

IN THE MATTER OF  
BRISTOL-MYERS COMPANY, ET AL.

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

*Docket 8917. 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 "Bufferin," "Excedrin," "Excedrin PM" or any other nonprescription internal analgesic has been proven to be safer and more effective than other pain relieving products, unless such claim has been substantiated by two well-controlled clinical tests. The manufacturer must have a reasonable basis to support claims of freedom from side effects, or any claim which represents that its pain relievers are therapeutically superior to others. The order prohibits respondents 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 identity of a product's analgesic ingredient. The manufacturer and the Ted Bates ad agency are further barred from claiming that doctors recommend Bufferin more often than any other pain reliever, or from otherwise falsely claiming any endorsement or recommendation for their products.

*Appearances*

For the Commission: *W. Benjamin Fisherow, Ira Nerken, Leslie R. Fax, Randell Ogg, James H. Skiles, Melvin Orlans and Teresa Hennessy.*

For the respondents: *Gilbert H. Weil, Gerald Guttman, Bruce R. Hafner and Lydia C. Russo, Weil, Guttman & Davis, New York City, for respondent Bristol-Myers Company. Gerald J. Brown and Donald Mulvihill, Cahill, Gordon, Sonnett, Reindel & Ohl, Washington, D.C. and Elhanan C. Stone, in-house counsel, for respondent Ted Bates and Company. Sidney S. Rosdeitcher and Ronald W. Meister, Paul, Weiss, Rifkind, Wharton & Garrison, Washington, D.C., for respondent Young & Rubicam, Inc.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Bristol-Myers Company, a corporation, and Ted Bates & Company, Inc., a corporation, and Young & Rubicam, 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 Bristol-Myers Co., 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 345 Park Avenue, New York, New York.

Respondent Ted Bates & Co., Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its principal office and place of business located at 1515 Broadway, New York, New York. [2]

Respondent Young & Rubicam, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its principal office and place of business located at 285 Madison Avenue, New York, New York.

PAR. 3. Respondent Bristol-Myers Co., is now and for some time last past has been engaged in the manufacturing, advertising, offering for sale, sale and distribution of certain non-prescription internal analgesic preparations which come within the classification of "drug", as said term is defined in the Federal Trade Commission Act.

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

1. *Designation:* Bufferin

*Active Ingredients:*

Acetylsalicylic Acid  
Aluminum Dihydroxyaminoacetate  
Magnesium Carbonate

*Directions for Use:*

DOSAGE: 1-2 tablets, 1-6 times daily as needed. For children 5-12, one-half dose.

2. *Designation:* Excedrin

*Active Ingredients:*

Acetylsalicylic Acid

Salicylamide  
Acetaminophen  
Caffeine

*Directions for Use:*

Adults, two tablets with water. Repeat if necessary every four hours or follow directions of your physician. Dosage should not exceed 8 tablets per day. For children (6-12) use half the adult dosage.

*Designation:* Excedrin PM

*Active Ingredients:*

Acetylsalicylic Acid  
Salicylamide  
Acetaminophen  
Methapyrilene Fumarate [3]

*Directions for Use:*

For best results take 2 tablets at bedtime to help relieve pain and aid sleep. May be repeated once, after 4 hours. For children (6-12) use half the adult dosage.

Respondent Ted Bates & Co., Inc., is now, and for some time last past has been, an advertising agency of Bristol-Myers Co., and now and for some time last past, has prepared and placed for publication and has caused the dissemination of advertising material, including but not limited to the advertising referred to herein, to promote the sale of Bufferin.

Respondent Young & Rubicam, Inc., is now, and for some time last past has been, an advertising agency of Bristol-Myers Co., and now and for some time last past, has prepared and placed for publication and has caused the dissemination of advertising referred to herein, to promote the sale of Excedrin and Excedrin PM.

PAR. 4. In the course and conduct of its aforesaid business respondent Bristol-Myers Co. causes the said drugs, 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 Bristol-Myers Co. maintains, and at all times mentioned herein has maintained, a substantial course of trade in said product in commerce. The volume of business in such commerce has been and is substantial.

PAR. 5. In the course and conduct of their said businesses, respondents Bristol-Myers Co., Ted Bates & Co., and Young & Rubicam, 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. 6. Typical of the statements and representations in said advertisements, disseminated as aforesaid, but not all inclusive thereof, are the following: [4]

A. By respondents Bristol-Myers and Ted Bates, for Bufferin:

1) The television commercial entitled "Solarization" opens with a surrealistic depiction of two women's bodies. One woman's stomach contains a tablet marked "A", and the other's, a tablet marked "B". In the illustration, the tablet marked "B" disintegrates more quickly than the other, and the disintegrated particles move more quickly to the head.

ANNOUNCER: What happens inside your system to plain aspirin and Bufferin? This illustrates most of Bufferin—with its extra speed is already going to your headache, when most of plain aspirin is still in your stomach. So with Bufferin, there's less to upset your stomach, when there's more pain reliever going to your headache. Bufferin—Faster to your headache. Better for your stomach.

2) The television commercial entitled "Camping" shows a family at a rustic camp site. The father does not appear to feel well as his children ask him to fix something and to take them into the canoe. A Bufferin bottle is shown, and the commercial then depicts a wrist watch cut in half to illustrate the statement that Bufferin goes to work in half the time. After taking Bufferin, the father again is shown with his children, returning from a fishing trip in the canoe. Instead of appearing to have a headache, he is happy and smiling.

GIRL: Daddy, breakfast's ready.

BOY: Hey, Dad, will you fix this for me? It got all tangled up.

GIRL: Daddy, when are you going to take me out in the canoe?

ANNOUNCER: What a time for a headache. You could take aspirin. But Bufferin goes to work in half the time. Half the time. Why? Because in the first critical minutes,

Bufferin speeds its pain reliever to your headache twice as fast as simple aspirin. So Bufferin goes to work in half the time. Half the time—that's Bufferin's time.

3) The television commercial entitled "Changing Face-Revised" opens showing a woman's face. At first, she is shown in the film negative and appears to have a painful headache. Gradually, the negative portions of the film disappear, and the woman begins to smile, her headache obviously gone. [5]

ANNOUNCER: Headache, every second can be a painful throb. Bufferin can change that fast, Bufferin goes to work fastest of the three leading headache tablets. Its pain reliever starts to your headache in just sixty seconds. Minutes later, relief without the stomach upset plain aspirin can cause. Of all leading brands you can buy, doctors specify Bufferin most. Faster, gentler, Bufferin.

4) The television commercial entitled "Arthritis/Applause" opens showing a grandmother with her grandchild at a concert. At the end of one musical piece, they begin clapping. However, the grandmother obviously finds clapping to be very painful because of arthritis in her hands. She takes two Bufferin tablets, and then is shown clapping with apparently no discomfort or pain.

GIRL: Didn't you like it, Grandma?

ARTHRITIC: I loved it, dear.

ANNOUNCER: Arthritis can do this. Its minor pain and stiffness can take a lot of enthusiasm out of hands, fingers. Take Bufferin. Doctors specify Bufferin for minor pain more than any leading brand of pain reliever you can buy. Tests published in medical journals show that in the first critical minutes, Bufferin delivers twice as much pain reliever as simple aspirin. Twice as much. Bufferin brings fast relief. Hours of relief from arthritis' minor pain and stiffness, so arthritic hands and fingers regain flexibility. And Bufferin can prevent the stomach upset aspirin often causes arthritic sufferers. For relief of arthritis' minor pain and stiffness, rely on Bufferin.

5) The television commercial entitled "College Professor" opens in a book-lined office, as a college professor is having a confrontation with a student militant. The student makes demands and the professor arranges a meeting for later in the day. The professor, who appears upset and emotionally involved in the situation, then takes two Bufferin tablets. He appears to become more relaxed.

STUDENT: Why don't you listen to us? This college has got to change.

PROFESSOR: Agreed.

STUDENT: But not your way.

PROFESSOR: All right. I've read it, Greg. Now can we keep our cool and all get together here at six?

STUDENT: Okay.

ANNOUNCER: Often, people who are sensitive to others can be more sensitive to headache pain. Bufferin is for these people. It's strong medicine that treats you gently.

Plain aspirin's fine, but Bufferin goes to work much faster, yet is gentler to your stomach. Because tough problems are tougher on sensitive people, we believe the strong medicine you need should treat you gently. Faster, gentler Bufferin. Strong medicine for sensitive people. [6]

6) The television commercial entitled "New Housing" opens with a government relocation official preparing to inform an elderly couple that their apartment building has been condemned and that they must move. He appears to be emotionally upset at the prospect of informing the tenants. In anticipation, he takes two Bufferin tablets. He then appears calmer and is shown smiling and telling the aged couple about their new home.

ANNOUNCER: What you have to tell them isn't easy. Not for you. Often, people who are sensitive to others, can be more sensitive to headache pain. They want all the help they can get as quickly as possible. Bufferin is for these people. It's better than plain aspirin because most of Bufferin has already started working at your headache when most of aspirin is still in your stomach.

MAN: That's the way it is. So you'll have to be out by Thursday.

OLD MAN: You know, our kids were born right here.

MAN: Wait'll they see your new place.

ANNOUNCER: Bufferin. For sensitive people. It's much better than plain aspirin.

7) The television commercial entitled "Father/Son" shows a father, mother and teenage son standing in a wooded area. The father shoots a rifle at a target and then offers the rifle to his son. The son states that he does not want it and walks away. The father appears angry and abruptly turns and fires the rifle. The mother tries to calm him by stating that the son does not believe he can shoot as well as the father. The scene then shifts inside the house where the son is shown looking out the window at his father, while the mother takes two Bufferin tablets. She then appears more calm and is shown moving towards her son, obviously attempting to console him.

FATHER: Go ahead, Son. Try it.

SON: I don't want to, Dad.

FATHER: I bought it for you. It's expensive. Now look.

MOTHER: You're such a good shot. He'll just feel inferior.

ANNOUNCER: Often, people who are sensitive to others can be more sensitive to headache pain. Bufferin is for these people. It's strong medicine that treats you gently. Plain aspirin's fine, but Bufferin goes to work much faster—yet is actually gentler to your stomach. We believe the strong medicine you need should treat you gently. Faster, gentler Bufferin. Strong medicine for sensitive people.

B. By respondents Bristol-Myers and Young & Rubicam, for Excedrin:

1) The television commercial "First Baby" shows a man sleeping in

bed. His pregnant wife wakes him and informs him that she is about to have the baby. He appears very nervous and [7] excited and has trouble finding his clothes and shoes. Finally, half dressed, he rushes out what he believes to be the front door, but which is really a closet, leaving his wife still in the house. The commercial then depicts the chemical formulae, but not the names, of Excedrin's four ingredients. One ingredient is described as giving "quick relief", one as giving "long lasting" relief, one as a tension reliever, and one as an anti-depressant.

ANNOUNCER: Excedrin headache Number 27. The first baby.

WOMAN: Honey, wake up.

MAN: I'm awake.

WOMAN: Let's go to the hospital.

MAN: You're going—

WOMAN: I'm ready.

MAN: You're going to have the baby?

WOMAN: Right away.

MAN: Are you? You're okay?

WOMAN: Everything's fine.

MAN: I just need my pants.

WOMAN: I have them.

MAN: I got my pants, honey.

WOMAN: Better put some shoes on, honey.

MAN: There they are. Oh, I've got the worst headache I've ever had. I got an Excedrin headache.

WOMAN: Oh, sweetheart, just a minute, I'll get you some Excedrin.

MAN: Would you, honey?

WOMAN: Here we are. And a little water.

MAN: And a little water.

WOMAN: That a boy. Easy.

MAN: OK now. Can't waste anymore time. Gotta go. I'll see you later, honey.

ANNOUNCER: The modern Excedrin formula gives you quick relief, long lasting relief, a tension reliever to relax you, an anti-depressant to help restore your spirits. Four ingredients, not just two. That's Excedrin. The Extra-Strength pain reliever.

2) The television commercial "Garner/Voodre/Arico" shows two women and a man describing how Excedrin helps them cope with everyday tense problems, such as fighting traffic and monetary trouble.

ANNOUNCER: These are Excedrin Headaches. Listen.

MRS. GARNER: You know, you have to drive back and forth fighting the freeway traffic and everything.

MR. VOODRE: Like I said, we've been having money problems.

MRS. ARICO: Being a mommy. (laughs)

ANNOUNCER: For Excedrin Headaches you want the Excedrin formula, with four ingredients, to relieve pain and its tension. [8]

MRS. GARNER: Well it's fast. Your headache doesn't come back.

MR. VOODRE: When you take two Excedrin you're able to cope with your problems a lot better.

MRS. ARICO: My biggest reason for buying it and using it is because it works for me.

MRS. GARNER: Well, it's extra strength. It does the job.

ANNOUNCER: Four ingredients. Not just one or two. That's Excedrin. The Extra-Strength pain reliever.

3) The television commercial "Miss Teresa Parkening" shows a young woman explaining how Excedrin relieved her headache quickly.

ANNOUNCER: What is an Excedrin headache? Listen.

TESTIMONY: Last night, as a matter of fact, I was at a recording session and they had, oh, so many strings and a Moog synthesizer and tympani players and gongs, and it was so loud, and I walked in there with a headache. So I took two Excedrin during one of the breaks, ten minute breaks, and it was gone. The sound was still loud but it went away.

ANNOUNCER: Excedrin works fast. It has a special ingredient for quick relief.

TESTIMONY: Something that works ZAP! It's really good.

ANNOUNCER: There are all kinds of Excedrin headaches, but there's only one Excedrin. The Extra-Strength pain reliever.

4) The television commercial "Snowdrift" shows snow blowing across a field. The audio describes how Excedrin is more effective for the relief of colds than other cold remedies.

ANNOUNCER: It's common about this time every year. And everyone seems to catch it. It's the common cold. But this year, you don't have to settle for common relief of its aches and pains. You can take Excedrin. It has more pain relievers, more fever reducers, more total strength than the common aspirin tablet. For the pains of the common cold, take Excedrin for uncommon pain relief.

5) The television commercial "Atlantic City" shows the actor David Janssen standing on a balcony overlooking Atlantic City, New Jersey. He describes a hospital study comparing Excedrin and aspirin.

DAVID JANSSEN: This is David Janssen. A hospital study has shown there may be something even more effective than aspirin for pain relief. At a medical convention held right here in Atlantic City, doctors heard the results of a new clinical study about how pain relievers perform among hospitalized patients. A study on pain, different, more [9] prolonged than headache pain. In this study it took more than twice as many aspirin tablets to give the same pain relief as two Excedrin. More than twice as many aspirin to be as effective as Excedrin. Not three aspirin, not even four aspirin. But more than double the recommended dosage of aspirin to give the same pain relief as two Excedrin. Yes, there may be something even more effective than aspirin. That's what this study among hospitalized patients showed. Two Excedrin were more effective for the relief of pain than twice as many aspirin. Isn't it time you tried Excedrin?



C. By respondents Bristol-Myers and Young & Rubicam, for Excedrin PM:

1) The television commercial "Difference" opens with the actor David Janssen.

DAVID JANSSEN: This is David Janssen. I'm not here to tell you about Excedrin. I'm here to tell you about Excedrin PM. They are different. Excedrin PM is the extra-strength nighttime pain reliever. Its special formula contains three pain relievers plus a mild sleeping aid. So it gives you extra-strength for relief from nighttime pain, and extra help to sleep. Two very good reasons to try Excedrin PM. The nighttime pain reliever.

2) The television commercial "Day into Night" opens on a scene showing several houses during the day. Gradually, night falls, and the lights in the houses go out one by one. Finally, one light is left, and it too ultimately is turned off.

ANNOUNCER: Daytime pain and nighttime pain can be different as day and night. Because at night, when it's quiet, even a tiny pain can hurt a lot. You could take a simple pain reliever. But it doesn't have anything extra to help you sleep. Excedrin PM does. It combines pain relievers with an additional ingredient to gently help you to sleep. Excedrin PM. The nighttime pain reliever.

3) The television commercial entitled "Sleeping Man" shows a middle-aged man sleeping peacefully.

ANNOUNCER: A short while ago, John Martin was too tense and achy to sleep. Nothing serious enough for a strong sleeping tablet. So he took Excedrin PM, a new nighttime formula from the makers of Excedrin. It combines pain relief with a special nighttime ingredient, that gently helps you sleep. Excedrin PM is a new idea. Excedrin PM. The nighttime pain reliever.

PAR. 7. Through the use of these advertisements, and others similar thereto not specifically set out herein, it was represented directly or by implication, [10]

A. By respondents Bristol-Myers and Ted Bates, that it has been established that:

- 1) Bufferin relieves pain faster than aspirin relieves pain;
- 2) Bufferin relieves pain twice as fast as aspirin relieves pain;
- 3) A recommended dose of Bufferin relieves twice as much pain as a recommended dose of aspirin will relieve;
- 4) Bufferin will not upset a person's stomach; and
- 5) Bufferin will upset a person's stomach less frequently than aspirin.

B. By respondents Bristol-Myers and Young & Rubicam, that it has been established that:

1) A recommended dose of Excedrin relieves more pain than a recommended dose of aspirin or any other non-prescription internal analgesic will relieve;

2) A recommended dose of Excedrin relieves twice as much pain as a recommended dose of aspirin will relieve;

3) Excedrin relieves pain for a longer period of time than a recommended dose of aspirin or any other non-prescription internal analgesic;

4) Excedrin relieves pain faster than aspirin or any other non-prescription internal analgesic relieves pain;

5) Excedrin reduces fever more effectively than aspirin;

6) Excedrin is a more effective pain reliever than aspirin or any other non-prescription internal analgesic;

7) Excedrin is a more effective pain reliever than aspirin or any other non-prescription internal analgesic because it contains four active ingredients;

8) A recommended dose of Excedrin PM will relieve more pain than a recommended dose of aspirin;

9) A recommended dose of Excedrin PM is more effective for the relief of pain which occurs during the night than a recommended dose of aspirin or any other non-prescription internal analgesic; and

10) Excedrin PM is a more effective pain reliever than aspirin because it contains three analgesic ingredients. [11]

PAR. 8. 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. 9. Furthermore, 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 Bristol-Myers and Ted Bates, that:

1) Bufferin relieves pain faster than aspirin relieves pain;

2) Bufferin relieves pain twice as fast as aspirin relieves pain;

3) A recommended dose of Bufferin relieves twice as much pain as a recommended dose of aspirin will relieve;

4) Bufferin will not upset a person's stomach; and

5) Bufferin will upset a person's stomach less frequently than aspirin;

B. By respondents Bristol-Myers and Young & Rubicam, that:

- 1) A recommended dose of Excedrin relieves more pain than a recommended dose of aspirin or any other non-prescription internal analgesic will relieve;
- 2) A recommended dose of Excedrin relieves twice as much pain as a recommended dose of aspirin will relieve;
- 3) Excedrin relieves pain for a longer period of time than a recommended dose of aspirin or any other non-prescription internal analgesic;
- 4) Excedrin relieves pain faster than aspirin or any other non-prescription internal analgesic relieves pain;
- 5) Excedrin reduces fever more effectively than aspirin;
- 6) Excedrin is a more effective pain reliever than aspirin or any other non-prescription internal analgesic;
- 7) Excedrin is a more effective pain reliever than aspirin or any other non-prescription internal analgesic because it contains four active ingredients;
- 8) A recommended dose of Excedrin PM will relieve more pain than a recommended dose of aspirin; [12]
- 9) A recommended dose of Excedrin PM is more effective for the relief of pain which occurs during the night than a recommended dose of aspirin or any other non-prescription analgesic; and
- 10) Excedrin PM is a more effective pain reliever than aspirin because it contains three analgesic ingredients.

PAR. 10. 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. 11. Furthermore, 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. 12. 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 Bristol-Myers and Ted Bates, that Bufferin relieves nervous tension, anxiety and irritability and will enable persons to cope with the ordinary stresses of everyday life,

B. By respondents Bristol-Myers and Young & Rubicam, that Excedrin and Excedrin PM relieve nervous tension, anxiety and irritability.

ty and will enable persons to cope with the ordinary stresses of everyday life, and

C. By respondents Bristol-Myers and Young & Rubicam, that Excedrin PM is an effective mild sedative.

PAR. 13. There existed, at the time of said representations, no reasonable basis for making the above representations, in that respondents had no competent and reliable scientific evidence to support such representations. [13]

PAR. 14. Furthermore, in advertising for Bufferin and Excedrin, respondents Bristol-Myers, Ted Bates and Young & Rubicam referred to the results of scientific tests or studies and the following representations were made directly or by implication:

A. By respondents Bristol-Myers and Ted Bates, that such tests or studies prove claims that Bufferin is twice as fast and twice as strong as aspirin in relieving pain; and

B. By respondents Bristol-Myers and Young & Rubicam, that such tests or studies prove claims that Excedrin is more than twice as strong as and more effective than aspirin in relieving pain.

PAR. 15. 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, concerning the validity, significance, or interpretation of such tests as they relate to such representations.

PAR. 16. Furthermore, respondents made said representations 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, respondents have failed to disclose material facts.

PAR. 17. Furthermore, in advertisements for Bufferin, and particularly through the use of the phrase "Doctors specify Bufferin for minor pain more than any leading brand of pain reliever you can buy," respondents Bristol-Myers and Ted Bates represented directly, or by implication, that physicians recommend Bufferin more than any other non-prescription internal analgesic products.

PAR. 18. There existed at the time of said representation no reasonable basis for making the above representation, in that respondents had no competent and reliable evidence to support such representation.

PAR. 19. Furthermore, respondents Bristol-Myers and Ted Bates marketed and advertised Bufferin and respondents Bristol-Myers and Young & Rubicam marketed and advertised Excedrin and Excedrin

PM, without disclosing in the advertising for such products that such products contain aspirin and that Excedrin contains caffeine. [14]

PAR. 20. In truth and in fact, aspirin and caffeine are well-known, commonplace substances, widely available in many products. Moreover, the use of aspirin or caffeine may be injurious to health and may cause undesirable side effects. Thus, respondents have failed to disclose material facts which, if known to certain consumers, would be likely to affect their consideration of whether or not to purchase such products.

PAR. 21. Furthermore, in advertisements for Bufferin, respondents Bristol-Myers and Ted Bates represented, directly or by implication, that the analgesic ingredient in Bufferin is other than ordinary aspirin; and in advertisements for Excedrin, respondents Bristol-Myers and Young & Rubicam represented, directly or by implication, that the ingredient giving "long lasting relief" is other than ordinary aspirin and that the "anti-depressant" is other than caffeine.

PAR. 22. In truth and in fact, the analgesic ingredient in Bufferin is ordinary aspirin; the ingredient giving "long lasting relief" in Excedrin is ordinary aspirin; and the "anti-depressant" in Excedrin is caffeine.

PAR. 23. Furthermore, in advertisements for Excedrin PM, respondents Bristol-Myers and Young & Rubicam have represented, directly or by implication, that it contains a special sedative or sleep-inducing agent available only in Excedrin PM.

PAR. 24. In truth and in fact, the substance referred to in the advertisement is methapyrilene fumarate, an antihistamine which is available in several other non-prescription preparations including, but not limited to, Cope, manufactured by Sterling Drug, Inc.

PAR. 25. The advertisements referred to in Paragraphs Seven, Nine, Fourteen, Nineteen, Twenty-One, and Twenty-Three were and are misleading in material respects as alleged in Paragraphs Eight, Eleven, Sixteen, Twenty, Twenty-Two, and Twenty-Four and constituted, and now constitute, false advertisements.

PAR. 26. The making of representations as alleged in Paragraphs Ten, Thirteen, Fifteen, and Eighteen constituted, and now constitutes, unfair or deceptive acts or practices in commerce. [15]

PAR. 27. The use by respondents of the aforesaid deceptive representations and the dissemination of the aforesaid false advertisements has had, and now has, the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said representations were and are true and into the purchase of substantial quantities of said drugs of respondent Bristol-Myers, by reason of said erroneous and mistaken belief.

PAR. 28. In the course and conduct of its aforesaid business, and at

all times mentioned herein, respondent Bristol-Myers has been, and now is, in substantial competition, in commerce, with corporations, firms and individuals in the sale of drugs of the same 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 Ted Bates 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 Young & Rubicam has been, and now is, in substantial competition in commerce with other advertising agencies.

PAR. 29. 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

SEPTEMBER 28, 1979

PRELIMINARY STATEMENT

On February 23, 1973, the Federal Trade Commission ("Commission" or "FTC") issued a Complaint charging Bristol-Myers Company ("Bristol-Myers"), Ted Bates & Company, Inc. ("Ted [2] Bates"), and Young & Rubicam, Inc. ("Y&R") 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 Bufferin, Excedrin and Excedrin P.M. Similar complaints were issued on the same date against American Home Products Corporation (Docket No. 8918) [98 F.T.C. 136 (1981)] and Sterling Drug Inc. (Docket No. 8919) [102 F.T.C. 395 (1983)], in connection with certain advertisements for certain nonprescription or over-the-counter ("OTC") internal analgesic products marketed by these firms.

On May 7, 1973, Bristol-Myers filed its answer to the Complaint, and on May 9, 1973, Ted Bates and Y&R filed their answers to the Complaint, each denying that it violated Sections 5 or 12 of the amended Federal Trade Commission Act. ALJ William K. Jackson, originally assigned to this proceeding, entered a Prehearing Order, dated March 13, 1974, setting forth the issues of fact and law to govern

the case. This case 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 by the parties.

By Order dated February 16, 1977, a joint hearing was ordered with respect to certain common marketing studies and witnesses for the presentation of complaint counsel's cases-in-chief in the three OTC internal analgesic cases (Docket Nos. 8917, 8918 and 8919). Joint evidentiary hearings were held from June 6, 1977 to August 15, 1977. The separate evidentiary hearings for the presentation of complaint counsel's case-in-chief were held from September 5, 1978 to February 21, 1979, after an initial decision in Docket No. 8918 was filed with the Commission. Respondents' defense hearings began on March 19, 1979 and continued until May 11, 1979. The evidentiary record was closed May 16, 1979.<sup>1</sup> The parties filed simultaneously their proposed findings, supporting memoranda and replies. Some 26 witnesses, most of whom were qualified as expert witnesses, testified. Transcripts of the joint and separate hearings number some 12,400 pages. Over 400 documentary exhibits, including copy tests, marketing studies and medical-scientific studies and analytical tabulations were received in evidence.

The proposed findings, conclusions and orders of the parties and their supporting arguments were carefully considered 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, irrelevant or immaterial. Any motion appearing on the record and not heretofore or hereby specifically ruled upon either directly or by the necessary effect of the conclusions in this Initial Decision are denied. Upon consideration of the [3] record as a whole and having considered the demeanor of the witnesses, I make the following findings of fact and conclusions of law and order:<sup>2</sup>

<sup>1</sup> By order dated May 23, 1979, the Commission extended the due date of this Initial Decision to September 28, 1979.

