicine at the Mayo Medical School, is an expert in evaluating analgesic studies using subjective pain response methodology and is preeminent in the field of clinical testing of drugs. Dr. Moertel's expertise in the analysis of patients' subjective responses to various kinds of drugs, including analgesics, has been developed over the last 24 years through his clinical and research activities at the Mayo Clinic (Moertel, Tr. 6234-36; CX 621A). [25]

55. At the Mayo Clinic, Dr. Moertel is involved in the evaluation of therapeutic agents. His involvement covers all of the Clinic's treatment programs designed to deal with malignant diseases starting in the gastrointestinal tract. He has done a great deal of work over an extended period of time in the evaluation of symptomatic and supportive care of cancer patients, and this involvement has encompassed the evaluation of analgesic agents, antiemetic agents, and diuretic agents (Moertel, Tr. 6240-42).

56. Dr. Moertel's work with analgesics evolved from the primary need of his advanced cancer patients to have effective treatment for

pain. Since the predominant part of his practice was to treat patients whose conditions had advanced beyond a point where surgery could help, 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. These studies were published in leading medical journals subject to peer review (Moertel, Tr. 6240-44; CX 621J, Q).

57. Dr. Moertel has also evaluated some of the newer chemical agents developed by pharmaceutical companies for analgesics purposes. He has conducted a number of clinical studies using antiemetic and chemotherapeutic drugs as well (Moertel, Tr. 6242). In all of these studies, Dr. Moertel has been involved in the analysis and evaluation of patients' subjective responses (Moertel, Tr. 6243).

58. In addition, Dr. Moertel has authored articles dealing with analgesics in a broader sense and drawing upon his clinical experience in the management of cancer pain. These articles have appeared in several textbooks of which he has been the primary author, or in which he was invited by the primary author to contribute (CX 680E, F, G, J, K; CX 621G, H, I, K, L).

59. As a practicing physician, Dr. Moertel prescribes, administers, and advises patients on a daily basis in the use of analgesics, including aspirin (Moertel, Tr. 6243-44).

60. Dr. Moertel is a member of the FDA's Oncologic Drugs Advisory Committee and advises the FDA on clinical test protocols for new drugs intended for use in the treatment of cancer patients. Dr. Moertel also serves on the Phase One Study Group of the National Cancer Institute and 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. 6238). Dr. Moertel is eminently qualified to present expert testimony concerning clinical tests, the evaluation of patients' subjective responses, and the clinical testing of analgesics. [26]

Donald D. Stevenson, M.D.

61. Dr. Donald D. Stevenson is a member of the allergy/immunology division at the Scripps Clinic in La Jolla, California. Dr. Stevenson, who also holds a clinical appointment in the Department of Internal Medicine at the University of California, has extensive experience in the 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 and controlled challenges

in order to determine the asthmatic and allergic effects of aspirin ingestion.

62. Dr. Stevenson has lectured and taught generally on the subject of immunology and particularly on the asthmatic and allergic effects of aspirin ingestion. He has published articles and studies relating to these topics and is familiar with the literature and current thoughts regarding aspirin side effects.

63. Dr. Stevenson is associated with various scientific and medical groups, including the American Academy of Allergy and the West Coast Allergy Society, with primary interest in asthma and allergy and has participated in meetings and conferences held by such organizations (Stevenson, Tr. 1454-71). Based on his background, training and experience, Dr. Stevenson is highly qualified to speak to immunology, asthma and allergy generally and specifically to the asthmatic and allergic side effects of aspirin and aspirin-containing products.

Karl Rickels, M.D.

64. Dr. Karl Rickels, Professor of Psychiatry and Pharmacology at the University of Pennsylvania, is an eminent practitioner with extensive training and experience in the diagnosis and management of patients exhibiting nonpsychotic 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 a large scale research with private patients of family physicians who suffer tension and stress (Rickels, Tr. 7895-7901, 7919-24).

65. Dr. Rickels has been Director of the Psychopharmacology Research Unit of the University of Pennsylvania since 1962, and has been appointed to an endowed chair in Human Behavior. He has also widely lectured and consulted both with industry and academics in the area of psychopharmacology and currently sits with the Clinical Pharmacology Study Session of the National Institute of Mental Health. Dr. Rickels has had extensive experience in the design, execution and review of clinical tests of drugs, including aspirin, for tension relief and has often [27] consulted with industry on the development of protocols for such clinical tests (Rickels, Tr. 7897-7902, 7906-13).

66. For three years, Dr. Rickels chaired FDA's OTC panel on Night-time Sleep-Aids, Daytime Sedative and Stimulants, and he has published widely on psychopharmacology topics including the effects of aspirin on tension relief (Rickels, Tr. 7903, 7913-15).

67. Based on his background, training, and experience, Dr. Rickels is an eminent expert well qualified to speak to psychopharmacology and tension and particularly to the effects of aspirin and caffeine on tension.

Ivan Ross, Ph.D.

68. 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, and marketing and marketing research (CX 603; Ross, Tr. 5713-21). Dr. Ross is also familiar with the literature in these areas. In addition, Dr. Ross has had extensive experience working with advertisers and advertising agencies on advertising content and strategy for a wide variety of consumer goods and services and has used various consumer research techniques, such as focus groups, copy tests, penetration studies, and image studies (Ross, Tr. 5717-18, 5722-23). Dr. Ross has also been a consultant with the Food and Drug Administration's Bureau of Foods (Ross, Tr. 5724-25).

69. Dr. Ross is a member of a number of professional associations in the areas of psychology, marketing, advertising, and consumer research and he has held both elected and appointed positions within these organizations (Ross, Tr. 5725-27). He has also served as an editor and reviewer of articles and papers in consumer behavior and advertising research for journal publication presentations before various professional organizations and has presented papers before professional organizations in the areas of marketing, consumer research, and psychology. His articles, studies, and other writings in fields such as consumer beliefs, consumer behavior, and advertising have been published in peer-reviewed journals and other publications (Ross, Tr. 5727-29; CX 603). Furthermore, Dr. Ross has been chosen to arbitrate complaints about advertising for the Minnesota Advertising Review Board and to mediate consumer complaints for the Better Business Bureau of Minnesota (Ross, Tr. 5726-27). Finally, he has appeared as an expert witness in a number of legal proceedings and testified regarding the conduct and evaluation of consumer research (Ross, Tr. 5723).

70. Dr. Ross' training, professional experience, and familiarity with the literature qualify him as an expert in psychology, specializing in consumer psychology and consumer behavior, marketing, and marketing research. He gave expert [28] testimony regarding various marketing and advertising issues in this proceeding, including the meaning of advertisements and the messages advertising is likely to convey to consumers, the consumer images of Bayer Aspirin and the source and duration of such images.

B. For Sterling Drug Inc.

1. Respondent's Advertising Experts

Arnold E. Amstutz, Ph.D.

71. Dr. Arnold E. Amstutz is qualified as an expert in consumer marketing research, specifically as an expert in the design and evaluation of instruments to measure consumer perceptions of products and to measure the impact of communications and product experience in changing consumer attitudes and behavior (Amstutz, Tr. 9993-94).

72. Since 1959, Dr. Amstutz has been involved in the design, execution and analysis of surveys measuring the impact of communications upon consumer attitudes, behavior and perceptions of products. He has developed and used modeling and simulation techniques to study and predict market behavior, which includes behavior anticipated from advertising campaigns. This has involved the extensive use and analysis of various survey methodologies to determine the consumer perception of products, the consumer image and value system, and to evaluate the impact of advertising campaigns, usually by testing several applications of advertising strategies. Dr. Amstutz has used this approach in work on marketing and communications analysis for leading firms in the United States and Europe (Amstutz, Tr. 9984-90).

72A. Dr. Amstutz received a Ph.D. from the Massachusetts Institute of Technology (MIT). He was on the faculty at the MIT Sloan School of Management from 1967 to 1972, where he taught and conducted research on marketing strategy and the application of information technology to marketing. Since then, Dr. Amstutz has worked in connection with various organizations, including being the founder and chairman of Decision Technology, Inc., a firm engaged in designing and implementing management systems; a partner in Cantor, Achenbaum & Heekin, a market counseling firm; a founder and chairman of ISIS Systems, Inc., which is engaged in providing management information systems, including application of information technology and systems to consumer marketing communications. He has published widely in the fields of his expertise. It was in connection with ISIS Systems, Inc. that Dr. Amstutz performed the work relevant to his testimony (Amstutz, Tr. 9989-93; RX 253).

73. At the request of respondent's counsel, and under the supervision of Dr. Amstutz, ISIS Systems analyzed and reviewed two studies performed by Dr. Hans Zeisel under contract for the FTC complaint counsel (CX 520 and CX 521) and prepared documentary material which was introduced in evidence (Amstutz, Tr. [29] 9994-95). The ISIS documents—RX 141A, "Analysis of the Use of Combined

Data From TV Ad and Print Ad Surveys in the Zeisel Advertising Study, CX-520"; RX 141B, "Response Count Analyses of Survey Data Used in the Zeisel Advertising Survey, CX-520"; RX 142, "Analyses of Survey Data Used in the Zeisel Image Study, CX-521"—were prepared under Dr. Amstutz's direction and supervision (Amstutz, Tr. 9995). In addition, for rebuttal purposes, Dr. Amstutz analyzed material referred to in the testimony of Dr. Ross and Dr. Brock (*See, e.g.*, Amstutz, Tr. 10142-53, 10154-60). In this, Mr. Cortesi was responsible for preparation of the data base and review of survey design and administration, while Dr. Amstutz was responsible for overall supervision of programming criteria and for analysis of both the design and conclusions of the Zeisel studies (CX 520 and CX 521) and of the ISIS data reported in RX 141A, RX 141B, and RX 142 (Cortesi, Tr. 9784; Amstutz, Tr. 9994-95).

Robert W. Chestnut, Ph.D.

74. Dr. Robert W. Chestnut is qualified as an expert in the area of consumer psychology, particularly with regard to marketing and advertising effects, memory effects, persuasion, consumer attitudes, and consumer decisionmaking behavior (Chestnut, Tr. 12242). Dr. Chestnut is well qualified to provide expert testimony in the areas of marketing and advertising effects, memory effects, persuasion, consumer attitudes, and consumer decisionmaking. He received his Master's and Doctoral degrees in the field of consumer psychology from Purdue University. Dr. Chestnut's graduate work at Purdue began with a grant from the National Science Foundation under Professor Jacoby and involved numerous studies in the area of nondurable purchasing behavior including package label use and other aspects of consumer information search in purchasing. Analgesics was one of the product categories he studied. Dr. Chestnut's Doctoral dissertation concerned the impact which the attractiveness of an information source can have on a consumer's purchase behavior. His Master's thesis was a study of information acquisition as it is affected in shopping behavior. Since he began teaching at Columbia University, Dr. Chestnut has done considerably more work and has published extensively in the areas of persuasion and consumer information processing. He teaches graduate level courses and seminars in advertising, consumer behavior and marketing strategy, information processing in consumer decisionmaking, and persuasion in television advertising (Chestnut, Tr. 12233-41; RX 281).

75. Dr. Chestnut is a long-standing member of the Division of Consumer Psychology of the American Psychological Association and heads a committee of that organization. He is also a member of the

American Marketing Association and the Association for Consumer Research (Chestnut, Tr. 12240; RX 281).

76. In addition to his teaching and scholarly activities, Dr. Chestnut has engaged in consulting work for various organizations and companies. In the advertising area, this has involved [30] an assessment of the impact of advertisements on consumer response and a review of marketing research such as copy testing to determine how it might be used to estimate overall advertising campaign effectiveness. He has also worked in a consulting capacity with the Federal Trade Commission and the Food and Drug Administration (Chestnut, Tr. 12240-41; RX 281).

Alexander C. Cortesi

77. Alexander C. Cortesi was qualified as an expert in the methodology issues of consumer and marketing research, specifically relating to sample design, questionnaire design, coding, survey administration and data processing (Cortesi, Tr. 9783). Mr. Cortesi has had extensive experience in designing and reviewing consumer surveys and survey questionnaires. He has been involved in consumer and marketing research as well as developing information system since 1965. His work has included projects for major firms which market consumer products in the United States and Europe. From 1965 to 1971, he held senior positions in Decision Technology International, and Decision Technology America, firms engaged in marketing consulting, which included the design and use of consumer-based models to predict consumer behavior. From 1972 to 1976, he was President of Home Testing Institute, a subsidiary of American Can Company, which is engaged in contract market research, including consumer attitude and perception studies, product studies and tracking studies on a longitudinal basis. He also has had experience with sampling techniques, including national probability sampling. Since 1976, he has been President and Director of ISIS Systems, Inc., a company engaged in marketing research and information systems (Cortesi, Tr. 9766-73, 9775-83; RX 254).

Russell Haley, Ph.D.

78. Dr. Russell Haley is qualified as an expert in the design and analysis of consumer and marketing research (Haley, Tr. 10556-57).

79. Dr. Haley is a professor at the University of New Hampshire where he teaches advertising, marketing research, and marketing management at both the graduate and undergraduate levels. Prior to joining the faculty at New Hampshire in 1975, Dr. Haley taught part-time at Rutgers University and the University of Connecticut (RX 255; Haley, Tr. 10551). Dr. Haley received a B.A. degree from

Wooster College, an M.B.A. in statistics from Columbia University, and a Ph.D. in consumer behavior from Union Graduate School. Dr. Haley's dissertation was on selective perceptions (Haley, Tr. 10551-52; RX 255).

80. Dr. Haley has had extensive experience in the design and analysis of consumer and marketing research in his work at advertising agencies, market research firms, and currently, with a consulting company. Throughout his career he has been [31] involved in various kinds of consumer and marketing research including copy testing, segmentation studies, and image studies (Haley, Tr. 10553-54). Dr. Haley's professional experience in the analgesic market includes numerous copy tests and one large segmentation study which covered a complete range of consumer attitudes toward analgesics, behavior patterns, volume of use, occasions of use, classification data, and psychographic characteristics. In his advertising work, however, he has never had any responsibility for analgesic advertisements (Haley, Tr. 10557-58).

81. Dr. Haley has edited one book, written many articles, and given many speeches, all in the areas of advertising research, segmentation analysis, and attitude measurement. He belongs to a number of professional associations and has held positions in them, including editorial positions (Haley, Tr. 10555-56).

Miriam Lieber

82. Miriam Lieber is an expert in the design and execution of attitude research studies (Lieber, Tr. 16779-85; RX 426). She has a Bachelor's degree and a Master's degree from the University of Chicago, and was a Fellow at Harvard University in a Ph.D. program in educational sociology (Lieber, Tr. 16781; RX 426).

83. Miriam Lieber is President of Lieber Attitude Research, Inc., and is Chief Research Consultant to the firm's clients. As President, she also serves in a supervisory capacity in the firm. The firm's clients include Citibank, Bristol-Myers, Clairol, Hanes Corp., Procter & Gamble, many advertising agencies, and scholastic magazines. Lieber Attitude Research, Inc. performs all types of attitude research, including basic attitude research, focus group research, image tests and copy tests. Miriam Lieber has been involved with attitude research since 1951, and has been an independent consultant since 1961 (Lieber, Tr. 16779-85; RX 426).

84. Prior to becoming an independent consultant, Miriam Lieber worked for the Bureau of Applied Research at Columbia University, the National Opinion Research Center, and International Research Associates on a free lance basis from 1951 to 1953. She also edited a project done by the Bureau of Applied Social Research for the Army,

and did research for Radio Free Europe, Voice of America and International Research Associates. Miriam Lieber has also worked for Research Services, Ltd., an independent subsidiary of the British advertising agency known as the London Press Exchange, where she worked for Mark Abrams, a well-known economist and researcher. She also has worked for the Creative Research Department at Tatham-Laird, a Chicago advertising agency, where she served as [32] Associate Director (Lieber, Tr. 16781-83; RX 426). In addition to her position as an independent consultant and President of Miriam Lieber Attitude Research, Inc., Miriam Lieber sits on the New York Community Planning Board, an appointed position in New York City, and is a member of the New York Alliance for the Public Schools (Lieber, Tr. 16784; RX 426).

85. Miriam Lieber has performed hundreds of focus group studies, and much of the attitude research undertaken by her company has concerned advertising. She has done attitude research for OTC products, including Mylanta, Phillips Milk of Magnesia, Contac, and Nyquil. She has also done attitude research on all aspects of the feminine hygiene category. In addition to the study on Midol and Pamprin performed for Sterling Drug, Inc. (RX 230), Miriam Lieber has done a basic attitude research study on the menstrual protection category. She has undertaken between six and fifteen studies for Sterling (Lieber, Tr. 16784-85; RX 426).

Benjamin Lipstein, Ph.D.

86. Dr. Benjamin Lipstein is an expert in marketing research, including advertising research, the design of survey instruments and survey methodology, and in the analysis and evaluation of survey results (Lipstein, Tr. 11957). Dr. Lipstein received his Ph.D. from Columbia University in Economics and Statistics (RX 283; Lipstein, Tr. 11951).

87. Dr. Lipstein was appointed a tenured Professor of Marketing at the Graduate School of Business Administration at New York University in 1978, where he teaches graduate courses in market research, advertising research, multivariate methods in marketing, and mathematical models in marketing financial services (RX 283; Lipstein, Tr. 11945-46).

88. Prior to 1978, Dr. Lipstein was a Senior Vice-President of SSC&B, a large advertising agency, where he was responsible for all types of research activities, including advertising research, copy research, attitude research, product testing, mathematical modeling, and numerous other techniques designed to help advertisers understand advertising (Lipstein, Tr. 11946-48). In the course of his career, Dr. Lipstein has also worked at other advertising agencies and re-

search companies, and spent approximately ten years with the Bureau of Labor Statistics at the U.S. Department of Labor (Lipstein, Tr. 11949-50). Dr. Lipstein has written and lectured extensively (RX 283; Lipstein, Tr. 11950-51).

89. Dr. Lipstein has been a member of numerous professional associations, some of which are only by invitation, and has held offices in these associations. He is presently chairman of the Television Copy Research Council of the Advertising Research Foundation, a trade group (Lipstein, Tr. 11952). [33]

Virginia Miles, Ph.D.

90. Dr. Virginia Miles is an expert in advertising and marketing, with particular reference to the evaluation of representations made by advertisements, analysis of consumer beliefs, formation and duration of product images, and the analysis and evaluation of consumer and marketing research (Miles, Tr. 9253). Dr. Miles was educated at Wellesley College and Columbia University from which she received M.A. and Ph.D. degrees in psychology in 1938 and 1940, respectively (RX 252; Miles, Tr. 9241).

91. Dr. Miles has had extensive experience in the advertising profession, commencing in 1940 and continuing up to the present time. She has been involved in the design and analysis of all kinds of consumer and marketing research throughout her career. From 1940 to 1942, Dr. Miles worked at J. Stirling Getchell Advertising Agency as assistant to Dr. Ernest Dichter, founder of motivation research technique. In 1942, Dr. Miles went to work for R.H. Macy and Co. as project director in the advertising research department. When she left in 1946, Dr. Miles was Associate Director of Research and Director of Advertising Research. From 1946 to 1948, Dr. Miles taught psychology, statistics and market research courses at both the graduate and undergraduate levels at the College of the City of New York. From 1948 to 1950, she worked for Alexander Smith, a carpet and rug manufacturing company, as Director of Advertising Research (Miles, Tr. 9242-43).

92. In 1950, Dr. Miles went to work for McCann-Erickson Advertising Agency and its parent company, Interpublic. She served as Director of Motivation Research until 1955 when she was appointed Vice President and Director of Research at Marplan, a market research company set up by Interpublic. During her last two years there, she was Vice President and Director of Marketing and Research at Marschalk, an advertising agency bought by Interpublic (Miles, Tr. 9243-44).

93. Dr. Miles worked for Young & Rubicam, an advertising agency, from 1960 until 1975. She started as liaison between the creative

department and the research department. In 1961, she became Vice President of Special Planning. In 1964, she was appointed to the Strategy Review Board and the Creative Review Board. Throughout her career at Young & Rubicam, Dr. Miles worked as an in-house consultant. From 1969 until 1975, she directed CONCEPTS, Young & Rubicam's new product development and planning group (Miles, Tr. 9245-46). After 35 years in the advertising profession, Dr. Miles left her position as Senior Vice President of Young & Rubicam to become an independent consultant (Miles, Tr. 9237, 9246).

94. Dr. Miles has given speeches before such groups as the American Association of Advertising Agencies, the Association of [34] National Advertisers, the International Advertising Research Foundation (Miles, Tr. 9247). Dr. Miles has been a member of the American Association for Public Opinion Research, Advertising Women of New York, the American Association of Advertising Agencies, the Advertising Research Foundation, the American Marketing Association, and the American Psychological Association. She was one of the founders of the Society for the Psychological Study of Social Issues in 1939 (Miles, Tr. 9247-48).

2. Respondent's Scientific Experts

Gilbert S. Banker, Ph.D.

95. Dr. Gilbert S. Banker is Professor of Industrial Pharmacy and head of the Industrial and Physical Pharmacy Department at Purdue University. He is an expert in pharmaceutical technology, including principles of design, formulation, manufacture and evaluation of pharmaceutical products, particularly tablets, including aspirin tablets. He received a B.S. degree in Pharmacy from the Albany College of Pharmacy, Union University, and Master's Degree at Purdue University with a major in Industrial Pharmacy and minors in Statistics and Pharmaceutical Chemistry. Dr. Baker received his Ph.D. from Purdue University in 1957 with a major in Industrial Pharmacy and Pharmaceutical Chemistry and minors in Physical Chemistry, Statistics, Industrial Engineering and Education. In 1967, he was named head of a newly created Department of Pharmaceutics. Dr. Banker has been a consultant for many of the major drug companies in the United States, and has direct experience with industrial pharmaceutical operations. A significant part of his research and consulting work has involved aspirin. He has had a long standing relationship with Miles Laboratories of Elkhart, Indiana, the manufacturer of Alka-Seltzer (Banker, Tr. 12518-21, 12543; RX 257).

96. Dr. Banker is a member of numerous scientific and professional societies, including the American Pharmaceutical Association, the

Academy of Pharmaceutical Sciences, American Chemical Society, and the American Association for the Advancement of Science. He is also a member of several honorary societies. He has received the Award for Advancement of Industrial Pharmacy granted by the Academy of Pharmaceutical Science, a prestigious body of pharmaceutical scientists in the United States. Dr. Banker was elected a Fellow of the Academy of Pharmaceutical Science in 1971. Dr. Banker's research focuses on drug product quality, improved dosage form design, and the application of optimization methods to pharmaceutical products. Dr. Banker holds several patents on drug technology he has developed (Banker, Tr. 12523-27; RX 257).

97. Dr. Banker services on the Editorial Advisory Boards of several international journals, including the *Asian Journal of [35] Pharmaceutical Science* and the *International Journal of Pharmaceutical Technology and Product Manufacture*. He is a member of the Editorial Advisory Board of *Drug Development and Industrial Pharmacy*. He has served in numerous leadership roles in the Academy of Pharmaceutical Science, including service on numerous committees dealing with drug product quality. He was a member of the committee that developed the APHA DRUG Product Quality Statement. He is presently Chairman of the Science and Technology Policy Committee, a post he has held since 1970. In addition, he currently serves on an APHA task force which is working on the development of standards for excipients (Banker, Tr. 12527-29; RX 257).

98. Dr. Banker has just completed a five-year term on the USP Revision Committee. He has been re-elected to serve on the USP Revision Committee for *USP XXI*. Dr. Banker has published nearly 100 articles, and recently co-edited a major new pharmaceutical text entitled *Modern Pharmaceutics*. He is currently co-editing a book entitled *Pharmaceuticals and Clinical Pharmacy Practice* with Dr. Chalmer, a clinical pharmacist at Purdue University. Many of Dr. Banker's publications deal with the tablet dosage form. His articles involve, among other things, use of lubricants in tablets, the development of new physical test methods, granulating agents for compressed tablets, the effect of water vapor transmission on the stability of aspirin tablets, dissolution testing, controlled release delivery systems, stability of aspirin, salicylic acid sublimation and its relationship to aspirin stability, the optimization of drug products, and factors affecting aspirin stability in tablets. All of these articles have been published in refereed journals subject to peer review (Banker, Tr. 12530-40).

99. As a member of the USP Revision Committee, Dr. Banker had responsibility for all of the aspirin monographs for *USP XX*. These were assigned to him based upon his extensive background working

with aspirin. As a member of the USP Revision Committee on Medicinal Chemistry, Dr. Banker was assigned as a principal reviewer and drafter of recommendations or revisions with respect to all aspirin products (Banker, Tr. 12545-49). Dr. Banker is an expert with a national and international reputation in the area of improving dosage forms of drug products (Rhodes, Tr. 11050).

Ivan D. Danhof, Ph.D.

100. Dr. Danhof is an expert in physiology with a subspecialty in gastroenterology. He has both M.D. and Ph.D. degrees. He is a Professor of Physiology at the University of Texas Health Science Center-Southwestern Medical School and Associate Professor of Physiology at the Institute of Technology, Southern Methodist University. His professional [36] duties involve teaching courses relating to the gastrointestinal tract (Danhof, Tr. 16845-46).

101. Although he is not a board-certified gastroenterologist and his principal interest is in research in the gastrointestinal area, Dr. Danhof sees patients in consultation. He is a staff member of the Department of Internal Medicine, Division of Gastroenterology at Methodist Hospital in Dallas, a consulting member of the Internal Medicine Department, Gastroenterology, at Grand Prairie Community Hospital and a consulting staff member in internal medicine and gastroenterology at St. Paul Hospital, Dallas (Danhof, Tr. 16847-48).

102. Dr. Danhof is a member of numerous professional societies, including the American Physiological Society, the American Institute of Nutrition, Society for Experimental Biology and Medicine, and the AAAS. He has served as a consultant to the FDA as a member of several ad hoc committees, including the FDA's Gastrointestinal Drug Advisory Committee and the FDA's advisory review Panel on OTC Drugs—Laxatives, Antidiarrheals, Emetics and Antiemetics (Danhof, Tr. 16849-57).

103. Dr. Danhof has conducted research relating to the gastrointestinal tract, involving comparative absorption studies of drugs including aspirin (Danhof, Tr. 16849-51). He has published some 70 articles, including reports of his research in the area of drug absorption, including a 1972 article on salicylates. Dr. Danhof's research of absorption, bioavailability, intestinal irritation and blood loss involving salicylates has been supported by a long-term research grant-in-aid from Sterling's Glenbrook Laboratories division, beginning in 1967 and continuing until 1976. The bulk of his work on bioavailability studies done during this period remain unpublished. Dr. Danhof has continued his consulting work with Sterling on bioavailability issues (Danhof, Tr. 16853-74). Dr. Danhof is well qualified in the field of

physiology and gastroenterology and has had a long-term involvement in absorption studies of drugs including aspirin.

Constantine F. Falliers, M.D.

104. Dr. Constantine Falliers is an expert in the field of allergy, including causes and treatment of respiratory allergy. Dr. Falliers is also a clinical pharmacologist in the treatment of respiratory allergy. By education, training and experience, Dr. Falliers is a well qualified expert (Falliers, Tr. 13236-56, 13263; RX 278).

105. Dr. Falliers is board-certified in the specialty of allergy. He received his medical degree from the University of Athens Medical School in Greece. He completed residencies at the University of Colorado Medical Center, Denver, Colorado; the California Babies and Children's Hospital, Los Angeles, [37] California; and the Kaiser Foundation Hospital, Oakland, California. He is a recipient of a Fulbright Fellowship in Basic Medical Sciences and Clinical Pediatrics, University of Colorado Medical Center (Falliers, Tr. 13236, 13242; RX 278A).

106. Dr. Falliers spends about 75 percent of his time in private medical practice in Denver, Colorado, where he treats approximately 2,000 patients per year who are suffering from various allergies. Approximately half of his patients suffer from asthma (Falliers, Tr. 13240, 13244-45). Dr. Falliers spends approximately 25 percent of his time teaching and writing in the allergy area. He has taught in the field of allergy at the University of Colorado Medical Center since 1961, and currently holds the position of Associate Clinical Professor. His teaching duties involve not only lecturing, but treating patients at the National Jewish Hospital, including the Children's Asthma Research Institute of that institution. Dr. Falliers is Attending Allergist at various hospitals, including National Jewish Hospital, St. Joseph's Hospital, and General Rose Memorial Hospital. He is also connected with the Veterans Administration Hospital in Denver, where he is responsible for the allergy clinic (Falliers, Tr. 13239-41; RX 278A).

107. Dr. Falliers has been connected with the Jewish National Home for Asthmatic Children and Children Asthma Research Institute and Hospital ("CARIH") for more than 20 years. In 1957 he undertook a fellowship in pediatric allergy and clinical research at CARIH; in 1959-63 he was Director of Clinical Services at CARIH; in 1963 through 1969 he was Medical Director; and in 1969 through 1972 he was Head of the Clinical Research Division.

108. Dr. Falliers has published more than 100 scientific articles involving such areas as factors causing allergy, measuring allergic reaction, and treatment of various allergies (Falliers, Tr. 13249-51;

RX 278C-I), including an article regarding the incidence of aspirin sensitivity in asthmatics (Falliers, Tr. 13238-52; RX 278).

109. Dr. Falliers is a member of various professional societies, including the American Academy of Allergy where he is a Fellow and on the Board of Regents, the American College of Allergists where he is a Fellow, and the Society for the Care of Asthma. He has been a consultant to the Food and Drug Administration's Over-the-Counter Cough, Cold and Allergy Remedy Panel. He is a member of the Editorial Board of the *Annals of Allergy*, a recognized journal in its field (Falliers, Tr. 13243, 13248, 13254; RX 278B).

Alvan R. Feinstein, M.D.

110. Dr. Alvan R. Feinstein is a recognized expert in the history, design and use of randomized controlled trials as a [38] method for evaluating the clinical effectiveness of drugs (Feinstein, Tr. 16208, 16217; RX 279). Dr. Feinstein's reputation in the field of clinical testing is known to complaint counsel's witness (DeKornfeld, Tr. 8521).

111. Dr. Feinstein is Professor of Medicine and Epidemiology at Yale and Director of the Robert Wood Johnson Clinical Scholars Program. He earned a Master's degree in mathematics before receiving his medical degree from the University of Chicago. He did his internship and residency in internal medicine at Yale University, studied at the Rockefeller Institute in New York, and completed his clinical training as a specialist in internal medicine at Columbia Presbyterian Medical Center in New York. He is board-certified in internal medicine and is a member of the Board of Governors of the American Board of Internal Medicine. Dr. Feinstein taught at the New York University School of Medicine from 1956 until 1962, and has been on the faculty of the Yale University School of Medicine since 1962, where he both teaches and treats patients (Feinstein, Tr. 16190-93; RX 279).

112. Dr. Feinstein has been consultant to government agencies, including the Food and Drug Administration and the Veterans Administration, involving problems in the design and interpretation of clinical trials or other forms of research dealing with the safety and efficacy of drugs. Dr. Feinstein has been Chief of the Research Support Center and the Cooperative Study Support Center at the West Haven Veterans Administration Hospital, a coordinating center for clinical trials conducted by the Veterans Administration. Dr. Feinstein also served as a member of the Veterans Administration Cooperative Study Evaluation Committee, which reviews proposed clinical studies for the Veterans Administration. Dr. Feinstein has been a member of the FDA Biometric and Epidemiology Advisory Commit-

tee, which reviews clinical studies submitted to the FDA to decide whether those studies were appropriately designed and conducted (Feinstein, Tr. 16193-94, 16199-200; RX 279).

113. Dr. Feinstein is one of about 300 invited members of the prestigious Association of American Physicians. He is an invited member of both the American Society of Clinical Investigators and the American Epidemiological Society. He is a member of the Institute of Medicine, a Fellow of the American College of Physicians, and a member of the Institute of Statisticians. He is also a member of other professional and honorary societies in the fields of science and medicine (Feinstein, Tr. 16194-96; RX 279). Dr. Feinstein is a member of the editorial boards of several well-recognized publications in clinical medicine today, including *The Journal of Clinical Pharmacology and Therapeutics*, *The Journal of Chronic Diseases*, and *The Journal of the History of Medicine and Allied Sciences*. He also regularly reviews articles for approximately 30 other medical journals, and for the past ten years has written a [39] regular column for *The Journal of Clinical Pharmacology and Therapeutics* concerning the design and analysis of various aspects of clinical research, including clinical trials (Feinstein, Tr. 16196-98; RX 279).

114. Dr. Feinstein's research interests are in the areas of clinical epidemiology and clinimetrics and is considered a founding father of clinical epidemiology, which encompasses the quantification of diagnosis, prognosis and therapy (Feinstein, Tr. 16201-02; RX 279). His book *Clinical Biostatistics* deals with the "design and conduct of various aspects of clinical research with the architecture and design of different studies, whether they be clinical trials or other forms of research for the analysis" of medical and clinical data. Dr. Feinstein has written many papers on methodology of clinical trials, including articles on methodology, statistics, randomization, placebos, and controls. His curriculum vitae contains 191 primary publications, including two books and several chapters in standard medical texts, 81 secondary papers, 100 abstracts, numerous book reviews, letters to the editor and editorials (Feinstein, Tr. 16203-06). His numerous articles dealing with the issue of randomized controlled clinical trials include: "Should Placebo-Controlled Trials be Abolished?", *European Journal of Clinical Pharmacology*, Spring, 1980; "On Standards for Publication of Therapeutic Research", *The Journal of Chronic Diseases*, Vol. 33 (1980); "The Need for Humanized Science in Evaluating Medication"; *The Lancet*, August 22, 1972 (RX 279).

William S. Fields, M.D.

115. Dr. William Fields is an expert in the areas of neurology and clinical testing (Fields, Tr. 16558, 16573; RX 262). He is Professor and,

since 1973, Chairman of the Department of Neurology at the University of Texas Medical School in Houston. Dr. Fields is a Diplomate of the American Board of Psychiatry and Neurology, certified in neurology. For certification in the neurology specialty, he had additional training in the area of psychiatry (Fields, Tr. 16519, 16524-25; RX 262B).

116. Dr. Fields holds an A.B. degree from Harvard College and an M.D. degree from Harvard Medical College. He had postgraduate clinical training at National General Hospital, Vanderbilt University, Nashville, Tennessee, at the Children's Memorial Hospital in Montreal, Canada, the Royal Victoria Hospital, and Barnes Hospital, St. Louis, Missouri. He also did research at the Montreal Neurological Institute and was a Rockefeller Fellow in Neuropsychiatry at Washington University School of Medicine (Fields, Tr. 16520-21, 16524; RX 262A).

117. After completing his formal education, Dr. Fields became an Associate Professor of Neurology in 1949 at Baylor College of Medicine in Houston, Texas, was Professor of [40] Neurology at that college from 1951 through 1967, and became Chairman of the Neurology Department of Baylor from 1959 through 1965. Subsequently, Dr. Fields became Professor of Neurology at the University of Texas Southwest Medical School in Dallas. In 1970 he became Professor of Neurology at the University of Texas Medical School (Fields, Tr. 16525-26; RX 262B).

118. At the time Dr. Fields was connected with Baylor, he was Chief of Neurology at the Methodist Hospital, the City/County Hospital, Ben Taub General Hospital, and the Veterans Administration Hospital. Dr. Fields has also been a Consulting Neurologist at Hermann, St. Luke's, Texas Children's and Diagnostic Center Hospitals, all in Houston, Texas. From 1956 until present, Dr. Fields has been the consulting neurologist for the Air Force Hospital at Lackland Air Force Base. While Dr. Fields was connected with the University of Texas Southwest Medical School at Dallas, he was the Senior Attending Neurologist at Parkland Memorial Hospital, and Presbyterian Hospital in Dallas, and a consultant in neurology at St. Paul Hospital and Baylor University Medical Center in Dallas (Fields, Tr. 16526-28; RX 262C). When Dr. Fields returned to Houston to become Chairman of the Department of Neurology at the University of Texas Medical School in Houston, he also became the Chief of Neurology Service at St. Anthony's Center, a position he held until 1979. In 1973 he became Chief of Neurology Service, a position he still holds, at Hermann Hospital (Fields, Tr. 16528-29; RX 262C). Dr. Fields has been the Chairman of the Committee for the Protection of Human Subjects (also known as the Institutional Review Board) at the University of

Texas Health Science Center since its inception. The Committee is charged with responsibility for reviewing proposed clinical research at the University (Fields, Tr. 16533).

119. Dr. Fields has done extensive work in the area of clinical testing, including clinical tests on an investigational new drug ("IND") relating to treatment of headache, and the testing of a drug containing caffeine as a headache remedy. He has also been connected with the NIH Stroke Study ("AITIA" Study), a 10-center clinical trial to determine whether aspirin may help prevent stroke, sponsored by the National Institute of Heart, Lung and Blood Diseases ("NIHL&B"). Dr. Fields was overall coordinator of this study. As a result of this multicenter clinical study ("AITIA" Study), the FDA authorized the use of aspirin for the prevention of strokes in males. Dr. Fields has been associated with subsequent aspirin trials sponsored by the NIHL&B (Fields, Tr. 16536-52).

120. Dr. Fields was a consultant to the Social Security Administration from 1966 to 1976, and was a member of the Veteran's Administration Advisory Committee for Psychiatry, Neurology and Psychology Service from 1966 to 1974 (Fields, Tr. 16532; RX 262E). He is a member of numerous professional societies, including the American Neurological Association, the American Academy of Neurology, the Association for Research of [41] Nervous and Mental Diseases, the American Association of Neurology Surgeons, and the Association of University Professors of Neurology (Fields, Tr. 16531; RX 262C-D). Dr. Fields has published more than 175 learned articles and books in the area of neurology and nervous system, which includes pain and headaches (Fields, Tr. 16553, 16555-58; RX 262H-V).

Leonide Goldstein, M.D.

121. Dr. Leonide Goldstein is an expert in the area of the biological basis of human behavior, including electroencephalogram ("EEG") testing and analyses (L. Goldstein, Tr. 17724). Biological basis of human behavior involves consideration of the brain in terms of the kind of phenomena which takes place within the tissue that can be explained by biochemical changes, electrical changes or other ways which relate to the actual tissue or organs which are part of the brain (L. Goldstein, Tr. 17748-49). By education, training and experience, Dr. Goldstein is a well-qualified expert in this area.

122. Dr. Goldstein is a Professor in the Department of Psychiatry, College of Medicine and Dentistry at New Jersey State University Medical School. He is also a Professor in the Graduate School of Applied and Professional Psychology at Rutgers University. Most of Dr. Goldstein's responsibilities at the medical school involve work with electroencephalogram waves, referred to as EEG's. Dr. Goldstein

is the Director of the Quantitative Electroencephalograph Laboratory at the medical school. The work of this laboratory exclusively involves studies with humans (L. Goldstein, Tr. 17726-30; RX 267).

123. In addition to teaching, Dr. Goldstein conducts an extensive amount of research which occupies approximately 60 percent of his time. His principal research interest has been the study of the brain, to determine the relationship between brain functions, as manifested by quantitative EEG patterns, and behavioral states. In this area, he has done EEG testing on approximately 1,000 to 1,500 human subjects, and has tested more than 100 drugs or compounds to determine their effect on the brain, using both normal and mentally ill subjects. His EEG work has included various psychotropic drugs, such as stimulants, hallucinogenics, sedatives, sleep inducers and antidepressants, as well as analgesics including Bayer Aspirin (L. Goldstein, Tr. 17735). Dr. Goldstein's scientific publications exceed 190 in number (L. Goldstein, Tr. 17732-40; RX 267C-P).

124. Dr. Leonide Goldstein is a member of a number of professional societies, including the Society for Neurosciences, Society for Biological Psychiatry, the Association for the Psychophysiological Study of Sleep, American Statistical Association, and Fellow of the American College of Neuro[42]psychopharmacology. Dr. Goldstein is the editor-in-chief of the peer review journal, *Research Communications in Psychology, Psychiatry and Behavior* (L. Goldstein, Tr. 17731-32; RX 267B). Dr. Leonide Goldstein holds a Bachelor of Arts degree, a Master of Arts degree from Amherst College, and a Doctorate degree from the Sorbonne, University of Paris, Paris, France. Positions held by Dr. Goldstein include Associate Professor of Pharmacology at Emory University in Atlanta, Neuropharmacologist with the New Jersey Neuropsychiatric Institute in Princeton, and a visiting professorship at Princeton University (L. Goldstein, Tr. 17730-31; RX 267A).

Theodore Horner, Ph.D.

125. Dr. Theodore Horner is an expert in biometry, which is the application of statistical and mathematical methods to biological problems (Horner, Tr. 10735-43). Dr. Horner received a Ph.D. in Experimental Statistics from North Carolina State University. He is presently a consulting statistician in the area of applied statistics, with a primary interest in problems relating to biology and medicine. He has worked extensively with clinical trials, evaluations of pharmaceutical preparations, animal studies, toxicity studies, and other biometrical work. He has done consulting work for Abbott Laboratories, Hazelton Laboratories, and Litton Bionetics Laboratories, among others. Prior to becoming an independent consultant, Dr.

Horner was a principal scientist with Booz, Allen Applied Research, working with the application of statistics to biological defense problems. He has done consulting work for the Food and Drug Administration and the Federal Trade Commission (Horner, Tr. 10735-43, 10908; RX 282).

126. Dr. Horner taught statistics for four years at Iowa State University, and has taught operations research at Vanderbilt University. He is a member of the Institute of Mathematical Statistics, the American Statistical Association, and the American Society for Clinical Pharmacology and Therapeutics. He is a former Secretary-Director of the Eastern North American Region of the Biometric Society, an international organization (Horner, Tr. 10735-43; RX 282).

127. Dr. Horner has written numerous published and unpublished reports relating to biostatistics and biometrics (Horner, Tr. 10735-43; RX 282).

Christopher Rhodes, Ph.D.

128. Dr. Christopher Rhodes is a pharmaceutical scientist with expertise in the formulation and processing of drug products and their evaluation. Dr. Rhodes is Professor and Chairman of the Department of Pharmacy at the School of Pharmacy of the University of Rhode Island. He received a Bachelor of Pharmacy degree with honors from the University of London, [43] England, and Ph.D. for work concerning the physico-chemical properties of drug systems. Dr. Rhodes then pursued a course of post-doctoral study at Purdue University, under the direction of Dr. Gilbert S. Banker in the area of the design and evaluation of new dosage forms. He was formerly an Associate Professor at the State University of New York at Buffalo (Rhodes, Tr. 11048; RX 259).

129. Dr. Rhodes has taught undergraduate and graduate students of pharmacy research in the areas of formulation and dosage form design. He has performed clinical research in collaboration with medical doctors on several occasions. His research has concerned the design and evaluation of dosage forms, and the link between dosage form design and clinical response (Rhodes, Tr. 11050-52).

130. Dr. Rhodes' present research involves dosage form design, particularly with respect to the formulation and evaluation of compressed tablets in terms of biological availability or clinical trials. One of Dr. Rhodes' current projects involves research on new excipients in aspirin tablets. Dr. Rhodes is a pharmaceutical consultant to companies in North America and Western Europe, and is often invited to give lectures to professional groups of pharmacists and physicians, including government groups. He is an advisor to a number of government agencies, including the World Bank and the Population Council.

Dr. Rhodes is involved in research with scientists at the Brown University Medical School, and holds a scientific appointment at Roger Williams Hospital in Providence, Rhode Island, where he is working on the design and interpretation of clinical trials. He has lectured to medical students at Brown University on drug product selection and the role of biopharmaceutics and clinical performance. Dr. Rhodes has received grants from numerous pharmaceutical companies and from the National Institutes of Health (Rhodes, Tr. 11055-57; RX 259).

131. Dr. Rhodes has published two pharmaceutical texts and 110 scientific articles, 105 of which have appeared in peer-reviewed scientific journals. He is editor of the *Journal of Drug Development and Industrial Pharmacy* and has been invited to lecture to Food & Drug Administration (FDA) inspectors on a variety of topics (Rhodes, Tr. 11057-59; RX 259).

132. Dr. Rhodes has written articles and performed research relating to the properties and actions of salicylic acid (Rhodes, Tr. 11072-73; RX 259).

133. Dr. Rhodes is a member of the Academy of Pharmaceutical Sciences Regulations and Standards Committee. He is also a Fellow of the American Pharmaceutical Association, and a member of the Rhode Island Pharmaceutical Association, the American Association of Colleges of Pharmacy, the American [44] Association of University Professors, the Kappa Psi Pharmaceutical Fraternity, and the Sigma Xi Scientific Honorary. Dr. Rhodes also serves as a member of the United States Pharmacopoeic Convention and is a member of the United States Pharmacopeia Pharmaceutical Chemistry Committee, which is charged with evaluating the various official formulations (Rhodes, Tr. 11097-98, 11100; Banker, Tr. 12523-27).

Barrett Scoville, M.D.

134. Dr. Barrett Scoville, a former Director of the FDA's Division of Neuropharmacological Drug Products, is familiar with FDA practice and procedure relating to the regulation of drugs (Scoville, Tr. 14323, 14336).

135. The first position held by Dr. Scoville with the Food and Drug Administration, commencing in 1969, was that of Medical Officer in the Division of Neuropharmacological Drugs of the Bureau of Drugs. He had held this position for less than one year when he was promoted to the Deputy Director of the division. Dr. Scoville remained Deputy Director until 1973. He then advanced to Acting Director of the division in 1973-1974, and became Director of the division for the period 1974-1976 (Scoville, Tr. 14310-11, 14313-14; RX 266B).

136. The Neuropharmacological Division of the Bureau of Drugs of

the FDA was responsible for the safety and efficacy of drug products used for neurology, psychiatry and analgesia. The drugs regulated by this division included aspirin. The division was responsible for all prescription drug products falling in these categories, and until 1974 or 1975, was also responsible for regulating over-the-counter drug products in these categories (Scoville, Tr. 14311-12, 14322, 14329).

137. While employed by the FDA, Dr. Scoville was a member of the Medical Evaluation Committee. This Committee was concerned with compliance with FDA regulations in the marketplace and made decisions as to what action should be taken against defective products, such as recall. Dr. Scoville was also a member of the Medical Officer Review Format Committee, which was concerned with defining standards and procedures for Bureau of Drug personnel responsible for reviewing clinical data (Scoville, Tr. 14315-16, 14335; RX 266B).

138. Dr. Scoville was a member of the IND-NDA Task Force of the Bureau of Drugs (Scoville, Tr. 14316; RX 266B). IND refers to "investigational new drug application" and NDA refers to "new drug application". The IND is submitted to obtain permission for human testing of a new drug not yet authorized for marketing. The NDA is the application for approval to market a new drug. The Task Force had responsibility for developing better organization and guidelines for these processes. Members of the Task Force had a thorough understanding of the various [45] requirements and procedures for IND and NDA approvals. Dr. Scoville was also a member of the FDA's Committee on Evaluating Antidepressant Drugs, which had responsibility for developing testing guidelines (Scoville, Tr. 14317-18; RX 266B).

139. Dr. Scoville was an official spokesman for the FDA and as such participated in panels, symposia and seminars in which FDA practice and procedure was explained to experts and to the general public (Scoville, Tr. 14318-19; RX 266).

140. After leaving full-time employment at the FDA in 1976, he remained a consultant with the FDA until 1978 and a consultant to the National Institute of Neurological and Communicative Disorders and Stroke until 1979. He has continued to give lectures, participate in seminars and symposia with drug experts, and write articles dealing with FDA drug regulations (Scoville, Tr. 14320-21; RX 226D-F).

3. Respondent's Company Witnesses

George Goldstein, M.D.

141. Dr. George Goldstein is an expert in the area of the use, efficacy and safety of Sterling Drug analgesic products: Bayer Aspirin, Bayer Children's Aspirin, Cope, Vanquish and Midol, including the ingredients contained in those products (G. Goldstein, Tr. 14744, 14783; RX

274). Dr. Goldstein came to Sterling in January 1975, as Medical Director of Sterling's Glenbrook Laboratories division in January 1975, succeeding Dr. Robert John, who testified as a complaint counsel witness in this proceeding. Glenbrook Laboratories is the division of Sterling principally concerned with nonprescription drugs, including the analgesic products involved in this matter (G. Goldstein, Tr. 14724-25; RX 274A-B). The Medical Director of Glenbrook Laboratories is the highest medical position in Glenbrook (G. Goldstein, Tr. 14738).

142. Since January 1, 1979, Dr. George Goldstein has been Vice President and Medical Director of Winthrop Laboratories, the division of Sterling concerned principally with prescription drugs. His duties involve the supervision of all medical activities, including research and development, for all products manufactured by Winthrop Laboratories. The prior position held by Dr. Goldstein was that of Director of Regulatory Affairs for Sterling. His duties included liaison for all divisions of Sterling with the United States Food and Drug Administration and the Consumer Product Safety Commission. Dr. Goldstein assumed this position on January 1, 1977 and remained in it until becoming Vice President of Winthrop on January 1, 1979 (G. Goldstein, Tr. 14722-23; RX 274). Prior to becoming Director of Drug Regulatory Affairs in January 1977, Dr. Goldstein was a Medical Director of Glenbrook Laboratories, commencing in January 1975, and in January 1976 he became the [46] Vice President of Glenbrook Laboratories, as well as its Medical Director.

143. While with Glenbrook Laboratories, Dr. Goldstein was responsible for supervision of all scientific and medical aspects of the products manufactured by Glenbrook which included substantiation for advertisements for those products. Responsibility for substantiation encompassed both medical and pharmaceutical issues. As part of his duties, Dr. Goldstein kept abreast of current scientific literature and developments in the analgesic area (G. Goldstein, Tr. 14722, 14725-27).

144. As part of his duties as Medical Director of Glenbrook Laboratories, Dr. Goldstein was designated in 1975 by respondent Sterling as medical liaison to respondent's attorneys in this matter (G. Goldstein, Tr. 14742).

145. Dr. Goldstein has served on a number of committees within Sterling. One such committee is the Medical Research Committee which reviewed protocols for testing of drugs already on the market. He was also a member of the New Drug Committee which reviewed protocols for testing of any new drug (G. Goldstein, Tr. 14738).

146. Dr. Goldstein holds a Bachelor of Arts degree from Columbia University and an M.D. degree from the State University of New

York, College of Medicine at Syracuse. The bulk of Dr. Goldstein's post-graduate clinical training and practice was in the field of Pediatrics. He interned at Baltimore City Hospital and then served in the United States Air Force where he was Chief of the Pediatric Service and Chief of the Pharmacy Service of the 864th Medical Group. After completion of his military service, Dr. Goldstein was a resident in pediatrics at New York Hospital, Cornell Medical Center. Thereafter, he was in private practice for 12 years. While in private practice, Dr. Goldstein was connected with the Phelps Memorial Hospital where he was Deputy Director of Pediatrics and Chairman of the Pharmacy and Therapeutics Committee for a number of years. He was also an instructor in Pediatrics for approximately eight years at the New York Medical College (G. Goldstein, Tr. 14739-40; RX 274).

147. Dr. Goldstein is a Diplomate of the National Board of Medical Experts, certified by the American Board of Pediatrics, a member of the American College of Clinical Pharmacology, and a Fellow of the American Academy of Pediatrics (G. Goldstein, Tr. 14741; RX 274B).

James Alberts

148. James Alberts is Vice President and Director of Marketing and Advertising Services, Sterling Drug. His responsibilities include advertising, trade promotion, public relations, consumer response, and marketing research (Alberts, [47] Tr. 8913). Mr. Alberts has been with Sterling for 20 years and has worked there in various capacities in the areas of advertising and marketing. Mr. Alberts started as a product manager. During the period from 1969 to 1974, Mr. Alberts was a group product manager for Bayer Aspirin, Bayer Children's Aspirin, and Cope. He had no responsibility for Vanquish until he became Director of Marketing in 1977 (Alberts, Tr. 8914-16, 9018). As part of his job, Mr. Alberts has kept informed about the marketing positions of Bayer Aspirin, Bayer Children's Aspirin, Vanquish, and Cope which includes information on sales, market trends, consumer and research marketing and competitive advertising (Alberts, Tr. 8917-18).

Morris Auerbach

149. Morris E. Auerbach testified by deposition, due to age and ill health. He was deposed through written questions by respondent and oral cross-examination by complaint counsel. The written questions, answers and transcript of the cross-examination were introduced into evidence as RX 286.

150. Mr. Auerbach graduated in 1928 from New York State College for Teachers, receiving a Bachelor of Arts degree in English and Chemistry (RX 286B). He has no educational background, training, or

experience in the fields of medicine, toxicology or pharmacology (RX 286C). Mr. Auerbach was employed by Sterling Drug, Inc. from 1928 until he retired in 1969. He was hired as an assistant chemist and in the early 1940's he became Supervisor of the analytical laboratory at the Sterling-Winthrop Research Institute, a position he held until he retired (RX 286C).

151. Mr. Auerbach served in an individual capacity on several committees of the United States Pharmacopeia. He was not a representative of Sterling, nor any of its subsidiaries and aspirin was not one of the drug substances assigned to him. Dr. Klumpp was the official spokesperson on medical matters for Sterling and its subsidiaries during this time. Mr. Auerbach did submit comments regarding chemical testing and controls for aspirin to the USP in response to solicitations from Lloyd Miller, USP Director of Revision. These comments were not subject to review or authorization by Sterling (RX 286C-E).

Richard K. Hartman

152. Richard K. Hartman, presently an Account Supervisor at Thompson-Koch Advertising Agency, a wholly owned subsidiary of Sterling, has had responsibility for Midol advertising since 1964 in his positions as Account Supervisor and Account Executive (Hartman, Tr. 9135).

E. Clifford Hall

153. E. Clifford Hall was employed at Sterling from 1966 to 1977, as a Product Manager and Group Product Manager. As [48] Product Manager, Mr. Hall was responsible for Vanquish, Phillip's Milk of Magnesia, Campho-Phenique, and Haley's MO. He was Product Manager for Vanquish from 1969 to 1975. During that time, Benton & Bowles and Lois-Holland-Calloway were advertising agencies that worked on the Vanquish account. Mr. Hall was the principal contact at Glenbrook Laboratories with these advertising agencies during that period of time. Mr. Hall is presently employed at the Schering-Plough Corporation as Marketing Manager for International Operations (Hall, Tr. 9206-07).

Theodore Klumpp, M.D.

154. Dr. Theodore Klumpp testified by deposition, due to age and ill health, on behalf of respondent Sterling (Klumpp-RX 285). During the 1960's, Dr. Klumpp was the official spokesperson for respondent on medical and scientific matters (Klumpp-RX 285L). Dr. Klumpp has a Bachelor of Science degree from Princeton University and an M.D. degree from Harvard (Klumpp-RX 285Z034). Apart from positions at

Sterling, Dr. Klumpp has held positions as Assistant Clinical Professor of Medicine at Yale University Medical School, Chief Medical Officer of the Food and Drug Administration, Chief of the Drug Division of the Food and Drug Administration, and Director of the Division of Drugs, Food and Physical Therapy of the American Medical Association (Klumpp-RX 285E, RX 285Z34). Dr. Klumpp was elected Vice President and a Trustee of the United States Pharmacopeia Convention in 1950 and was re-elected in 1960 (Klumpp-RX 285E-F).

155. In 1942, Dr. Klumpp joined respondent Sterling as President of the subsidiary that became known as Winthrop Laboratories. Winthrop Laboratories deals principally with prescription drugs. Dr. Klumpp remained President of Winthrop Laboratories until 1970 (RX 285Z34). Dr. Klumpp also held the position of a Director of Sterling Winthrop Research Institute from 1950 until his retirement in 1973 (RX 285G). Dr. Klumpp, from 1960 until 1973, was also a member of the Board of Directors and Vice President of Sterling (Klumpp-RX 285E-H, RX 285Z34, RX 285Z53).

Edward Mannix

156. Edward Mannix is a coordinator for contract packagers at the East Greenwich plant of Sterling's Winthrop Division located near Rensselaer, New York. From 1939 to 1976, he was associated with the Glenbrook Division of Sterling, where he was laboratory assistant, laboratory supervisor, Assistant to the Director of Quality Control, and in 1962 became Director of Quality Control of the Trenton operation, taking over that position from Jerome Winig, who became Plant Manager. [49] Mr. Mannix left the Trenton plant in 1976 to work at the Winthrop Laboratories Division of Sterling in Rensselaer, New York. His initial position at Rensselaer was laboratory manager, and his responsibilities involved directing the operation of the control laboratories there (Mannix, Tr. 14603-04).

Gerard Mattimore

157. Gerard Mattimore is Group Marketing Director at Glenbrook Laboratories. He is responsible for marketing Sterling's nonanalgesic products, including Phillip's Milk of Magnesia and Diaperene Baby Products. He has been employed at Sterling since 1962, when he started as a salesman. From 1963 to 1968, Mr. Mattimore was in sales management, from 1968 to 1976 he was in product management, and from 1976 to 1977 he was in product management, and from 1976 to 1977 he was Director of Marketing Services (Mattimore, Tr. 15334-35).

158. In 1967 and 1968, Mr. Mattimore was Director of Sales Administration and Sales Administration Manager at Glenbrook

Laboratories, where his responsibilities included dissemination of all instructions and information to the field sales force of approximately 100 sales representatives. The great majority of communications to the sales force were initiated by Mr. Mattimore, who was the primary source for sales-related information. Mr. Mattimore was familiar with the system of distribution of Bayer Aspirin and other brands of aspirin and analgesic products (Mattimore, Tr. 15336).

Maurice Tainter, M.D.

159. Dr. Tainter joined Sterling in 1943 as Director of Research, and held this position until 1969. Dr. Tainter was founding director of Sterling-Winthrop Research Institute, a drug research institute at Rensselaer, New York (1946-1960). Dr. Tainter was also a vice-president of Sterling from 1946 to 1969. In 1960, Dr. Tainter became vice-chairman of the Sterling Research Board, and, as Director of Research, had responsibility for a research staff of 700. His duties included research and policy matters, as well as research for new products (RX 284C-E, RX 271).

160. Dr. Maurice Tainter received an A.B. in 1921 and an A.M. in 1924 and an M.D. in 1925 from Stanford University in California (RX 284B-C, RX 271). Dr. Tainter is the author of approximately 250 publications in the fields of medical and dental pharmacology, therapeutics, toxicology, research administration, and the history of medical research. Dr. Tainter has been on the editorial boards of various medical and pharmacologic journals, including *Clinical Medicine*, *Pharmacological Reviews* and *Toxicology and Applied Pharmacology* (RX 284B-C, RX 271). Dr. Tainter is a member of a number of [50] professional organizations, including the New York Academy of Sciences (President, 1955), the American College of Clinical Pharmacology and Chemotherapy (Charter Member and Fellow), the American Physiological Society, and the American Society for Clinical Pharmacology and Experimental Therapeutics (RX 284B-C, RX 271). Prior to joining Sterling, Dr. Tainter held professional academic positions in the Department of Pharmacology at Stanford University Medical School (1925-1943), and was head of the Physiological Sciences Department in the College of Physicians and Surgeons Dental School, San Francisco (1940-1943) (RX 284B-C, RX 271).

161. Dr. Tainter has been qualified as an expert in court and has testified at congressional proceedings (RX 284E-F; RX 271).

Monroe E. Trout, M.D.

162. Dr. Monroe E. Trout, Senior Vice President of Medical and Scientific Affairs at Sterling, has been employed by Sterling since 1968. He was elected Senior Vice President in 1978. Prior to that time,

he held various positions with the company, including Medical Director and Vice President of Winthrop Laboratories, Medical Director of Sterling U.S.A., Medical Director of Sterling Drug, and Corporate Vice President of Medical Affairs (Trout, Tr. 16078-79). Dr. Robert John, Medical Director of Glenbrook Laboratories from 1971 to 1974, reported to Dr. Trout (Trout, Tr. 16084).

163. Prior to joining Sterling, Dr. Trout practiced medicine for seven years, both in the U.S. Navy and as Chief of Medicine at a large state hospital in Harrisburg, Pennsylvania. He also worked for Pfizer, Inc., in their Regulatory Affairs Department and as Assistant to the Vice President for Pharmaceuticals (Trout, Tr. 16079-80).

Jerome Winig

164. Jerome Winig worked for Sterling for 42 1/2 years prior to his retirement in August 1977. He joined Sterling in 1935 as a Bench Chemist. In 1943, he became Chief Control Chemist. After helping design the new plant in Trenton, Mr. Winig was promoted to Director of Quality Control in 1947. In 1960 he became Assistant Plant Manager, and in 1962, Plant Manager. In 1967 Mr. Winig became Vice President of the Glenbrook Laboratories Division of Sterling. In 1970, he was promoted to Divisional Vice President for Manufacturing of Sterling, and retained this position until his retirement in 1977 (Winig, Tr. 13614).