<sup>2</sup> For the purposes of this Initial Decision, the following abbreviations were used:

- BMF - Bristol-Myers' Proposed Findings.
- BMM - Bristol-Myers' Supporting Memorandum.
- BRM - Bristol-Myers' Reply Memorandum.
- CM - Complaint Counsel's Supporting Memorandum.
- CPF - Complaint Counsel's Proposed Findings.
- CRM - Complaint Counsel's Reply Memorandum.
- F. - Findings in this Initial Decision.
- Tr. - Transcripts of hearings, sometimes preceded by the name of the witness.
- CX - Complaint counsel's documentary exhibits.
- RX,
- BMRX- Bristol-Myers' documentary exhibits.

## FINDINGS OF FACT

## I. PRELIMINARY FINDINGS

1. Bristol-Myers Company ("Bristol-Myers") is a corporation organized 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 345 Park Avenue, New York, New York. Bristol-Myers manufactures, advertises, offers for sale, and sells and distributes certain nonprescription over-the-counter (or OTC) internal analgesic preparations which fall within the classification of "drug," as the term is defined in the Federal Trade Commission Act. The brand-name designations used by Bristol-Myers for three such preparations are "Bufferin," "Excedrin," and "Excedrin P.M." (Answer of Bristol-Myers, Paragraphs 2 and 3).

2. The active ingredients in one tablet of each of the three preparations are as follows:

Bufferin:	aspirin (5 gr.) aluminum glycinate magnesium carbonate
Excedrin:	acetaminophen (1.50 gr.) salicyclamide (2.00 gr.) aspirin (3.00 gr.) caffeine (1.00 gr.)
Excedrin P.M.:	acetaminophen (2.5 gr.) salicyclamide (2.00 gr.) aspirin (3.0 gr.) [4] methapyrilene fumarate (25 milligrams)

(Answer of Bristol-Myers, Appendices 1, 2, 3; CX 925R-U; CX 927B).

Aspirin is a well-known substance widely used in over-the-counter drug products (BMRX 23, 24). Caffeine is a well known substance widely used in food products and over-the-counter drug products (BMRX 23, 24).

3. In the course and conduct of its business, Bristol-Myers causes Bufferin, Excedrin, and Excedrin P.M. to be transported from its place of business located in various States of the United States to purchasers thereof in various other states and in the District of Columbia. In the course of its business, Bristol-Myers maintains, and at all times mentioned herein has maintained, a substantial course of trade in commerce (Answer of Bristol-Myers, Paragraph 1). From 1971 to 1973 annual consumer sales for Bufferin, Excedrin, and Excedrin P.M. averaged approximately \$50 million, \$30 million, and \$5 million respectively (CX 660A). The average price in 1970 for 100



tablet bottles of Bufferin and Excedrin was \$0.99 and \$1.01 respectively. The average price in 1970 for an 80 tablet bottle of Excedrin P.M. was \$1.30 (CX 661B-D).

4. In the course and conduct of its business, Bristol-Myers has disseminated, and causes the dissemination of, certain advertisements concerning Bufferin, Excedrin, and Excedrin P.M. by the United States mail and by various means of commerce including, but not limited to, advertisements inserted in magazines and newspapers, and in television broadcasts transmitted by television stations located in various States of the United States and 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 has disseminated, and caused the dissemination of, advertisements concerning said drugs by various means, including but not limited to the aforesaid medium, for the purpose of inducing and which were likely to induce the purchase of said drugs in commerce (Answer of Bristol-Myers, Paragraph 4). These activities have included the dissemination over a number of years and through various media of the advertising challenged in this matter, including the advertisements in evidence (CX 800; CX 801; CX 802).

5. In promoting these products in advertising from 1960 to 1973 Bristol-Myers expended over \$171 million for Bufferin, over \$98 million for Excedrin, and over \$15 million for Excedrin P.M. (CX 925P, CX 928B). Thus annual advertising expenditures between 1960 and 1973 have averaged approximately \$12 million for Bufferin, \$7.5 million for Excedrin, and \$3 million for Excedrin P.M. [5]

6. According to National Analgesic Market Survey prepared by Young & Rubicam, the advertising agency for Excedrin, the average prescription price at surveyed pharmacies of aspirin in 1971 was \$1.08 per hundred tablets. For the same year, the average prescription price per 100 tablets was \$2.15 for Bufferin and \$2.59 for Excedrin (CX 380Z003, Z001, Y). This survey finding is in accord with our common knowledge and experience which shows one ordinarily expects to pay, and does pay, somewhat higher prices for Bufferin and Excedrin than for plain aspirin at retail stores.

7. Young & Rubicam International Inc., formerly Young & Rubicam, Inc. ("Young & Rubicam") 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 place of business located at 285 Madison Avenue, New York, New York (Answer of Young & Rubicam, Paragraph 2).

8. In the conduct of its business at all times mentioned herein, Young & Rubicam has been in substantial competition in commerce,

with other corporations, firms, and individuals in the advertising business. Young & Rubicam maintains offices in the commercial centers of the country, including New York City, Detroit, Chicago, Los Angeles and Houston. Among its advertising accounts are some of the largest corporations throughout the United States, including Time, Inc., General Foods, Gulf Oil Corp., and Proctor & Gamble Co. (CX 656).

9. Ted Bates & Company, Inc. ("Bates") is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York with its principal office and place of business located at 1515 Broadway, New York, New York (Answer of Bates, Paragraph 2).

10. In the conduct of its business at all times mentioned herein, Bates has been in substantial competition in commerce, with other corporations, firms and individuals in the advertising business. Bates maintains offices throughout the world and in New York City to serve national and multi-national corporate clients. Among its clients are The Chase Manhattan Bank, ITT Continental Co., Warner-Lambert Co. and Yardley of London (CX 655).

II. THE QUALIFICATIONS OF EXPERTS WHO TESTIFIED  
IN THIS PROCEEDING

A. *Complaint Counsel's Experts*

*Dr. Daniel L. Azarnoff*

11. Dr. Daniel L. Azarnoff, presently Senior Vice-President, Director of Research and Development, for the three medically [6] related subsidiary companies of G. D. Searle and Company, is an eminent clinical pharmacologist (Azarnoff, Tr. 9159-60; CX 687A).

12. Until recently, Dr. Azarnoff was a Distinguished Professor in the field of Medicine and Pharmacology at Kansas University Medical Center where he served as Director of the University's Clinical Pharmacology-Toxicology Center (Azarnoff, Tr. 9160-61; CX 687A). He has received a number of honorary awards for his outstanding work in medicine and pharmacology, including election as a Markle Scholar in Academic Medicine, election as a Burroughs Wellcome Scholar in Clinical Pharmacology, and designation as a Fulbright Scholar (Azarnoff, Tr. 9165-68; CX 687B).

13. He has served as a consultant to the Food and Drug Administration, specifically a member of the Endocrine Metabolism Advisory Committee. In this capacity, he reviewed foreign therapeutic trials of various drugs to determine if this information should be accepted by the FDA in its evaluation of the safety of these drugs. He has also served as a consultant to the World Health Organization for the

evaluation of drugs in human beings, and is currently serving as Secretary of the Clinical Pharmacology Section of the International Union of Pharmacologists. He has been a member and Vice-Chairman of the AMA Council on Drugs; a consultant to various institutes of the National Institute of Health; and has consulted for several other medical organizations (Azarnoff, Tr. 9165-72; CX 687C).

14. As part of his work as a Distinguished Professor of Medicine and Pharmacology, Dr. Azarnoff teaches medical students, graduate students in pharmacology and practicing physicians. In addition to his extensive teaching commitments, he has also been involved in research activities and in clinical hospital service. His research has involved him in approximately 150 studies, 10 to 15 of which focused on the therapeutic effects of various drugs on human beings. His clinical hospital service has given him the opportunity to work with inpatients and outpatients alike (Azarnoff, Tr. 9162-65, 9174-76).

15. Dr. Azarnoff's clinical research has given him considerable exposure to the various ways of measuring patients' subjective responses. In each of the 10 to 15 therapeutical studies in which he has participated, he has been involved in all phases of the study, ranging from the initial development of the protocol through the execution of the study, and then on through the analysis and interpretation of the data (Azarnoff, Tr. 9164, 9174-75). Dr. Azarnoff has worked with drugs that influence the autonomic nervous system, drugs that influence the central nervous system, drugs that attempt to control angina, and aspirin, among others. In each of these clinical studies, he has been primarily concerned with the elevation of patients' subjective responses to the drugs in question (Azarnoff, Tr. 9164, 9174-75).  
[7]

16. Dr. Azarnoff is also an editor or advisor to a number of noted American and foreign journals (Azarnoff, Tr. 9170-72; CX 687C). As is evidenced by the evidentiary record and his *curriculum vitae*, Dr. Azarnoff is highly qualified to provide expert testimony in the fields of clinical pharmacology, clinical testing of drugs, including analgesics, and the usage of analgesics in the clinical situation.

*Dr. William Beaver*

17. Dr. William Beaver is presently an Associate Professor of Pharmacology and Anesthesia at the Georgetown University Schools of Medicine and Dentistry and is a recognized expert in the field of analgesics and clinical trials of analgesics (Beaver, Tr. 5896).

18. Dr. Beaver gained extensive expertise in analgesics studies while working as a research associate and then an associate at Memorial Sloan-Kettering Cancer Center with Dr. Raymond Houde between 1963 and 1968. Since 1963, Dr. Beaver has conducted clinical

research concerning analgesic drugs, and in 1976 he received a special citation from the Commissioner of the Food and Drug Administration for his advisory work in the area of analgesics and clinical trial design (Beaver, Tr. 5896).

19. Dr. Beaver has written extensively and has published several dozen analgesics studies in medical journals subject to peer review. In addition, he has written chapters in textbooks relating to analgesic drugs (Beaver, Tr. 5897). In 1965, he published in the *American Journal of Medical Science* a comprehensive review of the pharmacology of mild analgesic drugs. That article was based on submissions from manufacturers, including Bristol-Myers, and Dr. Beaver's review of some 1,000 papers on the subject, of which about 400 were directly cited in the review article (Beaver, Tr. 5897-99).

20. Dr. Beaver is one of the leading experts in the field of analgesics and clinical testing of analgesics (Laska, Tr. 10406-07; 10463, 10626; Sunshine, Tr. 9803, 9826-27, 9864).

21. Dr. Beaver served as a member of the Panel on Drugs for Relief of Pain, conceived in 1966 under the auspices of the National Research Council, a subsidiary of the National Academy of Science. The National Academy of Science, chartered by Congress, is an organization whose members are drawn from among the foremost scientists in the country. The purpose of this group is to provide the government with access to a prestigious group of scientists so as to further the development of science (Beaver, Tr. 5901). Members of the National Research Council are experts in various scientific/technical fields. At the request of the Federal Government, the group will sponsor [8] scientific inquiries where they view such inquiries as appropriate and in the national interest (Beaver, Tr. 5901).

22. The FDA, pursuant to various amendments to its enabling act, requested in 1966 that the NAS/NRC carry out an efficacy review of drugs put on the market between 1938 and 1962 (Beaver, Tr. 5900). This responsibility was accepted by the National Research Council. Panels for different subject areas were set up, consisting of six or seven members who were well-recognized experts in particular subject areas (Beaver, Tr. 5902).

23. The Panel on Drugs for the Relief of Pain, of which Dr. Beaver was a member, was given material which had been submitted by drug companies to FDA between 1938 and 1962 for new drug application approval (Beaver, Tr. 5903). This Panel was chaired by Dr. Louis Lasagna, a well-recognized clinical pharmacologist, and it included Dr. Beaver; Dr. Maurice Seevers, who was chairman of the Pharmacology Department at the University of Michigan; Dr. Thomas Kantor of NYU, who was experienced in the evaluation of mild

analgesics; Dr. Gravenstein, who was experienced in analgesic research; and Dr. William Martin, who was head of the Drug Addiction Center in Lexington (Beaver, Tr. 5903). The appropriate review panel for each drug was chosen by the central NAS/NRC office on the basis of the indications in its labeling. Materials on specific drugs were then assigned to a panel member based on his expertise and workload (Beaver, Tr. 5904). Dr. Beaver served as co-primary reviewer for Bufferin submissions (Beaver, Tr. 5910). The primary reviewer then considered the drug company data along with the archival literature, which included published and unpublished studies. New issues of safety were considered as were certain claims, *e.g.*, superiority, in light of any new information. A preliminary review was prepared and circulated to the entire Panel (Beaver, Tr. 5905). A final report was prepared by the Panel as a whole. Final editing was done by the NAS/NRC central office (Beaver, Tr. 5906). The final approval prior to release to FDA was then secured from the Panel chairman.

24. Bufferin was among the drugs considered by the Panel since it was granted a New Drug Application ("NDA") between 1938 and 1962. Bristol-Myers was asked to submit literature references with respect to indications in labeling, but initially did not submit any literature references (Beaver, Tr. 5907-08). Because the Panel believed that certain Bufferin claims in labeling went beyond accepted indications for aspirin, another letter was sent to Bristol-Myers requesting substantiation for claims addressing speed of onset of action, lack of gastrointestinal side effects and tension relief. In response, Bristol-Myers submitted reprints of published articles and certain in-house, unpublished blood level studies dealing primarily with the pharmacokinetics of Bufferin compared to other aspirin. These materials and the published literature were reviewed by Dr. Beaver and Dr. Seevers, the co-primary [9] reviewer. Bristol-Myers was only required to submit evidence that supported its claims for Bufferin, rather than *all* pertinent data relating to a particular indication, whether favorable or not (Beaver, Tr. 5909-11).

25. A draft report was prepared by Drs. Beaver and Seevers and was submitted for the approval of the entire Panel (Beaver, Tr. 5911-13). When the final report was approved after editing, it was turned over to the NAS/NRC and forwarded to FDA (Beaver, Tr. 5915).

26. Based on these reports, FDA set up a Drug Efficacy Study Implementation (DESI) group to address what should be done with respect to the issues raised in the various reports, such as CX 511 (Beaver, Tr. 5916). The Panel's evaluation (CX 511) was published in the *Federal Register* (Beaver, Tr. 5917-19) and a copy was sent to Bristol-Myers (Beaver, Tr. 5919).

*Dr. Byron William Brown*

27. Dr. Byron Brown holds a Ph.D. degree in biostatistics from the University of Minnesota. Currently he is Professor and Head of Biostatistics at Stanford University (Brown, Tr. 4843-45; CX 694). Dr. Brown is involved in academic duties and is consulting with research investigators, the Federal Government and pharmaceutical manufacturers in problems involving research in biology and medicine (Brown, Tr. 4845).

28. Dr. Brown's primary interests center on the application of biostatistics to biological assays and related clinical trials. However, his statistical consultancies involve him in joint efforts with investigators in other fields of biology and medicine (Brown, Tr. 4846). For example, Dr. Brown is a consultant to the National Academy of Sciences, the National Cancer Institute, and American Heart Association, the National Aeronautics and Space Administration, the University Group Diabetes Project, the Food and Drug Administration, the Institute for Nutrition for Central America and Panama, as well as numerous other organizations, committees and associations (CX 694B).

29. Approximately one-quarter to one-half of Dr. Brown's publications (CX 694C-H) deal with the evaluations of drugs, including some specifically devoted to the evaluation of analgesics (Brown, Tr. 4846-47).

30. Dr. Brown is one of the leading experts in biostatistics, including the applications of that discipline to the design and analysis of clinical trials of analgesics and other drugs. [10]

*Dr. Frederick Evans*

31. Dr. Frederick J. Evans is Senior Research Psychologist in the Unit for Experimental Psychiatry, Institute of Pennsylvania Hospital. He is also an associate professor of psychology at the University of Pennsylvania. He was a Fulbright Scholar, and conducted research at the Harvard Medical School (Evans, Tr. 6311-14). Dr. Evans is a highly experienced researcher in the psychology of pain and pain control and subjective response methodology (Evans, Tr. 6313-17). He is a member of the board of the American Pain Society, a member of the executive committee of the eastern chapter of the International Association for the Study of Pain, and is associate editor of the *International Journal of Clinical and Experimental Hypnosis* (Evans, Tr. 6318; CX 692A-D). He has served on a number of peer review groups evaluating pain studies for the United States and Canadian governments, as well as for numerous learned journals (Evans, Tr. 6318). He has also served as a consultant on and reviewer of grants and studies involving analgesic testing (Evans, Tr. 6335). He has published widely in the field of subjective response methodology (CX 692G-O).

32. The Unit for Experimental Psychiatry with which Dr. Evans is associated concerns itself with laboratory research into problems of mental health and human suffering. The research is concentrated on the interrelationships between subjective processes (*i.e.*, subjective response) and observable behavior in the laboratory, and the evaluation of subjective behavior such as pain and placebo response (Evans, Tr. 6314). To these ends, Dr. Evans devotes approximately one-fourth of his full-time research employing several different models of experimental pain (Evans, Tr. 6334). Dr. Evans' laboratory is also well known for its research into the methodological problems of generalizing laboratory study findings to the clinical situation (Evans, Tr. 6325).

33. By his background, training and experience, Dr. Evans is well qualified to speak to issues of pain and its response to treatment, the psychological factors and experimental pain methodology.

*Dr. Richard S. Farr*

34. 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 of 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).  
[11]

35. Dr. Farr has been deeply involved in the clinical study of aspirin side effects since 1969 and is responsible for the development of the aspirin challenge procedure originating at National Jewish Hospital (Farr, Tr. 2553-60).

36. 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 (Farr, Tr. 2558-60).

37. 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).

38. Dr. Farr is a leading expert in the fields of asthma and allergy in general and the asthmatic and allergic effects of aspirin and aspirin-containing drugs in particular.

*Dr. William H. Forrest*

39. Dr. William H. Forrest is an Associate Professor of Anesthesiology at Stanford University. He is a recognized expert in the field of analgesic testing and has had extensive experience evaluating analgesics. In fact, he has spent half of his time supervising, performing, or evaluating clinical research on analgesics (Forrest, Tr. 8848-49; 8860-63; 8869-71; 8875).

40. Dr. Forrest has had extensive experience working with and developing subjective response methodologies. His introduction to clinical research came while he was a research fellow at Stanford in 1962. During this year, he worked under Dr. J. W. Bellville, a respected researcher in the field of analgesic evaluations and Chairman of the FDA Analgesics Panel until he died (Forrest, Tr. 8850-51).

41. Dr. Forrest later became Chairman of the Veterans Administration Cooperative Analgesic Study. In the landmark Cooperative Study, analgesics were evaluated using a subjective response methodology in five to seven different Veterans Administration hospitals located in various parts of the country. The results of the Cooperative Study demonstrated that carefully trained and supervised nurses and researchers could perform the same work in several different settings and obtain sound data relating to the efficacy and relative potency of a variety of intra-muscular and orally administered analgesics. The Cooperative Study spanned a 14-year period and involved over [12] 100 clinical analgesic studies (Forrest, Tr. 8854-56; 8858-59; 8864-65; 8872-73; 8876-81; CX 678A-B).

42. During the last 14 years, Dr. Forrest has also been actively involved in various capacities with the National Research Council of the National Academy of Sciences (Forrest, Tr. 8856-57). He was involved in the 1960's in the planning phases of the National Halothane Study sponsored by the Council (Forrest, Tr. 8852). He has acted as a consultant to the Council on Anesthesia; and attended annual meetings sponsored by the Council for researchers working in the field of analgesics. At these meetings, Dr. Forrest has also presented numerous papers in the field (Forrest, Tr. 8856-57; 8865-67; CX 678B). In addition, he has published over 60 articles dealing with analgesics, clinical testing, and the subjective response methodology (Forrest, Tr. 8860-63; CX 678D-I).

43. Dr. Forrest is an eminent expert in the fields of clinical testing of analgesics, the subjective response methodology, and the efficacies, comparative efficacies, and side effects of various analgesics.

*Dr. Morton Grossman*

44. Dr. Morton Grossman, Chief of the Gastroenterology Section of



the Veterans Administration Wadsworth Hospital in Los Angeles, 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 one of six Senior Medical Investigators in the Veterans Administration, 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. 7789-93).

45. 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. In this regard, Dr. Grossman has done research on the mechanism and effects of aspirin ingestion on the gastrointestinal track and has published many articles on this topic in learned journals. Dr. Grossman has also served on various editorial boards of scientific journals, such as the *American Journal of Physiology*, and currently chairs the editorial board of *Gastroenterology*, the official journal of the American Gastroenterological Association. Dr. Grossman has [13] published over 350 articles in journals, contributed to scores of textbooks and other resource works on gastroenterology (Grossman, Tr. 7792-96).

46. Dr. Grossman has also been the recipient of major awards and honors in his field, including the Freeden-Wald medal of the American Gastroenterological Association, which is its highest award. He also has held high offices with many of the professional societies concerned with problems of gastroenterology (Grossman, Tr. 7796-97).

47. 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, as well as the effect of buffers in such products.

*Dr. Charles G. Moertel*

48. 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 patients' subjective responses to analgesics and is preeminent in the field of clinical testing

of drugs (Moertel, Tr. 5515; CX 680A). 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. 5520-23).

49. 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 the cancer patient, and this involvement has encompassed the evaluation of analgesic agents, anti-emetic agents, and diuretic agents (Moertel, Tr. 5517, 5520-22).

50. 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. Both of these studies were published in leading [14] medical journals subject to peer review (Moertel, Tr. 5521-22; CX 680J, N).

51. In addition to these two studies, Dr. Moertel has evaluated some of the newer chemical agents developed by pharmaceutical companies for analgesics purposes (Moertel, Tr. 5522). He has conducted a number of clinical studies using antiemetic and chemotherapeutic drugs as well (Moertel, Tr. 5522). In all of these studies, Dr. Moertel has been involved in the analysis and evaluation of patients' subjective responses (Moertel, Tr. 5523).

52. In addition to contributing articles dealing with specific research studies, Dr. Moertel has also submitted articles for publication which have dealt with analgesics in a broader sense and have utilized his overall 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). Dr. Moertel is a member of the Editorial Board of the *Journal on Cancer*, and he is an Associate Editor of *Cancer Medicine*, a standard textbook in medical oncology (Moertel, Tr. 5518).

53. As a practicing physician, Dr. Moertel prescribes, administers, and advises patients on a daily basis in the usage of analgesics. In his

practice he has had occasion to prescribe aspirin in these clinical situations (Moertel, Tr. 5523).

54. Dr. Moertel was appointed by the FDA to its Oncologic Drugs Advisory Committee. As a member of this Committee, he advises the FDA on clinical protocols for new drugs for use in the treatment of cancer patients. Dr. Moertel also serves on the Phase One Study Group of the National Cancer Institute. In this capacity, he helps to evaluate the types of protocols that will be most appropriate to determine the clinical value of new agents for the treatment of malignant diseases (Moertel, Tr. 5518-20). For all of these reasons, Dr. Moertel is eminently qualified to present expert testimony concerning clinical tests, the evaluation of patients' subjective responses, and the clinical testing of analgesics.

*Dr. Karl Rickels*

55. Dr. Karl Rickels is Professor of Psychiatry and Pharmacology at the University of Pennsylvania. Dr. Rickels is an eminent practitioner in the diagnosis and management of patients exhibiting non-psychotic symptoms, such as anxiety and tension. Dr. Rickels also 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. 6489-91). [15]

56. Dr. Rickels, Director of the Psychopharmacology Research Unit of the University of Pennsylvania since 1962, was recently appointed to an endowed chair in Human Behavior. He has 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 consulted with industry on the development of protocols for such clinical tests (Rickels, Tr. 6495, 6499-6502).

57. 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. 6492-95; 6501-02).

58. 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.

*Dr. Eugene Smith*

59. Dr. Eugene Smith is a psychologist at the Massachusetts Gener-

al Hospital in the Department of Anesthesia and Psychiatry. He is also an associate professor of psychology at the Harvard Medical School. Dr. Smith holds a Ph.D. degree from the University of Rochester. Dr. Smith has been continuously associated with Harvard and the Massachusetts General Hospital since 1954 (Smith, Tr. 5387-88). His work has concentrated in the effects of drugs on mood, physical and mental performance; and he has done a large number of studies in pain and subjective responses to pain. Much of his work has been in the area of experimentally induced pain. However, he has done a number of subjective response studies investigating the activity of analgesics in post-partum and post-operative pain (Smith, Tr. 5388-89). Dr. Smith is a member of numerous professional associations, and most of his studies have been funded by agencies of the U.S. Public Health Service or the National Institutes of Health (Smith, Tr. 5389-90).

*Dr. Donald D. Stevenson*

60. Donald D. Stevenson, M.D., is a member of the allergy/immunology division at the Scripps Clinic at La Jolla, California. Dr. Stevenson, who also has a clinical appointment in the Department of Internal Medicine at the University of California, has extensive experience in the clinical diagnosis and management of patients suffering from various allergies and asthmatic conditions, including those associated with aspirin. [16] 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.

61. 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 thinking regarding aspirin side effects.

62. 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.

*Dr. Timothy Brock*

63. Dr. Timothy C. Brock is Professor of Psychology at Ohio State University and is a licensed psychologist. Dr. Brock holds a Ph.D. degree 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 the field of persuasion and communication studies, and has had extensive experience in evaluating the formation, reinforcement and endurance of beliefs and attitudes. This experience includes conducting and evaluating research in this area, including the formation of attitudes about consumer goods and services (Brock, Tr. 8537-40; 8549-53; CX 826B-H). Dr. Brock has extensively contributed since 1957 to the body of literature regarding the role of communication in attitude formation and change. His numerous publications encompass research and analyses of persuasion techniques, measurement of attitude change, and identification of public opinion and attitudes (CX 826B-H), including a number of studies regarding beliefs and attitudes about consumer products, such as small toys, food, paint, and cigarettes (Brock, Tr. 8554-56, 8559-61). Dr. Brock's research has also included studies on the endurance of people's beliefs and attitudes (Brock, Tr. 8567-68). The research methodology employed by Dr. Brock has been substantially similar to that employed by the marketing community (Brock, Tr. 8565-66). Dr. Brock has also performed two studies that address the role of persuasive communications on consumers' perceptions of the performance of drugs. That research showed that advertising, like communications, had a direct effect on the desire to self-medicate, and that consumers' beliefs about [17] drugs were heavily influenced by the information they received regarding their performance (Brock, Tr. 8559-61). Dr. Brock has also served on the editorial boards of several professional journals and has frequently reviewed articles relating to the formation and persistence of attitudes submitted for publication to a number of other professional journals. The research includes work in the fields 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. 8545-47).

64. Dr. Brock is a member of numerous 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 has been elected by his colleagues to Fellowship status in the American Psychological Association, the American Sociological Association and the American Association for the Advancement of Science as recognition

of his professional contributions (Brock, Tr. 8544). Recently, Dr. Brock was invited by the American Psychological Association to deliver a paper entitled "Designs for Corrective Advertising" (Brock, Tr. 8653). He was also elected Secretary-Treasurer of the Evaluation Research Society, a national society of professionals concerned with the measurement and assessment of the long-term effects of various social and educational programs (Brock, Tr. 8541).

65. Dr. Brock is a highly qualified expert in social psychology, with special expertise in the techniques and effects of persuasion on the source and duration of consumer beliefs and attitudes. He is also qualified as an expert in analyzing the role of communications as a source of consumer attitudes and beliefs and as an expert in the design and analysis of research that assesses the source, nature, and endurance of consumer attitudes and beliefs.