165. As Director of Quality Control and Chief Control Chemist, Mr. Winig's responsibilities involved approving or rejecting material used in the manufacture of Bayer Aspirin. He [51] was also responsible for approval of all outgoing shipments. When he became Plant Manager, Mr. Winig relinquished responsibility for quality control. Edward Mannix became Quality Control Director at that time (Winig, Tr. 13617). As Vice President of Glenbrook Laboratories, Mr. Winig was responsible for five manufacturing plants (Winig, Tr. 13618).

166. During his entire tenure at Sterling, Mr. Winig had responsibilities and duties associated with Bayer Aspirin. He also helped to design the Bayer Aspirin plant in Trenton. The design of that plant involved many advances in manufacturing processes and standards. It took about six years to develop equipment for the new plant (Winig, Tr. 13619). Mr. Winig was responsible for the development of the formula and manufacturing process for Bayer Children's Aspirin in the late 1950's (Winig, Tr. 13619). During his tenure at Sterling, Mr. Winig was fully familiar with the manufacturing processes and quality control procedures at the Trenton plant (Winig, Tr. 13620).

167. Mr. Winig is a member of the American Chemical Society, the American Pharmaceutical Association, the American Institute of Chemists, the Academy of Pharmaceutical Sciences, the Society for

the Advancement of Management in the United States, and the Manufacturing Controls Committee of the American Proprietary Association. Mr. Winig became active on the Manufacturing Controls Committee of the American Proprietary Association in 1965 by invitation. On that committee, he worked closely with the Food and Drug Administration in designing procedures and changes in drug manufacturing practices. The committee included Mr. Winig's counterparts at other companies and other management and manufacturing personnel.

III. RESPONDENTS MADE THE ADVERTISING REPRESENTATIONS
ALLEGED IN THE COMPLAINT

A. *The Meaning of Advertisements*

168. In determining whether an advertisement made a particular representation, the appropriate standard to be applied is whether, taking the advertisement as a whole, the representation constitutes one reasonable interpretation of the advertisement which some consumers may reasonably understand the advertisement as making.

169. The primary evidence with respect to the meaning of advertisements in the record consists of the advertisements themselves.

170. The record also contains secondary evidence regarding the meaning of advertisements, including:

(a) The expert testimony of Drs. Ivan Ross, Timothy Brock, Virginia Miles, and Russell Haley. [52]

(b) The copy test data from the Zeisel Copy Tests (CX 520), the Burke "Day After Recall" Tests (CX 441, 442, 451 and 452) and the "ASI Audience Reaction Tests" (CX 567 and 568) and, to a limited extent, some verbatim comments of consumers in response to comprehension and recall questions reported therein.

(c) Certain consumer studies regarding consumer understanding of some attributes of OTC internal analgesic products, such as effectiveness, safety, strength and speed (CX 404, 440).

171. In arriving at a determination of whether respondents' advertisements in the record made the representations as alleged in the Complaint, I have primarily and in the first instance relied on my own judgment based on my knowledge and experience in interpreting the meaning of each advertisement separately. I further relied on secondary evidence as confirmation of my conclusions. I have not relied on secondary evidence when, after careful study and reflection, I found it unpersuasive and inconsistent with my initial determinations. In this connection, I have focused on what appears in each advertisement in terms of its audiovisual contents, and disregarded the so-

called advertising campaign themes and other extraneous information not contained in an advertisement.

172. Among the various kinds of data which are useful in determining the message that consumers take from a particular advertisement are copy tests. These tests are generally conducted with respect to a particular advertisement or advertisements shortly after respondents have viewed them. The object of such tests is to collect data from those surveyed regarding their impressions of the content or the meaning of such advertisements.

1. The ASI Audience Reaction Tests (CX 567, CX 568)

173. The ASI Audience Reaction Tests received into evidence as CX 567 and CX 568 were conducted by Audience Studies, Inc. (ASI) on television advertisements for Bayer Aspirin. The tests were of standardized design. The purpose of these surveys was to measure the effectiveness of one advertisement in comparison to the effectiveness of other advertisements for products in the same category (CX 567, CX 568, CX 638B).

174. The stipulated testimony of Gerald Lukeman, President of ASI, concerned the mechanics of conducting Audience Reaction [53] Tests (CX 638). ASI's principal line of business is the measurement of communication in one form or another. Since 1961 most of ASI's work has involved the measurement of television and print advertising, network pilot program material, and motion pictures. ASI offers various testing services including the "theatre" system or "Audience Reaction Test," the use of cable television for "on-air" testing, and the miniature supermarket system.

175. ASI has, throughout the period that is relevant in this case, utilized standardized procedures in (1) selecting respondents to participate in Audience Reaction Tests and (2) conducting such tests and processing the data collected therein. Such standardization is called for by the nature of the service which ASI offers clients for whom it tests television commercials: the ability to compare the results of a test of one commercial with the results of tests conducted on others for products in the same category. Thus, while there have been minor modifications in the methods used over time, as indicated below, the basic procedures have remained essentially the same and were followed in CX 567 and 568 (CX 638B).

176. The audiences which viewed the advertisements reported upon in CX 567 and 568 were recruited from the Los Angeles metropolitan area. Recruitment was accomplished, in part, by in-person contact in high traffic areas, such as shopping centers. The different shopping center locations where such recruiting occurred were chosen in an effort to secure a sample that reflects the differing geographic and

socio-economic characteristics within that metropolitan area. Recruiting quotas were based on the characteristics of age and sex. Audiences are generally recruited so as to provide an approximately 50/50 sex distribution and to secure approximately half of the respondents below age 35 and half above age 35 (CX 638B).

177. In-person recruiting was supplemented by telephone calls using a central telephone facility. This supplemental telephone call recruiting was accomplished through the use of "reverse" directories which list people by their addresses. These were used to foster the best possible geographic and socio-economic dispersion of those ultimately recruited (CX 638C).

178. The ASI standard sampling procedures were designed to produce a sample whose age, sex and socio-economic characteristics are comparable to samples previously recruited and tested by ASI (CX 638C).

179. ASI recruiters were instructed to inform potential respondents that they were being invited to preview network television programs. They were not to be told about ASI. If respondents asked for an explanation as to why there was no charge for the program, recruiters were instructed to tell them [54] that they would be asked for their opinions about the material they would see (CX 638C).

180. Upon arriving at the ASI testing facility, according to ASI's standard procedure, certain respondents were selected by ASI personnel to operate the dials of a recording machine at their seat designed to measure their reactions to the materials they were to view. A second subsample was selected for the test reported in CX 567 to participate in a "focus group" discussion held at a point in the evening after the commercials had been viewed (CX 638C-D, CX 567 at pp. Z005-Z013).

181. After the ASI employees completed the subsample selections, the ASI standard procedure called for the respondents to be seated in a theater and asked to fill out a classification questionnaire requesting various demographic and product usage/preference information. This questionnaire also asked respondents to select products from various product categories which they would desire to win as a prize (a pre-exposure selection measure). An example of the classification, demographic and pre-selection questions is to be found in CX 567, pages Z020 through Z024 (CX 638D).

182. ASI generally recruited more respondents than were required for its 250 person standard sample. Thus, approximately 350 people—on an average—participated in a typical ASI test evening. Thereafter, the responses of certain respondents, whose age, sex or other socio-economic characteristics were over-represented in the audience, were eliminated by a randomized process (CX 638D).

183. Following collection of the classification and pre-selection questionnaires, the audience was shown a "control" cartoon which had been used as a standard for most ASI sessions. Use of the "control" cartoon was designed to permit those in the segment of the audience to learn to manipulate their dials; it was also designed to permit ASI employees to compare this audience's dial reactions to the same material (the same "control" cartoon) reacted to by many other audiences. If the audience's reactions to the "control" cartoon did not satisfy ASI that this audience was reacting in reasonable accord with norms based on past audiences' reactions, the data generated through the subsequent questionnaire regarding "program" material would be discarded and that program material retested at a later date (CX 638D).

184. Following the "control" cartoon, a television program was shown to the entire audience. Those with dials reacted to the program by manipulating the dials, and at the conclusion of the television program all audience members were asked to fill out a questionnaire about the program. It is ASI's practice not to include the results of this questioning in its reports (CX 638E). [55]

185. After the television program was shown, the audience was told that it would be seeing a series of five commercials ("commercial" material) and a five-section commercial questionnaire booklet was distributed. Then the first commercial was shown. As with the "control" cartoon, the first commercial is always a "control" (*i.e.*, a commercial tested many times previously for which audience reaction is known). As with the "control" cartoon, ASI monitored the audience's reaction to the first "control" commercial to determine if it was reacting within normal limits established through ASI's prior experience with reactions to the same commercial. If the audience's reactions to the "control" commercial did not satisfy ASI that this audience was reacting in reasonable accord with norms based on past audiences' reactions, the data generated through subsequent questionnaires regarding the "commercial" material would be discarded and that commercial material retested at a later date (CX 638E).

186. Following the showing of this first "control" commercial, the audience was asked to fill out the first section of its five-page questionnaire. Immediately thereafter the second commercial was shown, and the audience filled out the second section of the questionnaire (CX 638E). This procedure was followed until all five commercials were shown and all five sections of the questionnaire was completed (CX 638E-F).

187. After the five commercials, the audience was shown a second television program segment and filled out a short questionnaire regarding it (CX 638F).

188. Thereafter, the audience was told that the pre-selection preference questionnaire was the incorrect one. A "correct" prize selection questionnaire containing an additional product category was thereafter administered giving the audience a second chance to select the product from an available list that they would like to win as a door prize. This second, or "post-selection," prize questionnaire was then collected (CX 638F).

189. Finally, the audience was given a "recall questionnaire" which asked the audience to think back to the commercials they saw earlier and to write down the products and brand names and everything else they remembered about each commercial. This "recall questionnaire" (e.g., CX 567 at p. Z025) was administered approximately 30 to 40 minutes after the commercials were viewed. After the "recall questionnaire" was collected, prizes were awarded and the evening was concluded (CX 638F).

190. The procedure outlined above applied to all members of the audience except for the group chosen earlier to participate in group discussions. This group, composed of 10 to 12 people, [56] was taken out of the theater after the commercials were aired and, in a session led by a trained ASI moderator, the group discussed, among other things, some or all of the commercials they had viewed. People were initially invited to participate in focus groups based upon the opinion of an ASI moderator that they were not nonverbal and, thus, would be willing to discuss their opinions of the commercials they viewed (CX 638G).

191. Responses to the open-ended questions asked in the various questionnaires were coded internally by ASI's coding department. That department consisted of a supervisor, one or two assistants, and a staff of coders. The supervisor's responsibility extended to assigning work to coders, checking the accuracy of coding and spotting problems that may exist in coding or in establishing coding categories. The assistants' responsibilities included checking and accuracy of coding and training coders.

192. Coding of open-ended responses to the "main idea of the commercial" question and the "recall" question began with the preparation of a recommended coding outline for each question. This outline was based upon a coder's review of the commercial itself, prior ASI reports on other commercials for the same product, and approximately half of all responses given to the particular question. The recommended coding outline was approved by the coding supervisor and then by the project director. ASI's policy is, as much as possible, to use the same codes over a period of time for advertisements for the same product in order to permit comparisons across tests. After the recommended outline of codes was approved by the project director, the

coder took each verbatim comment and coded it by placing it into what the coder thought was the appropriate category. The accuracy of coding was to be checked first by the coding supervisor. If a project was especially complex, or if questions or problems were encountered in the coding process, a project director's assistance was enlisted (CX 638H-I).

193. Coded open-ended responses together with closed-ended (or "check off" type) responses were sent to ASI's internal keypunching department where they were to be keypunched and processed by a computer. ASI's procedure called for all data to be "double-punched" so that the accuracy of keypunching could be verified. Key-punchers were hired only if they had at least two years' experience. Applicants were required to take at least two tests at ASI, one concerning visual speed and accuracy and the other on the keypunching machines themselves. Key-punchers thereafter hired were trained by ASI's key-punching supervisor (CX 638I).

194. After the keypunched data was fed into a computer, the computer's printout of coded responses was also checked, according to ASI's standard procedures, by the coding supervisor, the project director and ASI's department in charge of editing final reports prior to issuance (CX 638I). [57]

195. The computer printouts of all responses (open-ended) are checked by the computer operator before they are released from that department. Thereafter, all the computer-tabulated data are delivered to a project director who also checked on the accuracy of the data (CX 638I).

2. The Burke "Day After Recall" Surveys (CX 441, 442; CX 451-454)

196. The six "Day After Recall" tests received into evidence (CX 441, 442, 451, 452, 453, and 454) were conducted by Burke Marketing Research (Burke) for Glenbrook Laboratories and Thompson Koch on two Midol advertisements under challenge here ("Woods and Stream," CX 296(A); "Life", CX-296(B)) and for DFS on several Bayer advertisements, among them, three under challenge here ("Inside Story #1, CX 38; "Inside Story #2," CX 39; "Library," CX 18). These were communications tests primarily for the purpose of determining whether television commercials could be remembered a day after being seen on the air in their formal environment. These tests were not designed to be national probability tests (Granger, Tr. 4163; Lipstein, Tr. 12074). The tests were of standard design—Burke has conducted fifteen to twenty thousand such tests for nearly 25 years for package goods manufacturers of over-the-counter internal analgesics (Granger, Tr. 4163-34, 4166).

197. James Granger is the group vice-president for client and project services for Burke Marketing Research. Burke Marketing Research is a full-service custom marketing research company which (in addition to copy testing) conducts studies in the areas of product testing, concept testing, advertising evaluation and a variety of other services (Granger, Tr. 4163). CX 441 and CX 442 were compiled and reported by Burke while CX 451-454 were compiled and reported by DFS. However, Burke did the field work for all six tests (Granger, Tr. 4165-6).

198. Burke tests are run on ads which are actually aired, either nationally or in three or four selected geographically dispersed cities (Granger, Tr. 4166-8). In those three or four cities which are chosen for the test, selection of the subjects is done by random selection of phone numbers from local telephone directories (Granger, Tr. 4168-9).

199. The standard Burke questionnaire or a variation of the standard questionnaire was used in the six identified CX (Granger, Tr. 4173). The questionnaire in each of these tests first asked the subject if on the preceding night (s)he saw any part of the program segment in which the test ad was scheduled; if so, whether (s)he saw an ad for the test products' class of products (*e.g.*, "menstrual remedies" or "headache remedies") and if so what brand. If the correct brand was not mentioned up [58] to that point the subject was asked if during the program (s)he happened to see an ad for the test brand. Once the subject indicated (s)he recollected an ad for the test brand (s)he was asked to tell anything (s)he remembered about the test advertisement, what the commercial looked like, what it said, and what ideas about the product the ad brought out. Finally, subjects were asked what activity they were engaged in just before, during and after the time the ad was run, using prompts describing the program segments (Granger, Tr. 4173, 4175-7, 4180-1; CX 441R-U; CX 442L, Q; CX 452Z007; CX 4530, R; CX 454S, T). This latter activity question is used to determine the size of the commercial audience which in turn is the base on which the "related recall" score is calculated (Granger, Tr. 4176-7). The size of the commercial audience for each of these six Burkes in evidence was typical. For example, CX 442, with a 200 program audience quota, had a commercial audience size of 116, which was typical. Commercial audience sizes for the other Burkes was as follows: CX 441, 121; CX 441, 167; CX 452, 170; CX 453, 153, and CX 454, 153 (Granger, Tr. 4179).

200. Analysis of data in the six tests in evidence began with whether subjects claimed to have seen the test ads, ("claimed recall"), whether, first, in response to the brand category cue, or second, in response to the brand name cue (Granger, Tr. 4180-81). Then responses to the

questions calling for subjects to tell what the advertisement said are analyzed to determine if the verbatim responses related to what was actually in the ads ("related recall"). This data was broken out again on the basis of whether subjects were prompted by the brand category cue or the brand name, and was displayed on the basis of response codes of two major classes, whether related recall relates to sales message or situation visual (Granger, Tr. 4181-82). Finally, the verbatim responses to the questions asking what the ad said were reproduced, first, those verbatims included in related recall results and those not included in related recall results (CX 441F-K; 442F-K; 451-I-M, P-S, V-X, Z001-Z003; CX 452H-Q, T-Z; CX 453G-K; CX 454F-M).

201. Verbatim answers were recorded using a verbatim recording technique. The interviewer was trained in how to write out in long hand the narrative answer that the respondent gave to the open-ended questions that asked what the ad said. (Granger, Tr. 4172-74). Interviewers engaged in probing questions such as "what," "tell me more about that" and "in what way," when a respondent gave an answer which was unclear. (Granger, Tr. 4174-75). Editing of the verbatim responses was done anytime the respondents did not respond to the questions. (Granger, Tr. 4175).

202. Two important quality control techniques were used in the tests. First, there is a technique department in Cincinnati that is responsible for a study as it is going on. If there are any problems in the local field office, the manager is [59] instructed to call the technique department to get it resolved (Granger, Tr. 4182-83). Once a problem is decided by the technique department, all other field supervisors are alerted to the decision. Second, completed questionnaires are monitored by Burke's quality control department to check whether the interviews are being conducted in the standard format (Granger, Tr. 4183-84).

203. All interviewers are Burke employees and are trained by Burke. This is to ensure that the manner of conducting interviews is standardized and of uniform quality. The interviewers are trained on the basic techniques of interviewing and are given some basic marketing research information and special techniques they will be called upon to use in their interviewing (Granger, Tr. 4170).

204. Part of the interviewer training consists of several days of actual practice conducting interviews among themselves and on the telephone. During the interview, interviewers are supervised by the office manager of a particular Burke office or another individual who is designated as job supervisor for that particular test (Granger, Tr. 4171).

205. Though the related recall score is a measure of the memorabili-

ty of the commercial, the verbatim responses are a better measure of the meaning of the ad than the related recall scores (Granger, Tr. 4222).

206. The copy tests in evidence by ASI and Burke were performed in a standard and reliable fashion. These tests or tests substantially identical to them were and are relied upon by large numbers of businesses, including manufacturers of OTC internal analgesics, for purposes of making normal business decisions. The Burke and ASI copy tests in evidence are reliable and probative evidence of consumer recall of advertising content for ads challenged in this proceeding.

3. CX 520—The Zeisel Copy Tests

207. Pursuant to a contract with the Federal Trade Commission, Dr. Hans Zeisel was responsible for the execution of three copy tests on three Bayer Aspirin advertisements—one print advertisement, CX 157, and two TV commercials, CX 52 ("Lee Trevino") and CX 75 ("Truisms"). The data from these surveys was analyzed by Dr. Zeisel and the resulting report is CX 520 (March, 1977) "The Consumer's Understanding of Three Bayer Advertisements."

208. The purpose of CX 520 was to determine the message conveyed to consumers by the two Bayer television commercials [60] and one print advertisement. These advertisements had been widely distributed through the media (CX 603E, H, U, V). Specifically, the study attempted to determine to what extent these advertisements were perceived as promising superior effectiveness of Bayer aspirin (CX 520B).

209. Dr. Zeisel was the principal author of CX 520. He was involved in the design of the study, the design of the questionnaire, the design of the samples, the examination of the samples size, and drafting of the final report (Zeisel, Tr. 4651). The Gallup Organization and Dr. Irving Crespi, then of Gallup, participated in the design of the questionnaire and did the field work for the print advertisement portion of CX 520 (Crespi, Tr. 4316-17). Response Analysis Corporation and Dr. Herbert Abelson participated in the design of the questionnaire and did the fieldwork for the TV advertisement portion of CX 520 (Abelson, Tr. 4520-21).

210. The three Bayer commercials selected were thought by Dr. Zeisel to be typical of Bayer commercials in general and were ones on which a substantial part of Blue Book funds were spent (Tr. 4655).

211. The print advertisement (CX 157) was shown to a probability sample of the U.S. population 18 years and over. The television advertisements (CX 52 and CX 75) were shown to a nonprobability sample consisting of persons 18 years and over in a variety of cities and walks of life (CX 520J).

212. After the advertisement was shown to the respondents, each respondent was asked a sequence of questions about the advertisement with successively narrowing focus. In the first questions, the respondent was asked what was the main point or points of the advertisements. Next, the respondent was asked what the advertisement said about Bayer aspirin as compared to other brands of aspirin. The next focus was even narrower, as the salient claim of the particular advertisement was quoted to the respondent, who was then asked what does the advertisement mean by that claim. Finally, each respondent was asked to answer the most narrowly focused question: "Does the advertisement suggest or does it not suggest that Bayer is more effective in relieving pain than any other brand of aspirin?" The questions were asked in this order of successively narrowing focus so that the consumers' answers to the earlier question would not be tainted by knowing in advance the content of the subsequent narrower questions (CX 520J-K).

213. Dr. Crespi reviewed the print questionnaire (CX 520Z008-Z012) to CX 520 and presented it to determine whether it conformed to good professional practices. The pretest indicated to Dr. Crespi that no major changes were required (Crespi, Tr. 4316-17). [61]

214. Dr. Abelson reviewed the TV questionnaire (CX 520Z014-Z024) to CX 520 and pretested them. A total of four pretests were carried out by Responses Analysis (Abelson, Tr. 4528). The initial pretest identified that the early drafts of the questionnaires were, in fact, leading some of the respondents. He testified that through the process of redrafting and pretesting, these problems were eliminated and the final questionnaire design was not leading and conformed to good professional practice (Abelson, Tr. 4530-4542).

215. Dr. Ivan Ross, (CPF 12) acknowledged the acceptability of the questionnaire design in CX 520 and identified it as a "funneling approach" (Ross, Tr. 5770-01). A funneling approach refers to a set of questions moving from an unaided form to a progressively and more aided form (Ross, Tr. 5771). Dr. Ross uses such a procedure for most of the copy tests that he conducts (Ross, Tr. 5771-72). The funneling technique is fairly standard in copy test research of consumer interpretations of advertisements (Crespi, Tr. 4322; Ross, Tr. 5771-72).

216. Dr. Crespi analyzed the questionnaire for CX 520 to satisfy himself that the questions were understandable and not confusing, were answerable in the terms in which they were formulated, were not biased or leading, produced data about the issue being investigated, and were physically and psychologically administratable. In approving the questionnaire, Dr. Crespi felt that these concerns had been adequately addressed for CX 520 (Crespi, Tr. 4317-18).

217. The respondents to CX 520 who were asked about CX 157, a

Bayer print advertisement, were selected on a national probability basis. The respondents were interviewed personally in their home by field representatives of the Gallup Organization. Respondents were selected from a sample drawing from Gallup's master national probability sample of interviewing areas. This sample is based upon the latest data available from the Census Bureau. The country is divided up into blocks or clusters of blocks by a standard method, various blocks of clusters were selected for use in this study. Within a block or cluster, a starting point was selected by Gallup in a random manner. Gallup interviewers were then given a map of the area to which they were assigned and this randomly starting point was indicated on the map. The interviewers were instructed to conduct an interview at each of the households. Then using a randomized procedure they selected one of the individuals in the household to be interviewed. If that selected individual was not at home, the interviewer was to make a call back to attempt to complete the interview in that household. Up to four calls were made in each household. No substitution of households were permitted (Crespi, Tr. 4326-28). [62]

218. Once the Gallup interviewers were granted access to a respondent's home, the Gallup interviewer read the text of CX 157 to the selected respondent. Next the respondent was handed the advertisement and allowed to read it. After the respondent had finished looking at the advertisement, the Gallup interviewer took CX 157 back and did not show it again to the respondent. Next, the interviewer asked the respondent the questions set forth in CPF 106, recording the answer fully in the respondents' own words (CX 520Z009). The interviewers did not summarize or paraphrase the respondents' answers (Crespi, Tr. 4331-32). The response rate to the print portion of CX 520 was about 60%.

219. Through the process of validation, Gallup took steps to be certain that the interviewers actually conducted the designated interviews. Gallup validated one-third of the interviews and the validation revealed no problems (Crespi, Tr. 4334, 4350).

220. When Gallup received the final and completed questionnaire from the fieldworkers, personnel at Gallup went through a standard quality control procedure to verify the interviews had been conducted in accordance with the instructions. Gallup then sent the completed and filled out questionnaires to Ilsa Zeisel for coding (Crespi, Tr. 4337).

221. The answers to the print portion of the results of CX 520 were statistically weighted according to demographic characteristics. The standard Gallup weighting procedure was used to adjust the data for any slight over or under representations of the population. This procedure is based upon a system that is used by the Census Bureau in its

monthly population surveys and by many other large survey organizations. The result of this weighting is to bring the final calculations as close as possible to the true population characteristics (Crespi, Tr. 4339). According to Dr. Crespi, although some of the questionnaires were not weighted, the impact of such missing weights was minimal on the final results to CX 520. The effect of the missing weights would have had, at most, about a one percentage point impact on the final results (Crespi, Tr. 4365-71).

222. Respondents to the TV portion of CX 520 were shown two 30-second commercials, one control commercial followed by a Bayer Aspirin commercial. After the commercials were run, the respondents filled out a self-administered questionnaire (Abelson, Tr. 4555-47; CX 520Z045-Z051).

223. Data were collected from 240 respondents from nine separate groups. Group interviews were held in the areas Springfield, Massachusetts; Kansas City, Missouri; Atlanta, Georgia; and Providence, Rhode Island. [63]

224. The first commercial was the same for all nine groups—an advertisement for Scott Super Turf Builder. The second commercial alternated between two Bayer Aspirin commercials—the Trevino commercial (CX 52) and the Truisms commercial (CX 75). Four of the groups (92 respondents) saw the Trevino commercial and five of the groups (148 respondents) saw the Truisms commercial (Abelson, Tr. 4552-53; CX 520P).

225. The community groups from which the TV samples were recruited consisted, for the Trevino survey, of four groups—YWCA members and friends, Methodist Church members, Toastmasters' Club, and Catholic Women's Club; for the Truisms survey, a Golden Age group, PTA members, Black community group, community social club, and Rotary Club members (RX 306, RX 307).

226. The group approach was used because this is an economical way of getting data and groups to provide a way of getting diversity and variations in the characteristics of the people who were exposed to the copy test (Abelson, Tr. 4547).

227. Respondent disputes that the nonprobability group approach was necessary on cost grounds, noting that Dr. Lipstein has recently completed a national probability survey of consumer perceptions of a TV commercial in the context of other litigation (Lipstein, Tr. 11970).

228. The completed questionnaires from both the print portion and the TV portion of CX 520 were sent by the Gallup Organization and Response Analysis to Ilsa Zeisel for coding. Ilsa Zeisel coded the verbatim responses from the original questionnaires pursuant to the instructions of Dr. Zeisel (Zeisel, Tr. 4686).

229. Dr. Hans Zeisel established the coding scheme for the re-

sponses to CX 520 (Zeisel, Tr. 4679-81). For the purpose of tabulations, the respondent answers to the questions asked in CX 520 were classified and coded according to the system established by Dr. Zeisel. He established seven categories into which a consumer response might fall.

230. The first category included all consumers who perceived the advertisement as claiming that Bayer is the best aspirin by an explicit reference to Bayer superior effectiveness. The second category was comprised of all consumers who stated the advertisement's message to be that Bayer is superior to other aspirins with respect to effectiveness but these consumers did not explicitly state whether the superiority pertains to all other aspirins or to only some. The third category included all consumers who stated the message in terms of Bayer's effectiveness without referring to its competitive position. Categories 4, 5, and 6 followed the patterns of the first three categories except that the answers do not contain an explicit reference to Bayer's [64] effectiveness. The seventh category included all other answers. When a consumer gave more than one response to a question, he was classified according to his most explicit answer (CX 520M-0; Zeisel, Tr. 4680-82).

231. Appendix VIII of CX 520 (CX 520Z005-Z068) sets out the many codes used by Ilsa Zeisel. It also identifies how each code was classified into one of the seven categories established by Dr. Hans Zeisel, as set forth in CPF 122 (CX 520N).

232. The results of the coding, pursuant to the instructions and scheme established by Dr. Hans Zeisel, are set forth in Tables 1, 2, 3, 4, 5, and 6 of CX 520. Tables A-E of CX 520 contain cross tabulation of the data contained in CX 520 according to demographic characteristics.

233. To supplement the specific coding by Ilsa Zeisel, Dr. Hans Zeisel went through and read each questionnaire to determine whether the respondent perceived that the message of the advertisement was that Bayer is therapeutically superior to other aspirin. The results of Dr. Zeisel's analysis of the verbatims are reported in CX 520 at page Y (Zeisel, Tr. 4696-99).

234. Respondent is critical of many aspects of CX 520 and its experts note deficiencies in the selection of samples used in the surveys, the absence of a benchmark or control survey, the design of the actual questionnaire, and the coding classification and data analysis.

235. Dr. Zeisel has conceded that the TV survey samples are not probability samples. As a consequence, the samples cannot be considered representative of the universe and projectable to it. In addition, it is not possible to calculate an error with a measurable statistical degree of confidence. These are the two attributes of a nonprobability

sample. (Crespi, Tr. 4359–60; Zeisel, Tr. 4674, 4789–90; *see* Amstutz, Tr. 9999; Lipstein, Tr. 12012–13)

236. Dr. Lipstein, respondent's expert, testified that use of such samples did not meet current professional standards or practice (Lipstein, Tr. 11963, 11973–74), and that it is not proper to rely on the results of a study using such sampling to arrive at a judgment of the perceptions or attitudes or behaviors of consumers in general (Lipstein, Tr. 11968).⁵ [65]

237. Dr. Zeisel has recognized the limited application of this portion of his work. He stated with respect to the nonprobability samples in this case that "the best we can do with it is to claim that we will describe these people . . . demographically, as well as we can. Here is what these 300, I think there were 300 people, would say about it. That was all. There was no claim about general statements." (Zeisel, Tr. 4790, 4792). He also admitted that the averaging of data from the three copy test surveys is inappropriate (Zeisel, Tr. 4685).

238. Respondent's witness Cortesi undertook a demographic analysis of the TV survey samples according to age, education, income and sex, using data on the computer tapes supplied by the FTC (Cortesi, Tr. 9832, 9876–77). This is presented in RX 141(a), "Analysis of the Use of Combined Data TV Ad and Print Ad Surveys in the Zeisel Advertising Study, CX-520," pages E–O (Amstutz, Tr. 10002; Cortesi, Tr. 9832–34).

239. In this analysis, respondent's experts compared the demographics of the probability sample used for the print advertisement survey, of a second probability sample (also done by Gallup) for the image study, CX 521, and of the non-probability samples used for the TV ad surveys. The comparison was on the same demographic dimensions used by Dr. Zeisel—age, education, income and sex (adjusting the demographic breaks for comparability) (Cortesi, Tr. 9834–35). The results are presented in RX 141(a) E–O, Tables A–1 to A–4, B–1, B–2.

240. The results show that two probability samples—for the print advertisement survey in CX 520 and the image study in CX 521—were very similar, and the data show very high to high probability that they were drawn from the same population (Amstutz, Tr. 10004; RX 141(a) M, N, Tables C–1, C–2).

241. In contrast, the Trevino and Truisms samples differed from one another, each differed from the print advertisement probability sample, and these differences are statistically significant at a high confidence level (Amstutz, Tr. 10005–06; Cortesi, Tr. 9838–39; RX 141(a) M, N).

⁵ However, Dr. Lipstein could only recall one occasion when he had used a national probability sample in a copy test (Lipstein, Tr. 12074), and Dr. Lipstein himself acknowledged that national probability samples are not necessary for measuring possible consumer interpretations of advertising copy (Lipstein, Tr. 12059).

242. The TV samples differed significantly from the print advertisement survey sample in every demographic variable with a p-value of less than .05 to less than .001, so that there is no [66] chance that the TV samples were representative (RX-141(a) L-O; Amstutz, Tr. 10010-11). There is no chance that the Trevino sample came from the same population as the print sample on the dimensions of education, income and sex; for age, there was a 4% chance. There is no chance that the Truisms sample came from the same population as the print sample in terms of age, education or income. On sex, there was a small chance. The minimum confidence that can be applied to the assertion that the TV survey populations are different from the print ad probability population would be 96.1% for Trevino and 97.8% for Truisms (Amstutz, Tr. 10004-06).

243. The Trevino and Truisms samples were not similar. The differences between the two samples were statistically significant in two of the four demographic variables. In comparing the Trevino and Truisms samples, there is no basis for asserting that they are equivalent on age or sex; there is a low basis for asserting that they are similar on education and income (Amstutz, Tr. 10006; Cortesi, Tr. 9839).

244. The instructions given to Gallup interviewers conducting the print survey explicitly stated that only questions as written on the questionnaire were to be asked. There must be no explaining of questions in the interviewer's own words. Interviewers were cautioned not to ask probing questions since the series of prescribed questions were regarded as the only permitted probes (CX 520Z043). However, review of the print survey questionnaires by respondent's expert Cortesi disclosed that a number of the questionnaires contained notations such as (P) or (X) which is the usual shorthand for a probe. Eighty-eight questionnaires, or 12% of the sample, contained such notations (Cortesi, Tr. 9828-29).

245. Complaint counsel's witness, Dr. Crespi, testified that the parenthetical indications on the questionnaires probably designate the instances when the interviewer repeated one of the questions. It is a standard practice (and stated in the Gallup interviewer's manual) to repeat a question when a respondent indicates an inability to answer the question (Crespi, Tr. 4402-04). He believed it would be inappropriate to eliminate such questionnaires from the data base (Crespi, Tr. 4404).

246. Several of respondent's expert witnesses attested to the principle that the proper procedure is to eliminate a questionnaire and not include it in the resulting data if it is found that an interviewer had used improper or unauthorized probes. Among complaint counsel's witnesses, this was stated to be the practice of the Burke organization

by the official testifying for complaint counsel (Granger, Tr. 4217; RPF 5.167). It was agreed to by Dr. Crespi of the Gallup Organization as a proper principle (Crespi, Tr. 4400). [67]

247. It was also Dr. Lipstein's judgment that when interviewers violate instructions in gathering data, the questionnaires evidencing violations of instructions must be discarded. Dr. Lipstein described his experience in discarding survey questionnaires containing such interviewer errors in a survey where the cost of the interview was very high, citing the high standards required for litigation purposes (Lipstein, Tr. 11975-76).

248. Dr. Zeisel acknowledged that if there was a probe in the first two questions, then the respondents could not be properly classified as reporting Bayer therapeutic effectiveness for purposes of his Table 1 in CX 520, which was intended to cover only the answers to the first two prescribed questions without further probing (Zeisel, Tr. 4978-79).

249. The effect of eliminating the disputed questionnaires would be to reduce the response rate. The response rate in the print survey was stated by the Gallup witness, Dr. Crespi, to be about 60% (Crespi, Tr. 4335). Zero weightings had reduced the response rate to about 59% (Crespi, Tr. 4362-63); Cortesi, Tr. 9834; Zeisel, Tr. 4708-10). Dr. Crespi regarded that 60% was in conformity with generally accepted standards for personal interview surveys of individuals in a national sample (Crespi, Tr. 4335). He acknowledged that below 50%, no projections were possible and a survey at such low completion rate should have studied the nonrespondents or undertaken other procedures (Crespi, Tr. 4419-20, 4422-23). Mr. Cortesi regarded the standard for consumer surveys using probability samples done door-to-door to be a 75% response rate (Cortesi, Tr. 9831). If the questionnaires with unauthorized and unidentified probes were eliminated, the sample would be reduced to below what is considered acceptable (Amstutz, Tr. 9999-10000, 10018; Cortesi, Tr. 9831).

250. Respondent argues that a benchmark could have been developed by use of a reference advertisement, a neutral or unchallenged advertisement, and showing the control advertisement and the test advertisement to comparable groups. The resulting statements by respondents about the control advertisement would be compared to the statements reporting perceptions of the test or challenged advertisement, and the difference could be attributed to the representations in the test or challenged advertisement (Amstutz, Tr. 10023, 10025; Lipstein, Tr. 11960-61, 12219).

251. Another approach would be to use a before and after mechanism in which respondent gives perceptions of products before seeing

an advertisement and after seeing an advertisement, to measure the impact of the advertisement (Amstutz, Tr. 10023).

252. But, as noted by complaint counsel, it was not Dr. Lipstein's testimony that a control ad was necessary to meet [68] acceptable survey designs. This is less serious than some of respondent's other criticisms of CX 520.

253. The survey questionnaires were administered in a way that greatly increased the attention and recall of respondents. Thus, in the TV surveys, respondents were instructed that they would see films and be questioned thereafter (CX 520Z014). This is not the kind of situation normally experienced at home. It substantially increased the level of recall of advertising claims compared to a real-life situation (Miles, Tr. 9334; Lipstein, Tr. 11977, 11980).

254. Dr. Zeisel acknowledged that a good copy test simulates as closely as possible a real-life situation. He further acknowledged that the copy tests in CX 520 were artificial in that one does not normally review an advertisement with the expectation of being questioned about it, and that directing the consumers' attention to an advertisement results in a heightened tension focus and awareness of it (Zeisel, Tr. 4777-4778). Thus, in comparison to a Burke survey, you would expect a higher level of response from the method used by Dr. Zeisel; 100% of the respondents should have remembered the advertisements as compared to about 20% in a Burke (Zeisel, Tr. 4780-82).

255. In the print survey, the series of questions to be asked (and recorded) by the interviewer was:

1. What would you say is the main point of this advertisement?
2. Does the advertisement make any other points? What are they?
3. What does the advertisement say about Bayer aspirin as compared with other brands of aspirin?
4. What else does the advertisement say about Bayer as compared to other brands of aspirin?
5. The advertisement said that "Bayer makes a better quality aspirin." What does the advertisement mean by "better quality?"

(CX 520Z009)

256. In the TV surveys, the series of questions, to be answered by respondents, was:

1. Thinking just of the aspirin commercial, what would you say was the message of this commercial? [69]
2. What were the other messages in this aspirin commercial?
3. What did the commercial say about Bayer aspirin as compared with other brands of aspirin?
4. For Trevino - The commercial said that "Bayer is the best aspirin." What does the commercial mean by that? In what way or ways is Bayer the best aspirin?

5. For Truisms - The commercial said that no other leading brand of aspirin could match Bayer's overall high standards. What does the commercial mean by that?

(CX 520Z016-Z019)

257. I have relied on only the responses to the first two questions (Questions 1 and 2 in print survey, Questions 2 and 3 in TV surveys) as a basis for ascertaining the message conveyed by the tested advertisements.

258. Respondent concedes that the first question in the surveys was unobjectionable, a fair, open, free-response question (Miles, Tr. 9334, Cortesi, Tr. 9810). Dr. Lipstein was critical of the first question because it implied that there was a particular message in the commercial. In his view, a question such as "Tell me everything you remember about the commercial" is preferable (Lipstein, Tr. 11978). The classic survey approach is to provide as little structure as possible because, each time a question is asked, information is given (Lipstein, Tr. 11977).

259. The second question in the print survey was a reasonable probe—Does the advertisement make any other points? What are they? (Cortesi, Tr. 9810; Miles, Tr. 9343). However, the probe in the TV questionnaires was criticized. It was in the form—"What were the other messages in this aspirin commercial?" This is unacceptable because it tells respondents that there must be other messages, and forces them to come up with points in addition to those already given (Miles, Tr. 9335; Cortesi, Tr. 9818-19; Lipstein, Tr. 11978).

260. Dr. Crespi stated that Question 2 in that survey was probably worded "Does the advertisement make any other points? What are they?" to avoid telling the respondents that there were other points, but simply to let them decide and then respond. This was in contrast to asking what other points does the advertisement make (Crespi, Tr. 4407). The probe in the TV survey did in fact ask what other messages there were, and is subject to criticism on that ground.

261. Respondents' witnesses find the subsequent questions to be unacceptable, and their arguments are persuasive. The [70] next question or questions (Questions 3 and 4 in the print survey, Question 4 in the TV surveys) tell respondents that a comparison was made and further that the comparison was between Bayer and other brands of aspirin, all of which was information which the respondent may not have noticed. Further, this question would lead respondents to guess what Bayer would be likely to say versus other brands of aspirin, and invited respondents to come up with puffery statements of being better, common to advertising. This was highly suggestive and improper, leading to forced responses (Miles, Tr. 9336; Cortesi, Tr. 9810-12; Lipstein, Tr. 11979). Dr. Zeisel acknowledged that the questionnaire

could have asked whether the commercial said anything about Bayer versus other aspirin and then inquired what does it say. This was the form of one of the earlier drafts of the questionnaire (Zeisel, Tr. 4922-23).

262. The next question (Question 5 in print and TV surveys) took a quotation from the advertisement and forced respondents to focus upon it whether or not they had perceived or remembered it. The statements taken from the advertisements were out of context, and respondents were required to speculate.

263. The first draft of the TV survey questionnaire contained the question, "Did the commercial say anything about Bayer Aspirin being the best aspirin?" with followups. According to Dr. Abelson of Response Analysis Corp., the purpose of this formulation was to avoid telling the respondents what the commercial said, and to minimize any cue or suggestion from the question (Abelson, Tr. 4580-81). Question 5 in the surveys, as eventually used, did not avoid that risk but in fact forced respondents to respond to what the question told respondents about them.

264. The above questions were followed in all the surveys by Question 6, a direct question asking respondents whether the advertisement "suggested" that Bayer was more effective in relieving pain than any other brand of aspirin and requiring them to answer yes, no or not sure (CX 520Z010, Z020). Question 6 was not justified by the need to determine whether "inarticulate" respondents got the alleged therapeutic message, as argued by Dr. Zeisel (Zeisel, Tr. 4665).

265. In the CX 520 survey, after obtaining the TV survey data, Response Analysis developed a full coding system to cover the range of responses received in the survey and submitted tabulations and analyses in terms of a full range of response categories (Abelson, Tr. 4611-15; RX-308).

266. This Response Analysis Corp. report was submitted to Dr. Zeisel. Dr. Zeisel redid the coding and classification of the verbatim responses. He told Dr. Abelson that Response Analysis codes were not specific enough and that more information could be gleaned from the open-ended comments (Abelson, Tr. 4524-25, 4575-76). [71]

267. Under instruction from Dr. Zeisel, the responses to the three copy tests in CX 520 were coded by his sister, Ilse Zeisel, into a large number of codes. Dr. Zeisel personally assigned the codes to the following seven classifications:

1. Bayer is best with explicit reference to effectiveness;
2. Bayer is better than other aspirins with explicit reference to effectiveness;

3. Bayer is praised without explicit comparisons to other aspirins with explicit reference to effectiveness;
4. Bayer is best without explicit reference to effectiveness;
5. Bayer is better than other aspirins without explicit reference to effectiveness;
6. Bayer is praised without explicit comparisons to other aspirins without explicit reference to effectiveness;
7. All other aspirins.

(Zeisel, Tr. 4681; CX 520L-N)

268. Dr. Zeisel focused attention on the sum of categories 1 and 2 as reflecting respondents who were classified as reporting Bayer superior effectiveness according to his coding and classification system. These two categories did not include comparative pharmaceutical and manufacturing quality responses (Zeisel, Tr. 4682; CX 520; Z056-57; Z061-Z062).

269. Respondent has argued that the inadequacy of Dr. Zeisel's approach was made apparent by the fact that the miscellaneous category "all other comments" was abnormally large, including an unduly large percentage of respondents, in Table 1, 29 to 62% of respondents (CX 520P) (Cortesi, Tr. 9785-86; Miles, Tr. 9348; Lipstein, Tr. 11996). This violates professional standards (RPF 5.308-5.311). In addition, although these advertisements were about quality, Dr. Zeisel failed to have any classification for quality (Miles, Tr. 9348). Mr. Cortesi also noted that CX 520 presented an "average of all surveys", combining results from three different copy tests, which is not normal or accepted practice (Cortesi, Tr. 9785-86). Dr. Zeisel later in his testimony sought to withdraw the latter data (RPF 5.251).

270. CX 520V, Table 4, sets forth what Dr. Zeisel called "The Message Conveyed by the Bayer Advertisements as Reflected by the Consolidated Free Answers." This purported to [72] "consolidate" the results of all the verbal responses to Questions 1-5 in the print survey, Questions 2-5 in the TV survey. According to CX 520, the "consolidation" of the answers was accomplished by classifying each respondent by "the most explicit answer" in those responses (Zeisel, Tr. 4688; CX 520 U).

271. In the course of his study, Dr. Zeisel made a number of changes in coding and general conception. The coding structure was changed, as evidenced in the difference between the code structure on the tapes and the final format. In addition, the report itself, CX 520, went through three revisions. There was an initial document in May 1976, an August 1976 revision, and a March 1977 revision. These required changes in the data on the computer tapes because Dr. Zeisel changed

certain codes and categories in which responses were classified (Cortesi, Tr. 9805, 9807-09).

272. On February 14, 1977, by letter to respondent's counsel, Dr. Zeisel made a number of changes in coding of specific responses from the earlier version of his report. In addition, Dr. Zeisel stated that he had reread all the questionnaires and undertaken to classify respondents based upon his reading of their questionnaires as a whole, apart from the coding and classification system previously used addressed to specific responses (Zeisel, Tr. 4835-39; RX 314). Based upon such classification of questionnaires as a whole, Dr. Zeisel added Table 4A and Table 6A to CX 520. Table 4A classified all respondents either into his category 1 or 2, or "All Other Responses" based upon reading questionnaires as a whole. Table 6A correlated such classifications with the respondent's answer to the direct Question 6 (CX 520Y, Z006; RX 314).

273. In his testimony in this case, Dr. Zeisel acknowledged that the changes referred to in his letter of February 14, 1977, which made coding changes, and which made category changes from reading the questionnaires as a whole, were in the direction of increasing the number of respondents who reported Bayer's superior effectiveness (Zeisel, Tr. 4837). He acknowledged that, before doing the surveys in this case, he had never before read through all the questionnaires in a survey to make a decision about their classification and the results of the survey (Zeisel, Tr. 4834).

274. In his testimony, Dr. Zeisel stated that he relied upon his reading of the CX 520 questionnaires as a whole, and proposed that the Commission should give it the "greatest weight." Tables 4A and 6A resulting from his reading were, he said, "crucial." They were the "final tables." the "final analysis," they "superseded" the tables produced by his coding and classification system (Tables 4 and 6) and should be the focus of attention (Zeisel, Tr. 4699, 4703, 4712, 4847, 4901).

275. In cross-examination, Dr. Zeisel refused to be bound by the listing in his letter of February 14, 1977, of specific [73] answers in the questionnaires which were the basis for his reclassification of certain respondents by the coding and classification system. Dr. Zeisel stated that the letter was an error, and he would only consider the classification of respondents by looking at all the responses in the questionnaire taken as a whole (Zeisel, Tr. 4842, 4849, 4995, 4998).

276. Dr. Zeisel explained that in his reading of the questionnaires as a whole for purposes of Tables 4A and 6A, he classified respondents by combining the responses to various questions. Thus, he combined a statement in response to one question reflecting Bayer's superiority *without* reference to effectiveness, *e.g.*, Bayer is best, with a statement

in response to an entirely separate question reflecting Bayer's efficacy *without* any comparative, *e.g.*, Bayer is effective. His position was that one statement referred to or explained the other regardless of which came first, regardless of the number of intervening statements and regardless of the absence of any stated or indicated connection between them (Zeisel, Tr. 4845, 4850-51, 4870, 4943-44, 4957, 5001-02, 5007-08).

277. A number of respondents were classified as reporting Bayer's therapeutic effectiveness by Zeisel and they inconsistently did not answer "Yes" to the direct question, whether the advertisements suggested that Bayer was superior in effectiveness to other aspirin. This involved 7% of the Trevino respondents, 9% of the Truism respondents (compare CX 520Y, Z006).

278. A number of specific errors of classification of questionnaires and coding of responses by Dr. Zeisel were brought out during the hearing.

279. Dr. Zeisel stated that one questionnaire in the Trevino survey, No. 14204, should be eliminated from the list of those classified as reporting Bayer superior effectiveness in Table 4A. There was no way to establish that the respondent believed the commercial indicated Bayer's superiority to other aspirins, because the statement "it is fast at killing pain, it's good for headaches," was not comparative (Zeisel, Tr. 4775).

280. On cross-examination, Dr. Zeisel acknowledged error in classifying another questionnaire in the Trevino survey, No. 12221, in the group reporting Bayer therapeutic superiority. This was an error because the answers to Questions 2 and 3 did not specifically refer to Bayer, and so was incorrectly classified for purposes of Table 1 and Tables 4A and 6A (Zeisel, Tr. 5011-12). Dr. Zeisel acknowledged that the commercial had two messages, aspirin vs. other pain relievers and Bayer vs. other aspirins. It is not possible to tell from the response "Works best" what the respondent was referring to (Zeisel, Tr. 5012).
[74]

281. Dr. Zeisel made a similar acknowledgment with respect to the use of the word "it" or "they" in the responses to the first questions of another questionnaire in the Trevino survey, No. 11312, which stated "That they have better result" and "It is the leading brand of other headache products." This would be a dubious classification for purposes of CX 520, Table 1, because the language could refer to the aspirin group rather than Bayer (Zeisel, Tr. 5013-14; *see also* 4921).

282. Similarly, Dr. Abelson agreed that the answer to the first question in another questionnaire in the Trevino survey (No. 14215) was addressed to the part of the commercial dealing with straight aspirin vs. other pain relievers and indicated that it was that message

that registered with the respondent. This was also probably true of the response to Question 3. It is possible that, without the cue about Bayer in the following questions, this respondent would have played back only responses that had to do with aspirin vs. other pain relievers (Abelson, Tr. 4606-07, *see also* questionnaires discussed at Tr. 4608).

283. Dr. Abelson also acknowledged, with reference to a questionnaire in the Truisms survey, which referred to a benefit for "colds" in response to the first question (No. 2110), that the respondent could have been talking about the general product category, since the question did not specifically refer to Bayer Aspirin, the answer did not contain any mention of Bayer, and there was nothing in the advertisement that made reference to colds (Abelson, Tr. 4586-87).

284. Dr. Zeisel classified a number of respondents as reporting Bayer's therapeutic superiority because of the term "best pain reliever." He would not have so classified them if the answer had been "best analgesic" and did not so classify "best aspirin" (Zeisel, Tr. 4878, 4887). On cross-examination, Dr. Zeisel reluctantly agreed that "pain reliever" could refer to a product category (Zeisel, Tr. 4879, 4937-38). It was a reasonable inference that "best pain reliever" could be often used as meaning "best analgesic" as a product category without referring to specific benefits (Zeisel, Tr. 4937-38).

285. Dr. Zeisel later went further and discussed the impact of removing from Table 4A those so classified because of the use of the term "best pain reliever." He made certain computations with respect to the effect this would have upon the TV ad survey results; he had not had time to undertake the same review for the print ad survey (Zeisel, Tr. 5028, 5033).

286. Dr. Zeisel acknowledged that safety or freedom from side-effects may properly be considered as separate and distinct from effectiveness in relieving pain. On that basis, those questionnaires which he had classified as reporting Bayer's superior effectiveness because of statements relating to safety would be subtracted from the classification (Zeisel, Tr. 4816-17, 4871, 4960). [75]

287. There were 16 or 17 questionnaires in the Truisms survey in which handwritten changes were made on Question 5 by the person administering the survey to a Golden Age group. If Dr. Abelson of Response Analysis had discovered these handwritten changes at the time the questionnaires were received, he would have eliminated the questionnaires from the survey (Abelson, Tr. 4592). They should be eliminated from the Truisms survey.

288. There are two questionnaires in the Truisms survey which appear to be identical—with similar misspellings, almost identical responses and similar handwriting; if the correspondence between

these two questionnaires had been noted when they came back, a judgment would have been made about whether to eliminate them (Abelson, Tr. 4593-94). These should be eliminated from the Truisms survey.

289. In connection with one questionnaire in the print survey (No. 377), Dr. Zeisel stated that the answer did not indicate "best," but rather one of the best. He stated that it was good enough that Bayer be better than some to be classified as a report of Bayer's therapeutic superiority, and also indicated that this was a "marginal case." (Zeisel, Tr. 4945-46).

290. Even assuming that these questionnaires were inappropriately classified, the impact of their removal from the 757 responses to CX 520, (CX 520P) is serious, but does not totally negate Dr. Zeisel's findings.

291. Dr. Lipstein testified that established professional standards dictate that the person who organizes and conducts a study, especially for litigation purposes, should not do the coding of the study to avoid bias or interaction of the experimenter with the experiment (Lipstein, Tr. 12214).

292. While this might be a preferred practice, it appears that various surveyers have different policies on this aspect (Crespi, Tr. 4394, 4398; Zeisel, Tr. 5022-23).

B. A Number of Sterling Advertisements Made the Challenged Representations

1. Complaint Paragraph 10(A)

293. Sterling represented, directly or by implication, that Bayer Aspirin is superior in terms of significant therapeutic effect to any other plain 5-grain aspirin. This representation was made in the following advertisements: CX 13, 15, 19, 37-39, 47, 48, 50-52, 54, 56-58, 60-67, 69, 70, 72, 74, 79, 99, 101-104, 109, 117, 122-129, 145-147, 150, 152, 155-158, 161.

294. The advertisements listed in F. 293 contain one or both of the two following claims: [76]

(a) That Bayer Aspirin is faster acting and/or gentler aspirin than any other aspirin (e.g., CX 47, 48, 51, 79, 99, 109, 155-158, 161); and

(b) That Bayer Aspirin is the best pain reliever or the best aspirin (e.g., CX 13, 15, 19, 37-39, 48, 50, 52, 54, 56-58, 60-67, 69, 70, 72, 74, 101-104, 122, 123, 126).

295. For example, CX 51 (CX 51a is a film) is a 1971 Bayer television commercial (30 seconds) entitled "Alike." Although the commercial begins by suggesting that all USP aspirin is not the same quality because Bayer surpasses USP standards "in many ways," a good half

of this short commercial is devoted, while the announcer is holding up the Bayer bottle, to the statement:

For example, Bayer standards require complete tablet disintegration within thirty seconds. That's ten times faster than the accepted five-minute standard. It's one of the things that help make Bayer fast and gentle.

Viewing the commercial as a whole, the representation that Bayer Aspirin is faster and more gentle than other aspirins and is therapeutically superior to other aspirins is clear and unequivocal.

296. CX 99, a 30-second commercial entitled "Bayer Man—Bill Joyce" uses identical language and appears to be a radio version of CX 51.

297. To cite a few more examples, CX 48 is the storyboard of a 1972 television commercial (60 seconds) entitled "Ozzie Nelson." Although the main message of this commercial is that all aspirin is not alike and plain aspirin is preferred to combination products, the advertisement also suggests that a "new study" found Bayer Aspirin to have "superior" "speed of disintegration," among others. Some consumers may reasonably perceive this commercial as representing also that Bayer is a faster-acting aspirin and therapeutically superior to other aspirins.

298. Although CX 48 mentions "speed of disintegration" only in passing (as compared with CX 51 which dwells on that theme), CX 48 suggests Bayer is therapeutically superior to other aspirins by also claiming "aspirin's the best pain reliever, and [77] Bayer is the best aspirin." The "best aspirin" claims in the context of the advertisement as a whole clearly suggests that Bayer is the best pain reliever and therapeutically superior to other aspirins.

299. CX 52 (52a) is a 1971 television commercial (60 seconds long) for Bayer Aspirin entitled "Lee Trevino." This was one of the two television commercials studied in the Zeisel Copy Tests (CX 520). The content of this advertisement is similar to CX 48 "Ozzie Nelson" discussed in F. 297 *supra*, except that CX 52 does not mention "speed of disintegration" while both CX 48 and CX 52 refer to "purity" and "freshness." However, CX 52 claims "Bayer makes the superior aspirin" and closes the commercial with the familiar tag line "aspirin is the best pain reliever and Bayer is the best aspirin." Many consumers may reasonably perceive the commercial as representing that Bayer Aspirin is therapeutically superior to other aspirins.

300. The Zeisel Copy Tests (CX 520) provide confirmatory evidence with respect to CX 52. Table 1 of the Zeisel Study shows that about 13% of the respondents (subject to a sampling error of $\pm 7\%$, assuming the sample were a probability sample which it was not) received

a superior "effectiveness" message for Bayer in response to open-ended questions 2 and 3 (CX 520F, P, Z37).

301. CX 157 is a print advertisement for Bayer Aspirin, which was copy tested in CX 520, the Zeisel Copy Tests. The main message of this advertisement is "Bayer makes a better quality aspirin," headlined in oversize prints. The small print body of the advertisement also says Bayer is "the finest quality aspirin you can buy." However, the small prints also refer to "speed of disintegration" and closes with the tag line "aspirin is the best pain reliever, and Bayer is the best aspirin." Many consumers may reasonably perceive CX 157 as representing that Bayer is a therapeutically superior aspirin.

302. The Zeisel Copy Tests (CX 520) provide confirmatory evidence with respect to CX 157. Table 1 shows that about 11% of the respondents (subject to a probability sampling error of $\pm 3\%$) played back "superior effectiveness" message for Bayer in response to open-ended questions 1 and 2 (CX 520D, p. Z37).

303. CX 13 (13a) is a 1967 television commercial (30 seconds) for Bayer Aspirin entitled "Epidemic Crawl." Although the main message of the commercial is that for the relief of symptoms of cold or flu, aspirin is a recommended remedy, the advertisement also claims that Bayer is "the world's best aspirin." The "best aspirin" claim is likely to be reasonably perceived by consumers as saying that Bayer is therapeutically superior to other aspirins.

304. CX 15 (15a) is a 1969 television commercial (30 seconds) for Bayer entitled "Foul Weather Friend." Although the [78] main message of the commercial is Bayer Aspirin is good for aches and pains "all year round," it also claims Bayer is "the best pain reliever." The phrase "the best pain reliever" clearly means "therapeutic superiority" to most consumers. CX 15 is thus a clear example of a representation of therapeutic superiority for Bayer Aspirin.

305. When an advertisement makes a claim of "best" for an aspirin (instead of "best quality"), the unqualified claim will be understood by consumers in the context of superior therapeutic efficacy. Because the advertisements in question are about a drug product which is taken primarily for the relief of pain, the use of unqualified comparatives (such as "superior," "better" or "best") will be perceived by consumers as claiming greater therapeutic effect, unless the comparative is expressly or unmistakably directed to some other attribute, such as quality ("superior quality," "better quality" or "best quality"). (CX 105, a 1972 radio commercial for Bayer discussed in F. 318, *infra*, is one example of an advertisement wherein each comparative is expressly and unmistakably coupled with "quality" throughout the commercial.)

306. "Puffery" or "puffing" is a recognized phenomenon in advertis-

ing and employs such superlatives as "the best," "the world's best," and other hyperbolic expressions. When recognized by consumers as such, puffing is discounted by them. Consumers know by common sense and daily experience that puffing is not meant to be taken seriously (Zeisel, Tr. 4896; Haley, Tr. 10569).

307. Whether consumers will recognize such phrases as "the best" and "the world's best" as puffing in a given advertisement or commercial depends on how "the best" or "the world's best" is used and in what context, viewing the commercial as a whole. In other words, whether a claim is mere puffing is a question that can be determined only on the basis of what the commercial, as a whole, says.

308. In the Bayer commercials discussed in F. 305, *supra*, such phrases as "the best aspirin" or "the world's best aspirin" are more than puffing in the context of the commercials as a whole, for the commercials also did refer to the AMA and/or tests. Respondent's expert witness Dr. Haley agreed that "best" is not puffery when the claim is backed by scientific support (Haley, Tr. 10572). In fact, a large number of the viewers took the trouble to write in for the booklet mentioned in these commercials.

309. A good example of puffery is the tag line "Bayer works wonders" in a few of the pre-1970 Bayer advertisements in evidence. For example, CX 27 is a 1969 television commercial for Bayer (60 seconds) entitled "Ever Improved." The message of CX 27 is simply that no other OTC analgesic product is stronger or faster than "good old" Bayer Aspirin and that Bayer is good [79] for all kinds of aches and pains and fever—It works *wonders*. There is no suggestion in CX 27 that Bayer is superior, better or best for anything which might confuse or mislead consumers. It simply suggests that one cannot improve on good old Bayer Aspirin. When viewed as a whole, it is clear that "it works wonders" is a general praise and puffery not to be taken literally.

310. A dangling superlative is a claim that makes a comparison to another product without specifying the attribute being compared. The claim that "Bayer is the best aspirin" is a dangling superlative and thus invites the audience to supply the missing attribute. Dangling superlatives tend to confuse consumers by suggesting diverse inferences based on different plausible interpretations beyond the content of the incomplete statement (Miles, Tr. 9568-72, 9578-79, 9588-90).