*Dr. Ivan Ross*

66. 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 699; Ross, Tr. 6907-20, 6926-38). This has included extensive training and experience in evaluating advertising and the effects of advertising over time on consumers and upon their attitudes and beliefs. It has also included extensive training and experience in conducting and interpreting research in these areas. Dr. Ross is familiar with the literature in these areas. In addition to his academic training (Ross, Tr. 6908) and work in the areas of advertising and promotion, [18] consumer behavior, marketing and marketing research (Ross, Tr. 6909-12; 6914-15), Dr. Ross has had extensive experience working with advertisers and advertising agencies on advertising content and strategy for a variety of consumer goods and services and with various consumer research techniques, such as focus groups, copy tests, penetration studies, and image studies (Ross, Tr. 6913-14, 6916-18, 6927-29). Dr. Ross has also been a consultant with the Food and Drug Administration's Bureau of Foods (Ross, Tr. 6926).

67. Dr. Ross is a member of a number of professional associations in the areas of psychology, marketing, advertising, and consumer research (Ross, Tr. 6929, 6933) and has held both elected and appointed positions in these organizations (Ross, Tr. 6929, 6933). He has also served as an editor and reviewer of articles and papers in consumer behavior and advertising research for journal publication and presentation before various professional organizations (Ross, Tr. 6933). Dr. Ross has presented papers before professional organizations in the areas of marketing, consumer research, and psychology, and his arti-

cles, 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. 6933-35; CX 699). His model for studying techniques of advertising evaluation has been cited by a leading textbook in advertising, and he is currently writing textbooks on marketing and advertising (Ross, Tr. 6933-35). 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. 6930-32). Finally, he has appeared as an expert witness in a number of FTC cases and his testimony involved both the conduct and evaluation of consumer research (Ross, Tr. 6926, 6928).

68. 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 has a broad background in evaluating advertising, including the effects of advertising on consumers and on their attitudes and beliefs, as well as in the conduct and interpretation of advertising and consumer research (CX 699; Tr. 6907-20, 6926-38).

#### *B. Respondents' Experts*

##### *Dr. Abraham L. Sunshine*

69. Dr. Abraham L. Sunshine is a practicing physician specializing in internal medicine and clinical pharmacology. Dr. Sunshine received his undergraduate training and a masters degree at University of Wisconsin and attended and received an M.D. degree from the Temple University School of Medicine in 1953. He has held a National Institute of Health Research [19] Fellowship in immunology at the University of Wisconsin and was an intern and resident of Bellevue Hospital in New York City. Dr. Sunshine was an instructor in medicine at the NYC College of Medicine and, while on active duty with the USAF, was Chief of the Cardiovascular Section and Chief of the Department of Medicine at Clarks Air Force Base in California and Director of Out-Patient Services at Travis Air Force Base.

70. Dr. Sunshine holds a diploma from the American Board of Internal Medicine, is a Fellow of the New York Academy of Medicine, The American College of Physicians, and is a member of the New York County and American Medical Associations, The New York Heart Association, The American Federation for Clinical Research, The American College of Clinical Pharmacology and Chemotherapy, The New York Academy of Sciences and the International Association of the Study of Pain. In addition, Dr. Sunshine has been appointed Chairman of the Analgesic Section of the American Society for

Clinical Pharmacology and Therapeutics, which publishes the *Journal of Clinical Pharmacology and Therapeutics*.

71. Dr. Sunshine is a Professor of Clinical Medicine at New York University Medical Center and is an attending physician at the Arthur C. Logan Memorial Hospital, Bellevue Hospital and New York University Hospital. Dr. Sunshine has published extensively in the area of clinical pharmacology and therapeutics and the methodology of subjective response clinical studies (Tr. 9592-95; BMRX 38).

72. Dr. Sunshine has been studying subjective response research methodology, particularly in relation to analgesic, hypnotic and sedative drugs for the past 19 years. Dr. Forrest, one of complaint counsel's witnesses, recognized Dr. Sunshine as a "very, very able investigator in the field of analgesics." (Tr. 9596).

73. Dr. Sunshine's research has been conducted at Knickerbocker Hospital, Bellevue Hospital (part of New York University Medical Center), Philadelphia General Hospital, The University of Puerto Rico, The University Hospital and The Maternity Hospital in Caracas, Venezuela, and his own office in New York City (Tr. 9597).

74. Dr. Sunshine held a National Institute Health Grant to study pain and the influence of aspirin on pain as well as the methodology of investigating those phenomenon (Tr. 9598). Much of the work done by Dr. Sunshine and Dr. Laska has since been emulated by other researchers in the field. Dr. Forrest's opinions of Drs. Sunshine and Laska would be shared by his peers (Tr. 9017).

75. Dr. Sunshine has consulted with and done research for most of the major drug companies in the United States including [20] Sterling Drug, Eli Lilly & Co., Pfizer, Merck, McNeil, Warner-Lambert and Parke Davis (Tr. 9599-9600).

76. Some of the companies for which Dr. Sunshine consulted market products in competition with those of Bristol-Myers (Tr. 9600).

77. Dr. Sunshine qualified as an expert in internal medicine, clinical pharmacology and the conduct of subjective response tests of oral analgesic products (Tr. 9647).

*Dr. Eugene M. Laska*

78. Dr. Eugene M. Laska is Deputy Director for Research and Development of the Rockland Research Institute and is a mathematician practicing in the field of mathematical statistics. In the course of his duties, he directs the Information Sciences Division of the Rockland Research Institute that deals with the computer developments in the fields of health and mental health. Dr. Laska has been involved in the last 12 years in developing information systems for use in health research in health-related matters including one system that deals specifically with research in mathematical statistical models for the



analysis of data resulting from clinical trials (Tr. 10145). Dr. Laska has also recently been appointed Research Professor in the Department of Psychiatry at the New York University Medical School (Tr. 10146).

79. Dr. Laska has, from May 1974 through May 1976, been the American Statistical Association representative to the American Association for the Advancement of Science section on medical science (Tr. 10149).

80. Dr. Laska was, from 1972 to 1976, a member of the Computer and Biomathematical Science Section of the National Institutes of Health (Tr. 10150-51). In his capacity as a member of that section, Dr. Laska reviewed grant applications for possible NIH funding.

81. Dr. Laska has been a consultant to many drug manufacturers and has also been closely associated with a number of investigators conducting clinical trials in analgesics including Dr. Abraham Sunshine and Dr. Thomas Kantor (Tr. 10151-52).

82. Dr. Laska has frequently met with the Research Committee on drug addiction headed by Dr. Nathan Eddy and attended meetings of the Association of Clinical Pharmacology and Therapeutics that is chaired by Dr. Abraham Sunshine, giving a paper recently at the Association of Clinical Pharmacology and Therapeutics (Tr. 10154).

83. Dr. Laska also was a consultant to the Veterans Administration Cooperative Program on analgesic testing headed [21] by Dr. William Forrest. Dr. Forrest acknowledged Dr. Laska as "a very excellent biostatistician who has spent a good portion of his time, if not the major portion of it, in this whole problem of bioassay of analgesics." (Tr. 10155).

84. Dr. Laska has met with such clinical researchers as Dr. Raymond Houde, Mr. Stanley Wallenstein, Dr. William Beaver and others (Tr. 10155).

85. In the course of his work with statistics and biostatistics involved in bioassay studies, Dr. Laska is intimately involved in the design of those experiments. His participation included the formulation of the way in which the observer asked questions, the kind of information to be elicited, the assumptions to be made in the analysis of data, the kind of information to be collected (Tr. 10157-59).

86. Dr. Laska testified that he participated in approximately 100 subjective response studies including head-to-head studies in the fields of sleep and psychiatric evaluation. In addition, he has read hundreds of articles on analgesic research and methodology, including head-to-head trials (Tr. 10160).

87. Dr. Laska was qualified as an expert in comparative testing of analgesic drugs (Tr. 10166; BMRX 7).

*Dr. Ben Marr Lanman*

88. Dr. Lanman is Vice President and Medical Director of the Bristol-Myers Products Division and has been employed by Bristol-Myers since 1962. He received his M.D. degree from the Jefferson Medical School in Philadelphia, Pennsylvania, was an intern at Jefferson Hospital and a resident in surgery and thoracic surgery at the Columbia Presbyterian Medical Center, Columbia University and Bellevue Hospital in New York. From 1953 to 1962, Dr. Lanman was Medical Director of Shenley Industries dealing with primarily prescription drugs (Tr. 11404-07). As Medical Director of Bristol-Myers Products, Dr. Lanman is responsible for all medical aspects of products sold by the division including testing for efficacy, safety and advertising substantiation (Tr. 11407-08).

89. Dr. Lanman and the other members of the Bristol-Myers Products Medical Department keep current with the medical literature insofar as it relates to and concerns the products manufactured by the Products Division (Tr. 11409-10). Dr. Lanman and the other members of the Medical Department of the Products Division attend meetings of the American Society of Clinical Pharmacology and Therapeutics, the meetings of the committee on Drug Dependence of the National Research Council, The American Pain Association, The Eastern Pain Association, The American Association for the Study of Headache. Dr. Lanman has presented a paper at a meeting of the American Association of [22] Clinical Pharmacology and Therapeutics (Tr. 11411-13). Dr. Lanman regularly meets with independent outside clinical researchers. For example, Bristol-Myers Products co-sponsored and Dr. Lanman co-chaired a symposium on pain in 1964 or 1965 at which the outstanding experts in the analgesic field, including Drs. Sunshine, Laska, Kantor, Belleville, Forrest, Houde, Brown, Beaver and Wallenstein, participated (Tr. 11414-15).

90. In the course of his discussions with the investigators who worked for Bristol-Myers, some of whom are well-known and well-respected in the field, Dr. Lanman contributes to the design and methodologies to be used in conducting those researches for Bristol-Myers (Tr. 11416-17), although Dr. Lanman has not participated in any clinical study.

91. Dr. Lanman has been qualified as an expert in the study and research methodologies used to investigate analgesic drugs and their activities (Tr. 11420-21; 11427; BMRX 1).

*Dr. Walter B. Elvers*

92. Dr. Walter B. Elvers is Associate Medical Director of Bristol-Myers Products, a division of the Bristol-Myers Company (Tr. 10745).

Dr. Elvers obtained his bachelor's degree at Columbia University, and was awarded the DDS degree and attended post-doctoral training in orthodontics at Columbia University Dental School (Tr. 10746). Dr. Elvers served two years in the Army Dental Corps and was in private practice in orthodontics for several years prior to joining Bristol-Myers (Tr. 10746).

93. His principal duties at Bristol were to initiate studies, to suggest and negotiate the design features of them, to supervise the study in progress and interpret the results of the studies at their conclusions (Tr. 10747-48). Dr. Elvers is familiar with and has kept current with the design and methodologies involved for clinical and experimental studies (Tr. 10752-53). Dr. Elvers has been involved with (and has had primary or supervisory responsibility for) over 2,500 studies in the past 20 years. The vast majority of this work is in clinical rather than experimental research (Tr. 10748-49). Over 275 of the studies in which Dr. Elvers has been involved concerned analgesics and approximately 170 were clinical studies (Tr. 10749-50). However, Dr. Elvers himself has not conducted any analgesic study, or other clinical study of drugs.

94. Dr. Elvers was qualified as an expert in the design, conduct and analysis of clinical tests of analgesics (Tr. 10754; BMRX 2).

*Dr. Jacob Jacoby*

95. Dr. Jacob Jacoby is a Professor in the Psychological Sciences Department at Purdue University, where he heads the [23] Consumer Psychology Program which is widely known for its innovative and extensive work regarding the application of the science of psychology to the study of consumer behavior. In addition to his teaching, Dr. Jacoby has done extensive empirical research and has published numerous articles dealing with consumer decisionmaking and behavior and the effects of various factors, including advertising, upon consumers (Tr. 9484-9513).

III. THE MARKET RESEARCH AND OTHER DOCUMENTARY EXHIBITS  
OFFERED BY COMPLAINT COUNSEL ARE RELIABLE

A. *Image and Advertising Penetration Studies*

1. CX 346: The Assets and Liabilities Study (1967)

96. The 1967 "Assets and Liabilities Study of Adult Analgesics" (CX 346) was designed by Dancer-Fitzgerald-Sample, Inc., and executed by Crossley Surveys for Sterling Drug, Inc., the manufacturer and marketer of Bayer brand aspirin. Its stated purpose was to "provide assets and liability profiles for Bayer Aspirin and other leading brands of analgesics products," and to "serve as a 'benchmark' against which

data from future assets and liabilities studies may be measured" (CX 346C; Miller, Tr. 209-10). It is a replication of an earlier study that Crossley Surveys had done for Dancer-Fitzgerald-Sample (hereinafter "DFS") (Leonard, Tr. 88-89).

97. The survey of households through personal interviews was designed and executed by highly experienced individuals and companies. Dancer-Fitzgerald-Sample, Inc. is a major national advertising agency. It held the Bayer Aspirin account of Sterling Drug, Inc. at the time the study was performed. DFS designed many consumer research studies for its clients, who included General Mills, Hanes and CPC (Miller, Tr. 208-09). Lloyd C. Miller, who designed CX 346, was and is Vice-President and Associate Director for Research of DFS. Mr. Miller testified concerning the design and analysis of the study. He had held his position with DFS for 13 years at the time of his testimony. His academic background includes a Bachelor's degree in Business Administration from City College of New York and an MBA from New York University. He had been involved in conducting all types of marketing research for over 16 years at the time of the 1967 study (Miller, Tr. 206-07).

98. Crossley Surveys, Inc. has over 50 years' experience in sample survey research for all types of clients, including manufacturers, media, government, and advertising agencies. It has conducted attitude studies, new product research, media research and public opinion research for a variety of clients including Gillette, General Foods, American Oil and Texaco (Leonard, Tr. 86-87). [24]

99. Franklin B. Leonard, who personally supervised the execution of the 1967 Assets and Liabilities Study, is President of Crossley Surveys, and has been employed at the company for 26 years. He holds a B.S. degree in Industrial Engineering from Yale University, and since has held positions at Crossley ranging from trainee to project director (Leonard, Tr. 83-87).

100. The sample for this study was a "multi-stage stratified area sample." The sample design provides for the selection of individual respondents by dividing the country as a whole into smaller and smaller units, from major markets to minor civil divisions to blocks, and from blocks to households. "Stratification" refers to that control designed to insure that the sample fairly represented diverse demographic attributes of the population as a whole. Such stratification related to sex (that it was half men and half women), and to geography. The sample was designed to be representative of the U.S. population in terms of the proportional representation of the four geographical regions, three sizes of standard metropolitan statistical areas and one size of nonmetropolitan counties in the U.S. (Leonard, Tr. 95-96). Thirty-five primary units, or markets, were selected from

a national probability sampling frame of 80 primary sampling units to be representative of the whole United States. Within those 35 markets, Crossley Surveys selected minor civil divisions in proportion to their relative population (Leonard, Tr. 97-98). Within individual divisions, urban block clusters were selected systematically from census block statistics whenever that was possible. Once a particular block was selected, a random technique was used to designate a starting point on the block for interviewers to commence their interviewing. From that starting point, interviewers were given explicit instructions on which houses to contact (CX 1007). These instructions left no discretion in the hands of the interviewer (Leonard, Tr. 100).

101. The sampling procedure outlined above is consistently used by Crossley Surveys. It yields results upon which marketing decisions are made (Leonard, Tr. 102-05). The procedure was discussed with, and explicitly approved by, Dancer-Fitzgerald-Sample, Inc. (Leonard, Tr. 102).

102. The 1967 "Assets and Liabilities Study" was executed according to Crossley Surveys' normal survey procedures. Most of the field work supervisors and interviewers on the project were people with whom Crossley Surveys had had substantial favorable experience (Leonard, Tr. 107). All interviewers were personally briefed by their supervisors and provided with detailed written instructions for administering the questionnaire (Leonard, Tr. 87, 107-10; CX 1000, 1002).

103. The questionnaire for this study consisted of a notebook with 31 pages. Each page was a self-contained rating scale [25] on a separate attribute, positive ratings at the top and negative ratings at the bottom. The rating of the products was to be made by the interviewees by inserting cards bearing the names of products into one of six pockets, corresponding to the intensity of their feeling about those products on each attribute (CX 346D, Z158-160).

104. The design of CX 346 was similar to that of other image studies commissioned by DFS (Leonard, Tr. 86-88). And the "Assets and Liabilities" type of notebook-questionnaire used in this survey had been used by DFS since 1953 or 1954 for major clients such as General Mills and Falstaff Brewing Company (Miller, Tr. 214). This study design is comparable in quality to others for measuring images of products (Leonard, Tr. 94).

105. Validation of interviews at Crossley Surveys was a two-step procedure, conducted both by interview supervisors and then by Crossley's headquarters (Leonard, Tr. 110, 115, 138-39; CX 1001). This process provided a total of 15% of total interviews validated. As a third check on the interviewers' work, DFS itself validated an additional 10% of the interviews (Miller, Tr. 229-30).

106. Coding of the results of the survey was performed by Crossley's editing and coding department. A trained, experienced editor was normally responsible for that task. Given the absence of open-ended questions on the questionnaire necessitating interviewers' recording verbatim responses, coding for this project was a ministerial task. After the coding and editing tasks were accomplished by Crossley, the results were delivered to DFS, which analyzed them and prepared the report (Leonard, Tr. 115-16; Miller, Tr. 235).

107. The 1967 study was not conducted in anticipation of litigation. Sterling Drug, Inc. was DFS' client and requested the study in the regular course of business. Sterling was satisfied with the quality of the work and its presentation (Miller, Tr. 209-10, 235-36). Crossley Surveys itself had no direct contact with Sterling Drug, Inc. nor any interest in any particular outcome of the study (Leonard, Tr. 87).

## 2. CX 310: The 1969 Excedrin Study

108. The "1969 Excedrin Study" (CX 310) was designed by Young & Rubicam, Inc. for and in consultation with Bristol-Myers Company (Rosenbluth, Tr. 2865-66). It was a follow-up of an earlier survey conducted in 1966 and was intended to serve as a study of the penetration of Excedrin's advertising; of Excedrin's image among consumers; of the public's use of [26] different brands of analgesics; and of consumer's "wants and needs" in analgesics (CX 310J-K).

109. Leon Rosenbluth testified for complaint counsel regarding the design of the survey. At the time CX 310 was conceived, he was the manager of survey research for Young & Rubicam, Inc. (Rosenbluth, Tr. 2856). Mr. Rosenbluth holds a Bachelor's degree in statistics from City College of New York and a Master's degree from New York University in sociology. He has had considerable experience in the design and analysis of market and advertising research (Rosenbluth, Tr. 2856-60). Young & Rubicam, Inc. is a major advertising agency with a research department that has performed advertising research for numerous major corporate clients, such as Union Carbide, Remington and Proctor & Gamble (Rosenbluth, Tr. 2860). It is the advertising agency for Bristol-Myers for Excedrin.

110. William Nudorf testified for complaint counsel regarding the execution of CX 310. At the time the study was executed, Mr. Nudorf was field director of Grudin Appel, a full-service market research organization. His responsibilities included coordinating the field-work/interviewing tasks with the sampling and coding tasks associated with the study to insure that quality was maintained throughout. Mr. Nudorf and his subordinates did not know for whom the study was being performed (Nudorf, Tr. 2901-05). Mr. Nudorf holds a degree in journalism from the Pennsylvania State University, with a major

in advertising. He had 14 years' experience in market and advertising research at the time the study was executed (Nudorf, Tr. 2898-2900). Grudin Appel was chosen by Bristol-Myers to execute the study. It had an excellent reputation among its clients and made consistent efforts to attract the best people in the market research field. Its clients included major advertising agencies, such as Young & Rubicam and BBD&O, and major consumer goods manufacturers, including General Foods, Gwaltney and ITT-Continental Baking (Nudorf, Tr. 2901-02; Rosenbluth, Tr. 2865, 2868).

111. Stanley Randall testified regarding the analysis of the survey results. At the time he analyzed those results for Young & Rubicam, he had been a research consultant with 15 years' experience in marketing and opinion research. His consultancy clients had included other major advertising agencies, such as J. Walter Thompson and McCann-Erickson, and his responsibilities involved all aspects of research from initial client contact to study design, questionnaire design, analysis, report preparation and presentation. Mr. Randall was hired by Leon Rosenbluth to analyze the results of the 1969 Excedrin Study on the basis both of excellent recommendations and of a review of initial drafts that he had worked on (Randall, Tr. 2978-80; Rosenbluth, Tr. 2871-73). [27]

112. At the direction of Bristol-Myers, the sample for this survey was limited to Nielsen "A" and "B" counties (urbanized counties) across the United States (Rosenbluth, Tr. 2866). Grudin Appel was well-equipped to design and implement a probability sample of these urban areas. It had developed a master sampling plan based upon standard metropolitan statistical areas (SMSA's) and their contiguous counties (CX 1056). These areas accounted for over two-thirds of the national population. Interviews were apportioned to each U.S. geographic region based on that region's share of the total SMSA population. A sampling frame was constructed for each region, and within each region's sampling frame, sampling points were distributed over the population by using randomized procedures (Nudorf, Tr. 2932-45; CX 1056; CX 1057A-L).

113. Grudin Appel performed survey research using sampling procedures of this type on a frequent basis. This study therefore presented no unusual tasks to be performed (Nudorf, Tr. 2904-06).

114. Interviewers were given extensive instructions to implement the sampling plan. These instructions were sufficiently detailed to prevent the interviewers from exercising discretion in selecting respondents (CX 1057M-Q; Nudorf, Tr. 2942-44). This sampling procedure was typical of that used in other advertising penetration and image studies, and it produced a result that was projectable to all "A" and "B" counties in the United States (Nudorf, Tr. 2944-45).

115. The study was conducted according to Grudin Appel's regular standards of professional quality in all respects. The questionnaire was pretested and extensive instructions regarding its administration were given to interviewers. The instructions given to interviewers had been tested and proven in the past. By 1969, they were so standardized that Mr. Nudorf did not have to rewrite them for each survey. Rather, he would review them for their suitability for particular surveys (Nudorf, Tr. 2909-30).

116. The interviewers used in this project worked for supervisors whom Mr. Nudorf had selected as the best he knew of in each metropolitan area; he had developed that level of familiarity and expertise in selecting supervisors over a 10-year period while he was employed by the research department of a major ad agency, traveling throughout the country doing advertising research (Nudorf, Tr. 2946). Interviewers were thoroughly trained to administer the questionnaire by their supervisors, who validated a portion of interviews after they were completed. Between 15 and 20 percent of all completed interviews were validated by Grudin Appel, and if any discrepancy arose in any portion of an interviewer's work, all of that interviewer's work would be validated. This validation was performed by Grudin Appel's in-house staff (Nudorf, Tr. 2948-[28]50). The coding of the completed questionnaires was performed by Grudin Appel's large and experienced coding department. Tabulations of the coded questionnaires were performed by Donovan Data, a company with a good reputation for processing data (Nudorf, Tr. 2951-52).

117. Stanley Randall prepared the final report of CX 310. Before analyzing the data, he checked the coding of the questionnaires. He also checked the final tables prepared under his direction against the original tabulations before beginning any analysis for the final report. The final report of CX 310 was accepted by Young & Rubicam (Randall, Tr. 2985-92).

### 3. CX 347/348: Study of Vanquish's Market Opportunities (1970)

118. The 1970 "Study of Vanquish's Market Opportunities" was designed by Benton and Bowles, Inc., an advertising agency, for Sterling Drug, Inc., as part of the development of an advertising campaign for Vanquish. CX 347 was designed to measure consumers' attitudes toward analgesics in general, their opinion of some leading analgesic brands, including Vanquish, and to determine what sort of consumer Vanquish was most likely to attract (CX 347E).

119. Joseph Pernica, the Associate Research Director and Vice-President of Benton and Bowles, Inc. at the time had full responsibility for developing the design, methodology, and questionnaire for the survey, and for overseeing its execution (Pernica, Tr. 1893). He testi-



fied for complaint counsel concerning those areas. Mr. Pernica is an experienced market researcher who had devoted 10 years to the field by 1972. His experience includes six years as manager of market research for J. Walter Thompson, another major advertising agency. Mr. Pernica's academic background includes a Bachelor's degree in Business Administration from the University of Prague and a Master of Economics degree from Sydney University in Australia (Pernica, Tr. 1887-89).

120. Liberman Research Corporation of New York was responsible for executing CX 347. Arnold Fishman, the Vice-President of Lieberman Research, testified for complaint counsel concerning the procedures used for conducting the study, including sampling procedures, interviewing, and coding and tabulating. Lieberman Research is a large marketing research company which also performs some public opinion research. Three-quarters to ninety percent of its work, however, is consumer research like the Vanquish study. Lieberman Research's consumer research clients include General Foods, Bristol-Myers, Sterling, and most of the major advertising agencies (Fishman, Tr. 1284). Lieberman had a high reputation for quality work with advertising agencies (Pernica, Tr. 1889). Arnold Fishman started as a Research Assistant and became a Vice-President of Lieberman [29] Research after five years' experience with the organization. He holds a Bachelor's degree in Psychology from Brooklyn College and has completed all the requirements for a Master's Degree from City University of New York except his thesis (Fishman, Tr. 1281-82).

121. The sampling procedure for the 1970 Vanquish Study was developed by Lieberman Research according to specifications set by Joseph Pernica of Benton and Bowles. These specifications included the sample size, the number and type of markets in which the survey would be conducted, and the desired 50/50 sex distribution of the respondents. Benton and Bowles instructed Lieberman to investigate the Mid-Atlantic and Pacific regions and also wanted to concentrate some interviews in three known high-share Vanquish markets, Atlanta, New Orleans and Oklahoma City. Lieberman Research was given a list of cities in the Mid-Atlantic and Pacific regions and chose the cities in which it had the best interviewers (Fishman, Tr. 1292-93; Pernica, Tr. 1918-19).

122. Within each market chosen, the sample was randomly selected from addresses listed in telephone directories. A random number was picked as the page on which to enter each phone book, and to get to successive pages, a skip interval equal to the number of remaining pages divided by the number of desired interviewing clusters was determined. In order to minimize the sampling error due to use of

telephone listings, interviewers were instructed to interview a resident of the house adjacent to the one picked from the phone book (Fishman, Tr. 1299-1301). This procedure left no discretion to the interviewer in selecting respondents.

123. This sampling procedure was standard at Lieberman Research, and the sampling instructions given to interviewers were the company's standard written instructions (Fishman, Tr. 1339-40; 1300). It was not designed to produce a national probability sample. However, Lieberman considered the degree of deviation from strict adherence to all probability standards in this sampling pattern to be small and typically recommended that marketing decisions could be made based upon the data generated (Fishman, Tr. 1367-68).

124. The Vanquish Study was based on personal interviews. The questionnaire was carefully reviewed and revised by Arnold Fishman at Lieberman Research in order to eliminate ambiguities and to ensure correct question order. After it was put into final form, it was pretested in the field to ensure that it could be easily administered. The pretesting indicated that there were no significant problems with the interview (Fishman, Tr. 1295-97). Lieberman Research chose its interviewers and supervisors carefully, using only supervisors who were known to have done timely work of high quality in the past, and encouraging the supervisors to use only their best inter[30]viewers. The supervisors were responsible for training interviewers, for passing on Lieberman Research's standard written instructions, for acting as intermediaries between them and the central office, and for validation of the interviewer's work. Lieberman did not rely solely upon the supervisor's validation, but validated an additional fifteen percent (15%) of all questionnaires in the central office. If validation of an interview uncovered a problem, all the work of that interviewer would be validated. In addition to these two validations, a third validation check was run by an outside service to ensure objectivity (Fishman, Tr. 1317-18).

125. Coding, keypunching and tabulations were performed by Lieberman Research according to its normal procedures for studies of this type. The codes for open-ended answers were developed by Lieberman Research's coding staff under Arnold Fishman's supervision. Joseph Pernica, of Benton and Bowles, approved the final codes (Pernica, Tr. 1929). A portion of every coder's work was checked by the coding staff supervisors to verify that coders were correctly interpreting verbatim responses (Fishman, Tr. 1319-21). Keypunching and tabulations were performed by Data Probe, a research computer company selected by Lieberman Research with the approval of Benton and Bowles, Inc. All of the coded questionnaires were "machine-cleaned" (checked for the logic of responses) and all the keypunching was verified by machine

at Data Probe. Data Probe produced the tabulations of the results, CX 348, according to specifications set by Benton and Bowles, and Lieberman Research checked the tables for conformity with those specifications. Mr. Pernica received the tabulations from Lieberman Research and used them as the basis for his analysis presented in CX 347 (Fishman, Tr. 1321-25; Pernica, Tr. 1929-30).

#### 4. CX 326: 1971 Advertising Penetration Study

126. CX 326, a telephone survey, was designed and analyzed by Ted Bates & Company, Inc., and was conducted by Valley Forge Information Services (hereinafter "Valley Forge"), for Bristol-Myers Corporation (CX 1019-20). Its purpose was to measure the advertising penetration of Bufferin and other OTC analgesics (CX 326C, E-K; CX 1009). The questionnaire design is typical of earlier Bates penetration studies, many of which were also performed for Bristol-Myers Corporation. Two other such studies were identified and cited as comparable, earlier penetration studies in the final report (CX 326D). Employees of both Ted Bates and Valley Forge testified that the questionnaire was typical of those used in assessing advertising penetration (Weitz, Tr. 731; Fratto, Tr. 810).

127. Ted Bates and Company, Inc. is the advertising agency for the Bristol-Myers Company for Bufferin. Ms. Anne Jack [31] (formerly Anne Weitz),<sup>3</sup> a Vice President of Bates, testified for complaint counsel regarding the design and analysis of CX 326. Ted Bates' research department performs a wide range of research on all types of products for its clients (Weitz, Tr. 809). Ms. Jack has a Bachelor's degree from Holland College and a Master's degree from Duke University, both in psychology. She had worked for Ted Bates on research positions since 1960, and advanced within the agency from Project Director (in 1964) to Vice-President (in 1973). Her responsibility had included designing questionnaires since 1960 (Weitz, Tr. 807-10).

128. Valley Forge Information Services, a wholly owned division of Burlington Industries, is a market research firm with extensive experience in telephone surveys. Although it was originally formed in 1966 to work only for Burlington, it expanded to offer its services to other research companies, advertising agencies, and manufacturers, primarily involving telephone surveys (Fratto, Tr. 718-19). Kenneth Fratto was the President of Valley Forge from its inception until February 1977. He has a Bachelor's degree from Colgate University in Economics, and a Master's degree in Marketing from the Columbia Graduate School of Business. He worked in marketing research for Alfred Pollitz Research and Ogelsby, Benson Advertising Agency

<sup>3</sup> When Ms. Jack testified with respect to CX 326, during the Joint Hearings of 1977, her name was Anne Weitz (Jack, Tr. 6095). Accordingly, all citations which refer to her 1977 testimony appear here as "(Weitz, Tr. \_\_\_\_)".

from 1957 to 1966, and rose to the position of senior vice-president in Alfred Pollitz Research in 1966. He has conducted over 300 studies in media research, product testing, advertising research, and market penetration (Fratto, Tr. 716-17).

129. The sample for the 1971 Ted Bates Advertising Penetration Survey was designed to be a national probability sample based upon telephone listings (CX 326Z004). Both Ted Bates and Valley Forge had done national probability samples before. Valley Forge had developed the capability for doing such samples during 1969-1970 and had done about one per month since then (Weitz, Tr. 819-20, 836).

130. Valley Forge designed the sampling plan for this survey very carefully. The first step was the construction of a "master probability sample." This was obtained by dividing up the entire country, according to published photostats from the Census Bureau, first into a census region, and then into four city-size classifications within the census regions. The "sampling points" within the four city-size classifications are randomly selected from within the counties listed in each classification. While one could obtain any number of sampling [32] points, the one hundred points used in this survey were found more than adequate by Kenneth Fratto (Fratto, Tr. 737-38).

131. The telephone numbers of individual survey respondents were selected randomly from within these sampling points. Telephone directories were obtained from telephone companies for each county in the master sampling plan, a standing order being placed with each company to ensure that the directories were current. If, for example, 1,000 completed interviews were required, 2,500 numbers would be selected, 25 from each of the 100 sampling points in the master sample. A randomized "skip pattern" within each phone book, starting from a random starting point, would also be established (Fratto, Tr. 738-40).

132. All interviewers were instructed orally about the correct way to select a particular column on a page and a particular number down in that column. In other words, the smallest detail was attended to as carefully as the drawing of the original master sample (Fratto, Tr. 739-41). In order to minimize a nonresponse bias, each number at which there was no response received two call-backs (Fratto, Tr. 744).

133. The questionnaire was easily administered, because it required no skips and very simple probes (CX 1009). Nevertheless, all interviewers received both written and oral instructions in conducting the interviews (CX 1021; Fratto, Tr. 740). In addition, training of the interviewers involved actual testing of their ability by supervisors who had at least one year's experience in interviewing and who were experienced in dealing with people (Fratto, Tr. 724). This degree of

care in conducting interviews was a standard procedure at Valley Forge (Fratto, Tr. 720).

134. The interviewers' WATS lines were connected to a monitoring facility so that each interview could be listened to as it was conducted without the interviewers being aware of the monitoring process (Fratto, Tr. 742). In addition, all completed questionnaires were checked by Valley Forge's supervisors for thoroughness and accuracy. Finally, there would be a third check by a group of editors who would review the questionnaires before they were sent to the client (Fratto, Tr. 745).

135. Coding, keypunching and tabulation were performed by Ted Bates after it received the completed questionnaires (Fratto, Tr. 745). Because the questionnaires contained open-ended verbatim responses, Ted Bates employees expended a large amount of time and effort in developing appropriate codes for the verbatims despite the fact that the basic framework for coding had been developed during earlier Bates market penetration studies (Weitz, Tr. 823-24; CX 1016). [33]

136. The mechanics of coding and tabulating were performed by hand by Ms. Jack herself and a trainee under her close supervision (Weitz, Tr. 826).

#### 5. CX 345: The 1973 Headache Remedy/Pain Reliever Usage and Advertising Penetration Study

137. CX 345, a telephone survey, was designed to determine current advertising penetration and usage levels of selected analgesics (CX 345C). The study was designed, executed and analyzed by Sobel-Chaikin Research Associates at the request of and in cooperation with American Home Products Corporation (Sobel, Tr. 461-64). Sobel-Chaikin Research Associates is the research division of Market Probe International (hereinafter, "M.P.I."), an organization formed in approximately 1964 to perform market research, computer analysis and data processing for manufacturers and advertising agencies. Its major clients include Pan American Airlines, IBM, Citibank, and Doyle Dane Bernbach (Sobel, Tr. 451-53). Charles Sobel testified for complaint counsel regarding both the design and the execution of CX 345 for which he had ultimate responsibility. Mr. Sobel is Senior Vice-President and Director of the research group at M.P.I., and the founder of Sobel-Chaikin Research Associates. At the time of the survey, he had approximately 23 years' experience in market survey research similar to CX 345. Indeed, almost every consumer survey that Mr. Sobel had been involved in had some questions that related to advertising penetration (Sobel, Tr. 447, 451-52, 455, 457-66).

138. The study design called for a telephone sample to be randomly selected from telephone directories in 10 major urban markets (CX

345C; CX 1007; Sobel, Tr. 467-68). Interviewers in each market were assigned a random starting page in the telephone book for that market and were instructed to skip a random interval number in order to obtain each succeeding page (CX 1007). They were instructed to start at the top of the second column of each page and proceed down the column until they had completed a series of five interviews. These instructions left no discretion to the interviewer in the selection of respondents (Sobel, Tr. 467-68).

139. The questionnaire for this survey was short, and it was easy to administer because it contained few skip patterns for interviewers to follow (CX 345 Z101-104). The questions were unambiguous and were directed both to advertising recall and usage of analgesics. The questionnaire was developed in consultation with American Home, and was typical of those used previously by Sobel-Chaikin for advertising penetration studies (Sobel, Tr. 461-62; 484).

140. The survey was conducted according to standardized procedures followed by Sobel-Chaikin Associates in all their [34] research work. All interviewers received extensive instructions regarding the administration of the questionnaire and were personally trained by supervisors who were known to the principals of the firm or to one of their field supervisors, on the basis of prior favorable experience (Sobel, Tr. 471-72). Completed interviews were validated in a two-step procedure. Supervisors were instructed to validate work received from all their interviewers. In addition, 15% of the completed interviews submitted by supervisors were validated by an outside validation service hired by Sobel-Chaikin (Sobel, Tr. 477-81).

141. M.P.I.'s in-house coding department coded the responses on the completed questionnaires. The task involved building codes for verbatim responses to open-ended questions on the questionnaire asking about advertising recall. The final codes were prepared by Mr. Sobel and were approved by American Home. Checks on the quality of coding were supplied by M.P.I.'s coding supervisor and by having individual coders redo each other's work for comparison purposes (Sobel, Tr. 483-85; CX 1005-06).

142. M.P.I.'s own data processing group keypunched the completed questionnaires. The keypunching was performed by experienced operators and was checked both by verification and by automatic controls placed into the computer programming that produced the tabulation runs. The tabulation plan was developed in accordance with specifications approved by American Home Products. The report of CX 345 was prepared by Mr. Sobel and was submitted to American Home (Sobel, Tr. 484-87).

#### 6. CX 349: "The Leavitt Study" (1975-1976)

143. Dr. Clark Leavitt, an expert witness in the design and analysis of research which measures consumers' images and beliefs about products (Leavitt, Tr. 6160-72; CX 701), testified concerning a consumer telephone survey he designed for the Federal Trade Commission.

144. Dr. Leavitt holds a Ph.D. degree in Social Psychology from the University of California. He has taught at two colleges and now teaches at the Ohio State University, concentrating in various subdisciplines of psychology including social psychology, consumer behavior and research methodology (Leavitt, Tr. 6160-62). He supervises graduate and post-graduate student research and conducts research for publication in professional journals (CX 701). He also currently designs and conducts applied research as a consultant for clients, including advertising agencies (Leavitt, Tr. 6166-69).

145. Dr. Leavitt has had extensive experience in the design and implementation of consumer research related to effects of advertising and to consumer attitudes and images about products. He has worked in marketing and consumer research for two advertising agencies, E.H. Weiss & Co. (1955-1957) and Leo [35] Burnett Company (1957-1972). At Weiss, Dr. Leavitt conducted exploratory consumer research on basic consumer beliefs and motives, and the relationships between advertising, public awareness and sales. At Leo Burnett, he supervised all marketing research for a group of clients, and became creative research supervisor and thereafter Director of the Communications Laboratory. He was responsible for the design of marketing research for all of Burnett's clients, including Proctor & Gamble, Pillsbury, Carter-Wallace, All-State Insurance, Motorola, Pfizer, and manufacturers of drug products. Research for many of these clients concerned consumers' purchases and opinions about products and their awareness of advertising, and many of his projects have involved the development of rating scales to measure consumer perceptions of predispositions. He has supervised or conducted thousands of studies which test consumers' beliefs and attitudes (Leavitt, Tr. 6162-65).

146. Dr. Leavitt's own research has involved the measurement of the relationship between the advertising and the stability of people's opinions or attitudes; other research involves distributions of advertising schedules, patterns of forgetting with respect to advertising, and source credibility. At least 50% of the articles he has published in professional journals have involved research measuring attitudes, beliefs or images. Dr. Leavitt is an active member of the American Marketing Association, the Association for Consumer Research, the

American Psychological Association and the American Association for Public Opinion Research. He is a former President of the Division of Consumer Psychology of the American Psychological Association and has served on the editorial boards of various professional publications (Leavitt, Tr. 6166-70; CX 701).

147. Dr. Leavitt is well qualified as an expert in the design and analysis of consumer research which measures consumer images, beliefs and attitudes about products (F. 144-46, *supra*).

#### *The Design of the Study*

148. Unlike the other image studies in evidence, the questionnaire and methodology of CX 349 were designed by Dr. Leavitt to measure respondents' *comparative* beliefs about the effectiveness, speed, strength and gentleness of Bufferin, Excedrin, Anacin and aspirin. The products and the four performance attributes that he surveyed were specified by the FTC staff before he began to design the study (Leavitt, Tr. 6173-77). The control of response bias was one of Dr. Leavitt's primary considerations in the design of the questionnaire (Leavitt, Tr. 6178-81).

149. The effect of Question 1 of Dr. Leavitt's questionnaire was to inform respondents that they would be asked about four [36] separate products in the survey: Anacin, Bufferin, Excedrin and aspirin (CX 349W). The word "aspirin" was chosen by Dr. Leavitt as a product to rate along with Bufferin, Excedrin and Anacin because of his understanding of the nature of this case as explained by complaint counsel, and because of his belief that for the purposes of the study, the word "aspirin" was the most sensible one (Leavitt, Tr. 6179-81, 6187, 6191).

150. Questions two (2) through five (5) of the Leavitt questionnaire set forth the basic rating scale constructed by Dr. Leavitt to measure consumers' beliefs about these products on the four attributes of interest. The scale consisted of four verbal points: "extremely," "very," "fairly" and "not." Consumers were asked to rate the effectiveness, speed, strength and gentleness of each of the four products on this scale (CX 349W; Leavitt, Tr. 6182-85). His method permitted a conclusion about comparative image held by individual consumers about the four products without asking them a direct but leading question about their comparative image with regard to a particular product attribute.

151. A comparative question such as "Do you believe that Bufferin is a more effective pain reliever than aspirin," could have produced biased results (Leavitt, Tr. 6179). For one thing, such a direct, comparative question suggests that Bufferin and aspirin do perform differently (Leavitt, Tr. 6179-80). Moreover, there are general tendencies, or "sets," among many consumers to answer "yes"



throughout or "no" throughout to all interview questions that are put to them in that form (Leavitt, Tr. 6180). This positive or negative set may manifest itself in uniform answers to "yes/no" questions regardless of what the substance of the question is. Asking absolute or neutral questions of respondents avoids this bias (Leavitt, Tr. 6180-81).

152. The four-point rating scale used in the Leavitt questionnaire provides an acceptable measure of the intensity of a consumer's belief about a product on a particular attribute. The four points in the scale have an ordinal relationship to each other in the sense that "extremely" ratings are appreciably more intense than "fairly" ratings, which are in turn more intense than "not" ratings (Leavitt, Tr. 6182-83). Based on his experience, Dr. Leavitt believed that the four point scale should provide for more positive responses ("extremely," "very" and "fairly") about a product than negative ones ("not") because people tend ordinarily to rate products more positively than negatively. Accordingly, more steps on the positive side of the scale are necessary to compensate for this predisposition (Leavitt, Tr. 6183-84).

153. A neutral response was not included in the scale in order to increase the sensitivity of responses. It is known that some portion of the population tries to avoid either a [37] positive or negative response to particular questions asked in a survey. Failure to provide for a middle-of-the road response overcomes that tendency and encourages a true response (Leavitt, Tr. 6184).

154. Dr. Leavitt had considerable experience with rating scales using the four adjectives used here (F. 153, *supra*; Leavitt, Tr. 6182-83). Based upon his review of the literature and upon his extensive experience, he concluded that the steps on a rating scale ought to be anchored by verbal descriptions rather than by simple numbers like a thermometer (Leavitt, Tr. 6182-83). He had found that a verbally anchored scale produced more reliable, more stable kinds of data than other scales he had tried which relied upon numbers or other techniques to anchor its points (Leavitt, Tr. 6183).

155. Because the ratings of products in a series may be effected by the order in which the products are presented (order or position effects), the study design included a control on that bias by rotating the order in which products were presented to respondents for rating. One quarter of the sample started out with each different product out of the four and ended with each different product (Leavitt, Tr. 6180, 6188-89; Crespi, Tr. 2274, 2276; CX 349W, CX 352B).

156. On the other hand, the order of presenting product attributes (as opposed to products) was not rotated because Dr. Leavitt believed it was necessary to start all interviews with a specific performance attribute rather than a general one. "Effectiveness" is a general at-

tribute in the sense that it evokes consumers' overall assessment of an analgesic product (Leavitt, Tr. 6189). Asking for a general rating first may produce another type of response bias, *i.e.*, creating an early commitment in a respondent to an overall favorable or unfavorable evaluation of a product that would affect his subsequent ratings of other attributes (Leavitt, Tr. 6189). In order to avoid this bias, the attributes were presented in the order of increasing generality, from "gentleness" to "effectiveness" (Leavitt, Tr. 6189; CX 349W). And, because the order in which the products were presented was rotated, any consequence of the fixed order in presenting attributes for rating would have been spread equally across all products.

*The Execution of the Study*

157. Dr. Leavitt determined the basic specifications for the field work of CX 349, including the number of interviews and the sample procedures. Between 700 and 800 interviews were decided upon to assure that there would be enough responses to conduct meaningful analyses which could be generalized beyond the sample itself (Leavitt, Tr. 6186; Crespi, Tr. 2280). In Dr. Leavitt's opinion, telephone interview was the best way to obtain the information needed in the study (Leavitt, Tr. 6186). [38]

158. Dr. Leavitt approved the selection of the Gallup Organization to conduct the field work for this study because he believed it was an organization that had considerable experience in drawing representative samples of the type he was considering. He was also familiar with the excellent reputation of Dr. Irving Crespi, his contact at Gallup Organization (Leavitt, Tr. 6175-76). Dr. Crespi testified regarding the sample design, its implementation and about the field interviewing procedures used by the Gallup Organization in the study. At the time of the study, Dr. Crespi was Executive Vice President of Gallup (Crespi, Tr. 2268).

159. The Gallup Organization specializes in marketing, consumer and public opinion survey research for clients which include many of the major consumer goods manufacturers and marketers in the United States (Crespi, Tr. 2262-63). It also conducts the "Gallup Poll." Dr. Crespi received a Ph.D. degree in Sociology from the New School for Social Research. He had been employed at Gallup for 20 years and was involved in all aspects of the organization's survey research functions, including the development of questionnaires, the proper implementation of survey design, the reporting of results and maintaining client contact. He has been personally involved in marketing research for numerous major corporations. Dr. Crespi had risen to the position of Executive Vice President at the time he left Gallup in April 1976, and he maintained direct supervisory responsibility for

survey research projects until he left. Dr. Crespi has been a member of the Board of Directors of the American Marketing Association; he is past President of the American Marketing Association; he is past President of the American Association for Public Opinion Research; and, at the time of his testimony, was President of the World Association for Public Opinion Research. He has published several articles dealing with consumer research in professional journals in the marketing field (Crespi, Tr. 2262-65; CX 702). Dr. Crespi is well qualified as an expert in the execution of consumer research.

160. Dr. Crespi obtained specifications from Dr. Leavitt and complaint counsel regarding the number of interviews to be conducted, the fact that the survey was to be conducted by telephone, the fact that the people under 18 were not to be interviewed, the fact that people who were not aware of at least one of the four products surveyed were not to be interviewed, and the fact that the sample of between 700 and 800 was to be projectable (Crespi, Tr. 2268, 2277-79; Leavitt, Tr. 6191-92).

161. After receiving Dr. Leavitt's questionnaire, Gallup reviewed it and pretested it to see that it conformed to good professional practice. The pretest led to Gallup's recommending some modifications. The pretesting disclosed that some respondents were unwilling to rate products because they had not [39] personally used them, and the introduction to Question 2 (the beginning of the rating scale) was changed to emphasize that the interviewer was seeking their product images regardless of whether they used the products (Crespi, Tr. 2269-70; CX 349W). Other minor modifications were made in the introduction to the interview, in Questions 7 and 8, and in formulating the questions designed to obtain the demographic characteristics of the respondents. Based upon Dr. Crespi's experience, the modified questionnaire was a standard questionnaire using techniques representing the norm in brand image research (Crespi, Tr. 2277).

162. The population of telephone numbers that was sampled by Gallup was generated by adding a random digit to the telephone number of respondents who had been previously interviewed in their homes for the Gallup Poll (Crespi, Tr. 2282-84). The sampling design used for the Gallup Poll is carefully designed to remove any personal judgment or discretion of the interviewer as to whom to interview. The Poll is based upon a sampling of people at three hundred (300) separate, randomly selected points throughout the country. Sampling points are either city blocks (in urban or metropolitan areas) or minor civil subdivisions (in rural areas). Each interviewer for the Poll is given a randomly selected starting assignment at a particular sampling point, and is given instructions on how to proceed from residence to residence. This procedure produces a sample of households

whose results are reasonably projectable to all households in the nation at large (Crespi, Tr. 2285-88). To develop the reservoir of telephone numbers actually sampled in the *Leavitt Study*, a random digit (the number "5") was added and subtracted to the last digit of the telephone numbers of these sampled households. This procedure produced a sample of residential telephone households which reasonably represents the national population of telephone households (Crespi, Tr. 2288; Leavitt, Tr. 6191-93).

163. The population sampled in the Leavitt Study was limited to people over 18 years of age who were aware of at least one of the four named products. Accordingly, the telephone sample used is representative of the people over 18 who live in households with telephones and who heard of at least one of the four products: aspirin, Anacin, Bufferin and Excedrin (Leavitt, Tr. 6192-93):

164. Interviewers who conducted the telephone interviews were given the actual telephone numbers obtained in the Gallup Poll and written instructions on how to generate the telephone numbers to be called in this study. They were required to record each of the telephone numbers they generated and each of the numbers of the households where they completed an interview. If a generated number was busy, or there was no answer, or a respondent of proper age was not at home, the interviewers were instructed to call back in another attempt to [40] complete the interview (CX 352A-C). The rate of interview refusals and break-offs in this survey conformed with Gallup's experience in other telephone surveys. The overall interview completion rate of 50% is rather low, but Dr. Crespi testified that it conformed to Gallup's experience in studies of this type where two attempts are made to complete an interview (Crespi, Tr. 2295-96; CX 1053).

165. The telephone interviewers used in this Study worked for Gallup on a regular basis and their work was subject to systematic quality checks by Gallup directly. The interviewers were supervised by an interviewing department at Gallup under an experienced supervisor with specific responsibility for the telephone interviewing staff (Crespi, Tr. 2288-90). The interviewers were unaware of both the purpose and the sponsors of the study (Leavitt, Tr. 6190). The interviewers were under strict instructions not to deviate from the wording of the questionnaire in any way. If a respondent did not understand a question the interviewer was instructed to read it again but not to reword it (Crespi, Tr. 2292). With respect to Questions 1 through 6, all the interviewer had to do was check the appropriate response box precoded on the questionnaire. With respect to Question 7, an open-ended question, interviewers were instructed to write down the respondents' answers verbatim. Therefore, interviewers were given no

discretion whatsoever in the conduct of the interview (Crespi, Tr. 2292-93). An 8% subsample of all interviewees was recontacted by Gallup, who verified that the interviews had taken place and on the proper topic. Gallup's interviewers' work had been regularly validated by this technique in their previous work experience with Gallup and had been shown time and again to be genuine (Crespi, Tr. 2293-94).

166. The responses recorded by interviewers were coded by Gallup's experienced coding department. The questionnaire was precoded to a significant degree, which reduced both the opportunities for interviewer discretion and the complexity of the coding task. Interpretative codes were used only for responses to Question 7, which dealt with respondents' uses of aspirin, Bufferin, Anacin and Excedrin for things other than pain relief (Crespi, Tr. 2292, 2297-98). Key punching was done by Gallup internally. The keypunched cards were verified according to Gallup's standard procedures, and the data were checked for inconsistencies, or "edited." If any inconsistencies were found, they were either edited by the computer while tabulating the data, which is Gallup's standardized editing process, or the original questionnaires were checked. There were no editing problems with this study (Crespi, Tr. 2304). At the conclusion of its assignment Gallup delivered a "clean deck" of punched cards to Dr. Leavitt, together with supporting materials on interviewing procedures and the key-punching plan (Leavitt, Tr. 6196; CX 351, CX 352). [41]

167. The Leavitt Study was designed and executed by highly qualified personnel, experts in their respective fields, according to well recognized standards in the industry and using procedures consistent with these individuals' prior extensive experience in the design and execution of survey research. The results of the survey are reliable and probative on the issues to which they are addressed.

7. CX 343, 344, 1058, 1059: The Attitude Study  
In Depth of Heavy Users of Analgesics and Follow-Up

168. CX 343 and its follow-up, CX 344, were performed in 1967 and 1970 by Oxtoby-Smith, Inc. for Whitehall Laboratories, a division of American Home Products Corporation. They were designed by Oxtoby-Smith to study the images of OTC analgesic products among consumers, under the supervision of Martin Weinberger, the Research Director, who testified for complaint counsel regarding the design, execution and analysis of CX 343 and 344. Mr. Weinberger has 15 years' experience in designing and executing consumer attitude studies at Oxtoby-Smith and was involved in approximately 1,000 such studies during his career with that organization. In addition to his practical experience at Oxtoby-Smith and another major research

organization, Mr. Weinberger holds a Bachelor's degree and has done graduate work in public opinion research at Columbia University (Weinberger, Tr. 5205).

169. Oxtoby-Smith is one of the largest custom-design consumer research organizations in the U.S. It designs and executes research for a wide variety of clients and product categories. The organization focuses on decisions about consumer attitudes and behavior (Weinberger, Tr. 5206). CX 343 was conducted in 1967, at the request of American Home Products' research director; thereafter Oxtoby-Smith was called upon to do a follow-up study in 1970 (Weinberger, Tr. 5219).

170. CX 343 and 344 were conducted according to Oxtoby-Smith's standard procedures for surveys of this type. The interviewers conducting the survey were personally trained by their supervisors. The supervisors themselves had generally been used by Oxtoby-Smith in the past, or they were recruited for this study based upon their reputation with Oxtoby-Smith's field directors (Weinberger, Tr. 5225).

171. The questionnaires for the two studies were drafted by Mr. Weinberger and were approved by Whitehall's research director (Weinberger, Tr. 5219-20). The questionnaires were pretested according to Oxtoby-Smith's standard procedures (Weinberger, Tr. 5220-21).