311. In the case of a dangling superlative, what particular product attribute a viewer will supply in order to complete the incomplete comparison is often determined by the nature of the product involved. In the case of a dangling superlative in aspirin commercials, the

viewer will look for the unspecified attribute in terms of the primary function of the product involved.

312. Respondent's expert witness Dr. Russell Haley testified on direct examination as to how consumers would interpret the claim "best":

What I was trying to say was the "best" is interpreted in the context of the category to which it applies. And so if you have a product which is supposed to do one specific thing, whatever that category is, and people are asked "What does it mean?" they will automatically respond with whatever the primary function of that product category is. So you can guess, if you know what the primary function of the category is, what the best thing is . . . In a therapeutic category it is curing whatever it is supposed to cure. (Haley, Tr. 10574)

313. The tag line used in a series of Bayer advertisements, "Aspirin is the best pain reliever and Bayer is the best aspirin" contains a dangling superlative "the best aspirin." However, the "best aspirin" claim follows the opening phrase "Aspirin is the best pain reliever." Thus the tag line as a whole clearly suggests that Bayer is the best pain reliever. *E.g.*, CX 48, 52, 157).

314. It is found that a substantial number of respondent's Bayer advertisements in evidence did not make the representation [80] alleged in Complaint Paragraph 10(A). They include, by way of examples, CX 73-78, 80-83, 105-108, 110-116, 162, 163.

315. For example, CX 78 is the storyboard of a 1973 television commercial (30 seconds) for Bayer Aspirin entitled "Woman's Place." The clear message of this commercial is that all aspirin is not alike and that Bayer's own test showed Bayer to be "the better quality aspirin." Throughout the commercial, every comparative (such as "better" or "superior") is qualified and clearly directed to "quality." There are no dangling superlatives or tag line closings which might confuse and mislead consumers to perceive this commercial as suggesting that Bayer is therapeutically superior to any other aspirin. It simply says Bayer is the "better quality aspirin" throughout the commercial. What it suggests is clearly that "you can count on Bayer," that Bayer will do what aspirin is supposed to do.

316. To cite another example, CX 75 (CX 75a) is a 1972 television commercial (30 seconds) for Bayer Aspirin entitled "Truisms." This was one of the two television commercials studied in the Zeisel Copy Tests (CX 520). The message is similar to that of CX 78 discussed above. Although the "quality" message is not as sharp as it is in CX 78, there is nothing in this commercial to suggest that it is talking about something other than Bayer's overall high "quality." It simply says "you can count on Bayer."

317. The Zeisel Copy Tests (CX 520) provides confirmatory evidence

with respect to CX 75 (CX 75a). Table 1 of the Zeisel study shows that about 4% of the respondents (subject to a sampling error of $\pm 7\%$, assuming the sample were a probability sample which it was not) played back superior "effectiveness" message for Bayer in response to open-ended questions 2 and 3 (CX 520H, P, Z37).

318. CX 105 is the script of a 1972 radio commercial for Bayer Aspirin (30 seconds). The commercial tells the audience about a booklet that tells how Bayer "tested its aspirin for quality" against every leading brand and the tests showed "Bayer is better for quality." Another voice says Bayer is "a great product I can count on." The announcer tells the audience where to write for the booklet and says in closing "Find out why Bayer is the best quality aspirin." CX 105 is about "quality." The commercial expressly says Bayer is "a great product [one] can count on." Throughout the commercial, every comparative (such as "better" or "superior") is expressly qualified and directed to "quality." There are no dangling superlatives or unqualified comparatives that may confuse and mislead any listener to perceive this commercial as claiming superior therapeutic efficacy or safety for Bayer. There is nothing in this commercial to suggest anything other than product quality. [81]

319. CX 108 is the script of two 1972 radio commercials for Bayer Aspirin (30 seconds), recorded on the same day. Both versions (in identical language) talk about Bayer's better "quality" and state "I know I can count on [Bayer]." The announcer tells the audience where to write for the Bayer booklet and says in closing "Find out why Bayer is the best quality aspirin." Like CX 105, these commercials are about product quality and about Bayer being a product one can count on. Viewed as a whole, the advertisements do not suggest Bayer is "faster acting," "gentler," "more effective" or therapeutically superior in any other way to any other aspirin.

320. CX 162 is a 1973 print advertisement for Bayer Aspirin, Bayer-Timed Release Aspirin and Bayer Children's Aspirin. The message regarding Bayer Aspirin is that Bayer's own test showed for "quality" Bayer was superior and that "you can count on better quality Bayer." There is nothing in this advertisement to suggest anything other than "quality." The closing sentence expressly states "You can count on better quality Bayer."

321. It is found that an advertising claim that clearly and expressly says Bayer is the "better quality" aspirin or that Bayer can be counted on for "better quality" is a product quality claim and, as such, is distinguished from therapeutic superiority claims (such as "more effective," "faster acting" or "gentler" claim) discussed in F. 293-313, *supra*.

322. Product quality and high quality standards of manufacturers

are familiar concepts to consumers well-recognized in their daily experience, quite apart from the reason for being of the product category, which for aspirin is to relieve pain (Miles, Tr. 9328-29; John, Tr. 5586, 5592, 5594, 5596).

323. The underlying common sense reason for consumer recognition of the "product quality" concept is the consumer's natural desire that the product he or she purchases perform as expected and possess the attributes customarily associated with it—in other words that "it will do the job it is supposed to do" or "it can be counted on to perform as expected"; namely, "it will relieve pain and reduce fever." In fact, a number of Bayer product quality commercials discussed in this section expressly state that Bayer is "a great product you can count on" or "you can count on Bayer for better quality." In this sense, the concept of product quality with respect to aspirin is ultimately related to product performance, namely, the analgesic action. However, it is not reasonable to suppose that, therefore, a claim of superior product quality for aspirin will be understood by the consumer as meaning "superior therapeutic efficacy" in the same sense as a "stronger," "faster" or "gentler" claim for aspirin will be understood as meaning "superior therapeutic efficacy." The idea of quality has its own identity and content apart from the idea of efficacy, [82] although the two are ultimately related. In the former, product quality is a readily recognized, independent concept in the sense that it is universally thought to be a desirable attribute *for its own sake*, apart from the question of *more* or *less* pain relief (comparative efficacy). In the latter, "stronger" or "faster" has no meaning for aspirin users except in terms of "stronger pain relief" or "faster pain relief" (comparative efficacy). The idea of aspirin being "stronger" or "faster" can have no meaning other than "superior efficacy."

2. Complaint Paragraph 8(A)(1)

324. Sterling represented, directly or by implication, that it has been established that Bayer Aspirin is superior in terms of significant therapeutic effect to any other plain 5-grain aspirin. This representation was made in each of the advertisements listed in F. 136, *supra*, namely, CX 13, 15, 19, 37-39, 47, 48, 50-52, 54, 56-58, 60-67, 69, 70, 72, 74, 79, 99, 101-104, 109, 117, 122-129, 145-157, 150, 152, 155-158, 161.

325. The fact that the above representation was made is demonstrated by the advertisements themselves. The establishment representation in the challenged Bayer advertisements was made through a variety of methods and claims, including express statements, graphic support, and references to scientific studies or tests conveying the

impression that the underlying superiority claim for Bayer Aspirin was based upon strong medical or scientific fact (Ross, Tr. 5754-55).

326. Consumers tend to believe that when a claim of superior efficacy is made for a drug product, there exists a strong basis in medical-scientific fact for such claims. Scientific fact means that the fact or proposition has been accepted by the scientific community as a fact. When analgesic advertisements make claims of superior efficacy to other aspirin, they also represent, by implication, that the fact of superior efficacy has been established (Ross, Tr. 5756-57).

3. Complaint Paragraph 20

327. Sterling represented, directly or by implication, that Bayer Aspirin has been tested against 220 other brands of aspirin for quality, purity, freshness, stability and speed of disintegration and that the the results of the tests demonstrated that Bayer Aspirin is qualitatively superior to all other brands tested in all tested respects and therapeutically superior to all other brands tested. This representation was made in the following advertisements: CX 48, 50, 52, 54, 56, 58, 60-63, 67, 72, 74, 79, 102, 104, 155-158.

328. The fact that the advertisements listed in the preceding Finding made the claim alleged in Complaint Paragraph 20 is evidenced by the advertisements themselves. [83]

329. They not only claim, directly or by implication, that Bayer is therapeutically superior to other aspirins (for the reasons discussed hereinabove in connection with Complaint Paragraph 10(A)), but also refer to the so-called "223 test" and mention such factors as quality, purity, freshness, stability, and speed of disintegration, in varying combinations. A narrow interpretation of these advertisements is that the results of the 223 test showed that Bayer was qualitatively superior with respect to each of the attributes being expressly named in a particular advertisement.

330. However, it is also reasonable to interpret these same advertisements to mean that the results of the "223 test" showed that Bayer was superior overall for the tested attribute, including the factors not being expressly named. CX 155 (a print advertisement) is a good example. CX 155 says 221 brands were tested in 30 different ways and Bayer "was superior . . . showing greater stability, purity and freshness," and "no other aspirin tested met the overall high standards set by" Bayer.

4. Complaint Paragraph 15(A)

331. Sterling has represented in a very small number of advertisements that Bayer Aspirin relieves nervous tension, anxiety and irritability and improves the user's mood. This representation was made in

three television commercials (CX's 29, 30 and 33) and two print advertisements (CX 141 and CX 151).

332. CX 30 (CX 30a) is a 1969 television commercial (60 seconds) for Bayer entitled "Summer." This is a good example of how a television commercial, while the announcer speaks of headache pain relief, can also imply a distinct message of tension relief to the audience through a depiction of situational tension by the use of audiovisual technique that is uniquely television's.

333. CX 30 (30a) begins by depicting, through pictorial images and sound, a tense situation where a mother is supervising a noisy and crowded swimming pool party on a hot summer day, drying children, serving snacks. The picture shows an obviously harrowed, tense mother. What follows is the announcer's voice, against appropriate pictorial backgrounds, narrating what Bayer Aspirin can do for you when you have a "hot weather headache" and accompanying "tension" and "irritation." While the voice gives the direction, the mother reaches for Bayer, takes two tablets with a glass of water, lies down on a chaise, and returns to the party to cook hot dogs, relaxed and refreshed. Although the spoken message is innocuous, a viewer of this television commercial will come away with a distinct "tension relief" message apart from pain relief because of the very strong and effective audiovisual suggestion of a situational tension throughout the commercial. [84]

334. Confirmatory evidence of consumer understanding of CX 30 is found in the consumer responses to "A Qualitative Assessment of Recent Bayer Aspirin Commercials," by Dancer-Fitzgerald-Sample, one of Sterling's advertising agencies at the time. The moderator of a focus group viewing CX 30 found that "something about the situation portrayed seemed to emphasize tension at the expense of headache." Quotes from participants describing their recall of CX 30 include:

there was a real nervous feeling;

she built up tension with all the shouting and running around;

to me, it was much more of a nervous strain than a headache;

and her problem is nervous tension which is something all women have. (Miles, Tr. 9642-44).

335. CX 29 (29a) (a 60-second television commercial), CX 138 (a 30-second radio commercial) and CX 150 (a print advertisement) depict Bayer Aspirin as relieving sleeplessness due to small pains by relieving pain. The spoken message in CX 138 and the printed message in CX 150 are straightforward. There is no suggestion that Bayer

will make you sleep or relieve your tension in either CX 138 or CX 150. Taking each advertisement as a whole, a listener or reader is not likely to come away with a perception that these advertisements are claiming that Bayer is a sedative or tension relieving product. Although one cannot exclude the possibility that mere mention of the word "sleep" or "sleepless" in an advertisement may evoke a perception of sedation or tension relief, that possibility is remote with respect to CX 138 and CX 150, which clearly and repeatedly state that Bayer helps by relieving little aches and pains.

336. CX 29, however, is a television commercial and begins with magnified and persistent sound of a dripping faucet against pictorial images of a late night bedroom-bathroom scene, which depict a couple trying to sleep and obviously disturbed by the dripping faucet. This audiovisual sequence effectively establishes a situational tension before little aches and pains are mentioned. The message that Bayer is good when you are having trouble sleeping because of minor discomforts and little aches comes through clearly. At the same time, because of the opening audiovisual sequence which effectively evokes a lingering image of situational tension, viewers may reasonably perceive this television commercial as also claiming tension relieving action for Bayer. [85]

337. CX 141 is a Bayer print advertisement. Its main message is that Bayer is good for hot weather headaches. However, the printed words carry a distinct undertone of mood alteration apart from headache relief. They claim in explicit terms that when you are "in no mood to enjoy life or the company of others because you "feel so headachy and edgy that the simplest chore, the smallest disturbance becomes an irritation" you can "turn that mood around" by taking two Bayer Aspirin, sitting down and relaxing for a few minutes. A reader may reasonably perceive this print advertisement as also saying that Bayer can turn around one's mood apart from headache relief.

338. CX 151 is a Bayer print advertisement. It has two main messages: (1) that Bayer is good for "tension-caused headaches and general achiness," and (2) that Bayer is a high quality aspirin. The express claim that Bayer will relieve "tension-caused headaches" is confusing and strongly suggestive of "tension relief." It is reasonable to conclude that very few, if any, consumers will understand "tension-caused headache" as meaning "muscle-tension headache" and that most consumers will reasonably perceive a "tension relief" claim apart from headache relief in this advertisement.

*C. Specific Allegations Related to Bayer
Children's Aspirin Advertising*

1. Complaint. Paragraph 10(B)

339. Sterling has represented that Bayer Children's Aspirin ("BCA") is superior in terms of significant therapeutic effect to any other children's aspirin. This representation was made in CX 167-170, 175-185, 188, 194-198, 201-203, 205, 209.

340. A number of BCA advertisements make a therapeutic superiority claim by representing, expressly or by implication, that BCA is faster-acting and/or gentler than other children's aspirin. Such advertisements include CX 182-184, 209.

341. For example, CX 182 (182a) is a 1972 television commercial for BCA entitled "Behind You" (30 seconds). Although the main theme of the commercial is BCA, made by the maker of Bayer Aspirin, is a high quality children's aspirin. However, by expressly claiming that the blending of two kinds of aspirin crystals instead of one results in a smooth and gentle disintegration, the advertisement strongly suggests that, therefore, BCA is faster-acting and more gentle than other children's aspirins, which use only one shape of aspirin crystals.

342. In CX 184 (184a), a 1972 television commercial for BCA entitled "Slide" (30 seconds), the therapeutic superiority claim is made in a way similar to CX 182. CX 184 also suggests that the blending of two shapes of aspirin crystals instead of one [86] makes BCA go to work quickly and gently. Many consumers will reasonably perceive this commercial as claiming that BCA is a faster-acting and more gentle aspirin than others, which use only one shape of aspirin crystal. CX 209, a 1973 print advertisement for BCA, is similar to CX 183 and 184 in that it also refers to the blending of two shapes of aspirin crystals instead of one and suggests BCA is a faster-acting and gentler aspirin than others.

343. A small number of BCA advertisements expressly claim that BCA is made differently or uses a unique (or special) manufacturing process and thereby imply that BCA is therefore therapeutically superior to other aspirins. Such advertisements include CX 167, 175, 181, 183, 188, 195, 197, 203, 205.

344. A claim that BCA is "made differently" or that "no one makes aspirin like Bayer" or that BCA uses a "unique (or special) manufacturing process" is ostensibly directed to manufacturing process and thus related to product quality. However, such claims go beyond saying "BCA is a high quality product you can count on" or "BCA will do what you expect of children's aspirin to do" and further suggest a comparison in terms of therapeutic performance. Many consumers will reasonably perceive such claims as saying that because Bayer

uses a "special" or "unique" process no one else has, Bayer (BCA) is therapeutically superior to others.

345. A substantial number of BCA advertisements tie the best care parents wish to give to a sick child with an express claim that BCA is the best children's aspirin. They include CX 167-170, 175-181, 185, 194-198, 201-203, 209.

346. For example, CX 176 (176a), a 1968 television commercial for BCA entitled "Mother Knows" (60 seconds) begins:

Sneezes, runny noses, temperature—a hundred and one. The doctor says its a cold . . . and a mother knows what to do. She keeps the patient quiet . . . and she gives her children aspirin . . . to reduce the fever and relieve the aches.

CX 176 then continues:

She chooses Orange Flavored Bayer Aspirin for Children—because she knows Bayer makes the best children's aspirin . . .

Such "best" claims represent to consumers that the product is therapeutically superior to the other pain relievers it is being compared to, in this case, all other children's aspirin in the same manner discussed earlier in connection with Bayer Aspirin advertisements making "the best" claim (F. 305, *supra*). [87]

347. It is found that a number of BCA advertisements in evidence did not make a therapeutic superiority claim, although they contain a claim of superior product quality for BCA. Such advertisements include, for example, CX 162, 163, and 187. These advertisements contain claims regarding quality control ("made with extra care," "200 tests," "highest standards"), which are directed to "product quality." "Product quality" and "quality control" are concepts familiar to and readily recognized by purchasers of analgesic products and are distinguished from such therapeutic superiority claims as "stronger," "faster-acting" and "gentler." (See F. 314-323, *supra*).

2. Complaint Paragraph 8(A)(2)

348. Sterling has represented that it has been established that BCA is superior to any other children's aspirin in terms of significant therapeutic effect (Complaint Paragraph (8)(A)(2); CX 167-170, 175-185, 188, 194-198, 201-203, 205, 209).

349. The representation that the therapeutic superiority of BCA has been established is explicitly contained in the BCA advertisements which assert specifically that the crystalline composition of the aspirin in BCA is different from that in any other children's aspirin, and that this difference results in improved therapeutic performance. For example, in CX 184, actress Jane Wyatt states:

I know what it's like being a mother. Only the best is good enough. So when you child gets a cold or flu, you should know that every children's aspirin tablet is made up of tiny crystals. But instead of using just one shape of crystal, Bayer Children's Aspirin blends two shapes . . . to help it go to work quickly and gently. I'm Jane Wyatt and I know that if Andy (holds baby) were my child I'd give him children's Bayer.

This advertisement clearly conveys the impression of a type of superiority grounded in accepted scientific fact. Similar representations are made in CX 182, 183, 209.

350. The references to and depictions of the unique manner in which a product is manufactured conveys to consumers the impression that the superiority of that product has been established (Ross, Tr. 5757). Such establishment representations by references to the unique or special manner in which BCA is made are found in CX 167, 175, 182-185, 188, 195-197, 203, 205, 209.

351. In addition, each of the BCA advertisements listed in F. 348, *supra* as making a claim of therapeutic superiority for [88] BCA also represented, by implication, that such therapeutic superiority has been established, for the reasons discussed earlier in connection with Bayer Aspirin advertisements claiming therapeutic superiority for Bayer Aspirin (F. 326, *supra*).

D. Specific Allegations Relating To Vanquish Advertising

1. Complaint Paragraph 12(B)(1)

352. Sterling represented that a recommended dose of Vanquish is more effective for the relief of pain than a recommended dose of aspirin or buffered aspirin. This representation was made in CX 224, 226, 235-236, 241-247, 250-256, 258-264.

353. Vanquish has been portrayed as more effective than the leading "extra strength" tablet because Vanquish contains other extra ingredients (CX 252-253, 256, 258, 264). In other instances, Vanquish is depicted as a special "extra strength" product (CX 245-247, 250-252). The clear implication of such claims is that, because of Vanquish's "extra strength," it is more effective than other analgesics. Sterling's witness Dr. Miles agreed that such "extra strength" claims represented to consumers that the product is superior in terms of efficacy (Miles, Tr. 9495-97). Similar "extra strength" or "extra ingredients" claims are also made in CX 224, 226, 236, 241-244, 259-263.

354. A number of Vanquish advertisements depict the product as being so special or effective that, in contrast to other pain relievers, one's headache should not come back after taking Vanquish (CX 224, 226, 235, 241-243). The clear impression of such advertisements is that Vanquish is more effective than other analgesics.

355. Vanquish has also been depicted as having a unique, different, or special formula (CX 224, 226, 235, 236, 241-247, 250-251). Such claims of uniqueness may reasonably be interpreted by consumers as meaning that Vanquish is more effective than the recommended doses of other aspirins.

2. Complaint Paragraph 8(B)(2)

356. Sterling has represented that it has been established that a recommended dose of Vanquish is more effective for the relief of pain than a recommended dose of aspirin or buffered aspirin. This representation was made in CX 224, 226, 235, 236, 241-247, 250-256, 258-264. All such advertisements make the core representation that Vanquish is more effective than aspirin. [89]

357. The Vanquish advertisements depict the superiority of Vanquish in conjunction with various indicia of scientific establishment. For instance, various advertisements depict the formulation of Vanquish with chemist's instruments (CX 224, 226, 241-244). Vanquish has been characterized as containing "two *medically-proven* ingredients" (CX 254), or as combining the "*proven* effectiveness of aspirin with other *powerful* ingredients" (CX 224). Such advertisements convey the impression that Vanquish's superiority has been predicated upon scientific or medical fact.

358. Because the advertising claim alleged in Complaint Paragraph 8(B)(1) has not been scientifically established in accordance with the standards established and adhered to by qualified experts in the scientific community, the claim was made in the face of substantial question as alleged in Complaint Paragraph 13.

3. Complaint Paragraph 12(C)

359. Sterling has represented that a recommended dose of Vanquish is more effective for the relief of pain than the largest selling "extra strength" tablet. This representation was made in CX 252-253, 255-256, 258-264.

360. CX 252-253, 255-256, 258-264 all explicitly compare the effectiveness of, or ingredients in, Vanquish to the leading or largest selling "extra strength tablet." Such advertisements claim that Vanquish has "more pain relievers" than the largest selling tablet. A clear implication of such claims is that Vanquish, because it contains "more pain relievers," is more effective than the extra strength tablet. Dr. Miles, Sterling's witness, agreed that consumers perceive the claim that a product "has more pain-relieving ingredients" to mean that the product is more effective (Miles, Tr. 9495-96).

4. Complaint Paragraph 8(C)

361. Sterling has represented that it has been established that a recommended dose of Vanquish is more effective for the relief of pain than the largest selling "extra strength" tablet in CX 252-253, 256, 258-264.

362. CX 252-253, 255-256, 258-264 represent that Vanquish is more effective than the largest selling extra strength tablet. All such advertisements explicitly compare Vanquish's superiority to another drug. Since each of these Vanquish advertisements makes a claim of comparative efficacy over another drug, such Vanquish advertisements represent to consumers that such superior efficacy has been established for the same reasons discussed earlier in connection with certain Bayer Aspirin advertisements containing a superior efficacy claim (F. 326, *supra*). [90]

5. Complaint Paragraph 12(B)(2)

363. Sterling has represented that because Vanquish contains "gentle buffers" it will result in less gastric discomfort than any nonprescription internal analgesic not containing buffers in CX 224, 226, 235-236, 241-247, 250-256, 258-264.

364. For example, in CX 245 (245a), a television commercial for Vanquish entitled "Tuesdee Testa" (60 seconds), a female jockey is depicted as looking for a strong analgesic with "gentle action." CX 245 states that "Vanquish is different from the others." Vanquish is then compared to the "leading extra strength pain reliever" which has no buffers. The advertisement then concludes that Vanquish "gives you extra strength and gentle buffers" and that it is "gentle enough to your system." The clear implication of such claims is that Vanquish is more gentle on the stomach because it contains "gentle buffers."

365. CX 247 (247a) is a television commercial for Vanquish entitled "Round Ones" (60 seconds). It compares three leading pain relievers, including the extra strength product without buffers, with Vanquish and states that "Vanquish gives you extra strength and gentle buffers. It's the only leading pain reliever you can buy that does." The advertisement then concludes with the claim that Vanquish gives you extra strength "yet is gentle enough for your system." Similar claims are found in slightly varied form in CX 246, 250 and 251).

366. A number of Vanquish advertisements claim that Vanquish has "two buffers" (CX 224, 226, 252, 253, 255, 256, 258-260), "gentle buffers" (CX 236, 241, 242, 244-247, 250, 251, 261-264), or "buffers" (CX 235, 243). References to Vanquish containing "gentle buffers" are also made on the Vanquish package which is conspicuously displayed in many of the Vanquish advertisements (*e.g.*, CX 254, 255, 258-264).

Consumers would understand such references to the presence of "buffers" in Vanquish to mean that buffers are put in Vanquish to reduce the incidence of gastric discomfort (Ross, Tr. 5792, 5800-01). Thus, the advertisements set forth in F. 363, *supra*, represented that because Vanquish contains gentle buffers, it will cause less gastric discomfort than any other nonprescription internal analgesic not containing buffers.

6. Complaint Paragraph 8(B)(2)

367. Sterling has represented that it has been established that because Vanquish contains "gentle buffers" it will result in less gastric discomfort than any nonprescription internal analgesic not containing buffers. This representation was made in CX 224, 226, 235, 236, 241-247, 250-256, 258-264. [91]

368. The advertisements set forth in the preceding Finding make the core representation that because Vanquish contains buffers it will cause less gastric discomfort than any other internal analgesic not containing buffers. In addition, various such advertisements contain references to science, and language which communicates the impression that the claims have been established as scientific or medical fact. For instance, while the language of various advertisements represents Vanquish as giving the "proven effectiveness of aspirin" with "buffers," the video portion of these ads depicts the formulation of Vanquish with chemist's instruments, such as the mortar and pestle (CX 224, 226, 241-244). Vanquish is also explicitly represented as a "more complete formula, designed for more complete relief." (CX 235, 236, 243, 244). Reference to a unique or special formula specifically designed for greater relief implies that the composition of Vanquish is the end product of a scientific or medical inquiry which developed a formulation superior in terms of efficacy and freedom from side effects.

369. Since each of the Vanquish advertisements set forth in F. 363, *supra*, makes a comparative superiority claim over another drug, they also represented to consumers that such superiority has been established for the same reasons discussed in connection with comparative efficacy claims made for Bayer Aspirin (F. 326, *supra*).

7. Complaint Paragraph 23

370. Upon a review of the Vanquish advertisements in evidence, Sterling (except in CX 224) did not mention that Vanquish contains aspirin. Therefore, Sterling failed to disclose that Vanquish contains aspirin (Non-Contested Issue 18; CX 226, 235, 236, 241-247, 250-256, 258-264).

371. Sterling believed that disclosing in advertising the aspirin

content of Vanquish would remove a "valuable mystique" of that product (CX 485).

E. *Specific Allegations Related To Cope Advertising*

1. Complaint Paragraph 12(A)

372. Sterling represented that Cope was more effective for relief of "nervous tension headache" pain than a recommended dose of all other nonprescription internal analgesics. This representation was made in CX 272-276, 283, 287, 293-294.

373. For example, CX 272, a 1970 television commercial for Cope entitled "Important" (30 seconds), states that for the relief of "nervous tension headaches . . . a combination of [92] pain reliever and a sedative provides *greater relief* than either medication alone." (emphasis added). Sterling witness Dr. Miles agreed that promises in analgesic advertisements of greater or more complete relief were perceived by consumers as promises of superior effectiveness (Miles, Tr. 9494-97). CX 272 next states that *only* Cope contains this combination of ingredients. Thus, because the advertisement claims that Cope, and only Cope, contains this special combination, a reasonable interpretation is that Cope is more effective for the relief of "nervous tension headaches" than a recommended dose of any other nonprescription internal analgesic. This representation is also made in a similar manner in CX 273-275, 283, 287, 292-294.

374. Similar superiority claims have been made in other Cope advertisements characterizing Cope's formulation for the relief of the nervous tension headache as "unique," or "uncommon" (CX 273-275, 292-294). These claims of uniqueness imply that Cope's special formulation provides superior nervous tension headache relief to any other analgesic.

2. Complaint Paragraph 8(A)(3)

375. Sterling has represented that it has been established that a recommended dose of Cope is more effective for the relief of "nervous tension headache" pain than other nonprescription internal analgesics. This representation was made in CX 272-276, 283, 287, 292-294).

376. The Cope advertisements listed above include explicit references to scientific findings, as well as language representing that the efficacy claim is based upon scientific or medical fact. For example, CX 272, 283, and 287 portray the efficacy claims for Cope as having been proved by "important studies made at the world's leading headache clinic" which "show" that Cope's formulation provides superior efficacy. This message clearly represents that the superiority claim has been proved or established by appropriate scientific testing.

377. Cope also has been portrayed as containing a unique formula, specifically developed for the relief of a special type of pain—the nervous tension headache. Some Cope advertisements have claimed that the Cope formula is “unique” (CX 274, 275, 292–294). These claims clearly imply that Cope is the end product of scientific evaluation proving that the “unique” ingredients in Cope provide superior relief for “nervous tension headache.”

378. Each of the Cope advertisements set forth in F. 375, *supra*, contains an implied claim of comparative efficacy for the same reasons discussed in connection with Bayer Aspirin advertisements (F. 326, *supra*). [93]

3. Complaint Paragraph 18

379. Sterling has represented that, by referring to the results of tests or studies in Cope advertisements, such tests or studies prove the claim that a recommended dose of Cope is more effective for the relief of “nervous tension headaches” than recommended doses of all other nonprescription internal analgesics. This representation was made in CX 272, 283, and 287.

380. CX 272, 283, and 287 state explicitly that “important studies made at the world’s leading headache clinic show that for the relief of severe nervous tension headaches,” the formulation in Cope provides the greatest amount of relief. These three advertisements thus represented that tests or studies prove Cope’s superiority for the relief of the nervous tension headache.

4. Complaint Paragraph 22

381. Sterling has represented that Cope contains a unique formula in that it alone among nonprescription headache remedies contains both a pain reliever and an ingredient with sedative properties. This representation was made in CX 272–276, 283, 287, 292–294).

382. For example, CX 272 represents that Cope contains a unique formula: “Of all leading remedies you can buy, only Cope combines a gentle relaxer with a powerful pain reliever.” Other Cope advertisements expressly represented that Cope contains a “unique” (CX 274, 275, 292–294) or “unduplicated” (CX 273) formula because it alone combines a pain reliever with a sedative ingredient. Thus, Sterling has represented in such advertisements that Cope’s formula is unique in that Cope alone contains both a pain reliever and a sedative.

383. The Cope advertisements making the representation alleged in Complaint Paragraph 22 were disseminated to the public between January 1969 and June 1971 (CX 633). Excedrin PM was introduced into two test markets in February 1969 and was then marketed nationally beginning in August 1969 (CX 638, admission 1069).

5. Complaint Paragraph 15(B)

384. Sterling has represented that Cope relieves nervous tension, anxiety and irritability and will enable persons to cope with the ordinary stresses of everyday life. This representation was made in CX 272-276, 283, 287, 292-295.