172. The sample for the study was designed to concentrate on heavy users of analgesics. The term "heavy" was defined as [42] those consumers who took six or more pain relievers for headaches in the two-week period prior to interview. Equal quotas were set for each of the leading analgesic brands, and for users of nonleading brands, and for "light" (under six pills) users of analgesics. This quota sample design was employed, at least in part, to eliminate the possibility that unequal numbers of users of the brands studied might bias the results of the survey as a whole (Weinberger, Tr. 5223-24). Interviewers were instructed to proceed on a house-to-house basis until they filled their quotas of various users (Weinberger, Tr. 5226). These sampling procedures were developed in consultation and with the approval of Whitehall (Weinberger, Tr. 5228). The sample was taken in 21 cities (CX 343Z085; Weinberger, Tr. 5224).

173. The completed questionnaires were returned to the interviewers' supervisors who validated 15% of all interviews done in that city. Thereafter, the questionnaires were returned to Oxtoby-Smith and an additional 15% of interviews were validated. These were standard validation figures for Oxtoby-Smith (Weinberger, Tr. 5251-52). Coding was performed internally under the direction of coding supervisors in Oxtoby-Smith's coding department (Weinberger, Tr. 5253-54). Key punching of those coded responses was also performed internally with standard procedures employed to check on its accuracy (Weinberger, Tr. 5254). The punched cards were thereafter sent to

an outside tabulation house for computer processing (Weinberger, Tr. 5258). The end product of this process was the series of tabulations in evidence as CX 1058 and 1059. Mr. Weinberger then drafted reports which analyzed this data and presented them to his client (Weinberger, Tr. 5256).

B. *Survey Research Measuring Consumers' Awareness of the Ingredients in Bufferin and Excedrin*

1. CX 333: Consumer Use of Headache Remedies and Knowledge of Their Ingredients

174. The 1964 study, "Consumer Use of Headache Remedies and Knowledge of Their Ingredients" (CX 333), was designed, conducted and analyzed by the Gallup Organization, Inc., for Bristol-Myers Company. It was designed to measure consumers' awareness of the ingredients of eight major analgesic products, and especially their knowledge as to whether Bufferin contained Di-Alminate as its advertising campaign stressed at the time. In addition, it measured the extent to which consumers knew that these products contained aspirin (CX 333A, C, D).

175. Dr. Irving Crespi, who was Executive Vice-President of The Gallup Organization, Inc., in 1964, testified regarding the design and execution of the survey. His credentials, and those of The Gallup Organization, Inc., in the field of market research are excellent (F. 159, *supra*). [43]

176. The sampling plan was designed to produce a national probability sample of the adult civilian population 21 years old and over (CX 333C). This plan was used regularly by The Gallup Organization, and differed only in two minor details from that used subsequently in 1975 in CX 349 (F. 162, *supra*). First, the minimum age for respondents had been lowered from 21 to 18 by 1975, and second, the two original 150-point master samples used in 1964 had been merged by 1975 into one 300-point master sample (Crespi, Tr. 2326).

177. The questionnaire used in CX 333 was easy to administer. It was short and contained no skip patterns. The questions eliciting unaided answers were short and clear. The order of questions asked about the four major brands was rotated in order to control the order effects (CX 333C, D). The questionnaire was pretested according to Gallup's standard procedures. Two or three interviewers conducted three to six interviews each and then attended a debriefing session with Dr. Crespi to discuss the pretest (Crespi, Tr. 2324).

178. The interviews were conducted according to The Gallup Organization, Inc.'s standard procedures. First, every individual interviewer was tested in a trial assignment process before he or she could

become a member of Gallup's regular interviewing staff; only members of this staff were assigned to work on the 1964 survey. Second, interviewers for this study were provided with extensive written instructions in the Interviewer's Bulletin. Third, almost all supervision was conducted out of Gallup's central office, so that the supervisors reported directly to headquarters. Finally, a high percentage of completed interviews (20 to 30%) were validated by postcard (Crespi, Tr. 2327-29). Procedures for coding and keypunching were identical to those used in CX 349 in 1975 (Crespi, Tr. 2331; F. 166, *supra*). Tabulations of the responses were either done internally by Gallup on its counter sorter or by an outside computer company to Gallup's specifications (Crespi, Tr. 2331-32). The resulting tables, apart from accompanying analysis, are to be found on pages F, H, J, K, L, and O of CX 333.

## 2. CX 314: Pain Reliever Telephone Study

179. The 1972 "Pain Reliever Telephone Study" (CX 314) was designed by Bristol-Myers Company to measure consumer usage of analgesics in general, their opinions of major brands, and their awareness of news reports about analgesics, and was conducted by Edward Blank Research Company for Bristol-Myers Company (CX 314A). Of special importance to this case, the study also measured consumers' knowledge of the ingredients of five leading brands of OTC analgesics (CX 314Z019-Z021; Blank, Tr. 2666-67).

180. Edward Blank testified for complaint counsel as to the execution of the 1972 survey by the Edward Blank Research [44] Company, of which he is founder and president. His experience in the field of market research includes the design and conduct of survey research for National Broadcasting Company concerning the effectiveness of their advertising, and the design of consumer studies for Benton and Bowles Advertising Agency. Immediately prior to forming his own company, he was manager of marketing information for ROYFAX, an office copier manufacturer. He holds an undergraduate degree in economics, and has taken graduate courses in marketing research from New York University's Graduate School of Business (Blank, Tr. 2658-63).

181. Edward Blank Research Company, formed in 1969, has performed research for several leading corporations and advertising agencies, including Gillette, Continental Can, and Doyle Dane Bernbach. Mr. Blank has been personally involved in all of the nearly two hundred studies it has conducted (Blank, Tr. 2662-63).

182. The sampling procedure used by Edward Blank Research Company for the 1972 survey was designed to be generalizable to all adults in telephone households within five major urban markets (New York,



Atlanta, Chicago, Denver, and San Francisco). The sampling plan was a standard procedure with Edward Blank Research Company and met the requirements of Bristol-Myers Company (Blank, Tr. 2668-70). Within each of the five urban markets selected, a quota of 60 women and 40 men over 18 were to be interviewed. Respondents were selected randomly from the market's telephone book by interviewers who were given straightforward written sampling instructions. Each interviewer was assigned a randomly selected starting page, column, and line and was instructed to contact the person so identified. Then the interviewer was instructed to get to the next page of the book by skipping a number of pages equal to the total number of pages in the telephone book divided by one hundred. The interviewer was instructed to select the next respondent from the identical location on that page as on the previous one. These instructions left no discretion to the interviewers in selecting respondents (Blank, Tr. 2665-72).

183. Edward Blank himself took steps to insure that the interviews for CX 314 were conducted competently. First he worked on the questionnaire he received from Bristol-Myers so that it would be easy to administer and the questions would flow in a logical sequence. The resulting questionnaire is a simple one, consisting almost entirely of multiple-choice questions. It required only that the interviewer check a box to record respondent's answer. In addition, there are interview administration instructions included on the questionnaire itself (Blank, Tr. 2663-67; CX 314Z019-21). The telephone interviewing was contracted out to independent interviewer supervisors in the five markets sampled. Blank chose only those supervisors he knew to have competent interviewers on their staffs either from prior experience or recommendations. Fifteen percent (15%) of [45] all completed questionnaires were validated by an independent WATS-line company (Blank, Tr. 2669-75).

184. Coding and tabulating were performed according to Edward Blank Research Company's standard procedures. The company's own coding department developed a coding system for verbatim responses after studying at least one hundred responses to each question. After the code was developed, and after its approval by Edward Blank, the mechanics of coding would be performed under the guidance of the department supervisor. Tabulation of the coded questionnaire was performed by DATATAB, a data processing company selected by Blank based upon prior satisfactory experience. The tabulations were performed according to specifications given to DATATAB by Edward Blank, who checked DATATAB's work for conformity to instructions and accuracy, and the tabulations were delivered to Bristol-Myers Company (Blank, Tr. 2677-81). The final report consists mainly of 24 tables which measure consumers' use of, awareness of advertising for,

and knowledge of the ingredients of OTC analgesics (CX 314D, F-Z018).

*C. Survey Research of Audience Reaction and Recall*

1. The ASI Audience Reaction Tests

185. The 17<sup>4</sup> ASI Audience Reaction Tests in evidence were conducted by Audience Studies, Inc. (hereinafter "ASI") on television advertisements for Bufferin, Excedrin and Excedrin P.M. to measure their effectiveness. The tests are of standardized design, and seeks to evaluate consumer reactions to advertisements in terms of persuasiveness, involvement and recall (CX 811A, B).

186. Gerald Lukeman, ASI's President, testified for complaint counsel concerning the design and general procedures of ASI testing. Mr. Lukeman has primary responsibility for sales and service; he also is involved in modification of the design of the testing when necessary. Mr. Lukeman has worked at ASI since 1953, having had three years' experience with a predecessor, the Schwerin Company. Prior to joining ASI, he earned a Bachelor's degree from Dartmouth College with a major in Psychology (Lukeman, Tr. 4303-04). ASI's field of expertise involves research in communications, especially advertising (Lukeman, Tr. 4305). It has measured the effectiveness of advertising in all of the commonly used media, and it tests audiences' reactions to approximately 1,500 commercials every year. Its clients vary greatly in size, but tend to be the nation's largest manufacturers and advertising agencies (Lukeman, Tr. 4305-06). ASI has conducted tests on commercials for OTC analgesics at a minimum frequency of 70 tests per year [46] for at least 10 years (Lukeman, Tr. 4306-07). During the time the ASI studies in evidence were conducted, Mr. Lukeman supervised the Bristol-Myers account and was responsible for the proper execution of the tests, as well as the follow-up with the client regarding the nature of the resulting data (Lukeman, Tr. 4311).

187. Except for CX 264, all of the ASI studies were conducted in Los Angeles. CX 264 was a test performed in St. Louis on a "David Janssen" advertisement for Excedrin P.M. ASI tested the identical "David Janssen" ad in Los Angeles (CX 263). This substitution of cities was due to the fact that David Janssen ads for Excedrin were being televised on the West Coast, and ASI wanted to test the effectiveness of Janssen's ad for Excedrin P.M. in both exposed and unexposed geographic areas to see if differences existed (Lukeman, Tr. 4315). Like all of the studies, CX 264 was analyzed by ASI's Los Angeles staff (Lukeman, Tr. 4315).

188. The stipulated testimony of Roger Seltzer concerned the me-

<sup>4</sup> CX 245, 246, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 261, 262, 263, and 264.

chanics of conducting the Audience Reaction Tests (CX 811). Mr. Seltzer supervises ASI's Los Angeles office which is responsible for ensuring the appropriate execution of the tests (Lukeman, Tr. 4313-14). Audience Reaction Tests were conducted according to a procedure which remained virtually unchanged from 1967 to 1973 (Seltzer, CX 811B). Except for CX 264, the tests were conducted in a theatre in Los Angeles, housing an audience of approximately 350 respondents. The audience for CX 264 was recruited from the St. Louis metropolitan area, where testing for that advertisement was conducted (Seltzer, CX 811C; F. 187, *supra*). The audience for each test was recruited, either in person or by telephone, to attend a preview of television programs, with no charge or obligation except that they would be asked for their opinions of the programs they saw (Seltzer, CX 811C). As the audience entered the theater they were given seats, and according to ASI's standard procedure, certain respondents were selected by ASI personnel to operate the dials of a recording machine at their seats designed to measure their reactions to the materials they viewed. A second subsample was sometimes selected to have their reactions to materials they viewed monitored by basal skin resistance recorders which were at their seats. A third subsample was selected to participate in a "focus group" discussion held at a point in the evening after the commercials had been viewed (Seltzer, CX 811C, D).

189. Each member of the audience was given a questionnaire folder and while seating was being completed, he or she was asked to answer questions about various demographic characteristics and use and preferences for different brands of products. Finally, each respondent was presented a list of products and asked which he/she would prefer to receive as a door prize (*see, e.g.*, CX 254Z024-027) (Seltzer, CX 811D). [47]

190. After the respondents have filled out the preliminary questionnaires, they were shown a "control" cartoon (Seltzer, CX 811D-E; F. 191, *infra*). Next, they were shown a regular length television program. 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 (Seltzer, CX 811E). 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 (Seltzer, CX 811E). Then the first commercial was shown. Following the showing of this first commercial the audience filled out the first section of its five page questionnaire (*see, e.g.*, CX 254Z028-029). This procedure continued until the audience saw all five commercials and completed all five sections of

the questionnaire (Seltzer, CX 811F). After the five commercials, the audience was shown a second television program segment and filled out a short questionnaire regarding it (Seltzer, CX 811F). Thereafter the audience, given the impression that the pre-selection questionnaire (F. 189, *supra*) was the incorrect one, selected from a new questionnaire the product they would like to win as a door prize (*see, e.g.*, CX 254Z030). This second, or "post-selection," prize questionnaire was then collected (Seltzer, CX 811F). Thirty or forty minutes after viewing the commercials, the audience was given a "recall questionnaire" which asked them to write down all they recalled about the five commercials they saw earlier, including the products, brand names, and details of the ads (*see, e.g.*, CX 254Z031). After the "recall questionnaire" was collected, door prizes were awarded, and the evening was concluded (Seltzer, CX 811F, G).

191. Several controls used on the night of the presentation are designed to minimize any sampling error that may have arisen in the selection of respondents. First, of the 350 viewers in the audience who fill out questionnaires, usually only 250 will be used. This is because certain segments of the population tend to be overrepresented in the theater audience, and ASI requires that the sample it analyzes approximate a distribution which is comparable to samples previously recruited and tested by ASI (Seltzer, CX 811C). The second control involves use of a cartoon which has been used as a standard for most ASI sessions. The use of a "control" cartoon permits those in the segment of the audience using dials to learn to manipulate them; it also permits 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 do not satisfy ASI that this audience is reacting in reasonable accord with norms based on past audiences' reactions, the data generated through the subsequent questionnaire regarding "program" material is discarded, and that program material retested at a later date (Seltzer, CX 811D- [48] E). Finally, as with the "control" cartoon, the first commercial shown is always a "control," *i.e.*, a commercial tested many times previously for which audience reaction is known. Like the "control" cartoon, ASI monitors the audience's reaction to the first "control" commercial to determine if it is reacting within normal limits established through ASI's prior experience with reactions to this same commercial. If the audience's reactions to the "control" commercial do not satisfy ASI that this audience is reacting in reasonable accord with norms based on past audiences' reactions, the data generated through subsequent questionnaires regarding the "commercial" material is discarded and that commercial material retested at a later date (Seltzer, CX 811E-F).

192. The procedure described above (F. 188-91, *supra*) applied to everyone in the audience except the 10 to 12 people chosen earlier for the group discussions; they were taken from the theater after viewing the commercials and, in a session led by a trained ASI moderator, they discussed, among other things, the commercials they had viewed. These people were chosen for the focus groups based upon the opinion of an ASI moderator that they would be willing to discuss their opinions of the commercials they viewed (Seltzer, CX 811G). The ASI moderators who conducted these discussion groups were experienced and highly qualified (Seltzer, CX 811G). The focus group discussion transcript was recorded verbatim with only nonsubstantive editing for readability (*e.g.*, CX 254, Z008-017), and was included in the final ASI report. ASI offers five different services for clients regarding the focus groups, including transcripts, analyses, and tape recordings of the sessions (Seltzer, CX 811H).

193. ASI's audience recruitment procedures are designed to produce a sample that fairly reflects a cross-section of the population in the recruited metropolitan areas. From each of the sampling points, the desired quota of respondents in each age and sex group is selected, *i.e.*, audiences consist of approximately 50/50 sex distribution, and approximately half of the respondents are below age 35, half are 35 or older (Seltzer, CX 811B). Further, two separate selection procedures are used for each audience. Some viewers are recruited through personal contacts at high-traffic locations, such as shopping centers, in an effort to secure a sample that reflects the differing geographic and socio-economic characteristics within that metropolitan area (Seltzer, CX 811B). Others are selected via telephone, using a "reverse directory" system. Reverse directories list telephone numbers by street addresses rather than names so that ASI can secure a geographic balance among the respondents recruited by telephone (Seltzer, CX 811B-C).

194. The questionnaires, as can be seen from examining the 17 reports in evidence, are designed to be self-administered by members of the general public (*see, e.g.*, CX 245Z104-12). They [49] consist of simple multiple-choice questions, and equally simple open-ended recall questions. In order that the testing be run smoothly, ASI's theater operation employs only highly qualified individuals, and it trains them extensively (Seltzer, CX 811G).

195. Responses to the open-ended questions in the questionnaires were coded internally by ASI's coding department, which was adequately staffed, experienced and qualified (Seltzer, CX 811H-I). Both the supervisor and assistants checked the accuracy of coding and resolved possible coding problems (Seltzer, CX 811H). Coding of responses to both the "main idea of the commercial" and the "recall"

questions (*see, e.g.*, CX 254Z028, 031) included the preparation of a recommended coding outline for each question, based upon established criteria, which was approved by the coding supervisor and then by the project director (Seltzer, CX 811I). Whenever possible, ASI used the same codes in testing a particular product over a period of time for comparisons across tests. After the project director approved the outline, the coder coded each verbatim comment. The accuracy of coding was checked first by the coding supervisor, and second by the project director's assistant if a problem arose which warranted it (Seltzer, CX 811I).

196. Coded open-ended responses together with closed-ended (or "check off" type) responses were keypunched twice by ASI's internal keypunching department to ensure accuracy. Then they were processed by a computer. Key-punchers were experienced and qualified (Seltzer, CX 811I). The computer printouts of coded responses which followed keypunching were checked three times: by the coding supervisor, the project director and by the editing department (Seltzer, CX 811J). The printouts were checked by the computer operator before they were released from that department to a project director. The project director reviewed and analyzed the computer output presented, and approved the form of its presentation in the final report. These draft final reports were sent to the editing department for final checking before a senior ASI employee (a Research Unit Director or a V.P. Research) examined the final document (Seltzer, CX 811J-K). Verbatim audience comments (*see, e.g.*, CX 246) were transferred by typists from the original questionnaires. ASI's procedures permitted corrections for only obvious spelling errors, but no changes in wording (Seltzer, CX 811K). After the reports were completed (CX 245, 246, 249-259; CX 261-264) by the ASI office in Los Angeles, they were sent to both the client and to that product's account executive in ASI's New York office (Seltzer, CX 811K).

## 2. Copy Tests Prepared by Ted Bates

197. Five copy tests received into evidence (CX 267, 268, 269, 270, 271) are reports prepared by Ted Bates & Company of copy tests performed on various Bufferin television advertisements. Except for CX 271, these copy tests were performed [50] between February 1968 and May 1969, according to a method developed by Bates called "The Copy Lab" (Jack, Tr. 6089).

198. Anne Jack,<sup>5</sup> a former Vice President of Ted Bates and Company, testified for complaint counsel concerning the design and general procedures, as well as the mechanics of conducting these tests.

<sup>5</sup> Anne Jack is the former Anne Weitz. Her name appears as Weitz in this document to reflect testimony or documents which identify her as Ms. Weitz.

199. "Copy Lab" testing was based on the use of uniform methods of recruiting, questioning of respondents and reporting of results in all studies (Jack, Tr. 6089). When Bates determined to "Copy Lab" test the advertisements reflected in the above-mentioned reports, it contacted Graham Research, an independent contractor, and advised it of that determination. Bates then supplied this independent contractor with films of the advertisements to be tested, the questionnaires to be administered, specifications for the size of the sample, and recruiting quotas in terms of age, sex and education (*e.g.*, the "Copy Lab" sex quota specified 100 percent women) (Jack, Tr. 6089-90). With complete instructions, the independent contractor implemented the "Copy Lab" procedures. First, they positioned a specifically designed trailer in a shopping center in New York or New Jersey. From the shopping center, Graham recruited customers who, if they fit within the recruiting quotas above mentioned, were invited to enter the trailer and participate in the test (Jack, Tr. 6090).

200. A preliminary questionnaire was administered to respondents (*see, e.g.*, CX 299T-W). After filling out the preliminary questionnaire, respondents were shown a short film strip which contained one advertisement at the beginning, one at the middle and one at the end (Jack, Tr. 6090). Five-minute entertainment segments were interspersed between the three advertisements. The order of presentation of the three advertisements was rotated so that each appeared first, second and third, an equal number of times (Jack, Tr. 6091).

201. Immediately after the respondents viewed the material, they received another questionnaire which asked, first, their recall of various elements of the three advertisements they viewed; second, their comments about the Bufferin advertisements in particular; and third, their intentions to purchase various brands (*see, e.g.*, CX 299X-Z003; except that the question appearing at page Z003 was not a part of standard "Copy Lab" procedure) (Jack, Tr. 6091).

202. Graham submitted the completed questionnaires directly to Bates without editing or coding any of the responses (Jack, Tr. 6091). Upon receipt of the completed questionnaires, Bates [51] first checked for adherence to quota requirements and for general completeness. A Bates secretary retyped respondents' answers to the immediate recall open-ended questions (*see, e.g.*, CX 299Y) with no editing and at most corrections of obvious spelling errors.

203. Bates employees coded and tabulated respondents' answers to these open-ended recall questions. Bates typed verbatim responses, and the tables of coded responses to the open-ended recall questions were among other information included in a report of standardized format (Jack, Tr. 6092). Such reports were prepared by Bates and were submitted to Bates' Bufferin account management for review.

204. Under certain circumstances, Bates determined to copy test a particular advertisement by a less time consuming method. One manner of effecting an expedited test was to employ a system called the "Quick Copy Lab" (Jack, Tr. 6092). CX 229, 300 and 301 reflect the results of "Quick Copy Lab" tests of certain advertisements (Jack, Tr. 6092).

205. The difference in methodology between the "Copy Lab" and "Quick Copy Lab" systems centered in the area of respondent recruiting. Rather than stationing a trailer in a shopping center and recruiting respondents individually according to preset quotas (F. 119, *supra*), Bates instructed the independent contractor to recruit respondents in groups according to general age and education ranges, *e.g.*, organized clubs or other groups of consumers recruited as a whole. "Copy Lab" and "Quick Copy Lab" systems differed also in the location at which the materials described (F. 200, *supra*) were viewed. Rather than a mobile trailer which could accommodate only three to four viewers at a time, respondents in "Quick Copy Lab" reviewed the materials in a central location which could accommodate 25 to 30 people (Jack, Tr. 6093). Except for CX 301, the questionnaires administered in "Quick Copy Lab" were the same as those used in "Copy Lab" tests. The procedures for forwarding completed questionnaire to Bates and Bates' use of those questionnaires were also the same. Reports of the standardized format used in "Copy Lab" were not prepared for "Quick Copy Lab" tests (Jack, Tr. 6093).

206. With respect to CX 301, the questionnaire administered contained questions in addition to the standard individual recall/purchase interest questions. These questions asked about respondents' identification with and belief in the person featured in the advertisement and were designed to determine respondents' own experience with arthritis (Jack, Tr. 6093-94). Upon completion these questionnaires were sent for coding to Action Research, a subsidiary of Bates located in Universal City, California. The tabulations of coded responses to the questionnaires and the completed questionnaires were then forwarded to Bates, where CX 301 was then prepared. The typed [52] verbatim responses appearing at CX 301Z016-044 differ from the other Bates copy tests in that these report not only the responses to the standard open-ended recall questions (*see, e.g.*, CX 299Y-Z), but they also report answers to a question regarding reaction to the commercial. The precise wording of this latter question is not known, but it appears to have been worded as the corresponding question in CX 299Z003 (Jack, Tr. 6094).



### 3. Copy Tests by H.D. Ostberg Associates

207. Six copy tests in evidence (CX 271, 285, 286, 288, 289, 290) (Ostberg copy tests) are reports of copy tests conducted by H.D. Ostberg Associates on various Bufferin and Excedrin television advertisements involved in this proceeding (Ostberg copy tests). Henry Ostberg testified for complaint counsel regarding the conduct and reporting of these tests, which his company performed for the respondents.

208. At the time these tests were conducted, Mr. Ostberg was the owner and President of H.D. Ostberg Associates. This company is now a division of the Admar Research Company, of which Mr. Ostberg is Chairman of the Board (Ostberg, Tr. 4449-54). Admar Research provides services in marketing and advertising research and consulting (Ostberg, Tr. 4450). Certified Surveys, another company owned by Mr. Ostberg at the time these copy tests were conducted, is a field work and tabulation firm which, through retained independent contractors, supervised, collected, and tabulated the data of each test, but performed no analysis of the data. Currently, Certified Surveys is the company which conducts most of the field work for Admar Research (Ostberg, Tr. 4454-55). In addition to founding Admar Research and its predecessors, Mr. Ostberg's background includes a professorship in Marketing at the New York University for nine years, a law degree from the New York Law School, a Master's degree in Business Administration and a Ph.D. from Ohio State University (Ostberg, Tr. 4450). Ostberg Associates' clients have included Admar, Bristol-Myers, Lever Brothers Company, Miller Brewing Company, Philip-Morris, Nabisco, IBM, and BASF. For Bristol-Myers, Mr. Ostberg has conducted copy tests and tracking studies from 1965 to the present in various product categories, including OTC analgesics (Bufferin, Excedrin), deodorants, suntan lotions, and men's hair preparations. He also served as a consultant for Bristol-Myers in this proceeding (Ostberg, Tr. 4455-58). Mr. Ostberg's clients are generally advertisers, but he sometimes serves his client's advertising agency in an ancillary role, assisting in its preparation of marketing and advertising research for the client (Ostberg, Tr. 4456-57). He has also conducted studies for Young & Rubicam where the client was Bristol-Myers (Ostberg, Tr. 4457). [53]

209. Bristol-Myers first requested Mr. Ostberg to perform copy tests of Bufferin and Excedrin advertisements in the late 1960's. Mr. Ostberg collaborated with Dr. Edward Berdy, Director of Marketing Research for Bristol-Myers at that time, in the design, development and pre-testing of the "shopping center van technique" used in the six Ostberg copy tests of Bufferin and Excedrin advertisements in the record.

210. The execution of the copy tests and preparation of test results were directly supervised by senior executives of Admar, who reported directly to Mr. Ostberg (Ostberg, Tr. 4469-70).

211. The copy tests performed by H.D. Ostberg Associates for Bristol-Myers employed the so-called "shopping van technique." According to Mr. Ostberg (Ostberg, Tr. 4480-81) the methodology was as follows: Upon notification to H.D. Ostberg Associates that Bristol-Myers requested the copy testing of an advertisement, employees of independent contractors employed by Certified Surveys were sent to shopping centers in Philadelphia, Chicago, Detroit or Los Angeles to perform the actual tests (Ostberg, Tr. 4461, 4480). These employees would ask shoppers at the shopping center to participate in a television survey, and, if they agreed, have them enter a van equipped with a motion picture projector located at the shopping center. The shoppers were then asked a set of preliminary questions regarding product usage and preference (*see, e.g.*, CX 290Z022-023). Those shoppers who indicated that they used an analgesic were then shown a travelogue, including several advertisements, among which were the commercials to be tested. Afterwards, the shoppers were presented with an opportunity to select a discount coupon for one of several products in several different product categories. The shoppers then left the van. Within 24 hours the shoppers were telephoned by independent contractors of H.D. Ostberg Associates and asked recall questions about the commercial they had viewed the previous day. According to standard practice, H.D. Ostberg Associates would then perform limited validation to determine the genuineness of the results. The completed questionnaires were forwarded to H.D. Ostberg Associates, where the results were coded, keypunched, and tabulated internally.

212. The results were then put in a tabular format, which was either produced by computer or typed (Ostberg, Tr. 4483). The verbatim responses to recall questions were sometimes also attached (*see, e.g.*, CX 290Z007-Z021).

213. The results were then sent to Bristol-Myers or its advertising agency (Ostberg, Tr. 4484).

214. CX 285 through 290 were produced according to the procedures detailed above (F. 211, *supra*) (Ostberg, Tr. 4513, 4517-19, 4525). CX 271 includes two tables of coded responses bearing the notation "Recorded, ASW" (CX 271J-L). Anne S. Weitz (Jack), a former Vice President of Ted Bates, who testified [54] about CX 271, did not recall the exact circumstances of that notation (Jack, Tr. 6094-95).

215. The ASI Audience Reaction Tests are the most elaborate copy tests in evidence. The ASI copy tests appear to have been used by other advertisers and advertising agencies. Ted Bates' "Copy Lab" and "Quick Copy Lab" copy tests are not as elaborate as the ASI tests.

Neither are the Ostberg's "Shopping Van" copy tests. Although these survey results are not technically projectable to any general population or subgroup, the results have been used by advertisers and advertising agencies as a reliable and practical means of gauging likely audience reactions to proposed television advertising copies. In this proceeding, they are reasonably reliable confirmatory evidence on the issue of what a television commercial can reasonably be expected to convey to the viewer.

#### D. *Some Other Documentary Exhibits*

##### 1. The AMA Drug Evaluations

216. Dr. John Lewis is a pharmacologist, experienced in testing analgesics, who presently holds the position of Senior Scientist in the Department of Drugs of the American Medical Association (Lewis, Tr. 4159-61). Since associating with the AMA in 1960, Dr. Lewis has held a number of positions, each of which has involved supervising the publication by the AMA of monographs evaluating new drugs. Prior to development of the three editions of the *AMA Drug Evaluations*, such monographs were published in the *Journal of the American Medical Association* and the predecessor publication to the *AMA Drug Evaluations*, titled *New and Nonofficial Drugs* (Lewis, Tr. 4163-64). The Council on Drugs, a standing committee of the AMA, reviewed and commented on all material prepared by Dr. Lewis and his staff prior to publication (Lewis, Tr. 4165). The basis for evaluation and review of material published on new drugs included the published literature and unpublished data submitted to the Council by pharmaceutical manufacturers (Lewis, Tr. 4166). In many instances the information was the same as that submitted to FDA with a new drug application (Lewis, Tr. 4166).

217. The American Medical Association published three editions of the *AMA Drug Evaluations*, in 1971, 1973 and 1977. The publication was a comprehensive compilation evaluating all types of drugs available to the medical profession including single entity drugs and mixtures (Lewis, Tr. 4167). Virtually all of the drugs in the U.S. Pharmacopoeia and the National Formulary as well as 500 of the most commonly prescribed drugs were included in the evaluation (Lewis, Tr. 4170). The evaluations were based on all of the available information including published and unpublished work made available to the AMA and the advice and opinions of consultants, and the AMA's Council on Drugs (Lewis, Tr. 4171). Information in the book [55] includes the nonproprietary name of the drug, trade names, action and uses of the drug, comparative safety and efficacy, significant

adverse reactions, precautions, preparations available, and the manufacturer's name (Lewis, Tr. 4171).

218. The Council on Drugs of the AMA was comprised of 12 members, appointed by the AMA Board of Trustees for their expertise in the area of drugs, and was responsible for overseeing publication of the *Drug Evaluations* (Lewis, Tr. 4172). Two of the members of the Council—Drs. Wood and Adriani—were recognized experts in the field of analgesics, both having done considerable research and publishing in the field (Lewis, Tr. 4173). The Council chairman appointed an Ad Hoc Committee to review initial material submitted by staff and to make comments and suggestions on each chapter (Lewis, Tr. 4174). The Ad Hoc Committee included Dr. Alan Bass, Chairman of the Department of Pharmacology at Vanderbilt University, Dr. Daniel Rogers, a practicing physician, and the Council Chairman, Dr. Adriani. Draft chapters were also sent to outside consultants for their comments. For the first edition of the *Drug Evaluations*, the outside consultants asked to comment were chosen by staff of the Council on Drugs. Dr. William Beaver was among the outside consultants contacted for review of the first edition (Lewis, Tr. 4175-76). The Council member assigned to review the first edition's chapter on mild analgesics (CX 518) was Dr. Lauren Woods, an eminent authority in analgesics who is presently Vice-President for Health Affairs at the Medical College of Virginia and previously chairman of the Department of Pharmacology at University of Iowa Medical School (Lewis, Tr. 4177).

219. A revised copy of the Mild Analgesics chapter incorporating comments of consultants was reviewed and commented upon by Dr. Woods. His comments were then submitted to the Associate Director of the Department of Drugs and the Secretary to the Council on Drugs, Dr. Lewis, who considered comments and incorporated them into a revised chapter before it was submitted to the Ad Hoc Committee of the AMA's Council of Drugs. The final proof of the first edition of the book was commented upon by the Pharmaceutical Manufacturer's Association, who had requested an opportunity to review it. Errata sheets were included with the first edition to reflect necessary changes in keeping with those comments (Lewis, Tr. 4179). Approximately 165,000 copies of the first edition of the *Drug Evaluations* were distributed to all members of the American Medical Association and another 40,000 were sold (Lewis, Tr. 4179-80).

220. In preparing the chapter on Mild Analgesics (CX 512) for the second edition (1973) of the *Drug Evaluations*, an initial draft was prepared based on the first edition and then submitted to Dr. Lauren Woods for review and comment. A revised draft incorporating his comments was prepared by Dr. Lewis and his staff and then submitted to outside consultants (Lewis, Tr. [56] 4182). The consultants who

received copies of this edition were Dr. William Beaver, Dr. Abraham Sunshine, Dr. Louis Lasagna and Dr. Dixon Woodbury. Replies were received from Dr. Sunshine and Dr. Woodbury (Lewis, Tr. 4182). These comments were carefully reviewed and another revised draft was prepared for Dr. Woods and the Committee of the Council on Drugs. That Committee was not the same Ad Hoc committee which reviewed the chapter for the first edition, but had more members, including former Ad Hoc Committee member Dr. L. Paulson, an expert in endocrinology and a Professor of Medicine at the University of Washington, and Dr. Daniel Azarnoff, Professor of Medicine and Clinical Pharmacology at the University of Kansas Medical School, who reviewed the chapter (Lewis, Tr. 4189; Azarnoff, Tr. 9196-98).

221. A revised draft of the chapter on Mild Analgesics was also sent to drug manufacturers, including Bristol-Myers (Lewis, Tr. 4184-85). Comments were referred to Dr. Woods for his opinion and advice (Lewis, Tr. 4188).

222. A final revision of the chapter was sent to the publisher after Dr. Woods reviewed the comments (Lewis, Tr. 4188). Approximately 65,000 copies of the second edition were sold (Lewis, Tr. 4189).

223. Complaint counsel's experts have attested to the reputation and reliability of the *AMA Drug Evaluations* as a source for conclusions about the safety and efficacy of drugs used by physicians (Azarnoff, Tr. 9197-98; Moertel, Tr. 5634).

## 2. The Medical Letter

224. The *Medical Letter* was founded in 1969 to provide physicians with an unbiased source of scientific information about drugs. It is an independent publication that does not sustain itself through advertising or affiliation with any manufacturers (Abramowicz, Tr. 2712). The *Medical Letter* now has over 107,000 subscribers, most of whom are physicians (Abramowicz, Tr. 2720). The *Medical Letter* is structured with both an editorial board and an advisory editorial board. The editorial board is comprised of an editor, Mark Abramowicz, M.D., and two associate editors who are lay science writers. The advisory editorial board is composed entirely of physicians who are selected on the basis of their qualifications and expertise in various fields of medicine (Abramowicz, Tr. 2713-14).

225. Articles that are published in the *Medical Letter* first go through a peer review process. Proposed articles are first reviewed by the editor and then sent to the editorial board for comment. Drafts are also sent to the members of the advisory editorial board for their comments. In addition, it is the practice of the *Medical Letter* to have all drafts reviewed by outside consultants who have special expertise in the subject [57] matter of the proposed article. A proposed article

is usually reviewed by at least six to eight outside consultants, but on some occasion it may be reviewed by as many as 60 outside experts. Proposed articles are also sent to the senior authors of the articles cited in the draft and to the manufacturer of the drug the article involves. Drafts are also routinely sent to governmental agencies such as the Food and Drug Administration and the United States Pharmacopoeia (Abramowicz, Tr. 2714-16).

226. The *Medical Letter's* editorial staff also prepares a bibliography and reviews current literature for each proposed article. This process is calculated to ensure the accuracy of the statements made in the articles that appear (Abramowicz, Tr. 2219). Final articles that appear in the *Medical Letter* incorporate the comments and corrections made as a result of this extensive review process (Abramowicz, Tr. 2718). This review process was followed in the development of CX 510, the July 5, 1974 issue of the publication titled "Is All Aspirin Alike?" (Abramowicz, Tr. 2727-33). Dr. Gehrard Levy, an expert in pharmacokinetics (Lanman, Tr. 11660-61; Abramowicz, Tr. 2733) and a consultant to Bristol-Myers in this matter (Tr. 8991-92), was a member of the advisory editorial board of the *Medical Letter* and personally participated in the development of CX 510 (Abramowicz, Tr. 2733).

227. Because of the peer review process by highly qualified experts in the field and the thorough check for accuracy, the *Medical Letter* is a highly reliable source of information about the opinion of experts regarding the safety and efficacy of drugs. Two of complaint counsel's expert witnesses attested to the reliability of the *Medical Letter* for that purpose (Moertel, Tr. 5631-32; Azarnoff, Tr. 9198-99).

228. The *AMA Drug Evaluation* chapter on mild analgesics (CX 512) and the *Medical Letter* article "Is All Aspirin Alike?" (CX 511) were received in evidence for the limited purpose of corroborating other evidence in the record by showing that these publications expressed views in accord with the opinions of expert witnesses who testified for complaint counsel regarding common issues.

#### IV. RESPONDENTS' ADVERTISEMENTS MADE THE REPRESENTATIONS ALLEGED IN THE COMPLAINT

##### A. Representations: Applicable Standards

229. The standard for determining the meaning of an advertisement is whether, from an examination of the advertisement as a whole, an interpretation is reasonable in light of the claims made therein. The Commission or an administrative law judge may determine the meaning of an advertisement solely from an examination of

what is contained therein, without consumer [58] testimony or survey data regarding how consumers in fact perceived the advertisement.

230. In addition, the Commission or an administrative law judge may, where appropriate, consider other testimonial and empirical evidence as an aid in determining the meaning of an advertisement. The record contains the opinion testimony of Dr. Ross and reports of copy tests which were conducted on certain advertisements in evidence and certain consumer research. The so-called penetration studies generally are not designed to ascertain how certain consumers perceive the meaning of advertisements: their emphasis is on consumer recall.

#### *Expert Opinion Testimony*

231. In reaching his expert opinion as to whether the representations alleged in the complaint were made in advertising for Bufferin, Excedrin and Excedrin P.M., Dr. Ross employed appropriate standards (Ross, Tr. 6944, 8169-71). Dr. Ross based his conclusions as to whether the challenged advertisements could reasonably have been understood by consumers on his experience with consumers, adopting their frame of reference which included, indirectly, their background or prior experience (Ross, Tr. 8185). Dr. Ross' judgments as to the representations made in challenged advertising for Bufferin, Excedrin and Excedrin P.M. were his independent expert opinions and were reached without reference to or reliance on data contained in copy tests, penetration studies or image studies (Ross, Tr. 6944-46).

232. However, Dr. Ross did refer to examples of supporting or confirmatory evidence that there were consumers who perceived or understood television advertisements as meaning, saying or showing certain of the alleged representations. Such confirmation or support was in the form of verbatim comments in copy tests which were elicited in response to comprehension and/or recall questions, and in the form of transcripts of focus group discussions (Ross, Tr. 6946). Dr. Ross prepared CX 815, 817, and 820 which list the representations that the complaint in this matter alleges were made in advertisements for Bufferin, Excedrin and Excedrin P.M. respectively (Ross, Tr. 6943). He also prepared CX 816, 818 and 821 which reflect his evaluation of and testimony as to whether the alleged representations were made in the challenged advertisements (Ross, Tr. 6957). Also indicated on these matrices are the exhibit numbers of copy tests which were run on specific advertisements which were made available to Dr. Ross for his review (Ross, Tr. 6959).

B. *The Bufferin Advertisements In Evidence  
Make The Challenged Representations*

1. Core Representations [59]

a. *Complaint Paragraphs 9(A)(1) and 9(A)(2)*

233. Bristol-Myers has represented that Bufferin relieves pain faster than aspirin relieves pain (Complaint Paragraph 9(A)(1)) and that Bufferin relieves pain twice as fast as aspirin relieves pain (Complaint Paragraph 9(A)(2)). The "faster than aspirin" claim is contained in CX 1-19, 22-46, 61-98, 100, 101, 103-105, 107, 109-114, 717D-G, 719-21, 671S, T, V, W, Z018-20. The "twice as fast" claim is contained in CX 1-19, 22-46, 48, 49, 52-60, 61-98, 100, 101, 103-105, 107, 109-113, 719, 720, 721, 717D-G. Bristol-Myers has admitted that they represented through advertisements that Bufferin relieves pain faster than "plain" or "simple" aspirin relieves pain. (Answer of Bristol-Myers Company, Paragraph 7; Answer of Bates, Paragraph 9).

234. The fact that this representation, as alleged in Paragraph 9(A)(1), was made is shown by the advertisements themselves and confirmed by expert testimony (*see* CX 815, CX 816A-C; Ross, Tr. 6960-76). Confirmatory evidence is also found in the following copy tests: CX 245, 246, 249, 250, 251, 267, 268, 269, 270, 272, 299, 300, 301.

235. This representation was made wherever the "twice as fast" claim was made because "twice as fast" is merely a more extreme version of the same speed claim (Ross, Tr. 6960). In addition, the representation was made in the following advertisements which depict a tense situation where, "[P]lain aspirin's fine, but Bufferin goes to work much faster," CX 51A. (*See also*, for similar language CX 48, 49, 52, 53, 54, 55, 56, 57, 58, 59, 60.)

236. The advertisements cited in F. 233, *supra*, made the representation alleged in Paragraph 9(A)(1) because consumers would have understood them as representing that Bufferin relieves pain faster than aspirin. This understanding of the advertisements reflects two factors: (1) that consumers understand "goes to work faster" as meaning Bufferin relieves pain faster (Ross, Tr. 6963), not merely that Bufferin gets into the bloodstream faster, and (2) that consumers understand "plain" or "simple" aspirin to mean "aspirin." This understanding of the advertisements is confirmed by documentary evidence provided by comments in copy tests run on a number of different advertisements. With respect to the interpretation of "goes to work faster," viewers were asked what "how long it takes to go to work" means (CX 272). Given a choice of three alternatives, including "to get into the bloodstream," the majority chose "for your headache to start feeling better" (CX 272T; Ross, Tr. 6963). In a focus group



discussion run by A.S.I., the group was asked what was being referred to by "half the time." The response was, "From the time you take the product to the time you're relieved of your headache . . . [60] comparing it to aspirin or anybody else's product" (CX 245Z044). Recall of one advertisement, CX 82a, again shows that in comments related to speed, respondents said Bufferin "gets to your head/headache faster" (CX 250P, *see also* 251P for same results on a different advertisement, CX 74a). Verbatim comments on an advertisement where the "faster" claim is made, independent of the "twice as fast claim" (CX 53a), further support the fact that consumers equate "goes to work faster," with faster relief of pain. In responding to the question, "What was said about the brand," viewers said, "Better than aspirin, works faster to kill pain" (CX 299H, respondent 3), "Relieves headaches fast" (CX 299H, respondent 6), "Quicker relief" (CX 299I, respondent 19), and "Fast acting pain relief" (CX 299J, respondent 27). In a copy test run on another advertisement (CX 22a), respondents clearly understood the speed claim as referring to relief, "Gets headache better in half the time" (CX 267W, respondent 85), ". . . Bufferin cuts the time in half to reach the pain," (CX 267W, respondent 86), "Bufferin relieves in half the time," (CX 267W, respondent 88).

237. The fact that consumers understand the reference to "plain" or "simple" aspirin as a reference to "aspirin" as alleged in Paragraph 9(A)(1), is also reflected in the focus group discussions and verbatims. A number of the comments cited above refer specifically to "aspirin." Other verbatims which support this include the following: "Works twice as fast as aspirin" (CX 269Z003, respondent 125). Based on these verbatims it is reasonable to conclude that the representation as alleged in Paragraph 9(A)(1) was made and that the admission by respondents that they represented that Bufferin relieves pain faster than "plain" or "simple" aspirin (*see* F. 233, *supra*) is an admission that the representation as alleged was made.

238. The fact that Bufferin advertisements made the alleged representation in Paragraph 9(A)(2) is demonstrated by the advertisements themselves and by expert testimony (Ross, Tr. 6960, 6965-68). This representation was made through a variety of express and implied claims concerning Bufferin's ability to relieve pain twice as fast as aspirin and through the use of various audio/visual techniques:

(a) A close-up focusing on language in the Bufferin label which reads "Twice as fast as aspirin." (Ross, 6965, *see* CX 1-7, 22-23, 26, 27-28, 29-31, 34-35, 43-44, 61A, 64A-67, 73-75, 85, 90, 98, 99, 100-101 103-114).

(b) A picture of one-half of the face of a clock or watch is shown accompanied by language such as:

Bufferin can cut the waiting time in half. Half the time. That's Bufferin time. [61]

(CX 25, *see also* CX 1, 22, 23, 26, 27-28, 29, 31, 33; Ross, Tr. 6967).

(c) Anncr: In the first important 30 minutes Bufferin delivers twice as much pure pain reliever as the best known aspirin. Twice as much.

(Ross, Tr. 6965; CX 3A; for similar language *see also* CX 2, 4, 7, 10, 12-13, 15, 22-24, 26, 27-28, 29, 30-38, 61, 63-64, 67, 99).

(d) Bufferin goes to work in half the time.

(Ross, Tr. 6967; CX 1, 23, 24, 25, 26, 27-39).

(e) Certain graphic techniques make this representation without any direct literal or audio reference to the "twice as fast" claim. One of the techniques shows a computer typewriter printing out two columns, one "aspirin," the other "BUFFERIN." The "aspirin" column is printed out more slowly and ends up being about half the size of the "BUFFERIN" column. The image is one of speed, which is reflected in the height which the columns reach in the same time (Bufferin reaches its height "twice as fast") and enhanced by the use of a special computer typewriter which prints faster than an ordinary typewriter. (*See* CX 2-4, 7, 61, 63, 64, 67). Another technique uses the image of a tablet of aspirin and a tablet of Bufferin disintegrating, the particles of each moving from the stomach of an anatomical model, to its head. Twice as much of the Bufferin has disintegrated as the aspirin. The technique is used in both print and film advertisements and represents that the faster acting Bufferin is twice as fast as aspirin (CX 68-77, 82-84, 109-110). Finally, this effect is also achieved in the series of advertisements which show two whole Bufferin tablets in a circle with two half-tablets of aspirin. The announcer is shown moving both Bufferin tablets out of the circle and into another one representing headache relief while the aspirin tablets remain inside the first circle (CX 9-15). The graphic 2:1 comparison is thus another means of representing that Bufferin is twice as fast as aspirin. [62]

239. The advertisements cited in F. 238 (a-d), *supra*, made the representation alleged in Paragraph 9(A)(2) because consumers would have understood their comparative speed claims as representing that Bufferin relieves pain twice as fast as aspirin relieves pain (Ross, Tr. 6961-63, 6965). This perception by consumers, tying Bufferin's speed claim to onset of pain relief is evidenced in the verbatims of copy tests and in focus group discussions associated with these advertisements which repeatedly play back that consumers' understanding of these claims in the context of the amount of time it would take for them to perceive relief from headache pain. Confirmatory evidence support-

ing the allegation in Paragraph 9(A)(2) is contained in the following copy tests: CX 245, 246, 249, 250, 251, 267, 268, 269, 270, 272, 300, 301. The following examples from available copy test results supply evidence of how consumers understood the graphic techniques described in F. 238 (a), (b), (d) and (e):

(a) Relieved pain twice as fast as aspirin

(CX 301Z017, respondent 7, *see also* respondents 20, 21, 26, 27, 29, 32).

(b) "Cut headache time in half by using Bufferin which works twice as fast" (CX 267V, respondent 75), "... spoke about quickness that Bufferin gave in headache relief . . . cut time in half" (CX 267S, respondent 237); "Bufferin relieves you of a headache in half the time" (CX 270Z006, respondent 21).

(d) *See* discussion at F.236, *supra*, which explains that consumers understood the "goes to work faster" claim as referring to speed of onset of *pain relief*.

(e) In response to a question regarding recall of what was seen in an advertisement using the computer-typewriter graphic, the following comments were made:

"... and a diagram of how much faster it works than plain aspirin" (CX 301Z016, respondent 2); "typedwritten [sic] words for asperin [sic] and bufferin with bufferin in the lead for fast action in the stomach" (CX 301Z019, respondent 22).

In describing what was seen in those ads where Bufferin was shown rushing to the headache of an anatomical figure, these comments were made:

It's twice as fast as aspirin because most of the dose goes immediately to the head [63] and relieves the headache while aspirin stays in the stomach longer

(CX 300M, respondent 86).

b. *Complaint Paragraphs 9(A)(4) and and 9(A)(5)*

240. Bristol-Myers has represented that Bufferin will not upset a person's stomach (Complaint ¶ 9(A)(4)) and that Bufferin will upset a person's stomach less frequently than aspirin (Complaint ¶ 9(A)(5)). The absolute "no stomach upset" claim was made in the following Bufferin advertisements: (a) CX 2-7, 11, 17, 19A, 40-41, 42A-46, 61A-64A, 93-98, 105, 717F. The "less frequent upset" claim was made in: (b) 2-7, 11, 17, 19, 40-41, 43-46, 49, 715, 52-56, 61A-91, 96, 97, 109-112, 114, 717F, 719-721.

241. Bristol-Myers admitted representing through the challenged advertisements that Bufferin will cause upset stomachs less frequently than plain or simple aspirin (Answer of Bristol-Myers Company, Paragraph 7, Answer of Bates, Paragraph 9). This is a clear admission that Bufferin advertisements cited above made the representation as alleged in Paragraph 9(A)(5). This is confirmed by expert testimony (Ross, Tr. 6982-85; CX 815, CX 816) and verbatim comments contained in the following copy tests: CX 249, 250, 251, 299, 300, 301.

242. The fact that the "less frequent upset" representation was made is confirmed by verbatims from copy tests. For example: "Doesn't upset your stomach like plain aspirin," (CX 31Z016, respondent 2); ". . . and doesn't leave stomach upset as aspirin sometimes does," (CX 301Z019, respondent 22); "Does not upset your stomach like ordinary aspirin," (CX 301Z035, respondent 15); ". . . without upsetting stomach like plain aspirin." (CX 301Z037, respondent 27); "Doesn't have ill effect on stomach like aspirin," (CX 301Z038, respondent 33); ". . . does not upset your stomach the way aspirin does," (CX 301Z042, respondent 73); "Less upset stomach," (CX 300F, respondent 140); ". . . reaches your head pain with less upset stomach . . .," CX 300F, respondent 141); "Less stomach distress," (CX 300F, respondent 46); "It is milder for the stomach," (CX 299J, respondent 25); ". . . more gentle and more effective than any other brand," (CX 299M, respondent 55). Based on these verbatims, expert testimony and respondents' admissions, it is reasonable to conclude that the representation as alleged in Paragraph 9(A)(5) was made.

243. The fact that Bufferin advertisements made the "no upset" representation in Paragraph 9(A)(4) is demonstrated by the advertisements themselves, and confirmed by expert testimony (Ross, Tr. 6983-85; CX 815, CX 816). Further confirmatory evidence is contained in the following copy tests: CX 300, 301. [64]

244. These representations were made through a variety of express and implied statements making absolute, noncomparative claims which convey the message that Bufferin does not cause stomach upset. Bufferin's special quality of gentleness to the stomach is made through a noncomparative assertion which is communicated simultaneously with a comparative claim (Complaint ¶ 9(A)(5)):

(a) "Bufferin doesn't upset my stomach, the way plain aspirin sometimes did" (CX 3) (See also CX 2, 4-7, 40-41, 43 and 66 for similar language.)

(b) "Bufferin gives more of the pure pain reliever going against the headache. More pure pain reliever, faster than plain aspirin. *Without the stomach upset* plain aspirin can cause" (CX 11, emphasis added). See also, for similar language, CX 17, 19, 44, 45-46.

(c) "Special ingredients in Bufferin lets you take it 4, 5, 6 times a day *without fear of stomach distress* plain aspirin can often cause" (CX 96, emphasis added).

(d) "Bufferin is marvelous. And it doesn't upset my stomach the way plain aspirin sometimes did. ANNCR: (VO) Every single Bufferin analgesic tablet contains gentle antacids *specifically made to help prevent the stomach upset* that plain aspirin can cause" (CX 67, emphasis added).

245. The advertisements cited above made the representation alleged in Paragraph 9(A)(4) because consumers would have understood them as representing that whether because of special ingredients, faster dissolution or antacids, Bufferin will not upset a person's stomach (Ross, Tr. 6982).

246. The fact that consumers understood these advertisements as making the absolute "no stomach upset" claim as alleged in Paragraph 9(A)(4) is repeatedly played back in copy tests run on some of the advertisements cited in F. 240(a), *supra*. For example: "Doesn't upset stomach," (CX 301Z016, respondent 1); "Relieves pain—no upset stomach—. . .," (CX 301Z016, respondent 3; *see also* respondents 1, 2, 4, 6, CX 301Z016; respondents 5, 11, CX 301Z017; respondents 14, 20, CX 301Z018 for similar language). [65]

#### c. Complaint Paragraph 12(A)

247. Bristol-Myers has represented that Bufferin relieves nervous tension, anxiety and irritability and will enable persons to cope with the ordinary stresses of everyday life (Complaint ¶ 12(A)). These representations were made in the following Bufferin advertisements: CX 715, 48–49, 52–60, (tension relief ads).

248. The fact that the representations were made is evidenced by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 6985–90, 8212–14, 8216, 8219, 8222, 8224–25; CX 815, CX 816). Further confirmatory evidence is also contained in copy test CX 299.