385. Cope has been portrayed in CX 272-276, 283, 287, 292-294 as specially formulated for relief of the "nervous tension headache." A reasonable implication of this claim is that Cope will help relieve not only the pain associated with nervous [94] tension but also other symptoms associated with stress, such as anxiety and irritability.

386. For example, in CX 276 (276a), a 1970 television commercial for Cope entitled "Headache Three" (30 seconds), three persons at work are portrayed, through the use of audiovisual technique, as being in a stressful situation. A grimacing mother, with one hand stroking her forehead, says, "I get it on rainy days." A traffic policeman, with a similar gesture, says, "I get it during rush hour." A secretary, after showing a man looking over her shoulder, says with an harrassed look, "I get it when the boss looks over my shoulder." Then the announcer, against a blow-up of Cope tablets and package, says:

When the name of the pain is nervous tension the name of the remedy is Cope, because Cope gives you a powerful pain reliever plus a gentle relaxer. Yes, when the name of the game is nervous tension headache the name of the remedy is Cope.

Most viewers of CX 276 will come away with an implied but unmistakable claim that Cope is the right remedy not only for tension-headache pain but also for nervous tension and anxiety apart from headache.

387. In CX 292, 293 and 294 it is expressly stated:

a proven relaxer with the pain reliever doctors recommend, so two tablets work on both parts of your tension headache: the tension *and* the pain. In fact, Cope helps ease tension throughout your body, so you can relax and feel like yourself again [emphasis in original].

The clear implication of such representations is that Cope will relieve nervous tension and allow the user to better cope with stress. Such representations would be understood by consumers to mean that Cope relieves tension and related stress and anxiety wholly apart from any ability to relieve headache pain.

6. Complaint Paragraph 24

388. A review of the Cope advertisements in evidence shows that Sterling did not mention the fact that Cope contains aspirin in any

of the advertisements. Thus Sterling failed to disclose that Cope contains aspirin (Non-Contested Issue No. 18; CX 272-276, 283, 287, 292-294). [95]

F. *Specific Allegations Relating To Midol Advertising*

1. Complaint Paragraph 15(C)

389. In the advertisements for Midol in evidence, Midol has been expressly and consistently represented as a product developed especially for women's periodic pain and menstrual discomfort. None of the Midol advertisements claim, directly or by implication, that Midol will relieve any condition for anyone other than menstruating women. See CX 296A, 297-306, 306A-C, 306R, 306Z005, 306Z011, 306Z035, 306Z037, 306Z041, 306Z045, 306Z053.

390. In many of the Midol advertisements, it was represented that Midol will relieve nervous tension, stress, fatigue and depression related to menstruation and improve the mood of menstrual women (CX 296A, 297-300, 303, 306, 306A-C, 306R, 306Z005, 306Z011, 306Z035, 306Z037, 306Z041, 306Z045, 306Z053).

391. In CX 296A, a 1969 television commercial for Midol entitled "Wood & Stream" (30 seconds), Midol is represented as a product that "calms jumpy nerves" and is effective in fighting depression because "the overall action of Midol chases the blues away." Midol is further positioned as fighting the fatigue associated with menstruation because it allows the user during the period to "be an active girl, non-stop. No slow down." Thus, the advertisement clearly conveys the suggestion that use of Midol will improve menstrual women's mood. Similar claims, including virtually identical language, are found in CX 297-300, 303.

392. A review of the verbatim responses to CX 441, a Burke copy test of CX 296A, confirms that some female viewers perceived the claims in CX 296A as promising that Midol will relieve nervous tension, stress, fatigue, depression accompanying menstruation and improve women's mood during menstruation. In CX 441, responses included playbacks of themes relating to Midol's ability to relieve tension and depression. Such playbacks included: "it helps the headache and blues," "you don't feel blue" (CX 441F), "being for pain and to relieve tension and the blues" (CX 441G), "you don't feel under tension and makes you less nervous," "it relieves tension," "help ease and relax you," "you won't be nervous or depressed if you use Midol" (CX 441H), "it helps you get over the blues . . . keeps you from being down in the dumps," "use it for depression and minor things like that" (CX 441I), "it relieves pain and tension," and "for cramps and tension" (CX 441J).

393. Similar tension and mood altering representations are found in the Midol print advertisements in evidence (CX 306, 306A-C, 306R, 306Z005, 306Z011, 306Z035, 306Z037, 306Z041, 306Z045, 306Z053). In CX 306E, for example, Midol is portrayed [96] explicitly as containing "a mood brightener" which gives you a real lift . . . helps you go through the day cheerfully, alert."

394. Similar "mood brightener" language is found in all the Midol print ad in evidence. This impression is reinforced by the "before and after" pictorial representation in such advertisements as CX 306, 306A, B and C where Midol users are portrayed as "dismal," "sunk," "tense," or "blue" before taking Midol, but "bright," "saved," "happy," or "gay" after taking Midol.

2. Complaint Paragraph 26

395. Sterling has represented that the analgesic ingredients in Midol are other than ordinary aspirin and the stimulation in Midol is other than caffeine (CX 296A, 297-300, 303, 306, 306A-C, 306R, 306Z005, 306Z011, 306Z035, 306Z037, 306Z041, 306Z045, 306Z053).

396. Sterling has explicitly claimed that Midol's formula is unique or exclusive. For example, in CX 296B Midol is portrayed as having "an exclusive formula with medication ordinary pain relievers don't give you." This language clearly suggests that Midol's active ingredients are something other than aspirin (which is the active ingredient in the "ordinary pain relievers" with which Midol is being contrasted) and caffeine. Similar representations of uniqueness of formulation are made in CX 297, 300-302, 304, 306, 306A-C, 306R, 306Z005, 306Z011, 306Z035, 306Z037, 306Z041, 306Z045, 306Z053.

3. Complaint Paragraph 25

397. A review of the Midol advertisements in evidence shows that they did not mention that Midol contains aspirin. Therefore, Sterling failed to disclose that Midol contains aspirin (Non-Contested Issue of Fact No. 18; CX 296A-B, 297-300, 303, 306, 306A-C, 306R, 306Z005, 306Z011, 306Z035, 306Z037, 306Z041, 306Z045, 306Z053).

G. Allegations Regarding Inconsistent Claims (Complaint Paragraph 17)

398. Sterling has represented that Bayer Aspirin is as effective for the relief of headache pain (including "nervous tension headache" pain) as, and will cause gastric discomfort no more frequently than, any other nonprescription internal analgesic, including Cope and Vanquish (Complaint Paragraph 17(A); CX 3, 11, 14, 15, 17-21, 25, 31, 34, 35, 44, 45, 47, 48, 50, 52-64, 70, 88-91, 94, 97, 100-104, 118-123, 131, 140, 142-144, 153-156).

399. Sterling has represented that Cope is more effective for the relief of the "nervous tension headache" pain than any other nonprescription internal analgesic, including Bayer [97] Aspirin and Vanquish (Complaint Paragraph 17(B); CX 272-276, 283, 287, 293-294). See F. 372-374, *supra*.

400. Sterling has represented that Vanquish is more effective for the relief of headache pain than aspirin, including Bayer Aspirin, and will cause less gastric discomfort than any nonbuffered internal analgesic, including Bayer Aspirin (Complaint Paragraph 17(C); CX 224, 226, 235, 236, 241-247, 250, 255, 256, 258-264). See F. 352-369, *supra*.

401. The Bayer advertisements set forth in F. 398 were disseminated through national media from April 1969 through September 1972 (CX 630). The Cope advertisements set forth in F. 399 were disseminated through national media from January 1969 through June 1971 (CX 633). The Vanquish advertisements set forth in F. 400 were disseminated through national media from April 1969 through December 1974 (CX 632).

402. The representations made as alleged in Complaint Paragraphs 17(A), (B), and (C) are mutually inconsistent.

403. From April 1, 1969 through June 1971, Sterling disseminated through national media contemporaneous and inconsistent claims regarding Bayer, Cope, and Vanquish. Contemporaneous and inconsistent claims regarding Bayer Aspirin and Vanquish continued until September 1972.

404. Advertising proposals for products manufactured by Sterling are developed by advertising agencies which present proposed advertisements to the company for approval. Such approval must be obtained prior to any dissemination of the advertising (Alberts, Tr. 8998-99). Sterling maintains an established advertising approval procedure in which each prospective advertisement is reviewed by various company officials. The purpose of this advertising review procedure is to ensure that all advertising claims are accurate and that medical and scientific substantiation is adequate (John, Tr. 5576-79; Alberts, 8998-9000).

405. Sterling's process for reviewing analgesic advertising claims is as follows: The product manager for the particular product and the advertising agency for the product will design a proposed advertisement, portions of which are submitted to appropriate personnel for verification even prior to the formal approval procedure. That proposed advertisement will be put in the form of either a transcript or a storyboard or both and circulated in succession among specified people at Sterling for approval. Persons who must approve the proposed advertisement by placing their initials on a written form

include the Product Manager, the Group Product Manager, the Medical Director of Glenbrook Laboratories, the legal department, the President of Glenbrook Laboratories, and the Vice President for Sales or Marketing (John, Tr. 5576-79; Alberts, Tr. 8998-9000; G. Goldstein, Tr. 14784-85; Mattimore, Tr. 15359-60; CX 536). [98]

406. At each stage of the advertising review process, Sterling had professionals with expertise in their various fields exercising their best judgment as to whether claims in the advertising were supportable from a medical, advertising/marketing, or legal standpoint (John, Tr. 5577-81; Alberts, Tr. 8998-9000; Mattimore, Tr. 15359-60). For example, to determine the correctness of, and substantiation for, any scientific claim, whether pharmaceutical or medical, those responsible for reviewing and advertisements had access to inhouse Sterling experts, including pharmaceutical experts at the Bayer plant and scientists at the Sterling-Winthrop Research Institute, as well as access to outside experts. With respect to substantiation of medical or therapeutic claims, the Medical Director of Glenbrook Laboratories was the principal official directly responsible for the matter (Alberts, Tr. 8998-9000; G. Goldstein, Tr. 14785-90; Mattimore, Tr. 15361; Trout, Tr. 16089-90).

407. It was standard procedure for marketing personnel involved in the advertising review process to refer, for accuracy and substantiation, all proposed claims and statements relating to Bayer's pharmaceutical quality, pharmaceutical standards and manufacturing standards to Sterling's experts at its Trenton plant: Mr. Winig, head of the Trenton plant during the period involved in this case, or Mr. Mannix, then Director of Quality Control, or other knowledgeable persons (Alberts, Tr. 8998-9000; Mannix, Tr. 14634; Winig, Tr. 14759-61; Mattimore, Tr. 15359, 15361; Trout, Tr. 16089-90). Mr. Winig also was a member of the executive committee that approved all advertising (Winig, Tr. 14759).

408. In addition to access to scientific experts, all Sterling personnel responsible for advertising substantiation have access to Sterling's library resources (G. Goldstein, Tr. 14786-90; Mattimore, Tr. 15361; Trout, Tr. 16090-92). Among Sterling's libraries are those located at corporate headquarters in New York City and at the Sterling-Winthrop Research Institute in Rensselaer, New York. The Sterling-Winthrop Research Institute library is a resource for the approximately 700 scientists employed at the Institute (G. Goldstein, Tr. 14729, 14736-37). The library staff researches any subject requested by Sterling personnel by reviewing treatises, texts and published literature (G. Goldstein, Tr. 14730).

409. According to Sterling's officials, the Sterling librarians keep abreast of medical and scientific journals and are linked by computer

to the National Library of Medicine. A service of the American College of Physicians reviews literature on various products for the Sterling libraries. The Sterling [99] library in England reviews all European literature and translates important articles for transmission to the United States. The Sterling library itself generates a monthly abstract of important literature, including summaries of articles relating to analgesic products and ingredients, which is sent to top management, medical personnel, and appropriate marketing personnel. The full text of the summarized article is supplied to Sterling personnel upon request (G. Goldstein, Tr. 14730-37; Trout, Tr. 16090-92).

410. Sterling's medical and pharmaceutical personnel involved in the advertising review process often attend conferences, seminars and professional meetings. At such activities, papers are presented, including materials or studies either not yet published or that may never be published (G. Goldstein, Tr. 14801-02, 14844-45, 14849, 15058-59, 15061-64; RX 148).

411. It is fair to conclude that respondent, through its own resources or through arrangements with other institutions, has access to a large body of published literature, including books and treatises, that exist in the field of mild analgesics. It is Sterling's position that, through efforts by Sterling library personnel and otherwise, Sterling personnel directly involved in or consulted about substantiation keep abreast of current developments relating to mild analgesics (John, Tr. 5706-07, 5576-77; G. Goldstein, Tr. 14734-36, 14785-90).

412. In 1973 the FTC served a subpoena upon respondent requesting substantiation materials for the challenged advertising claims. In response to this subpoena, some documents were produced, dated through December 31, 1973. As part of this 1973 subpoena response, incorporated by reference, were substantiation documents produced to the Federal Trade Commission by respondent in response to prior subpoenas in 1966 and 1971 (G. Goldstein, Tr. 14834-38).

413. As part of such substantiation materials, a large number of documents were produced which included many published articles in the scientific literature and summaries and excerpts of such literature (e.g., RX 185; G. Goldstein, Tr. 14814-15). It is Sterling's position, taken at trial, that not all of the substantiating literature that Sterling had knowledge of and relied upon was produced at that time, as this would have been physically impossible and that only representative materials were produced (G. Goldstein, Tr. 14840). [100]

IV. THE SCIENTIFIC EVIDENCE SUPPORTS THE
ALLEGATIONS OF THE COMPLAINT

A. Sterling Did Not Have A Reasonable Basis For Its Claim That Bayer Aspirin Is Qualitatively Or Therapeutically Superior Or That Such Claims Have Been Scientifically Established

1. Well-Controlled Clinical Studies Are Necessary to Establish the Comparative Efficacy or Safety of Analgesic Drugs

414. In order to consider any scientific or medical proposition as established, experts in the pertinent field must be convinced that the proposition is proven or sufficiently supported by a type and quality of evidence that reduces the chance for error to an acceptable minimum and is unlikely to be due to chance (Moertel, Tr. 6309). In this connection, experts apply a set of well-controlled methodological and analytical criteria in order to determine whether a given body of evidence is sufficient to establish a proposition (Moertel, Tr. 6255; Grossman, Tr. 7767-69).

415. The record shows that Sterling also understood and used the term "established" in the same sense in documents dated January 7, 1957 and filed with the Federal Trade Commission protesting the adequacy of scientific substantiation for certain of its competitor's advertising claims for OTC analgesic products. In discussing the results of a clinical test comparing Bufferin and Bayer Aspirin and conducted by a well-known investigator, Sterling maintained that, "he [the investigator] recognizes the 'possibility' that Bufferin might be a little more irritating than Bayer aspirin but the figures were not sufficiently significant to establish this" (CX 371Z002).

416. The only type of evidence sufficient to establish the comparative efficacy of drugs is developed through well-controlled clinical tests using real patients with real symptoms (Moertel, Tr. 6255; Grossman, Tr. 7459, 7482; DeKornfeld, Tr. 8388-89; Feinstein, Tr. 16413, 16441-44; CX 466, p. 35371, 35444).

417. The criteria used to evaluate the validity and reliability of clinical studies for the purpose of establishing comparative efficacy of drugs include: (a) where analgesics are involved, an appropriate pain model using the subjective response methodology; (b) replication of results; (c) an experienced, unbiased investigator; (d) adequately trained personnel and appropriately instructed subjects; (e) a written protocol; (g) double-blinding; (h) where pain relief is being measured, use of a placebo control; (i) use of appropriate analytical techniques determined in advance; (j) use of a [101] recognized level of statistical confidence (the 5% level) to determine the statistical significance of

the observed results; (k) determination of the clinical significance of the test results; and (l) subjecting the study to peer review.

418. Other methods which purport to measure comparative efficacy of analgesic agents, or other techniques which try to assess their comparative efficacy without actual clinical measurement, have not been shown to be sufficiently reliable for the purpose of establishing the comparative efficacy of one agent or product over another.

419. Experts who study the therapeutuc performance of analgesics in clinical pain have used several "pain models"; surgical pain, orthopedic pain, post-operative pain, cancer pain, post-partum pain, pain from dental extraction, and headache pain (CX 466, p. 35382).

420. Since pain is a personal perception and subjective in nature, clinical studies of OTC analgesics usually employ the subjective pain response methodology that elicits the subject's report of his or her perception of pain and the degree of pain relief obtained after administration of the drugs under study (Moertel, Tr. 6259; DeKornfeld, Tr. 8390; Feinstein, Tr. 16441; CX 466, pp. 35377, 35444). Objective measures of pain relief, in the strict sense of the term, in the clinical situation are yet to be developed (Feinstein, Tr. 16223).

421. In order to establish the comparative efficacy of drugs, including OTC analgesics, for the relief of mild to moderate pain, at least two well-controlled, separately conducted clinical studies on the drugs in question are required (Moertel, Tr. 6289; Grossman, Tr. 7459, 7466; DeKornfeld, Tr. 8390, 8396-97, 8401; CX 466, pp. 35371, 35444). Replication of results in the hands of separate, competent investigators reduces the likelihood that the results obtained in the original study were due to chance (Moertel, Tr. 6278; Grossman, Tr. 7466; DeKornfeld, Tr. 8390) and avoids the possibility that errors or artifacts in the design or execution of any one study are carried over into the next (DeKornfeld, Tr. 8396-97). As Dr. DeKornfeld testified:

[Two studies] substantially decrease the likelihood of the one study being inaccurate. Statistically two studies showing the same thing are substantially more meaningful than a single study in an area where there is some question as to difficulty of the methodology (DeKornfeld, Tr. 8396).

422. A threshold requirement for an adequate and well-controlled study is an experienced investigator (Moertel, Tr. 6257; DeKornfeld, Tr. 8394). Moreover, the motivation of an investigator is a possible source of bias, and it is therefore [102] important to ensure that the investigator is truly independent (Moertel, Tr. 6482-83).

423. Where nurses or other persons are used to administer treatments, and to observe and record the subjective responses of patients under study, it is important that they be trained and experienced in

order to guard against intended or unintended distortion of the information provided by patients (DeKornfeld, Tr. 8403).

424. In out-patient clinical studies, where patients are ambulatory and record their own responses to treatment at their homes, due care must be exercised in order to insure that a trained technician accurately compiles the data and the patients themselves are carefully instructed to properly record their responses (Moertel, Tr. 6259-60).

425. A written protocol which sets forth in sufficient detail and in advance the objectives of the study and how those objectives are to be achieved is an important element of a well-controlled clinical study (Moertel, Tr. 6264; DeKornfeld, Tr. 8393). Such a protocol should cover not only the main features of study design, but also a plan for analysis (Moertel, Tr. 6275; DeKornfeld, Tr. 8393). Adherence to the protocol in both its design and analytic features provides a reader of the study with an additional means to judge whether there was an opportunity for uncontrolled bias to enter into the conduct of the study (Moertel, Tr. 6273).

426. The clinical study must employ a pain model that is appropriate for the proposition sought to be tested in the study (Moertel, Tr. 6260). In general, the best pain model is the type(s) of pain for which use of the drug is intended or for which a specific claim of efficacy may be made (DeKornfeld, Tr. 8395). Where a claim of comparative efficacy is made for ordinary headache pain, at least one of the well-controlled studies required to establish such claim should be in ordinary headache pain (DeKornfeld, Tr. 8395, 8444). The need for at least one study which tests the specific type of pain for which a claim is made becomes acute where the product involved is a combination of ingredients, which may act differently in different types of headaches or pain.

427. In a well-controlled clinical study, it is essential that subjects be randomly assigned to the various treatment groups in the study (Moertel, Tr. 6205-06; Grossman, Tr. 7490; Rickels, Tr. 7935; DeKornfeld, Tr. 8393; Feinstein, Tr. 16219, 16465; CX 466, p. 35444). Randomization is necessary to balance out the numerous variables, not only in the subject population but also in the design and conduct of the study itself, that cannot be identified and controlled directly by the investigator (Moertel, Tr. 6265). Randomization is the prerequisite for concluding that the uncontrollable variation inherent in all [103] research is fairly balanced across the treatment groups within determinable limits. Unless a clinical study is properly randomized, the validity of that study is questionable and all analyses of its results are compromised.

428. A technique to help assure that important, identifiable variables are balanced fairly across treatment groups is to stratify all

subjects according to such variables (*e.g.*, level of initial or base-line pain) and then randomly assign subjects within each stratum to the various treatment groups. Stratification makes it more likely that the critical variables will be distributed fairly equally in all treatment groups (Moertel, Tr. 6267).

429. An absolute prerequisite of any well-controlled clinical study, particularly in the area of mild analgesic drugs for the relief of mild pain, is double-blinding. That is, neither the test subject nor the investigator should be able to detect the treatment being administered (Moertel, Tr. 6265; Grossman, Tr. 7490-91; DeKornfeld, Tr. 8393, 8399; Feinstein, Tr. 16223; CX 466, p. 35444). Responses to pain relievers can be significantly affected by subjects' pre-existing beliefs and expectations (Moertel, Tr. 6265). Moreover, the conscious or unconscious biases of the investigator, nurse observers, the subjects and others involved in the conduct of the study can exert an influence that distorts the action of the actual treatments administered (DeKornfeld, Tr. 8398). Double-blinding effectively controls the expectations and beliefs of subjects and the biases and influences of those conducting the study, by assuring that these extraneous influences do not distort the results obtained with any given treatment (Moertel, Tr. 6265). To achieve an adequately double-blinded study, it is essential that the treatments look the same, taste the same and appear identical in all respects so that the subjects in one treatment group will not be prompted to expect something different from subjects in another and so that investigators will have no clue as to which treatment they are administering (Moertel, Tr. 6265; Feinstein, Tr. 16223).

430. Whenever possible, a well-controlled study comparing the efficacy of one drug against that of another, particularly mild analgesics, should include a placebo control (Moertel, Tr. 6268; DeKornfeld, Tr. 8393, 8399, 8482; CX 466, pp. 35372, 35444-45). The placebo, a pharmacologically inert substance, acts as a separate treatment in the study, and it serves as a built-in measure of the sensitivity of the study and an analytical tool to aid in the analysis of the results (Moertel, Tr. 6268; Rickels, Tr. 7938-39; DeKornfeld, Tr. 8399; Feinstein, Tr. 16221). Unless the results of a study demonstrate its ability to distinguish a standard analgesic compound—such as aspirin—from placebo, one cannot be certain that the study was sufficiently sensitive to detect differences between the standard and test compounds under study, even if such differences [104] in fact existed (DeKornfeld, Tr. 8482, 8484-85). Similarly, in the absence of a placebo control, the failure to find a difference between the treatments under study may be due to insensitivity of the study methodology rather than to the fact that no difference exists between the treatments (Moertel, Tr. 6344).

431. The statistical techniques to be employed in analyzing the results of clinical trials should be set out in advance and be appropriate to the design and purpose of the study (Moertel, Tr. 6275; Rickels, Tr. 7935; DeKornfeld, Tr. 8393-94, 8400). Deciding upon the statistical analysis in advance guards against the investigator "peeking" at the data and terminating a study prematurely when a desired result has been reached or choosing post facto to analyze a particular segment of the study that shows a desired result (Moertel, Tr. 6274, 6345). Failure to set forth statistical procedures in advance opens the door to a bias into the analysis (DeKornfeld, Tr. 8400) and raises a spectre of "data massaging" that may destroy the validity of the analysis (Moertel, Tr. 6346).

432. When a clinical study is designed for the purpose of determining whether two treatments are significantly different from each other a method must be provided with which to judge whether any observed differences may be due to chance or simple random variations in the data generated rather than to real differences in the effects of the treatments (Moertel, Tr. 6273). When the observed differences are shown through appropriate statistical analyses' to be significant at or beyond the 95% level, scientists generally, accept those differences as real and not being due to mere chance (Moertel, Tr. 6273; DeKornfeld, Tr. 8400). The scientific community will not accept, for the purpose of establishing a scientific or medical proposition, a greater-than-5% (or one in twenty) likelihood that the differences observed in a study are due to chance (Moertel, Tr. 6273; DeKornfeld, Tr. 8400). The 95% confidence level as a measure of statistical significance (sometimes expressed as $P < .05$) is a commonly accepted standard for testing the statistical significance of results in biomedical sciences, including the scientific literature (Moertel, Tr. 6273; DeKornfeld, Tr. 8400). For example, respondent's witness, Dr. Horner, in his statistical analysis of the FDA *in vitro* aspirin test data in RX 415, used the .05% confidence limits as his outermost measure of statistical significance (RX 415).

433. When a determination is made that an observed difference between two treatments is statistically significant at or beyond the 95% level, clinicians address the separate question of whether such statistically significant differences have clinical importance (Moertel, Tr. 6253; Feinstein, Tr. 16428). Differences, though statistically significant, may be so minor and insignificant clinically as to have no substantive impact upon therapeutic considerations (Moertel, Tr. 6253). [105]

434. Selection of a specific and objective standard of clinical importance—as opposed to the statistical significance—of differences observed between drugs is an important decision which investigators

must make before starting a clinical trial (Moertel, Tr. 6271). Unless a difference is statistically significant at or beyond the 95% level, it cannot be clinically important (Moertel, Tr. 6588). However, it is possible to demonstrate the statistical significance (at the 95% level) of even minute differences by expanding the test population sufficiently (Moertel, Tr. 6253; Feinstein, Tr. 16326, 16429-34). It is therefore generally recognized that in clinical trials statistical significance alone does not provide the basis for a conclusion about the therapeutic significance of those differences, which is ultimately a clinical question (Feinstein, Tr. 16335, 16428-29). Thus, differences may be statistically significant but not clinically significant (Moertel, Tr. 6253).

435. Publication of a clinical study in a reputable journal and the accompanying process of peer review adds further elements of reliability and confidence to a study (Moertel, Tr. 6280; DeKornfeld, Tr. 8394). It allows an opportunity for other experts in the field familiar with research methodology to see whether the study was properly designed and conducted, whether results have been properly interpreted and whether a protocol has been properly followed (Moertel, Tr. 6280). One of the important criteria used in coming to a conclusion about the validity and reliability of a study is whether it is published in a reputable, peer reviewed journal and whether, thereafter, it meets with the acceptance of other scientists in the field (Moertel, Tr. 6280).

436. On the other hand, a practicing physician may choose to try on a given patient a therapeutic agent whose superior efficacy has not been established in the manner discussed above. For example, a clinician may try buffered aspirin on a patient who had complained of gastric discomfort after taking plain aspirin simply on the basis of some historical or clinical data indicating that some subjects sometimes appeared to have suffered somewhat less gastric discomfort from buffered aspirin. If the patient under discussion does experience less gastric discomfort from buffered aspirin, the clinician will thereafter prefer buffered aspirin over plain aspirin for that patient. However, this is essentially a part of the trial-and-error process inherent in clinical practice and is an incidence of the well known fact of human variability. In this case, the difference between plain and buffered aspirin had "clinical significance" for the physician and the patient involved. This is not to say, however, that the evidence at hand is sufficient to support a comparative therapeutic proposition which the medical scientific community will accept as established. Thus, [106] clinical preference that clinicians may make on the basis of historical survey data or anecdotal clinical experience (in the absence of controlled clinical trials) is distinct from the evaluation of clinical significance of a statistically significant difference found be-

tween drugs. The former is a clinical judgment that a practicing physician must make in his daily practice on the basis of available evidence; the latter is a clinical judgment he makes of an agent whose efficacy or comparative efficacy has been statistically demonstrated through controlled trials.

2. The Claim That Bayer Aspirin is Therapeutically Superior to All Other Brands of Aspirin Lacked A Reasonable Basis and It is Reasonable to Require Well-Controlled Clinical Trials to Support Claims of Therapeutic Superiority For Bayer Aspirin.

437. Clinical trial methodology is not new. Dr. A. Bradford Hill, a British medical statistician, was instrumental in bringing about the recognition of clinical trials before 1950. Since the time of Hill, clinical trials have been recognized as the only reliable method for demonstrating the efficacy of drugs. The importance of clinical trials for this purpose is now widely recognized (Moertel, Tr. 6285; Grossman, Tr. 7462-66; 21 C.F.R. 330.10 (a)(4)). The use of randomized double-blind, controlled clinical trials dates back to the 1940's. During the early 1950's, Hill summarized the procedures and rationale for controlled clinical trials for the purpose of making therapeutic conclusions regarding drugs. During the same decade, Beecher, Houde and Modell elaborated on clinical study requirements in the context of analgesic studies. And in 1965, Dr. William Beaver summarized the procedures for conducting clinical trials of mild analgesics in a historic review article (Moertel, Tr. 6288). In recognition of the significance of such clinical trials, interest has grown in recent years in perfecting the methodology (Grossman, Tr. 7466; DeKornfeld, Tr. 8393, 8406; Feinstein, Tr. 16233, 16255, 16425, 16470-71).

438. Respondent's witness, Dr. Feinstein, testified on the need for incorporating what he refers to as "soft data" into the evaluation of medication. Soft data measures symptoms such as pain or digestive distress whereas hard data measures blood salicylate levels or brain wave pattern or pharmaceutical characteristics of drugs (Feinstein, Tr. 16444-49). He agreed that if the purpose of drug is to relieve a subjective symptom such as pain, it is of critical importance to directly measure the pain itself in people (Feinstein, Tr. 16441).

439. Dr. Raymond Houde, in discussing clinical measurement of pain in 1965 wrote:

In spite of the relative convenience and more rigorous controls which can be applied in the [107] laboratory, the control drug study in the clinical setting is now more than ever the crucial test of any new analgesic. This is true for several reasons. Most obviously, the only conclusive proof of the value of a drug in the therapy of a disease or the alleviation of a symptom lies in successful therapeutic trials in patients with that particular disease or symptom.

Indeed, an increasing number of investigators in the past decade or so have been able to show that controlled clinical experimentation can provide results which are reproducible and valid in the sense that they have held up well under the test of subsequent and more extensive clinical experience (RX 250-DeStevens; Goldstein, Tr. 15756).

This view was reiterated by complaint counsel's expert witnesses. They testified that the techniques for measuring differences in performance of mild analgesics are available and if used properly can lead to clinically significant results (Moertel, Tr. 6288; Grossman, Tr. 7462; DeKornfeld, Tr. 8460).

440. Well-controlled clinical trials need not be prohibitively expensive. Dr. Moertel, long experienced in the conduct of clinical trials of analgesics, noted that suitable patient populations are available at large medical centers for such trials. Thus, the only costs which need be incurred are those associated with the preparation of the drug, proper coding and cost of analysis of results (Moertel, Tr. 6288). Moreover, correspondence between Sterling and Food and Drug Research Laboratory (FDRL) in 1964 indicated that the costs of running the Cope clinicals was low—approximately \$25-\$27 per subject (RX 237F).

441. The concept of therapeutic superiority includes considerations of both safety and efficacy (Grossman, Tr. 7459). Where a side effect has a high enough incidence in the population, such as dyspepsia resulting from aspirin, clinical trials are appropriate to evaluate the relative safety of two mild analgesics (Grossman, Tr. 7459-60). Pre-clinical studies in animals on side effects can be valuable in finding areas of possible clinical side effects, but just as efficacy must be tested in appropriate studies in human patients, so must side effects be determined on the basis of human studies (Grossman, Tr. 7460).

442. As Sterling was well aware in 1971, both the medical and pharmacy professions universally believed that all aspirins were the same (CX 329). Presumably that belief was based on a [108] lack of evidence of clinically significant differences between different brands of aspirin.

443. The record shows that before and during the time Sterling made therapeutic superiority claims for Bayer, Sterling was aware of and familiar with clinical trial methodology and its application to comparative analgesiology. Sterling in fact demanded that its competitors meet this standard as substantiation for their superiority claims. Also, when Glenbrook Laboratories first contracted with FDRL for a series of comparative clinical tests of its combination products, Cope and Vanquish, in the early 1960's, FDRL advised Dr. Painter of Sterling in 1963 of the following, in a section entitled "Protocol—Evaluation of an Analgesic-Sedative Preparation":

Because FDA and FTC are refusing to recognize the validity of uncontrolled studies, particularly with drugs intended entirely for relief of symptoms, all such studies should be carried out double blind against a standard . . . If needed to substantiate an NDA or to strengthen claims for the FTC, more than one could be placed (RX 237C-D).

444. Sterling recognized the need for clinical trials as early as 1953 when it petitioned the FTC for issuance of a complaint against its competitor Bristol-Myers for unsubstantiated advertising claims. At that time Sterling said:

Three separate, distinct and independent studies have been made of this question, and to as great an extent as practicable, the double blind cross-over technique was used. All these tests were clinical tests which went to the heart of the matter by learning from the patient directly how quickly and how completely his pain was relieved. There is no known scientific method superior to this method. (CX 371Z001).

445. This belief in the need for clinicals to establish a claim of superiority is also reflected in more recent Sterling internal documents. Sterling's then advertising agency complained in 1970 to the television networks about false, unsubstantiated claims for Excedrin by its competitor Bristol-Myers. In criticizing a study supposedly supporting Excedrin's superiority claims, the agency posed the following questions, noting that "answers . . . ought clearly to be provided before the study can be evaluated as the basis for advertising claims" (CX 347C):

1. Did the study design utilize the customary "double blind" technique? If not, what steps [109] were taken to insure that the results would not be biased by the questioner? (This is highly important in view of the subjective questioning technique being tested in this research).

2. Since a "cross-over" technique apparently was not utilized, what controls were employed to insure that the patient samples were properly matched on all important variables; e.g., age, type of pain, length of time since delivery, etc.?

3. Similarly, what means were employed to insure that the individual patient samples were of sufficient size for meaningful analysis? (Instances in the charted results show, for example, that at certain intervals *two* aspirin tablets proved to be as efficacious as *four* Excedrin tablets and, for that matter, that two Excedrin tablets are *more* effective than four Excedrin tablets). (CX 347C).

446. Another indication of Sterling's recognition of the feasibility and reliability of clinical studies comparing the safety and efficacy of analgesics was its reliance on the results of the Lasagna-DeKornfeld study (RX 450) published in *Journal of the American Medical Association* ("JAMA") in 1962. Sterling disseminated Bayer advertisements citing the results of the study (*FTC v. Sterling Drug, Inc.*, 215 F.Supp. 327 (S.D.N.Y. 1963), *aff'd*, 317 F.2d 669 (2d Cir. 1963)).

447. More recently, in 1974, Dr. Monroe Trout, Senior Vice Presi-

dent and Director of Medical Affairs for Sterling Drug, appeared before FDA's Panel on OTC Internal Analgesics. Requesting that the Panel set down appropriate rules governing variances from the standard 325 mg dose of aspirin, he suggested:

... that OTC analgesic products containing aspirin, with or without additional ingredients ... include on their label [a disclosure that the product] is not superior in safety, effectiveness, speed of relief, or incidence of side effects to two 5 grain tablets or 650 mg of aspirin, *unless the superiority claimed or implied by such variance is adequately established by well-controlled studies of pain relief, anti-pyresis, anti-inflammatory, or side effects.* (CX 456M) [emphasis added]

448. And in 1976, Dr. George Goldstein, then Vice-President and Medical Director of Glenbrook Laboratories division of [110] Sterling, submitted comments to the OTC Analgesics Panel on its Draft Report. The Panel had classified buffered aspirin claims in Category III, which includes those claims for which available data were found to be insufficient to permit final classification. Dr. Goldstein urged that claims of superiority based on increased rate of absorption, decreased incidence of gastric distress or the inference of greater safety for buffered aspirin products be placed in Category II, requiring sufficient clinical demonstration before asserting the claim. As he explained "... getting into the bloodstream faster is only important if one has painful blood." (CX 574C-D). Thus, Dr. Goldstein reasserted Sterling's position held over the past 25 years—that nonclinical data, even blood level studies, are not sufficient to support claims of therapeutic superiority in light of available clinical trial methodology.

449. The FDA Monograph Panel on OTC Internal Analgesics, Antipyretic and Antirheumatic Products (or FDA Analgesic Panel), has incorporated these principles and requirements for well-controlled clinical studies into its Final Report published in July 1977 (CX 466, pp. 35371, 35444-45). Since the mid-1960's the FDA, in regulations promulgated pursuant to the 1962 Food, Drug & Cosmetics Act, has codified many of these principles into its regulations mandating the need for "substantial evidence" to support efficacy claims for new drugs (21 C.F.R. 314.111(a)(5)(ii)(a) through (c); 330.10(a)(4)). However, the record shows that during the period from 1963 through 1971, there was no FDA requirement with respect to currently marketed OTC drug products (such as aspirin products) that their efficacy be demonstrated through well-controlled clinical trials.

450. Apart from the fact that the medical scientific community has long recognized and accepted the need for clinical demonstration for drawing therapeutic conclusions, it is fair and reasonable, given respondent's familiarity with the standard and past recognition of its

feasibility, that it should be held to the same standard in the instant proceeding.

451. During the trial, however, Sterling vigorously advanced a position which would apply different standards of substantiation to therapeutic superiority claims for buffered or combination aspirin products on the one hand, and similar claims for plain 5-grain aspirin on the other. With respect to the former, Sterling would insist on well-controlled clinical studies. As to the latter, including therapeutic superiority claims for Bayer Aspirin and Bayer Children's Aspirin, Sterling would accept evidence of pharmaceutical or physicochemical differences between brands as adequate substantiation in the absence of well-controlled clinical studies. Indeed, Sterling contended that the FDA has modified its requirements for well-controlled clinicals to demonstrate efficacy and safety of drugs to accept or prefer nonclinical data, such as bioavailability [111] data (blood level data and dissolution/absorption data) in similar cases involving pharmaceutical equivalents such as plain 5-grain aspirin tablets. See RPF 7.1-7.459, 7.472-7.665, 7.696-7.754, 7.755-7.785, 7.786-782.

452. I have carefully reviewed the record as a whole and find Sterling's contentions unpersuasive. *First*, the record is clear that a proposition of therapeutic superiority of one brand of plain 5-grain aspirin over another correctly formulated brand based solely on physicochemical differences remains a hypothesis to be clinically tested even though the hypothesis may appear rational and plausible in terms of pharmaceutical and pharmacological principles. *Second*, even in terms of pharmaceutical and pharmacological principles, the inference to be drawn from physicochemical difference is often a matter of degree. The record also indicates not only that some physicochemical characteristics of plain aspirin tablets, such as dissolution, may have a greater bearing on the therapeutic performance of the tablet than other characteristics, but also that some of the desirable characteristics are mutually antagonistic, in the sense that one can be enhanced only at the expense of some of the others. Even in cases where statistically significant differences in some physicochemical characteristics are shown, the central question of whether such differences in themselves are sufficient to make a significant therapeutic impact *in actual use* can be resolved only through well-controlled clinical trials. The oft-heard assertion that, other things being equal, a plain 5-grain aspirin brand which is better than other brands in terms of one or more physicochemical characteristics is preferable is begging the question. *Third*, the various physicochemical studies of plain 5-grain tablets Sterling relied on at trial are equivocal or suggestive only or unreliable because of serious deficiencies in the design, execution and/or analysis of the studies or failure to show statistical signifi-

cance or because of serious doubts regarding the therapeutic significance of the observed differences (*e.g.*, blood level studies as a basis for comparative efficacy claims of aspirin products).

453. Since the early 1960's there has been little dispute in the biomedical scientific community that the efficacy and safety of drugs must be demonstrated by well-controlled clinical studies, including appropriate replication. The record shows that Sterling has subscribed to this view. In recent years, a vocal dissent from that position has emerged, mainly from those who believe that the strict FDA requirements are exacting excessive costs in terms of research and economic resources and speedy introduction of safe and effective new drugs. They urge that other less costly alternatives must be accepted. However, the dissent represents a minority view in the United States. It is found that the need for clinical demonstration becomes more acute when the issue is of comparative efficacy or safety. [112]

454. There appears to be a paucity of literature regarding the requirement of well-controlled clinical trials with respect to pharmaceutically equivalent drugs, such as plain 5-grain aspirin tablets. In the administrative law judge's view, a common sense explanation of this fact is that scientists generally believe, as a basic proposition, that pharmaceutical equivalents are therapeutic equivalents until the contrary is shown to be the case with respect to any given product. Thus, those who claim therapeutic superiority of one product over other pharmaceutical equivalents (for example, plain 5-grain aspirin tablets) must demonstrate the therapeutic superiority of that product through well-controlled clinical tests. Until this has been done, the superiority claim remains unsubstantiated. Complaint counsel's expert witnesses supported this view.

455. There is little dispute in the record that drug product quality is important because it can significantly affect the drug's therapeutic performance. It is the administrative law judge's view that the improvement of drug quality should be encouraged as a matter of public policy not only for this reason but also for its own sake.

456. On the other hand, those who claim superiority in terms of drug product quality (pharmaceutical superiority) must have and rely on adequate substantiation. In the case of plain 5-grain aspirins, such substantiation must include a scientifically and statistically sound comparative study of a representative sample of plain 5-grain aspirin brands which shows statistically significant differences that are also clinically significant.

457. A cornerstone of Sterling's evidence in support of its position that a claim of therapeutic superiority of Bayer Aspirin over other brands of plain 5-grain aspirin does not require clinical demonstration is the expert testimony of Dr. Alvan R. Feinstein, now Professor

of Medicine and Epidemiology at Yale and an expert in the history and use of well-controlled clinical trials as a method for evaluating the clinical effectiveness of drugs, and a number of published articles on the subject of controlled clinical trials Dr. Feinstein discussed during his testimony.

458. Although Dr. Feinstein's position appeared somewhat ambivalent, the conclusion of his testimony was that well-controlled clinical trials are the best way of establishing a therapeutic proposition. However, in Dr. Feinstein's view, that requirement has turned into an inflexible dogma and there is a need to develop alternative ways of evaluating therapeutic conclusions in cases where randomized controlled clinical trials are not feasible for well-founded and cogent reasons. Neither Dr. Feinstein nor any of the published literature he discussed suggested that controlled clinical trials should no longer be [113] required or that they be abolished for the purpose of establishing the comparative efficacy of one drug product over another. As a matter of fact, the most recent article Dr. Feinstein authored on this subject, "Editorial: Should Placebo-Controlled Trials Be Abolished?", *Eur. J. Clin. Pharmacol.* 17:1-4 (1980) (RPF 2.13(h)) is a succinct exposition of the fundamental rationale underlying randomized controlled clinicals and is a cogent defense of that requirement except for a few well-defined situations, which does not include the situation involved in this case.

459. Dr. Feinstein also testified that, where feasible, randomized controlled clinical trials are the preferred method of measuring therapeutic superiority, particularly where the therapeutic response is a primarily subjective entity such as pain (Feinstein, Tr. 16223). He further explained that "in making a therapeutic decision I would have a hierarchy of evidence. And in that hierarchy, direct evidence in clinical usage would have a higher position than physicochemical kinds of evidence" (Feinstein, Tr. 16380).

460. Even in clinical usage as identified by Dr. Feinstein, there is some gap in patients' pain responses and blood level data. Although a threshold blood level must be achieved before analgesic action begins, that level is subject to a wide variation among individuals. It is also well recognized that a correlation between blood levels and the onset, duration, or intensity of pain relief has yet to be shown. However, there is an even wider gap between actual clinical effect and the drug's physicochemical characteristics (such as rate of dissolution, disintegration, amount of impurities, particle size, aspirin content and tablet color). In fact, any such relationship remains hypothetical until it is demonstrated through clinical trials.

461. On the other hand, Sterling's pharmaceutical expert witnesses were more emphatic in their support of the proposition that physico-

chemical data is sufficient to support a conclusion of comparative efficacy of plain 5-grain aspirin brands. They include Drs. G.S. Banker and C. Rhodes, both well recognized pharmaceutical scientists. They testified to their own views and also discussed a number of pharmaceutical studies in evidence as well as a large amount of published material in the field of pharmaceutical sciences.

462. The burden of the testimony of Drs. Banker and Rhodes was that it was reasonable to make a comparative "therapeutic judgment" regarding different formulations of the same drug (such as plain 5-grain aspirin) solely on the basis of the differences in the various physicochemical characteristics among brands. They suggested that controlled clinical trials are superfluous and unnecessary in cases where, as in the case of plain 5-grain aspirins, physicochemical evidence alone can [114] provide an adequate basis for making a comparative "therapeutic judgment."

463. Sterling also presented the testimony of a few clinical pharmacologists who are also medical specialists. Essentially, they testified that the physicochemical data and the bioavailability data in evidence, together with other medical scientific literature they discussed at trial, provided a sufficient basis for making a comparative "therapeutic judgment" regarding Bayer Aspirin and other aspirin brands. Such expert witnesses include Dr. I.E. Danhof (a physiologist with special interest in gastroenterology) and Dr. W.C. Fields (a neurologist). Several company witnesses also testified in support of Sterling's position discussed in the preceding paragraphs.

464. In its proposed findings and post-trial brief, Sterling elaborated upon its "policy" and argued essentially that randomized controlled clinical trials, while appropriate for comparative efficacy or safety claims involving combination or buffered aspirin products, are not appropriate for comparative therapeutic claims involving different brands of plain 5-grain aspirin (RPF 7.811-7.825; RB 211-229).

465. On the other hand, complaint counsel's expert witnesses, who are eminently qualified in the field of analgesic testing, testified that while pharmaceutical and pharmacological principles, together with clinical observations, can suggest an hypothesis involving a comparative therapeutic proposition, it remains an hypothesis until it is verified and confirmed by well-controlled clinical studies. I find this view more logical, consistent and persuasive than the view advanced by respondent's experts. Although the FDA-OTC Analgesic Panel did not deal with comparative efficacy of different brands of plain 5-grain aspirin, it adopted a similar approach with respect to the question of buffered aspirin products. Faced with a substantial amount of literature and expert presentation suggesting the benefits of buffered aspirins, the Panel concluded that the proposition remains unproven

until conclusively demonstrated by well-controlled clinical studies and they disallowed label claims of greater safety of buffered aspirin tablets. That approach is applicable here with respect to alleged therapeutic superiority of Bayer over other USP aspirin tablets based on physicochemical differences alone. *See* CX 466 at 35469–70, 35480.

466. Robert John, former Medical Director of Glenbrook Laboratories, testified that there is an expectation in the scientific community that where a claim for therapeutic superiority is made it will be supported by clinical evidence [115] (John, Tr. 5661). He believed that claims for therapeutic superiority had to be supported by evidence showing a statistically significant clinical difference between drug products (John, Tr. 5570, 5661). Because there was no such evidence, he would have withheld approval of any advertising claim for therapeutic superiority for Bayer Aspirin (John, Tr. 5586–87). His understanding of the Bayer advertisements he reviewed while at Bayer was that they did not contain any therapeutic superiority claims and contained only pharmaceutical quality claims (John, Tr. 5586–87).

467. Various attempts to measure the simple and comparative efficacy of mild analgesics other than well-controlled clinical trials have not been shown sufficiently reliable to establish simple or comparative efficacy in humans.

468. The fact that an OTC internal analgesic product may contain a combination of ingredients, or more ingredients than another OTC analgesic product, is not acceptable evidence that it is more effective (CX 456M). In order to conclude that one analgesic—even with more ingredients—is more effective than another, one needs well-controlled clinical studies.

469. No correlation has yet been established between the amount of drug appearing in the bloodstream at some time point and the degree of pain relief afforded by an analgesic (CX 678, admission 722). Therefore, “blood level” studies, *i.e.*, studies that simply examine the amount of a drug in the bloodstream at various time intervals following ingestion of a product, are not a reliable basis for predicting comparative analgesic performance. Thus, studies which are limited to a showing that one analgesic preparation is absorbed more rapidly than another cannot support conclusions regarding the onset, duration or intensity of analgesic action of drugs. *See* F. 502, *infra*.

470. Studies employing experimental pain, *i.e.*, pain induced in humans in the laboratory, are insufficiently reliable for use in establishing the comparative efficacy of OTC internal analgesics. Experimental pain studies have failed to predict with any consistency the clinical performance of analgesic drugs, particularly those used for OTC medication (CX 466, p. 35444).

471. Consumers’ perceptions are not reliable evidence to establish

the efficacy or comparative efficacy of OTC internal analgesics because consumers cannot "evaluate" for themselves [116] the simple or comparative pharmacologic efficacy of drugs (DeKornfeld, Tr. 8421). The inability to "evaluate" refers to consumers' inability to distinguish the pharmacologic contribution supplied by a drug from a host of factors that are extraneous to the drug's true pharmacologic effect.

472. Expectations concerning the performance of drugs are an important extraneous factor and they play a powerful role in influencing the response of test subjects to drugs. Such expectations are directly affected by other extraneous factors such as the subject's general disposition, past experience with the drug, relationship with the physician or nurse administering treatment, the size, shape and taste of the pill taken and advertising the subject has seen (Feinstein, Tr. 16289).

473. Consumers on an unblinded basis cannot differentiate between a true pharmacologic response and a response due to extraneous factors, such as suggestions or expectations, that surround the taking of the drug. The influence of extraneous factors is often sufficient to cause even blinded subjects in a controlled test to report pain relief in the absence of any pharmacologic action of a drug (Moertel, Tr. 6544; DeKornfeld, Tr. 8405). Frequently described as the "placebo effect," these nonspecific factors alone are typically reported in scientific literature as producing pain relief in over 30-50% of subjects involved in controlled analgesic studies (Moertel, Tr. 6544; Feinstein, Tr. 16322). Furthermore, anyone on any occasion can be a "placebo responder" (DeKornfeld, Tr. 8405). Expectations and similar factors, and hence the "placebo effect," cannot be entirely eliminated from any situation where a human suffers pain. However, well-controlled clinical studies can control such expectations by ensuring that the treatments under study are equally affected by them (F. 427-430, *supra*).

474. It has not been established that Bayer is superior to any other plain 5-grain aspirin in terms of pain relief.

475. RX 450, "A Comparative Study of Five Proprietary Analgesic Compounds" ("Lasagna-DeKornfeld Study") was conducted by Drs. Louis Lasagna and Thomas DeKornfeld with Todd Frazier, a biostatistician. The purpose of the study, undertaken at the request of the FTC, was to determine if superior pain relief claims by any of the manufacturers of ITC internal analgesic products could be substantiated by clinical evidence (DeKornfeld, Tr. 8332).

476. Though Sterling's expert witnesses criticized the methodology applied by Lasagna-DeKornfeld in light of present day techniques, the record shows that, at the time it was published, respondent was not

only aware of the study (John, [117] Tr. 5546-47) but found it reliable. In fact, respondent relied upon it in advertising to support certain claims (CX 678, admission 713), and cited the study in formal complaints made to the Federal Trade Commission against certain advertisements of its competitors (CX 678, admission 714).

477. The Lasagna-DeKornfeld study was designed to be randomized, placebo controlled and double-blinded. In this cross-over study, all the patients were given all the treatments. Its purpose was to compare the efficacy of five over-the-counter internal analgesics in relieving post-partum pain (DeKornfeld, Tr. 8333). Of the products tested, Bayer and St. Joseph's were plain 5-grain aspirins, Excedrin and Anacin were combination analgesics containing aspirin, phenacetin and caffeine, and Bufferin was aspirin plus buffers (DeKornfeld, Tr. 8333).

478. The study was published in a 1962 issue of the *Journal of the American Medical Association*, a respected medical journal, and was subjected to peer review prior to publication (DeKornfeld, Tr. 8351). The methodology used in the Lasagna-DeKornfeld study was fairly conventional for 1962 (Feinstein, Tr. 16388) when the study was published.

479. At the time the Lasagna-DeKornfeld study was done, there was no regulatory requirement that the raw data be retained. Such requirements were imposed as a result of legislation enacted in 1962 (DeKornfeld, Tr. 8351). The editors of the journal in which the study was published were provided with the underlying data prior to publication (DeKornfeld, Tr. 8356). However, the underlying data is no longer available (DeKornfeld, Tr. 8351).

480. Post-partum pain is one of a number of pain models generally accepted in testing mild analgesic agents (DeKornfeld, Tr. 8370). Dr. DeKornfeld agreed that patients with post partum pain might be suffering episiotomy pain or uterine cramp pain. His study did not stratify for these two different types of pain (DeKornfeld, Tr. 8373). However, the different groups were examined afterward to assure an even distribution of variables which might have affected scoring the performance of the drugs and concluded that stratification in fact had occurred as a result of simple randomization (Tr. 8445-48).

481. A potential problem in cross-over pain studies is the possibility that a patient's pain might decrease by the time a second or subsequent dose is administered. Because of its nature, post-partum pain tends to be steadier for a longer period of time than other types of pain (DeKornfeld, Tr. 8478), thereby minimizing this problem. [118]

482. The Lasagna-DeKornfeld study was designed to be double-blinded, but because its purpose was to compare brands of aspirin and aspirin compounds in their commercially available state, the drugs did not all look alike at the time of administration (DeKornfeld, Tr.

8374). The patients were given aluminum foil packets containing the different brands and every attempt was made to assure that the patients did not see what they were taking. Patients were instructed not to look at the medication, and either Dr. DeKornfeld or one of his associates was physically present when all medication was administered to guard against the patients seeing or handling the drugs given to them (DeKornfeld, Tr. 8375; CX 450B). Even though the investigator who supervised the administration of the medication did not know what particular drug was administered to any patient, the interviewing of patients and the recording of their subjective responses to questions about pain relief was never done by the one who had administered the drug (DeKornfeld, Tr. 8377).

483. A random number table was used to assign patients to different treatment groups (DeKornfeld, Tr. 8453; CX 450B).

484. The sequence in which a series of drug treatments is administered may cause the drugs to perform differently. Such "order effects" were discovered in the 1960's by a group in New York led by Drs. Kantor and Sunshine (DeKornfeld, Tr. 8477). They determined that such effects can be significant in cross-over studies where each participant receives each of the tested drugs and that such effects could be eliminated by doing a "first dose" analysis. Data from the first dose, by definition, could not be influenced by the effects or the order of any subsequent treatments. Having been designed and executed prior to the discovery of order effects, the Lasagna-DeKornfeld study did not include a first-dose-only analysis (DeKornfeld, Tr. 8477).

485. In RX 450 pain relief scores were recorded at intervals of 15, 30, 45, 60, 120, 180 and 240 minutes after administration of drugs (RX 450B). As between the two 5-grain aspirin tablets tested in the study (St. Joseph's and Bayer), mean pain relief scores reflected no statistically significant difference for any of the time intervals (Table 1, RX 450B). In testimony about the results of the study, both Dr. DeKornfeld and Dr. Feinstein found the table confusing to read (DeKornfeld, Tr. 8503-04; Feinstein, Tr. 16405). Each concluded upon first review that the mean pain relief score for Bayer at 120 minutes was statistically significantly higher than that for St. Joseph's. Upon closer scrutiny, however, Dr. Feinstein stated that he was not quite sure although some of the data presented therein appeared to be "consistent with" an inference of a statistically significant difference. [119]

486. Dr. Feinstein agreed that the study does not show any clinically significant differences in therapeutic effectiveness between the products (Feinstein, Tr. 16397, 16437). A clinical difference is one "large enough to be really impressive" (Feinstein, Tr. 16397). Even assuming that the differences in mean pain relief scores were statistically significant, they would not be "really impressive" enough to

have clinical significance (Feinstein, Tr. 16397). Dr. Feinstein concluded that the study, as a whole, does not show a clinically significant difference in therapeutic effectiveness between Bayer and any other aspirin (Feinstein, Tr. 16437).

487. Although the Lasagna-DeKornfeld study is not free from shortcomings, it nevertheless demonstrates two points: (1) it shows that at the time the study was done, randomized, controlled clinical trials on mild analgesics were feasible and being carried out by respected scientists; and (2) respondent was aware that the results of the study found no clinically or statistically significant differences among the brands tested and respondent relied on those results in its advertising as well as in its formal complaints to the FTC.

488. Furthermore, the essential findings of the study themselves—no clinical difference between Bayer and St. Joseph's—should be accorded some weight in this proceeding. The study was conducted by experts with impeccable qualifications. It was randomized, placebo controlled and double-blinded. Although the double-blind protection was not air-tight, and while additional clinical evidence based on other pain models would be necessary to arrive at firm conclusions, the study offers the only clinical evidence extant which addresses the issue of comparative efficacy between brands of 5-grain aspirin tablets.

489. It has not been established that Bayer is superior in terms of number or severity of side effects to any other aspirin.

490. Clinical trials are appropriate to evaluate the relative safety of mild analgesics. Animal studies on side effects of drugs can be valuable in finding areas of possible side effects in humans, but just as efficacy for pain relief must be tested in appropriate studies in human patients, so must side effects be determined on the basis of human studies (Grossman, Tr. 7459-60).

491. Aspirin is known to cause gastric discomfort or dyspepsia in some individuals who take it at OTC doses (CX 466, p. 35387). Dyspepsia is a subjective response which is not necessarily related to acute gastric erosion (CX 466, p. 35387). The incidence of dyspepsia in the general population [120] is estimated to range between 5-10% and the literature contains reports of clinical studies designed to measure the relative incidence of side effects among patients taking different formulations of aspirin. Respondent relies on a number of such studies to support claims of superior gentleness for its combination product, Vanquish.

492. Respondent presented no evidence of controlled clinical trials in which the incidence of side effects resulting from Bayer Aspirin was compared to that of any other brand of aspirin. However, it offered animal studies conducted by Dr. Ivan Danhof in which he

compared the effect of Bayer and other experimental formulations of aspirin on the gastric mucosa of dogs (RX 167; Danhof, Tr. 17377).

493. The purpose of Dr. Danhof's studies, which were carried out for Sterling and remain unpublished (Danhof, Tr. 17237), was to compare the incidence and nature of lesions in the gastric mucosa resulting from application of varying aspirin formulations. Dr. Danhof agreed that these studies did not provide a basis for conclusions about comparative degree of injury caused by Bayer and other aspirins because the comparisons did not involve any other commercial brands of 5-grain aspirin (Danhof, Tr. 17377). There is no indication in the report containing these studies whether the results of the studies or the differences shown were statistically significant (Danhof, Tr. 17373). Moreover, evidence of lesions on the gastric mucosa of a dog does not constitute evidence of clinically important side effects in humans. As Dr. Grossman explained, a lesion is a term for any abnormality found in a tissue and may have no clinical importance. Animal studies are merely the basis for hypotheses and cannot be used to establish a biomedical proposition (Grossman, Tr. 7460).

494. Given the absence of any controlled evidence in humans that Bayer causes side effects less frequently than other aspirin, it has not been established that Bayer is superior to any other aspirin because it results in fewer side effects.

495. It is reasonably clear from the record that no well-controlled clinical evidence exists in support of claims that Bayer Aspirin is therapeutically superior to other aspirin. Sterling also knew that the medical profession and the pharmacy profession universally believed, presumably because of a lack of adequate evidence showing differences, that all aspirin is the same (CX 329J). That view was clearly articulated in 1971 by Glenn Johnston of Glenbrook Laboratories in a position paper on Bayer (CX 678, admissions 132, 134). Therefore the claim that the therapeutic superiority of Bayer Aspirin has been established is false.

496. Because Bayer's therapeutic superiority has not been established according to the criteria recognized and adhered to [121] by qualified experts in the scientific community, the claim for such superiority was made in the face of a substantial question recognized by such experts as to its validity, as alleged in Complaint Paragraph 9.

3. Evidence Other Than Well-Controlled Clinical Studies Do Not Provide a Reasonable Basis For Therapeutic Superiority of One Brand of Plain Five-Grain Aspirin Over Another Brand

497. Various measures of comparative therapeutic performance of different brands of plain, 5-grain aspirin upon which Sterling sought to rely in this proceeding have not been shown to be sufficiently

reliable to provide a reasonable basis for a claim that Bayer Aspirin is therapeutically superior to other brands of plain 5-grain aspirin. They are not accepted by experts in the evaluation of analgesic agents as reasonable evidence of comparative clinical performance. These attempted measures not using controlled clinical trials fall into three categories: animal test data; *in vitro* data, *i.e.*, nonclinical data generated by investigations conducted in laboratory equipment; and human *in vivo* data, *i.e.*, nonclinical data generated by investigations in humans.

498. While expert witnesses called by Sterling addressed these various measures in their testimony, their conclusions that such evidence provides reasonable scientific support for therapeutic superiority claims are not well supported.

499. The *in vivo* data in the record consist of (1) serum salicylate level (or blood level) studies which compare different brands of aspirin tablets in terms of absorption into the bloodstream and (2) gastroscopic tablet disintegration data. There is no dispute that aspirin must be absorbed in order to relieve pain. However, no direct correlation has been sufficiently demonstrated between blood levels and pain relief in the case of aspirin. The gastroscopic comparison of disintegration in human stomach of various brands of aspirin tablets included in the Paul study (RX 168) may be called *in vivo* data. However, as detailed in later Findings, comparative tablet disintegration data do not provide a reliable basis for predicting the comparative therapeutic performance of different brands of plain 5-grain aspirin tablets. Furthermore, the question of whether the nature of an aspirin tablet's dispersion, *i.e.*, breaking up into fine or coarse particles, is directly related to side effects associated with aspirin ingestion remains unsettled.

500. The *in vitro* data in the record include pharmaceutical data comparing different brands of plain 5-grain aspirin in terms of: (1) rate of dissolution; (2) rate of tablet disintegration; (3) aspirin content per tablet; and (4) amount of free salicylic acid ("FSA"), and other impurities such as [122] aspirin anhydride ("ASAN"), acetylsalicylsalicylic acid ("ASSA"), and salicylsalicylic acid ("SSA").

Blood Levels

501. Like many drugs, aspirin acts in humans by circulating in the bloodstream (Banker, Tr. 13033, 13045, 13057; Rhodes, Tr. 11539, 11751; CX 466, p. 35374). Therefore, it must be absorbed into the bloodstream before pain relief can occur following ingestion of aspirin (Miller, Tr. 6742; Rhodes, Tr. 11539-87). In order to determine the rate and extent of aspirin absorption into the bloodstream, blood level studies are conducted (John, Tr. 5637). These studies measure the

serum concentration of aspirin in blood samples drawn from human subjects at various time intervals after taking aspirin (John, Tr. 5637).

502. For many drugs, the relationship between the drug's levels in the blood and the drug's clinical effect has been determined (CX 466, p. 35377). However, in the case of aspirin, no direct correlation has been demonstrated between the amount of aspirin appearing in the bloodstream at any time and the onset, intensity, or duration of pain relief afforded by aspirin. This fact has been attested to by expert witnesses in this proceeding (Moertel, Tr. 6290-91; O. Miller, Tr. 6740; Grossman, Tr. 7577; DeKornfeld, Tr. 8408-11, 8414; Banker, Tr. 12940, 12999, 13045, and 13057; Feinstein, Tr. 16479, 16481-82; Danhof, Tr. 17269). That this view is widely shared by the scientific community is evidenced by: (1) the report of the FDA Panel on OTC Internal Analgesics (CX 466, pp. 35359, 35361, 35374, 35377-78); (2) the 1971 and 1973 editions of the *AMA Drug Evaluations*—a journal recognized by respondent as a reliable source of information on drugs (CX 467A and 468B; CX 678, admission 1052); and (3) the *Medical Letter*, a recognized publication relied upon by physicians and other scientists for information relating to the performance of therapeutic agents (CX 460A, B; CX 678, admission 1046).

503. The FDA's regulations concerning the bioavailability and bioequivalence of prescription drugs (*Bioavailability and Bioequivalence-Requirements*, 21 C.F.R. 320), do not support respondent's contention that comparative blood level tests are accepted as sufficient basis for predicting the comparative therapeutic performance of different brands of plain 5-grain aspirin. The purposes of the FDA bioequivalence regulations are (a) to identify pharmaceutically equivalent drugs "that are intended to be used interchangeably for the same therapeutic effect and that are not bioequivalent drug products"; and (b) to establish a "bioequivalence requirement for these drug products" (21 C.F.R. 320.50). Thus, "pharmaceutically equivalent drugs" (*i.e.*, drug products that contain identical amounts of identical active ingredients, *see* 21 C.F.R. 320.1(c)) become a concern under the regulations only if they are not "bioequivalent drug products." [123]

504. For purposes of the FDA bioequivalence regulations, Bayer and other well-formulated plain 5-grain aspirin are not only pharmaceutical equivalents, but also bioequivalent drug products. The regulations define "bioequivalent drug products" as pharmaceutical equivalents (or alternatives) "whose rate and extent of absorption [*i.e.*, bioavailability] do not show a significant difference when administered at the same molar dose of the therapeutic moiety under similar experimental conditions. . . ." The regulations further note that:

[s]ome pharmaceutical equivalents or pharmaceutical alternatives may be equivalent in the *extent* of their absorption but not in their *rate* of absorption and yet may be considered bioequivalent because such differences in the *rate* of absorption . . . are considered medically insignificant for the particular drug studied. (21 C.F.R. 320.1(e) (emphasis added)).

505. Differences in the *rate* of absorption become “medically significant” under the FDA regulations (and are therefore viewed as “bioequivalence problems”) only if they “would result in therapeutic failure or a hazard to the patient” (42 FR at 1626). Only where such “medically significant bioequivalence problems” exist will pharmaceutical equivalents (such as Bayer and other plain 5-grain aspirin) be found “not bioequivalent” for purposes of the FDA regulations. (See generally, *Criteria and evidence to establish a bioequivalence requirement*, 21 C.F.R. 320.52.) The record does not show that because of any difference in the rate of absorption between Bayer and other correctly formulated plain 5-grain aspirin brands, “therapeutic failure or a hazard to the patient” may result.

506. According to the FDA, the bioavailability of a drug and its efficacy are separate and distinct issues:

It is not . . . the intent of a bioavailability study to demonstrate effectiveness. The purpose of a bioavailability study is to determine the rate and extent of absorption. If a drug product is not bioavailable, it cannot be regarded as effective. However, a determination that a drug product is bioavailable is not in itself a determination of effectiveness. The requirement of evidence of bioavailability is intended to supplement, not [t] replace, clinical evidence of effectiveness. 42 FR at 1640. [124]

* * * * *

The bioequivalence regulations are not an attempt to equate evidence of bioequivalence with evidence of relative therapeutic effectiveness . . . 42 FR at 1625 (emphasis added).

507. Respondent’s witnesses contended that the FDA’s willingness to accept nonclinical data such as dissolution data in connection with its bioavailability and bioequivalence regulations shows the FDA’s willingness to accept blood level tests or *in vitro* tests where the effectiveness of a class of drugs (*e.g.*, plain 5-grain aspirin) has been demonstrated (Rhodes, Tr. 11152–54; Banker, Tr. 12566, 13045). However, the FDA’s preference for evaluation techniques other than well-controlled clinical trials relates only to the determination of bioavailability or bioequivalence, not comparative effectiveness (42 FR at 1639, 1640). Since clinical tests are not designed to and do not measure the rate and extent of drug absorption, the FDA prefers that a more direct “accurate sensitive [and] reproducible” means of measurement be used where the issue relates to bioavailability rather than to the clinical effects of drugs on patients (42 FR at 1640). In requiring bioavailability data in New Drug Applications (“NDAs”) *in addition*

to evidence of effectiveness from clinical trials, the FDA explained that such data is "needed to assure that the dosage formulation intended for marketing has the same characteristics as the dosage formulation used in clinical trials to determine safety and effectiveness and that there is batch to batch consistency." (42 FR at 1639). Thus, clinical tests and bioavailability tests perform different, although complementary, functions. Preference for verification of bioavailability, using evaluation measures other than clinical trials, in no way suggests any relaxation of FDA's clear requirements that issues of safety and efficacy of drugs be determined in clinical trials.

508. The purpose of FDA's bioavailability requirements is to ensure that different batches of an approved drug fabricated by an approved manufacturer, or a chemically identical product fabricated by another manufacturer, be bioequivalent to the original product which had been approved on the basis of well-controlled clinical studies (42 FR at 1632). Therefore, the bioavailability requirements are inapplicable to the question in this proceeding of whether one brand of plain 5-grain aspirin is therapeutically superior to other brands.

509. Aspirin is quickly and easily absorbed into the bloodstream (Rhodes, Tr. 11658, 11750, 11756-58, 11778; RX 318, p. 1054). *In vivo* studies which simply show that one brand of plain 5-grain aspirin is absorbed into the bloodstream more [125] rapidly than another cannot support conclusions regarding the comparative speed, intensity, or duration of pain relief afforded by the tested brands. *See* F. 469, 502, *supra*.

510. Respondent was aware of the absence of a scientifically demonstrated correlation between aspirin's blood levels and its analgesic effects during the period of 1969-1974 (CX 678, 722, 723, 734). The medical director for Glenbrook Laboratories during the period of 1971-1971, Dr. John, testified to his knowledge of this characteristics of aspirin (John, Tr. 5567). The medical director for Glenbrook Laboratories from January 1975 through December 1976, Dr. George Goldstein, also testified to his knowledge of these characteristics of aspirin (Goldstein, Tr. 15608-09).

511. As early as 1957, respondent relied specifically on the absence of such a correlation in challenging competitors' advertising allegedly based on blood level comparisons of OTC analgesic products. In a June 7, 1957 complaint to the Federal Trade Commission, Sterling criticized a competitor's alleged reliance on comparative blood level data for therapeutic superiority claims made for its OTC analgesic product and stated: "... there is not a shred of scientific evidence to support the assumption that there is a direct relationship between the salicylate blood level and the actual relief of pain." (CX 371Z008-Z010).

512. Correspondence between respondent and its then advertising

agency indicates that respondent maintained the same view 13 years later. In the September 1, 1970 correspondence, James Luther of Sterling, recommended to Joseph Mack, an official of the advertising agency (CX 678, admissions 52-53), that the following statement be included in a complaint to the networks and the National Association of Broadcasters about a competitor's advertising (CX 347Z050).

As you well know, blood level studies are not scientifically accepted as the basis for claims pertaining to onset, degree or duration of pain relief. Proof derived from clinical trials is required and insisted upon by the FDA and others whose function it is to weigh and evaluate the sufficiency of analgesic claims. (CX 347Z044-Z046).

On September 18, 1970 Mr. Mack forwarded a complaint to a network about the same advertising (CX 347Z050-Z058), incorporating this passage from Mr. Luther's recommendation (CX 347Z055-Z058). On October 12, 1970, Mr. Mack forwarded to two other networks substantially the same complaint which also incorporated the same passage (CX 347Z059-Z066).

513. Subsequent correspondence between an official of respondent and its advertising agency shows that respondent [126] continued to rely on this scientific fact. In November 18, 1973 correspondence, a Sterling official stated that "... blood level clinicals have never been accepted as the basis for efficacy claims in the past. We know of absolutely nothing in the medical literature which suggests that a change in this position is warranted." (CX 376A and B).

514. In any event, the comparative blood level data in respondent's possession during the time period of 1969-1974 does not show significantly superior blood levels for Bayer.

515. Respondent relied on a study entitled "Absorption of Salicylate from Ingestion of Various Brands of Proprietary Tablets Containing Acetylsalicylic Acid," by Leon A. Greenberg, M.D. of Yale University Laboratory of Applied Physiology, and E.M. Jellinek (1947) (RX 163). The purpose of this test was to determine relative rates of absorption of salicylate following the ingestion of nine proprietary plain aspirin and combination aspirin tablets (RX 163C).

516. In this crossover study, the investigators measured total salicylate levels in blood samples drawn from nine healthy subjects 2, 5, 10, 15, and 20 minutes after ingestion of aspirin products. The record indicates that the test methodology is deficient in several respects: (1) an inadequate number of subjects (Rhodes, Tr. 11478, 11480); (2) the report's incompleteness, *i.e.*, the absence of graphs which are textually discussed (RX 163W and X; Rhodes, Tr. 11743); (3) the failure to measure aspirin levels (Banker, Tr. 13103); (4) the failure to isolate the source of blood level variations solely attributable to the tested

brands (RX 163R); and (5) the absence of reliability afforded by publication in a peer-reviewed journal (Banker, Tr. 12911).

517. Concerning the plain 5-grain aspirin brands, the investigators reached the following conclusions: (1) salicylate absorption occurs very shortly after ingestion; (2) the rate of salicylate absorption occurring within 20 minutes after ingestion varies among people; (3) within 2 minutes after ingestion, salicylate absorption occurred most frequently with Bayer and Walgreen brands and less frequently with St. Joseph brand; (4) 20 minutes after ingestion, salicylate levels were highest for Bayer and Walgreen and lowest for St. Joseph; (5) subjects who moderately or poorly absorbed salicylate also differentiated to a higher degree among brands than those who quickly absorbed; and (6) Bayer and Walgreen were statistically significantly superior and St. Joseph was statistically significantly inferior to the other brands in terms of ease of absorption (RX 163Z007-Z008). [127]

518. Even if this blood level test's deficiencies were disregarded, the utility of the test results is limited because of the admitted shortcomings of the statistical evaluation. One author stated:

Since there are many sources of variation involved in these tests the task is to isolate the several sources of variation and to arrive at the net variation due to differences in brands. I may state right at this juncture that the analysis leads only to an approximate isolation of different sources of variation, particularly since some of the sources cannot be estimated at all in the present experiment. (RX 163R)

The authors also state that no statistically significant difference was shown between Bayer and Walgreen with respect to ease of absorption (RX 163Z008; Rhodes, Tr. 11744-46). Although they found one brand to be statistically significantly inferior to the other brands, they did not state that other brands, *i.e.*, Whelco, Squibb, Puretest, and Certified, were also statistically significantly inferior (RX 163Z008).

519. Respondent also relies on "Absorption Study of Competitive Aspirin Products," by L. Amsel, an employee of respondent (March 17, 1972) (RX 418). The purpose of this study was to evaluate the absorption and bioavailability of competitive aspirin tablets (RX 418A).

520. In this study, the Sterling employee measured the aspirin and salicylate levels in blood samples drawn from six people at 7, 15, 30, 45, 60, 120 and 180 minutes after ingestion of Korvettes, St. Joseph, and Bayer aspirin tablets (RX 418A). Each brand was represented by two samples, one stored at room temperature and one stored for two months at 70° (RX 418A). The record indicates that the test methodology is deficient in several respects: (1) an inadequate number of subjects; (2) no information regarding the investigator's qualifica-

tions; (3) no information on the protocol; and (4) the absence of reliability afforded by publication in a peer-reviewed journal.

521. Amsel reported the following conclusions: (1) Bayer's peak plasma levels occurred at around 30 minutes while Korvettes' and St. Joseph's occurred at around 45 minutes; (2) of the samples stored at 70°, Bayer and St. Joseph yielded statistically significantly greater aspirin plasma levels than Korvettes at 30–120 minutes; (3) of the samples stored at room temperature, no statistically significant difference appeared among the brands; (4) for area under the curve, St. Joseph yielded about 50%, and Korvettes yielded 50%–75%, less than Bayer; (5) of samples stored at 70°, Bayer and St. Joseph yielded significantly greater salicylate plasma levels than [128] Korvettes at 45–180 minutes; and (6) for salicylate plasma levels, no apparent differences existed between Bayer and St. Joseph (RX 418A and B).

522. Analytical methods for yielding precise, sensitive blood levels have been available since the mid-1960's (Rhodes, Tr. 11055, 11835; Banker, Tr. 13055). The scientific literature contains reports, dating from the early 1960's of blood level tests which involved brands of plain 5-grain aspirin (Banker, Tr. 13046–56; Rhodes, Tr. 11788–91). The record indicates that four such articles appeared in peer-reviewed journals, *i.e.*, the *Clinical Pharmacology and Therapeutics*, and the *Journal of Pharmaceutical Sciences*, recognized by respondent's witnesses as highly respected (*see, e.g.*, Rhodes, Tr. 11077, 11140, 11180). At least one, "Aspirin Formulation and Absorption Rate II: Influence on Serum Levels of Tablets, Antacids and Solutions," *J. Pharm. Sci.*, Vol. 53, No. 12, December 1964, by Lieberman and Wood, reported a blood level test which involved more than one brand of plain 5-grain aspirin tablets (Banker, Tr. 13049).

523. During 1971–1974, the Medical Director of Glenbrook Laboratories characterized the blood level data in respondent's possession as "inadequate" to executives of Sterling (John, Tr. 5686, 5708).

524. Respondent also offered a report which appeared in "*In Vitro* Evaluation of Physiological Availability of Compressed Tablets," Wood, Vol. 42, No. 3, *Pharm. Acta. Helv.* (March, 1967) pp. 129–51 (RX 250–Wood). The author did not identify the brands whose comparative blood levels he discussed in the article (RX 250–Wood, pp. 133–34). The author identified the brands as Bayer and St. Joseph in an affidavit (RX 251) which incorporated the text of a March 22, 1978 letter to respondent's counsel (G. Goldstein, Tr. 15777–78). According to this affidavit, the author's article reported the results of the blood level study conducted by Stanford Research Institute. The author indicated that at 20, 45, 90, and 120 minutes, Bayer yielded statistical-

ly significantly superior blood levels to those yielded by St. Joseph (RX 250-Wood, p. 134).

525. Even if the comparative blood level data discussed above were considered to show that Bayer produced statistically significantly superior blood levels to those produced by other plain 5-grain aspirin brands tested, this data would not serve as a reliable basis for predicting the superior therapeutic performance of Bayer. Dr. Banker, respondent's expert witness, testified that statistically significant differences should be evaluated for their "operational significance" (Banker, Tr. 12905), meaning clinical significance. Since the clinical significance of aspirin's blood levels to its analgesic action has not been demonstrated, the comparative blood level data [129] reviewed here does not constitute a reliable basis for predicting the comparative therapeutic performance of different brands of plain 5-grain aspirin tablets (F. 469, 502, *supra*).

526. During the period of 1969-1974, certain official standards, adopted by the FDA pursuant to the 1962 amendment to the Food, Drug & Cosmetics Act, applied to the manufacturing and marketing of plain 5-grain aspirin tablets in this country. Compliance with these standards was a legal requirement for marketing of aspirin tablets by manufacturers and distributors (*see, e.g.*, Miller, Tr. 7176; Banker, Tr. 12601-02). These standards included requirements established by the United States Pharmacopeia Convention ("USP") and in the FDA's Good Manufacturing Practices regulations ("GMPs") (Banker, Tr. 12573). Both sets of requirements were subject to enforcement by the FDA (*see e.g.*, Miller, Tr. 6944-57; Rhodes, Tr. 11138; Banker, Tr. 12573-75).

527. The purpose of the USP standards for aspirin is to ensure that aspirin products manufactured in this country are of a certain level of pharmaceutical quality with respect to their composition, purity, potency, stability and safety (Miller, Tr. 6678; Banker, Tr. 12530). To this end, the USP has established standards for certain *in vitro* characteristics, such as disintegration, aspirin content, and FSA levels (Miller, Tr. 6733; RX 151C). The USP monograph for aspirin has undergone review and revision from time to time. For example, a dissolution standard for aspirin products was added in 1980 (Banker, Tr. 12735-39; RX 151).

528. The FDA's GMPs, 21 C.F.R. 133 (April 1, 1979), contain requirements of a more comprehensive and general nature concerning the quality of manufacturing practices employed by drug firms. They apply to the maintenance of manufacturing facilities and equipment, qualifications of personnel, quality control procedures, and stability testing. These requirements have also undergone review and revision. For example, an expiration date requirement for 5-grain aspirin was

added in 1976 (Banker, Tr. 12589). Pharmaceutical companies which manufacture or distribute solely OTC drug products, formerly exempt from the GMP regulations, recently became subject to these requirements (*see, e.g.*, Rhodes, Tr. 11618).

529. If a drug manufacturer or the FDA discovers a drug product failing to meet the USP standards or the GMPs, either the manufacturer or the FDA can initiate a recall of the product (Miller, Tr. 6941-42).

530. It is generally recognized that the FDA's compliance monitoring and enforcement programs have been very modest over the years, especially with respect to OTC drug products. However, the FDA regularly publishes bulletins and notices of recalls and seizures of drug products, including aspirin [130] products. The bulk of aspirin seizures have been due to failure to comply with the GMPs.

531. The fact that different brands of aspirin are required to meet official standards does not mean that they are in fact either therapeutically equal or unequal (Banker, Tr. 12600, 12848, 12892-93; Rhodes, Tr. 11130, 11189). GMPs do not address the issue of ultimate therapeutic effect (Miller, Tr. 6947; Banker, Tr. 12576). Official product standards or manufacturing standards do not measure drug efficacy (Miller, Tr. 6928; Rhodes, Tr. 11112, 11282, 11295). Such physical and chemical data alone do not guarantee effectiveness (Banker, Tr. 12702). Meeting official standards or achieving supra-official standards, while important and desirable, does not address the question of whether one brand of USP 5-grain aspirin is therapeutically superior to other brands.

532. In recent years, as a result of several highly publicized and serious instances of bioavailability problems involving important drugs and potentially life-threatening conditions (such as digoxin and certain antibiotics) the issue of physiological or biological equivalence (bioequivalence) of pharmaceutically equivalent drug products has come to receive much attention from the medical scientific community in general and the pharmaceutical research community in particular (RX 259-Skelly; RX 250-Hodges; RX 250-Castle; RX 250-Ad Hoc; RX 250-Copper).

533. This concern focusing on the issue of bioequivalence of pharmaceutically equivalent drug products (having identical active chemical formulations) spurred new research in the emerging sciences of biopharmaceutics and pharmacokinetics. Biopharmaceutics is concerned with pharmaceutical factors influencing the disintegration, dissolution, and absorption of active ingredients in drug products. This concern has led to a detailed and critical inquiry into the manufacturing technology and physicochemical elements which bear on drug dissolution and absorption, including materials and equipment,

fabrication and tableting technology, and quality control procedures. Pharmacokinetics is concerned with metabolism of active drug ingredients in the human body, including all the principal phases of absorption, biotransformation, distribution, tissue adhesion, excretion and elimination. This concern has led to a detailed and critical examination, often with the aid of new technology and procedures, of important metabolic characteristics of various drugs. As a result, the 1970's have produced an explosion in the bioavailability literature and brought about a heightened awareness of the bioavailability and bioequivalence issues not only among the academic and research community, regulatory agencies and the drug industry, but also among practicing pharmacists and clinicians (F. 532, *supra*; OTA Report, RX 158 [official notice was taken of RX 158]). [131]

534. At the request of the American Pharmaceutical Association made in December 1971 and June 1972, the Joint Ad Hoc Committee on Drug Selection of the Academy of the General Practice of Pharmacy and the Academy of Pharmaceutical Sciences compiled in October 1972, and published in June 1973, "An Annotated List of Drugs With a Potential for Therapeutic Inequivalence Based on Current Evidence of Drug Product Bioavailability Inequivalence." (RX 250-Ad Hoc). The preamble of the List stated in part:

Present evidence indicates that different products of certain drugs (e.g., different dosage forms or different brands, sources or lots of the same drug dosage form) may have a potential for therapeutic inequivalence due to differences in bioavailability even though these products meet existing judicial and compendial standards. This potential may be a result of inherent properties of the drug or dosage form, the materials and methods used in manufacture and/or the clinical circumstances in which they are used. Those drugs for which bioavailability data are available have been listed in a "high," "moderate," or "low risk" category based on the criteria and clinical implications noted . . . This list is intended only as an alerting system and is not suggested to provide all necessary information for these decisions.

535. The Ad Hoc Committee listed "aspirin (when used in high dose levels, *e.g.*, in the treatment of rheumatoid arthritis and rheumatic fever) particularly when given as enteric coated tablets" in the "high risk potential" category. The Committee's criteria for "high risk potential" is set forth as:

Drugs used in very critical therapeutic situations and which have documented evidence of inequivalency. Inequivalence may lead to serious adverse effects. (p. 280, stamped 29)

The Committee further explained the "implications" of a "high risk potential" listing as:

Selection of product for initial therapy should be based on documented evidence of optimal bioavailability or clinical effectiveness as compared to a reference product with well-established clinical efficacy. This information should be available to and evaluated by a knowledgeable [132] pharmacist. Product interchange during therapy should be done in consultation with the attending physician and then only when sufficient information is available to the pharmacist on the bioavailability of the substituted product and/or an adequate surveillance is possible by reliable measurements of clinical or pharmacologic response. (*Id.*).

536. In February 1977, the American Pharmaceutical Association published its first "Bioavailability Monograph on Aspirin." (RX 250-Mayerson). The APHA monograph notes the bioavailability of aspirin products and its clinical significance and states in part:

Since the salicylate elimination rate is a function of the dose ingested, relatively small increases in dose result in more than a proportional increase in body salicylate levels. For example, a twofold increase in the daily salicylate dose from 2 to 4 g may result in a fourfold increase in body salicylate levels. . . . This observation is particularly important in patients who require large daily aspirin doses for various chronic conditions, especially as the amount of drug in the body often approaches toxic levels. Under such conditions, minor changes in aspirin bioavailability have a profound influence on the patient's therapeutic status. As a result of this unusual dose-dependent pattern of salicylate accumulation, relatively small changes in dose or bioavailability produce marked and greater than expected changes in therapeutic response as well as increased toxicity.

537. The record also includes references to RX 250-Koch-Weser. J. Koch-Weser, "N.E. J. of Med., 291(10): 503-506 (1974), a brief review article, lists "Aspirin" in "Table 4. Drugs for Which Bioequivalence between Differing Products Has Been Demonstrated," (p. 504) and "Table 5. Drugs for Which Therapeutic Inequivalence between Different Products Has Been Demonstrated" (p. 505). However, Koch-Weser's textual discussion is clear that the author's reference to aspirin is limited to its use as "anti-inflammatory" drug at high dose levels (p. 505).

538. The record discussions of elimination kinetics of aspirin and its clinical implications are limited to chronic use of aspirin at very high and near toxic levels, far exceeding the maximum daily doses of aspirin recommended by the FDA's Panel on [133] OTC Internal Analgesic, Antipyretic and Antirheumatic Products (CX 466 at 35358).

539. In discussing RX 250-Koch-Weser, Dr. Danhof, respondent's witness, agreed that demonstration of statistically significant differences in the bioavailability of one drug product from another does not prove that these products' therapeutic performance would differ in a clinically important fashion (Danhof, Tr. 17270). Thus, bioinequivalence does not necessarily imply therapeutic inequivalence (Danhof Tr. 17270; RX 250-Koch-Weser, p. 504). Another witness for respondent

ent, Dr. Rhodes, stated that, if a bioequivalence problem exists for aspirin when taken for analgesia such a problem has not been sufficiently defined or documented (Rhodes, Tr. 11176).

540. The FDA has not promulgated a bioavailability monograph for plain 5-grain aspirin (Rhodes, Tr. 11812; Banker, Tr. 12932-33). Respondent's witnesses, Drs. Rhodes and Banker, disagreed over whether the FDA has informally considered aspirin, when taken for analgesia, as posing a potential bioavailability problem. Dr. Rhodes testified that in recent discussions with representatives of the FDA concerning bioavailability problems, these representatives did not express such a concern about aspirin (Rhodes, Tr. 11813). Dr. Banker testified that the FDA was "very concerned" about aspirin (Banker, Tr. 12555).

541. Thus, this record contains no reports of therapeutic inequivalence among different brands of plain 5-grain aspirin, meeting official standards, when taken for OTC use. In addition, the Medical Director of Glenbrook Laboratories during 1971-1974 was unaware of medical literature suggesting or concluding that therapeutically significant differences might arise among different aspirin brands which met official standards (John, Tr. 5657, 5692).

Dissolution

542. It is important to note here that, as important as the physico-chemical characteristics of aspirin tablet may be to dissolution and absorption, the bioavailability of aspirin in the human blood is also determined, to a great, if not greater degree, by the complex and infinite human variability among individuals. Such variables include, among others, age, body weight, stomach content pH, liver function, individual metabolic rate and characteristics, and urinary excretion. It is fair to say that even when the materials, fabrication and tabletting technology with respect to aspirin products are perfected, the question of bioequivalence and bioavailability, to *the extent it may exist with respect to aspirin* (i.e., high maintenance doses in the treatment of rheumatoid arthritis and rheumatic fever, especially with enteric-coated aspirin) is likely to remain. Hence, the paramount necessity for determination of optimal doses for each individual through careful titration by [134] physicians, when aspirin products especially the enteric-coated) are being used at high dose levels for the treatment of rheumatoid arthritis and rheumatic fever.

543. It is an accepted principle of biopharmaceutics that the manner in which an aspirin tablet or any other drug is manufactured, including its physical and chemical characteristics, may affect the speed and nature of disintegration as well as the dissolution rate of the drug in tablet form. There appear to be measurable differences in

the rates of disintegration and dissolution among aspirin brands. The more rapid the dissolution of an aspirin tablet, the more likely the rapid absorption into the bloodstream. There appear to be measurable differences in rate of absorption among commercially available 5-grain plain aspirin tablets. It is a known principle that the rate of dissolution of a tablet can be influenced by the manufacturing processes and methods of making a tablet and its physical and chemical characteristics (Danhof, Tr. 16934-36).

544. The significance of comparative dissolution data is best understood by a discussion of the series of events which must take place for a drug to go from the tablet into the patient's bloodstream. A tablet first enters the stomach, and disintegrates, forming a very fine cloud of particles. The drug then must dissolve in order to cross the wall of the gastric mucosa and enter the bloodstream. This is absorption. Because aspirin is a hydrophobic drug, absorption is rapid, and thus, the rate-deciding step in getting the drug from the tablet into the bloodstream (absorption) is dissolution. At first, disintegration tests were the only tests applied to compressed tablets. Subsequently, it became increasingly obvious that there were more important absorption differences between a number of different drug products which contain the same drug substance. Therefore, the dissolution parameter has become of increasing importance in recent years (Rhodes, Tr. 11433; Feinstein, Tr. 16480; Danhof, Tr. 17067).

545. It is a recognized principle that the rate of dissolution of an aspirin tablet is the controlling factor relating to the rate of absorption. Thus, the faster the dissolution of the aspirin tablet, the more likely the rapid absorption of the tablet into the bloodstream (Danhof, Tr. 16989, 16992, 17067, 17011-12, 17067; CX 466 at p. 35470). However, the methodology has not been developed whereby we can determine with precision the exact amount of salicylates in the bloodstream required in a given patient to produce pain relief. Respondent's expert witness testified that it is, therefore, appropriate to look at such factors as the dissolution rates of different brands of aspirin to make a judgment relating to their therapeutic performance (Danhof, Tr. 17101-06).

546. Complaint counsel's and respondent's expert witnesses agreed that it is a basic principle in medical science that in [135] order for a drug to provide therapeutic relief, it must be absorbed in such a manner that allows a minimum threshold level to be reached in the bloodstream (Rickels, Tr. 8033-34; Danhof, Tr. 17059, 17060).

547. The principle of a threshold for minimum effective concentration level in the bloodstream is recognized and frequently discussed in the scientific literature (Danhof, Tr. 17060). For example, in the article, Koch-Weser, "Therapeutic Importance of Bioavailability Fac-