249. These representations were made through a variety of express and implied statements characterizing Bufferin as the drug of choice for relief in situations that produce tension, stress or anxiety. In certain of the cited advertisements, Bufferin is represented as having the ability to affect mood, whether it be to reduce stress, ease irritability or lessen tension. That effect is represented as one separate from relief of pain or headache pain and is generally conveyed, not literally, but rather by depicting a tense situation, relief from which is obtained after taking Bufferin (Ross, Tr. 6987). For example: (a) An angry student bangs on college professor's desk insisting that the college must change. Professor, trying to "keep cool," suggests a meet-

ing. "ANNCR: Often, people who are sensitive to others can be more sensitive to headache pain." [focus on aggravated professor] "Bufferin is for these people. It's strong medicine that treats you gently . . ." (CX 53). (b) With no voice-over, an ad shows Urban Relocation Department worker driving to home of two elderly people to tell them they are going to have to move. Announcer breaks in: "What you have to tell them isn't easy. Not for you. Often people who are sensitive to others, can be more sensitive to headache pain. They want all the help they can get as quickly as possible. [Man, obviously upset, shown taking Bufferin.] Bufferin is for these people." Man informs tenants of the news and announcer breaks in, "Bufferin, For sensitive people. [Super: For sensitive people. Better than aspirin.] It's better than aspirin." (CX 58).

250. It is clear that consumers would have understood the tension relief ads cited above to say that Bufferin can effectively relieve the anxiety or tension which would ordinarily arise in situations like those depicted in the advertisements, apart from Bufferin's ability to relieve pain or headache pain (Ross, Tr. 6987). The dominant theme of the tension relief advertisements is situational tension, not pain or pain relief. This is reflected not only in the text of the ads, but more vividly in the audio/visual portion of the ads (Ross, Tr. 6988, 8222, 8224-25). Thus, consumers would understand Bufferin to be a good tension reliever. [66]

251. This understanding of the advertisement by consumers is confirmed by the verbatim comments in copy tests done on Bufferin advertisements where respondents repeatedly play back the fact that they understand the claim in the context of tension/stress relief, independent of headache relief. Typical of their comments on CX 53A, a tension relief ad, as reflected in CX 299 are: "Relieves tension and headache," (CX 299J, respondent 26); "Young Dean pressured with student demand grabs a bottle of Bufferin to relief [sic] his tension," (CX 299J, respondent 28); "Relieves pain fast—also relieves tension," (CX 299M, respondent 54); "Helps calm nerves and tension," (CX 299M, respondent 59); ". . . Then the Dean took Bufferin to calm down," (CX 299I, respondent 14); ". . . Bufferin not only relaxed but helped the pain of headache," (CX 299K, respondent 24); "Take a Bufferin, calm down and then make decisions," (CX 299L, respondent 49); "Man under tension taking pills to relieve some," (CX 299N, respondent 69).

252. In certain advertisements, the tension theme, though less dominant, is still obvious (CX 32, 33, 37, 39). This perception by consumers was sometimes reflected in verbatims of copy tests run on some of those advertisements (e.g., CX 270). In an ad entitled "Dinner Party" (CX 32, 33), the hostess is shown amidst her guests who are

enjoying themselves while she is shown, hand to head, saying "What a time for a headache." One respondent characterized her as being struck with a headache at a "very important social situation," (CX 270W, respondent 14) which to many might be an anxiety provoking situation. Other, more specific comments include: "Relieves your headache quickly and relieves tension," (CX 270X, respondent 47); "Woman under stress at party. After taking Bufferin obviously relaxed enjoying herself," (CX 270Z006, respondent 25). Another ad, "Moving Day," (CX 37) portrays what viewers would readily identify as a stressful occasion. In this instance, "Mom" gets a headache as she is supervising the apparently gruff movers. The following verbatim from CX 269, a copy test on that advertisement, reflect that viewers associated Bufferin with tension relief: "Mother takes Bufferin for headache and tension," (CX 269V, respondent 27); "Woman in distress at moving time. Saw her take Bufferin and return to happy woman," (CX 269X, respondent 52); "Woman frantic . . . now refreshed after taking Bufferin," (CX 269X, respondent 53); "Lady said she was very upset and needed something to take for upset," (CX 269Z002, respondent 104). Another stressful situation appears in CX 39, "Beauty Parlor," where a hairdresser gets a headache in the midst of her busy work schedule but is relieved after taking Bufferin. Again, the tension theme is not dominant, but is clearly suggested and it is reasonable for viewers to identify with the situation and associate the relief of tension with Bufferin. Therefore, in these advertisements as well as those cited in F. 247, *supra*, respondents have communicated an association between Bufferin and relief from a tense situation. [67]

d. *Complaint Paragraph 17*

253. Bristol-Myers has represented that physicians recommend Bufferin more than any other nonprescription internal analgesic product (Complaint ¶ 17). These representations were made in the following Bufferin advertisements: CX 2-7, 41-46, 61, 65-67, 97, 107.

254. The fact that these representations were made is evidenced by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 6994-99; CX 815, CX 816). Further confirmatory evidence is also found in the following copy tests: CX 272, 301.

255. These representations were made through a variety of express and implied statements about the preferences and recommendations of physicians for Bufferin. Bufferin is represented as the brand doctors will specify more than all the leading pain relievers. For example: (a) . . . ANNCR: Of all leading brands of pain reliever you can buy for minor pain, doctors specify Bufferin most [Superimposed on screen: DOCTOR'S SPECIFY BUFFERIN MOST]. (CX 66). (b) AnnCR: . . . "Doctors specify [super: DOCTORS SPECIFY BUFFERIN MOST]

Bufferin most (close-up of super) of all leading brands of headache tablets you can buy . . ." (CX 41).

256. Consumers' understanding that doctors recommend Bufferin is confirmed by verbatim responses included in copy tests on Bufferin advertisements where respondents repeatedly played back the fact that the product was recommended by doctors. For example: "Doctors recommend bufferin," (CX 301Z042, respondent 58); "Recommended by most doctors for pain," (CX 301Z037, respondent 24); "It is good to know that there is a product that is actually better for one because a daactor [sic] sayd [sic] so," (CX 301Z034, respondent 90); ". . . and not harmful to the body—more doctors recommend Bufferin," (CX 272Z, respondent 5); "Works in 1/2 time more doctors recommend it," (CX 272Z001, respondent 19); ". . . recommended more often by doctors . . .," (CX 272Z003, respondent 45).

257. The "doctors recommend" claim expressly compares Bufferin to all *leading brands* of pain reliever. However, the copy test verbatims, not surprisingly, indicate that consumers understood the representation to compare Bufferin to "any other non-prescription analgesic product," e.g., "Doctors recommend it over all pain relievers," (CX 301Z032, respondent 83).

*e. Complaint Paragraph 21*

258. Bristol-Myers has represented that the analgesic ingredient in Bufferin is other than ordinary aspirin (Complaint Paragraph 21), and that representation was made in all of the [68] Bufferin advertisements listed in column 14 of CX 816 plus CX 717D-G, 719-21, 761R, S, T, V, W, Z018-20. The fact that Bufferin advertisements made the representation as alleged in Paragraph 21 is shown by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7000-01, 8230-31, 8236-37, 8238; CX 815, CX 816).

259. This representation was made through a variety of express and implied statements consistently positioning Bufferin so as to distinguish it from aspirin and, in fact, to avoid any possible inference that Bufferin contains aspirin (Ross, Tr. 8237). That is, in certain of the advertisements, Bufferin is represented as faster, gentler and able to provide greater pain relief than aspirin by directly comparing Bufferin and aspirin with respect to those qualities (Ross, Tr. 7000-01, 8230). For example: (a) "Anncr: You have a headache. You've taken aspirin. How long before it . . . goes to work? You should have taken Bufferin. Bufferin . . . can cut the time . . . in half. Half the time. That's Bufferin time. Because in the first critical minutes, Bufferin speeds twice as much . . . active . . . pain reliever . . . to your headache as simple aspirin . . . so Bufferin goes to work in half the time. Half the time . . . that's Bufferin time." CX 29. (b) "Anncr: What happens inside your system



to plain aspirin and Bufferin? This illustrates two reasons why Bufferin is better. Most of Bufferin . . . with its extra speed . . . is already going to your headache . . . at the time most of plain aspirin . . . is still in your stomach. So with Bufferin when there's less to upset your stomach . . . there's also more pain reliever on its way to your headache. Two reasons Bufferin is better than plain aspirin for you." CX 69. (c) "Anncr: In the first important 30 minutes Bufferin delivers twice as much pure pain reliever as the best known aspirin. Twice as much" . . . "Bufferin doesn't upset my stomach, the way plain aspirin sometimes did . . ." (CX 3). Furthermore, in many of the Bufferin advertisements, the "other than aspirin" representation is made visually by presenting an enlarged picture of the label on the Bufferin bottle which says "Twice as fast as aspirin" and the brand name, which fill the television screen (CX 44A; Ross, Tr. 7001).

260. By consistently failing to say that Bufferin's analgesic ingredient is aspirin, many Bufferin advertisements succeed in positioning the product as something quite distinct from aspirin. Consumers, therefore, would reasonably understand the Bufferin/"plain" aspirin distinction as one based on actual ingredient differences beyond the buffered/nonbuffered distinction (Ross, Tr. 8237-38). The fact that the advertisements frequently refer to aspirin as "plain" or "simple" does not change the fact that many consumers understand the distinction as one between aspirin and a pain reliever in Bufferin that is not aspirin (Ross, Tr. 8238). Thus, consumers would have understood a claim comparing aspirin and Bufferin with respect to speed and gentleness as one impliedly represent[69]ing that the analgesic ingredient in Bufferin is other than ordinary (plain or simple) aspirin.

261. It is not surprising that several copy tests in evidence confirms that conclusion. For example, the following comments from copy tests on three Bufferin advertisements (CX 3A, 53A, 69A) show a state of mind reflecting the fact that consumers think Bufferin does not contain aspirin: "Relieves headache faster than plain aspirin—contains no aspirin," (CX 300K, respondent 26); "It has the better pain relieving qualities than aspirin," (CX 299I, respondent 20).

*g. Complaint Paragraph 14(A)*

262. Bristol-Myers has represented that scientific tests or studies prove that Bufferin is twice as fast as aspirin in the following advertisements: CX 2-4, 7, 10, 13, 34, 61-64, 67, 91-96, 98-100, 113-114, 721.

263. That the representations were made is shown by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7022; CX 815, CX 816).

264. In certain of the challenged advertisements explicit reference is made to underlying scientific proof: "Test publishes [sic] in medical

journals show that in the first critical minutes Bufferin delivers twice as much pain reliever as simple aspirin . . ." (CX 63). Other advertisements referring to laboratory or clinical test results and graphs also made the representation by suggesting that the tests represent underlying scientific proof: "Bufferin laboratory tests show most of its pain reliever gets into the bloodstream 10 minutes sooner than plain aspirin" [Super: TEN MINUTES SOONER THAN ASPIRIN] (CX 91). See also CX 34, 92-96, 98-100.

## 2. Establishment Representations

265. The explicit references to scientific tests also imply a claim that it has been scientifically proven or established that Bufferin is faster and gentler than aspirin. Thus, all advertisements which made the claim challenged in Paragraph 14(A) (*see* F. 262, *supra*) also made the establishment claim challenged in Paragraphs 7(A)(1) and (2).

266. Consumers believe that when any comparative performance claim is made for a drug or medicine, there must exist a basis in scientific fact or medical opinion for such claims and that, otherwise, they would be prohibited (Ross, Tr. 7024, 7036). Indeed, as a matter of market fairness, consumers have a right to expect, and do expect, that the advertiser has such scientific proof. Therefore, every Bufferin advertisement which contains a claim of comparative superiority over other drugs implies that such superiority has been established. [70]

### a. Complaint Paragraphs 7(A)(1)-(5)

267. Bristol-Myers as a matter of fact has explicitly represented that it has been established that: (a) Bufferin relieves pain faster than aspirin relieves pain (Complaint ¶ 7(A)(1)), (b) Bufferin relieves pain twice as fast as aspirin relieves pain (Complaint ¶ 7(A)(2)), (c) A recommended dose of Bufferin will not upset a person's stomach (Complaint ¶ 7(A)(4)), (d) Bufferin will upset a person's stomach less frequently than aspirin (Complaint ¶ 7(A)(5)).

268. These representations were made in the following Bufferin advertisements: (a) CX 2-4, 71, 8, 10, 13, 34A, 39A, 61A-88A, 91-96, 98, 101, 102, 109, 110, 719, 720, 721, 749-51, 761S, T, V, W, Z018-020 made the representations alleged in Paragraph 7(A)(1); (b) CX 2-4, 7, 10, 13, 34, 39, 61-64, 67A and 96 made the representations alleged in Paragraph 7(A)(2); (c) CX 61-64 made the representations alleged in Paragraph 7(A)(4); (d) CX 61-64, and 109 made the representations alleged in Paragraph 7(A)(5). However, none of the Bufferin advertisements in evidence made, either directly or by implication, the claim that Bufferin will relieve twice as much pain as aspirin as alleged in Paragraph 7(A)(3).

269. The fact that Bufferin advertisements made these representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7007-7020, 7041-55; CX 815, 816).

270. These representations were made through a variety of express statements and graphic representations conveying the claim that Bufferin's greater speed and gentleness was based on scientific or medical fact or opinion (Ross, Tr. 7007-08, 7010-11, 7013-14): (a) The representation that it is established that Bufferin relieves pain faster than aspirin was conveyed by explicit references to tests (F. 268, *supra*) and through use of the following visual techniques: computer typewriter reports which suggest that a scientific test is being reported to consumers as if a meter were ticking out the results of tests, *see, e.g.*, CX 2, 4, 7 (Ross, Tr. 7009-10); anatomical models which suggest a medical demonstration, *see, e.g.*, CX 68, 69 (Ross, Tr. 7014); clocks which consumers might expect would be used in laboratory test procedures, *see, e.g.*, CX 34, 39 (Ross, Tr. 7013); bar graphs which appear to come out of a medical report or scientific presentation reflecting data gathered as substantiation for the claim, *see, e.g.*, CX 93 (Ross, Tr. 7010), (b) The representation that it has been established that Bufferin relieves pain twice as fast as aspirin was made through explicit references to tests (F. 268, *supra*) and through the use of the clock graphic, the computer typewriter report, and anatomical models, (c) The establishment claims of gentleness and comparative gentleness were made by explicit reference to [71] scientific tests. For example, CX 64 makes a comparative gentleness claim in such a context: "Try Bufferin. Doctors recommend Bufferin for minor pain more than any of the leading brands of aspirin. Scientific tests show that in the first critical minutes Bufferin gives you twice as much pain reliever as simple aspirin. Bufferin relieves arthritis minor pain and stiffness for hours . . . And Bufferin can prevent the stomach upset aspirin often causes . . ." In this instance, the initial references to doctors' recommendations and scientific tests provide a medical/scientific basis for the subsequent claim made, *i.e.*, that Bufferin will not upset a person's stomach (Ross, Tr. 7019). Moreover, respondent in CX 109 explicitly represented that "It has been clinically observed that Bufferin was gentler to the stomach than plain aspirin" (Ross, Tr. 7022).

### 3. Ingredient Disclosure (Complaint ¶ 19)

271. A review of the Bufferin advertisements in evidence clearly shows that respondents at no time disclosed directly or by implication that Bufferin contains aspirin.

*C. The Excedrin Advertisements In Evidence Made  
The Challenged Representations*

1. Representations of Superiority and Established Superiority  
(Complaint ¶¶ 7(B), 9(B))

272. Bristol-Myers has admitted that it represented Excedrin is a more effective pain reliever than aspirin tablets (Paragraph 7, Answer of Bristol-Myers Company). The explicit claim that Excedrin is more effective for the relief of pain than aspirin is found in numerous advertisements in evidence. They include: CX 115, 116, 153-61, 164-67, 170, 171, 173, 175-77, 179-182, 184, 185, 188-191, 193, 202-207, 208, 210, 211, 724, 725, 727-36, 760Z017, 760Z020, 760Z021, 760Z023, 760Z024, 760Z025, 761Z015, 761Z016, 761Z017.

273. Typical of the language employed in making this representation are the following:

(a) Tablet for tablet, Excedrin is 50% stronger than aspirin for relief of headache pain. (CX 115, 116).

(b) This is David Janssen. A major hospital study indicated there is something even more effective than aspirin for pain relief. Doctors attending a medical convention held right here in Atlantic City heard these results of this study: it would take more than twice as many aspirin tablets to give the same pain relief as two Excedrin. More than twice as many aspirin [72] to be as effective as Excedrin. Not three aspirin. Not even four aspirin. But more than double the recommended dosage of aspirin to give the same pain relief as two Excedrin. Yes, there is something even more effective than aspirin. That's the evidence doctors heard in Atlantic City. And that's what you should think about before you buy aspirin again . . . (CX 158)

(c) ACTRESS: What do you take for pain? If you take common aspirin tablets, there's something you ought to know: I think my pain reliever works better than your pain reliever . . . (CX 181).

(d) MAN: I don't practice medicine. So if I said Excedrin worked better than regular aspirin, you might not believe it. But what if there were medical evidence? Well, there is . . . (CX 189).

(e) ASPIRIN ISN'T BEST ANYMORE. That's the important new evidence about pain relievers . . . (CX 204).

(f) . . . 2 Excedrin = 3 Ordinary Tablets . . . (CX 729).

a. *Complaint Paragraph 9(B)(2)*

274. Bristol-Myers has represented that a recommended dose of Excedrin relieves twice as much pain as a recommended dose of aspirin (Comp. ¶ 9(B)(2)). This representation was made in the following advertisements: CX 153-161, 164-167, 170, 173, 176, 182, 184, 185, 202-204, 208, 736.

275. The fact that Excedrin advertisements made this representation is demonstrated by the advertisements themselves, and con-

firmed by expert testimony (Ross, Tr. 7074–79) and several ASI Audience Reaction tests (CX 254, 255 and 257).

276. This representation was made through a variety of express and implied statements of Excedrin's ability to relieve twice as much pain as aspirin (Ross, Tr. 7075). Each of the challenged advertisements cited in F. 274 represents that at least twice as many aspirin tablets are needed to equal the pain relief provided by Excedrin. CX 153 is typical of language and approach of these advertisements:

(b) DAVID JANSSEN: A major hospital study has indicated that there is something even more effective than aspirin for pain relief. [73] Doctors here in Atlantic City heard these results of this study: it would take more than twice as many aspirin tablets to give the same pain relief as two Excedrin. Not three aspirin, not even four. But more than double the recommended dosage to give the same pain relief as two Excedrin. Think about that before you buy aspirin again. Excedrin . . . more effective than twice as many aspirin.

277. These advertisements made the representation alleged in Paragraph 9(B)(2) because consumers would understand the claim that at least twice as many aspirin were needed to equal the pain relief provided by Excedrin as representing that a recommended dose of Excedrin relieves twice as much pain as a recommended dose of aspirin (Ross, Tr. 7074–79). This perception by consumers is evidenced in the focus group comments reported in ASI Audience Reaction tests of certain of these advertisements, where participants repeatedly played back the idea that Excedrin is twice as effective, or twice as strong, *i.e.*, relieves twice as much pain, as aspirin (*e.g.*, CX 254Z013; CX 255Z005, Z007; CX 257Z045; CX 258Z018).

b. *Complaint Paragraph 9(B)(5)*

278. Respondents have represented that Excedrin reduces fever more effectively than aspirin (Comp. ¶ 9(B)(5)). This representation was made in the following advertisements: CX 162, 163, 186.

279. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7092–96), and CX 256, the report of an ASI Audience Reaction Test (Ross, Tr. 7094; CX 256Q).

280. This representation was made through the statements in each of the advertisements listed in F. 278, *supra*, that Excedrin has "more pain relievers, *more fever reducers*, more total strength than the common aspirin tablet" (emphasis added). Consumers would reasonably conclude that an analgesic product that had *more fever reducers* than aspirin would reduce fever more effectively than aspirin (Ross, Tr. 7092, 7096).

*c. Complaint Paragraphs 14(B), 7(B)(2) and 7(B)(5)*

281. Bristol-Myers has represented that the results of scientific tests or studies prove claims that Excedrin is twice as strong as and more effective than aspirin in relieving pain (Comp. ¶ 14(B)). Largely through this representation, respondents have implied that it has been scientifically proven or [74] established that a recommended dose of Excedrin relieves twice as much pain as a recommended dose of aspirin (Complaint ¶ 7(B)(2)). Both of these representations were made in the following advertisements: CX 153-161, 164-167, 170, 171, 173, 176, 182, 184, 185, 202-204, 208, 736.

282. The fact that Excedrin advertisements made the alleged representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7086-92; 7126-28) and two reports of ASI Audience Reaction Tests: CX 254 and 255.

283. These representations were made through a variety of express and implied statements of proof based on the results of medical or scientific studies for Excedrin's claim of greater strength and effectiveness than aspirin.

284. Challenged advertisements such as those cited in F. 281, *supra*, made the alleged representation by referring to medical studies and hospital tests as proof that at least twice as many aspirin are needed to equal the pain relief provided by Excedrin. Examples of this approach include:

(a) This is where it all happened. [scene of large skyscraper] At a medical convention right here in Atlantic City. Here doctors heard new clinical evidence that there is a difference in how pain relievers perform. The results of this major hospital study: It took more than twice as many aspirin tablets to give the same pain relief as Excedrin. More than twice as many aspirin to be as effective as Excedrin. How much aspirin a pain reliever contains is one thing. How effectively that pain reliever performs is something else. And that's the important new evidence about pain relievers today. Two Excedrin . . . more effective for the relief of pain than twice as many aspirin. Isn't it time you tried Excedrin? [SFX: Excedrin bottle and the words: "More effective than twice as many aspirin"] (CX 155; *see also* similar language in CX 156-161).

(b) There's evidence that Excedrin is more effective than aspirin. Now you've been hearing that for over a year. But remember: the evidence is from a major hospital study . . . a study among patients with a kind of pain other than headache that medical science uses to compare pain relievers. In that study it took more than twice as many aspirin tablets to equal the pain relief of [75] Excedrin. With that kind of medical evidence— isn't it time you tried Excedrin? (CX 173; *see also* similar language in CX 165).

(c) A hospital study early in the 1960's could find no significant difference in pain relief between common aspirin and Excedrin. But medical research did not stop there. And a more recent hospital study revealed a significant advantage for today's Excedrin . . . evidence that Excedrin is more effective than aspirin. Both studies were conducted among patients with a kind of pain other than headache used by medical science for comparing pain relievers. But in this latest study, it took more than twice as many

aspirin tablets to equal the pain relief of Excedrin. Yes, more than twice as many! Since research in a hospital found evidence that Excedrin is more effective than aspirin, isn't it time you tried it at home? [SFX: Excedrin bottle and the words: "Isn't it time you tried Excedrin?"] (CX 176).

As seen in example (a) *supra*, the advertisements, which all feature actor David Janssen as a spokesperson, often refer to a backdrop of a purported medical convention site (see CX 155-161).

285. The reference in the advertisements to "a hospital study," would be understood by consumers to be a reference to the results of scientific tests or studies (Ross, Tr. 7127) as would references to "medical evidence," and "clinical evidence." The representation that at least twice as many aspirin are needed to equal the pain relief provided by Excedrin would be understood by consumers as a claim that Excedrin relieves twice as much pain as aspirin, and is twice as strong as and more effective than aspirin (Ross, Tr. 7088). Therefore, the reference to "a hospital study," and "medical evidence," as proof that twice as many aspirin tablets are needed to equal the pain relief provided by Excedrin would be understood by consumers as a representation that scientific tests or studies prove the claim (Ross, Tr. 7088-89). Therefore, the representation alleged in Paragraph 14(b) was made.

286. References to proof through scientific tests or studies is understood by consumers as a claim that it has been scientifically established that Excedrin relieves twice as much pain as a recommended dose of aspirin, since the claim would be interpreted as a statement of medical fact (Ross, Tr. 7217). Therefore, the representation alleged in Paragraph 7(B)(2) was made. [76]

287. Confirmatory evidence that the representations challenged in Paragraphs 14(B) and 7(B)(2) were made is found in CX 254 and 255, reports of ASI Audience Reaction tests. As to the proof through scientific tests or studies, a respondent in CX 254 noted, "I think [David Janssen] said it was clinically tested" (CX 254Z014). A respondent in CX 255 thought "the commercial [CX 153] says they have proof it is four times as effective as aspirin" (CX 255Z008).

288. Advertisements making the claim that Excedrin reduces fever more effectively than aspirin (F. 278, *supra*) do not explicitly represent that this claim has been established (Complaint ¶ 7(B)(5)). However, since these advertisements make a claim of comparative superiority over other drugs, they, by their nature, imply a claim that such superiority has been scientifically established.

## 2. Representations Of Superiority Over All Other OTC Internal Analgesics

### a. Complaint Paragraph 9(B)(1)

289. Bristol-Myers has represented that a recommended dose of Excedrin relieves more pain than a recommended dose of aspirin or any other nonprescription internal analgesic (Complaint ¶ 9(B)(1)). This representation was made in the following Excedrin advertisements: CX 115, 116, 122-128, 130-139, 141-142, 144-153, 155-157, 162, 163, 168, 169, 172, 174, 181, 183, 186, 188-191, 193, 202-211, 724, 725, 727-733, 735-741, 760Z017, 760Z021, 760Z023-25, 761Z015-17.

290. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7066). Confirmatory evidence is contained in CX 310, the 1969 Excedrin Study.

291. The advertisements cited in F. 289, *supra*, made the representation alleged in Paragraph 9(B)(1) because each contained the claim that it was *stronger* than any other nonprescription internal analgesic. Consumers would understand that an analgesic which was stronger than any other would relieve more pain than any other (Ross, Tr. 7066; CX 819). CX 310, the 1969 Excedrin Study, confirms that consumers would so interpret this claim: when asked to choose from among five descriptions of "extra-strength," over half the analgesics users queried ranked "more effective for severe pain" as their first or second choice (CX 310Z117).

292. Since consumers view relief of more pain as an attribute of a more effective pain reliever, consumers would [77] understand the representation that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic as claiming also that Excedrin relieved *more* pain than any other nonprescription internal analgesic (Ross, Tr. 7058-59; CX 819; CX 310Z115). Therefore, wherever the representation that Excedrin is a more effective pain reliever was made, the representation that Excedrin would relieve more pain than aspirin or any other nonprescription analgesic was also made. Furthermore, since the representation that Excedrin is a more effective pain reliever than aspirin or any other nonprescription analgesic because it contains four ingredients (Complaint ¶ 9(B)(7); F. 315, *infra*) is but a variation of the representation in Paragraph 9(B)(6): it too would convey the representation that Excedrin relieves more pain than aspirin or any other nonprescription analgesic (Ross, Tr. 7086; CX 819). Thus, wherever the representations alleged in Paragraphs 9(B)(6) and (7) were made, the representation alleged in Paragraph 9(B)(1) was also made.



b. *Complaint Paragraph 9(B)(3)*

293. Bristol-Myers has represented that Excedrin relieves pain for a longer period of time than a recommended dose of aspirin or any other nonprescription internal analgesic (Complaint ¶ 9(B)(3)). This representation was contained in the following advertisements: CX 115, 116, 122-128, 130-139, 141-142, 144-153, 155-157, 162, 163, 168, 169, 172, 174, 181, 183, 186, 188-191, 193, 202-211, 724, 725, 727-733, 735-741, 760Z017, 760Z020, 760Z021, 760Z023-25, 761Z015-17.

294. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7066-67, 7058-59), and by CX 310, the 1969 Excedrin Study, and CX 289 and 290, reports of copy tests conducted by the Ostberg organization.

295. This representation was made through a variety of express and implied statements of the longer-lasting relief given by Excedrin compared to aspirin and various other nonprescription internal analgesic products.

296. In many of the cited advertisements Excedrin is represented as a more effective pain reliever than aspirin or any other nonprescription internal analgesic because it contains four active ingredients. One of the active ingredients represented in these advertisements as making Excedrin a more effective pain reliever is an ingredient represented as providing "long-lasting relief." For example:

... For the headache that really bothers you, take new Excedrin, the extra-strength pain reliever. Look: [different chemical formulae are sequentially depicted] this is [78] the formula for aspirin. The heavily advertised product that talks of a new stronger formula merely adds caffeine to plain aspirin. But Excedrin has the strength of four medically tested ingredients. You get quick relief . . . *long-lasting relief* . . . a tension reliever to relax you . . . an antidepressant to restore your spirits . . . (CX 115; for similar language see advertisements listed in F. 315, *infra*).

These advertisements made the representations alleged in Paragraph 9(B)(3) because consumers would understand them as claiming that, by virtue of an added ingredient, Excedrin provided longer lasting relief than aspirin or any other nonprescription internal analgesic.

297. Many of the cited advertisements represent Excedrin as *stronger* for the relief of pain than aspirin or any other nonprescription internal analgesic (F. 289, *supra*). These advertisements made the representations alleged in Paragraph 9(B)(3) because consumers would view the ability to relieve pain for a longer period of time as an attribute of an analgesic product represented as stronger than others (Ross, Tr. 7066; CX 819, CX 310Z114, Z117).

298. The verbatim comments in CX 289 and 290, copy tests conduct-

ed by the Ostberg organization on advertisements (CX 141 and 125, respectively) containing both the "active ingredient" and "strength" claims, confirm that this representation was made. Respondents' comments regarding Excedrin included: "better, stronger and longer lasting" (CX 289Y); "works faster and gives longer lasting relief" (CX 289Z001); "it just lasted longer than other pain relievers" (CX 289Z002); "faster relief and relief lasts longer" (CX 289Z006); "Excedrin would work faster and last longer and was stronger than aspirin" (CX 289Z017); "it lasts for a longer time" (CX 290Z017).

299. Since consumers view longer duration as an attribute of superior analgesic effectiveness, consumers would also understand the representation that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic as claiming that Excedrin relieved pain for a longer period of time than aspirin or any other nonprescription analgesic (Ross, Tr. 7058-59; CX 819). Therefore, wherever an advertisement represented that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic (Complaint ¶ 9(B)(6); F. 308, *infra*) and/or that Excedrin is a more effective pain reliever because it contains four active ingredients (Complaint ¶ 9(B)(7); F. 315, *infra*) the representation that Excedrin relieves pain for a longer period of time than aspirin or any other nonprescription internal analgesic was also made (Ross, Tr. 7058-59). [79]

*c. Complaint Paragraph 9(B)(4)*

300. Respondents have represented that Excedrin relieves pain faster than aspirin or any other nonprescription internal analgesic (Complaint ¶ 9(B)(4)). This representation was made in the following advertisements: 115, 116, 122-128, 130-139, 141-142, 144-153, 155-157, 162, 163, 168, 169, 172, 174, 181, 183, 186, 188-191, 193, 202-211, 724, 725, 727-733, 735-741, 760Z017, 760Z020, 760Z021, 760Z023-25, 761Z015-17.

301. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves and by expert testimony (Ross, Tr. 7058-59). Confirmatory evidence is found in CX 310, the 1969 Excedrin Study; CX 255, report of an ASI Audience Reaction Test; and CX 287, 288, 289 and 290, reports of tests conducted by the Ostberg organization.

302. This representation was made through a variety of express and implied statements comparing Excedrin's speed in relieving pain to the speed of aspirin and other nonprescription internal analgesics.

303. In certain advertisements consumers are represented as experiencing pain relief in a matter of minutes with Excedrin and faster than they ever had before. For example:

(a) Over 19 million people have changed to new Excedrin for the relief of pain. Here's one of them . . . ACKERLY: I get terrible headaches from pressure and heat, and the fellow on the job said, 'Gee, I got something that'll take your headache away.' He gave me two pills and in about ten minutes my headache just left me and I said, 'Boy, what's the name of that stuff?' He says, 'Oh, it's Excedrin' (CX 115).

(b) ANNCR: What is an Excedrin headache? Listen . . . TESTIMONY: I was at a recording session [ . . . ] and I walked in there with a headache and I took two Excedrin during one of the breaks, ten minute breaks, and it was gone. The sound was still loud but it went away. ANNCR: Excedrin works fast. It has a special ingredient for quick relief. TESTIMONY: Something that works ZAP! It's really good . . . (CX 145).

(c) [ . . . ] MAN: I'd rather take Excedrin for a headache than anything else. WOMAN 2: The [80] faster something can work the better it is. I'm all for being rid of pain . . . (CX 146).

Advertisements making this representation convey the clear message to consumers that Excedrin relieves pain faster than aspirin or any other nonprescription internal analgesic.

304. In many of the cited advertisements Excedrin is represented as a more effective pain reliever than aspirin or any other nonprescription internal analgesic because it contains four active ingredients (Complaint ¶ 9(B)(7); F. 315, *infra*). One of the active ingredients which is represented in these advertisements as making Excedrin a more effective pain reliever is an ingredient (sometimes referred to as a "special" ingredient, *see, e.g.*, CX 145) represented as providing "quick relief" (*see* advertisements listed at F. 315, *infra*). These advertisements made the challenged representation because consumers would understand them as claiming that, by virtue of an added ingredient, Excedrin provided faster relief than aspirin or any other nonprescription internal analgesic (CX 819).

305.-306. Reserved.

307. Confirmation that the alleged representation was made is also found in copy tests of a representative selection of the challenged advertisements listed in F. 300, *supra*. CX 255, a report of an ASI Audience Reaction test on CX 153; and in CX 287, 288, 289 and 290, reports of copy tests conducted by the Ostberg organization on CX 135, 122, 141 and 125 respectively. Tabulations of the main ideas communicated in both the ASI and Ostberg tests demonstrate that the representation of Excedrin as the faster pain reliever was conveyed (CX 255Z005; CX 287M; CX 288P; CX 289O; CX 290Q). Participants in CX 289, for example, understood the advertiser ads representing that Excedrin "works faster and gives longer lasting relief" (CX 289Z001); "gets rid of your headache faster" (CX 289Z004); "is better than anything on the market," "Faster relief and relief lasts longer," "a faster and better pain reliever than others on the market" (CX 289Z006); "relieves pain faster and is better than other ones" (CX

289Z009); "it works faster" (CX 289Z010, Z014); "of course, [is] better and works faster than any other" (CX 289Z011).

d. *Complaint Paragraph 9(B)(6)*

308. Bristol-Myers has represented that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic (Complaint ¶ 9(B)(6)). This representation was made in the following advertisements: CX 115, 116, 122-128, 130-139, 141-142, 144-153, 155-157, 162, 163, 168, 169, 172, 174, 181, 183, 186, 188-191, 202-211, 724, 725, 727-733, 735-741, 760Z017, 760Z020, 760Z021, 760Z023-25, 761Z015-17. [81]

309. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7071-74). Confirmatory evidence is contained in CX 310, the 1969 Excedrin study; and CX 287, 288, 289, and 290, reports of tests conducted by the Ostberg organization.

310. This representation was made through a variety of express and implied statements concerning Excedrin's superiority to other pain relievers that referred to effectiveness or to particular attributes or dimensions of effectiveness, such as strength, speed and duration of relief.

311. Bristol-Myers has admitted that it represented Excedrin is a more effective pain reliever than aspirin tablets.

312. In certain of the challenged advertisements, Excedrin has also been represented as superior to aspirin and any other nonprescription internal analgesic in terms of the following attributes or dimensions of pain relief: (a) extra-strength; and (b) longer pain relief. The representation that Excedrin is superior to other analgesics as to one or more of these attributes or dimensions of analgesia would be viewed by consumers as a representation that Excedrin is a more effective pain reliever, since more pain relief and longer relief are viewed by consumers as components of greater effectiveness in a pain reliever (Ross, Tr. 7076; CX 819; CX 310 Z112-Z117).

313. Consumers would also understand the claim that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic because it contains four active ingredients (Complaint ¶ 9(B)(7)) as making the alleged representation because the former is but an extended statement of the latter (Ross, Tr. 7068; CX 819).

314. Confirmation that the alleged representation was made is found in copy tests of a representative selection of the challenged advertisements listed in F. 308, *supra*: CX 287, 288, 289, and 290,

reports of copy tests conducted by the Ostberg organization on CX 135, 122, 141 and 125, respectively. Tabulation of the main ideas communicated in the Ostberg tests demonstrate that the representation of Excedrin as a more effective pain reliever was conveyed (CX 287M; CX 288P; CX 289O; CX 290Q). Respondents in the Ostberg tests understood the advertiser to be claiming Excedrin as: "better, stronger, longer lasting" (CX 289Y); "the best pain reliever on the market" (CX 289Z); "among the different brands, the best" (CX 289Z004); "even though the others claim to be better for headaches" (CX 289Z004); "better than anything on the market" (CX 289Z006); "a faster and better pain reliever than others on the market" (CX 289Z007); "the best pain killer" (CX 289Z008); [82] "better than aspirin and the other brands" (CX 289Z009); "relieves pain faster and is better than the other ones" (CX 289Z009); "of all the other pain relievers, . . . the best and fastest working" (CX 289Z010); "better. Works quicker. Ingredients are stronger" (CX 289Z010); "better and works faster than any other" (CX 289Z011); "a lot more effective and was also a pain reliever (CX 289Z013); "a stronger pain reliever than the others" (CX 289Z015); "better than others for headache" (CX 290Z007); "relieves pain faster than anything else. Is more effective" (CX 290Z011); "the best product on the market. You should take it for all kinds of headaches;" "the best pain reliever made" (CX 290Z016); "much better than the others . . . stronger and more effective," (CX 290Z017).

*e. Complaint Paragraph 9(B)(7)*

315. Respondents have represented that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic because it contains four active ingredients (Complaint ¶ 9(B)(7)). This representation was made in the following advertisements: CX 115, 116, 120, 121, 124, 125, 132, 133, 138, 139, 141, 142, 144, 146-151, 209.

316. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7081-82). Confirmatory evidence is contained in CX 289 and 290, reports of copy tests conducted by the Ostberg organization.

317. The challenged advertisements cited in F. 315, *supra*, typically link the general representation of greater effectiveness conveyed by the "extra-strength" claim to a claim which expressly or impliedly attributes this "extra-strength" to four "medically proven ingredients," which are depicted graphically in a sequence of chemical formulas. For example:

(a) . . . For the headache that really bothers you, take new Excedrin, the extra-strength pain reliever. Look: (formulae shown in sequence) this is the formula for aspirin. The heavily advertised product that talks of a new stronger formula merely adds caffeine to plain aspirin. But Excedrin has the strength of four medically tested ingredients. You get quick relief . . . long lasting relief . . . a tension reliever to relax you . . . an anti-depressant to restore your spirits . . . Tablet for tablet, Excedrin is 50% stronger than aspirin for relief of headache pain . . . New Excedrin, the extra-strength pain reliever. (CX 115). [83]

(b) . . . The modern Excedrin formula gives you quick relief (formulae shown in sequence); long lasting relief, a tension reliever to relax you, an anti-depressant to restore your spirits . . . Four ingredients, not just one or two. That's Excedrin . . . the extra-strength pain reliever. (CX 125).

Other advertisements (*e.g.*, CX 147–150) simply state “Four ingredients, not just one or two . . . that’s Excedrin,” and others (*e.g.*, CX 118 and 121) buttress the four-ingredient claim by stating “Excedrin . . . with more quantity and more kinds of ingredients . . . than leading pain tablets!”

318. Challenged advertisements such as those cited in F. 315, *supra*, made the representation alleged in Paragraph 9(B)(7) because consumers would have understood the presence of four active ingredients as being put forward as a reason for Excedrin’s superior effectiveness, particularly where the number of ingredients in Excedrin is contrasted with the represented smaller number of ingredients in other nonprescription internal analgesics (“four ingredients, not just one or two . . .”; “more kinds of ingredients than leading pain tablets”) (Ross, Tr. 7081–82).

319. Confirmation that consumers so view the advertisements is contained in CX 289 and 290, reports of copy tests conducted by the Ostberg organization on advertisements (CX 141 and 125, respectively). These advertisements contained the four ingredient-chemical formula sequence. Tabulations of ideas communicated in both these tests demonstrate that the message of superior efficacy because of the presence of “more” ingredients was conveyed (CX 289Q; CX 290Q), as do the verbatim comments of respondents: “there was more pain relief in Excedrin because it has four pain relief ingredients” (CX 289Z005); “Excedrin was better than most other pain relievers because it has four ingredients” (CX 290Z002); “Excedrin is better and works faster than other products because of more things in it” (CX 290Z018).

### 3. Representations of Established Superiority for Excedrin Over All Other Nonprescription Internal Analgesics

320. Each of the Excedrin advertisements containing a claim of comparative superiority to any other nonprescription pain reliever

implies that such superiority has been scientifically established. See F. 266, *supra*.

a. *Complaint Paragraphs 7(b)(1), and 7(B)(3)–7(B)(7)*

321. Respondents have also explicitly represented, as a matter of fact, that it has been established that: [84]

(a) a recommended dose of Excedrin relieves more pain than a recommended dose of aspirin or any other nonprescription internal analgesic (Complaint ¶ 7(B)(1));

(b) Excedrin relieves pain for a longer period of time than a recommended dose of aspirin or any other nonprescription internal analgesic (Complaint ¶ 7(B)(3));

(c) Excedrin relieves pain faster than aspirin or any other nonprescription internal analgesic (Complaint ¶ 7(B)(4));

(d) Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic (Complaint ¶ 7(B)(6)); and

(e) Excedrin is a more effective pain reliever than aspirin or any other nonprescription analgesic because it contains four active ingredients (Complaint ¶ 7(B)(7)).

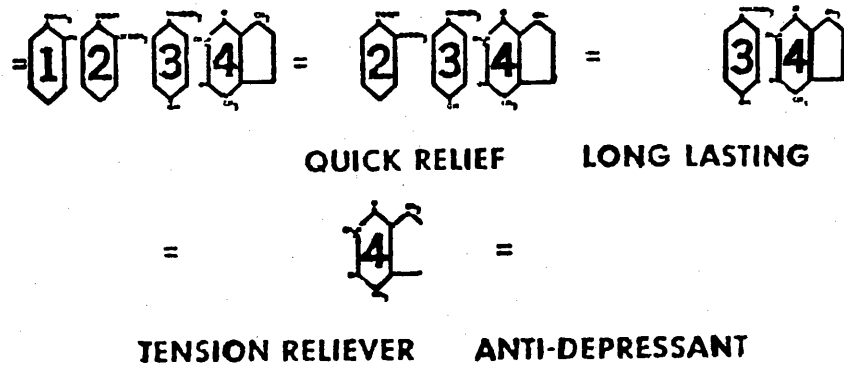
Each of these explicit representations of establishment as a matter of fact were made in the following advertisements: CX 115, 116, 124, 125, 132, 133, 138, 139, 141, 142, 144.

322. Respondent has represented that scientific tests or evidence prove that Excedrin is a more effective pain reliever than aspirin (CX 153–161, 164–167, 170–171, 173, 175–177, 179–182, 184–185, 188–191, 193, 195, 202–208, 210, 211, 760Z003–Z004, 760Z017–Z028, 761Z–Z002, 761Z015–Z017).

323. The fact that Excedrin advertisements made the alleged representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7117–20).

324. These representations were made through a number of express and implied statements, particularly graphic or other visual aids, of a basis in scientific or medical fact for Excedrin's superiority (Ross, Tr. 7008).

325. These advertisements feature an impressive graphic as well as a verbal representation of Excedrin's purported four ingredient chemical formula. For example:



[85] Consumers would have understood these advertisements as representing that Excedrin's superiority is scientifically established. The audio-visual presentation of a chemical formula as the basis for Excedrin's superior performance would be interpreted by consumers as a statement of medical fact. The chemical formula suggests that Excedrin's difference from other nonprescription internal analgesics, and thus its superiority, is due to a scientifically determined chemical structure and is a scientifically verified proposition (Ross, Tr. 7119, 7120).

326. Certain advertisements further enhance the audio-visual presentation of the formula by referring to "four medically endorsed ingredients," (CX 115, 116).

327. The audio-visual presentation of the formula consisting of four chemical components clearly suggests that the proposition that Excedrin is a more effective pain reliever than aspirin or any other nonprescription pain reliever because it contains four active ingredients (Complaint ¶ 7(B)(7)) is scientifically established. This claim subsumes the representation that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic (Complaint ¶ 7(B)(6); F. 328, *supra*). Furthermore, the representation that it has been established that Excedrin is a more effective pain reliever (¶ 7(B)(6)) would also be understood by consumers as a representation that it has been equally established that Excedrin relieves more pain and relieves pain for a longer period of time, because consumers associate these attributes of superior performance with a claim of superior efficacy (Ross, Tr. 7119). Moreover, the claims that Excedrin's greater speed and duration of pain relief are established are made even more vivid by explicit identification of those particular



components in the chemical formula which give "quick relief" and "long lasting" relief. Therefore, the representations alleged in Paragraphs 7(B)(1), 7(B)(3), 7(B)(4), 7(B)(6) and 7(B)(7) are closely interconnected and have been made. [86]

4. Representations That Excedrin Relieves Tension, That Its Ingredients Are Other Than Aspirin Or Caffeine, And Failure To Disclose These Ingredients

a. *Complaint Paragraph 12(B)*

328. Respondents have represented that Excedrin relieves nervous tension, anxiety and irritability and will enable persons to cope with the ordinary stresses of everyday life (Complaint ¶ 12(B)). This representation was made in the following advertisements: CX 115, 116, 121, 124, 125, 127, 128, 132, 133, 135-139, 141-144, 148, 150, 183.

329. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves, and confirmed by expert testimony (Ross, Tr. 7097-7101, 8246-50). Confirmatory evidence is contained in the reports of the following tests conducted by the Ostberg organization: CX 286, 287, 288, 289, 290.

330. This representation was made through a variety of express and implied statements of Excedrin's ability to perform a mood altering function apart from its ability to relieve headache or other pain (Ross, Tr. 7097-98).

331. Many of the cited advertisements state that Excedrin contains "a tension reliever to relax you and an antidepressant to restore your spirits," while chemical formulae labelled "TENSION RELIEVER" and "ANTIDEPRESSANT" are depicted graphically (CX 115, 116, 124, 125, 132, 133, 138, 139, 141, 142, 144). CX 183 speaks of "specifically, a tension reliever, a speed ingredient, an anti-depressant to put you on solid ground again."

332. In certain advertisements, situational tension is depicted or discussed and Excedrin is recommended for relief. For example:

(a) In CX 148 a consumer, after relating that he has been having money problems, claims that "when you take two Excedrin you're able to cope with your problems a lot better."

(b) In CX 135 a "woman's problem" is referred to, and Excedrin is claimed to offer "more for this time than plain aspirin. It's a combination of pain relievers and anti-depressant and . . . you can use some anti-depressing . . ."

(c) Many of the challenged advertisements depict situations which are labelled "Excedrin Headaches," and refer either to Excedrin's "tension reliever to relax you and anti-depressant to restore your

spirits" (CX 124, 125, 127, 138, 139, 142, 144; F. 328, [87] *supra*) or state that Excedrin is "made stronger against pain and its tension" (CX 128, 136, 137). In each case the advertisements depict, albeit humorously, situational tensions which are unrelated to headache or other pains. For example, in CX 133, a woman learns that her husband has wallpapered the powder room, but has glued the wallpaper upside down, and covered the medicine cabinet. In CX 136 and 137 an "Excedrin headache" is the nervous upset resulting from a rear end collision with a police car.

(d) In CX 183 a woman is shown walking on eggs and the announcer asks, "Is that how you feel when you get a headache, as though you're walking on eggs? And you feel like you'd like to smash every one of them. It's *not just the pain, it's what the pain does to you, and you want something for that too . . .*" The advertisement then refers to Excedrin's "tension reliever" and "antidepressant" to put you back on solid ground.

333. The advertisements cited in F. 328, *supra*, made the representation alleged in Paragraph 14(B) because, taking each advertisement as a whole, consumers would have understood them as representing that Excedrin relieves tension and related nervous upset and restores the user to a mood where he or she can cope with the situation apart from pain relief (Ross, Tr. 7097-7101).

334. Confirmatory evidence that the alleged representation was made is found in CX 286-90, reports of copy tests conducted by the Ostberg organization on CX 183, 135, 122, 141 and 125, respectively. Each of the advertisements tested in these copy tests refers to Excedrin's "tension reliever to relax you . . . an antidepressant to restore your spirits." Tabulations of ideas communicated in each test demonstrate that the advertisements conveyed the message that Excedrin relieves tension (CX 286M; CX 287M; CX 288P; CX 289O; CX 290Q). Respondents in CX 289, for example, understood the advertisement as representing the following claims related to tension relief: "Comparison of Excedrin to regular aspirin—pain reliever, anti-depressant, mild sedative" (CX 289Z004); "it relieves tension and it's more effective than aspirin" (CX 289Z005); "it said they are better than aspirin. They remove depression" (CX 289Z009); "if something gets on your nerves, Excedrin will help" (CX 289Z015); "they said they had something in it to combat depression and relieve the pain" (CX 289Z018); "in nerve wracking or frustrating situations, use Excedrin to calm down" (CX 290Z018). [88]

335. A specific reference to a tension relieving ingredient in Excedrin advertisements clearly communicates to the consumer that Excedrin contains an ingredient specifically useful for tension caused by problems other than pain. This is so even where a representation of pain relief is also made (Ross, Tr. 8244-46, 8252-61).

336. Where Excedrin advertisements depict situational tensions unrelated to pain, the advertisements communicate the alleged representation despite the reference to the situations as "Excedrin headaches," the humorous treatment given the situation and the claim that Excedrin is "stronger for relief of pain and its headache" (Ross, Tr. 8266-71). The depiction of a nonpain tension situation diffuses the notion that any headache is involved, and projects an independent tension claim (Ross, Tr. 8271). CX 288, an Ostberg copy test of an advertisement of this type, confirms that these advertisements convey the representation of tension relief to consumers (CX 288P; Ross, Tr. 7105-06, 8271).

b. *Complaint Paragraph 19*

337. Excedrin advertisements do not say that Excedrin contains aspirin and caffeine (Complaint ¶ 19). None of the advertisements in evidence disclose that Excedrin contains aspirin and caffeine (all challenged advertisements for Excedrin, *i.e.*, CX 115-116, 122-139, 141-186, 188-191, 193, 202-211, 724, 725, 727-733, 735-741, 760Z017, 760Z020-21, 760Z024-25, 761Z015-17; Ross, Tr. 7113).

338. Some Excedrin advertisements speak of an ingredient which gives "long lasting relief" and another which is an "antidepressant." While these are found on close inspection of the advertisements to be aspirin and caffeine respectively, consumers are led to believe that they are something other than aspirin and caffeine (Complaint ¶ 21; F. 337, *supra*).

339. Many of the Excedrin advertisements in evidence represent that Excedrin is a more effective pain reliever than aspirin or any other nonprescription internal analgesic because it contains four active ingredients (Complaint ¶ 9(B)(7); F. 315). These advertisements usually characterize the ingredients as giving "long lasting relief," or as acting as a "tension reliever" or "an antidepressant," but in no instance is aspirin identified as an Excedrin ingredient.

340. Some Excedrin advertisements in evidence suggest that the ingredients in Excedrin, whatever they are, do not include aspirin (CX 121, 141, 153, 159, 166, 173, 181-183, 203-204). Some advertisements claim that "tablet for tablet Excedrin is 50% stronger than aspirin for relief of headache pain" (*e.g.*, CX 115-118, 120, 121, 199). Other advertisements ask, "What's [89] better than aspirin?" and answer, "new clinical evidence says Excedrin" (CX 203). Still others announce that "Aspirin isn't best anymore," and represent that "in a major hospital study Excedrin worked better than twice as many aspirin tablets" (CX 204). CX 183 tells consumers, "You want Excedrin. Not plain aspirin

by consumers to mean that Excedrin is not an aspirin product (Ross, Tr. 7113, 7115).

341. Through the examples cited here and other advertisements in evidence, Excedrin has been advertised to consumers without disclosing that it contains aspirin or caffeine.

*c. Complaint Paragraph 21*

342. Respondents have also represented that the ingredient giving "long lasting relief" in Excedrin is other than ordinary aspirin and that the "antidepressant" is other than caffeine (Complaint ¶ 21). This representation was made in the following advertisements: CX 115, 116.

343. The fact that Excedrin advertisements made the alleged representation is demonstrated by the advertisements themselves, and confirmed by expert testimony (Ross, Tr. 7107-7112).

344. In fact, the ingredient identified as giving "long lasting relief" is aspirin, and the "antidepressant" is caffeine (Lanman, Tr. 121500). Yet, the advertisements contrast the ingredients in Excedrin with an aspirin/caffeine combination. The advertisements begin by telling the consumer to "take Excedrin, the extra-strength pain reliever." As the purported chemical formula for aspirin is depicted, the advertisements state, "Look: this is the formula for aspirin." Then depicting the purported chemical formula for caffeine added to aspirin, the advertisements claim that the product that "talks of a new stronger formula merely adds caffeine to aspirin." The advertisements then depict the formula for Excedrin underneath the caffeine-aspirin formula, the one bearing no apparent relationship to the other. The advertisements then state, "But Excedrin has the strength of four medically tested ingredients," and focusing on segments of the formula in turn, states, "You get quick relief, long lasting relief, a tension reliever to relax you, an antidepressant to restore your spirits" (CX 115-116).

344a. A closer inspection of the depicted aspirin-caffeine chemical formula and the Excedrin formula which is contrasted to it reveals that the formula depicted as aspirin and caffeine appears in segmented form in the depiction of the Excedrin formula. However, the aspirin-caffeine segments are arranged in such an order, and are so placed within the larger Excedrin chemical formula, that the consumer would not recognize them and would view the segments of the Excedrin formula which are stated as giving "long lasting relief" and being "an antidepressant," [90] as something other than aspirin and caffeine respectively (Ross, Tr. 7111).

D. *The Excedrin P.M. Advertisements In Evidence Made Certain Of The Challenged Representations*

1. Representations of Superiority for Excedrin P.M.

a. *Complaint Paragraphs 9(B)(8) and 9(B)(10)*

345. Respondents have represented that a recommended dose of Excedrin P.M. will relieve more pain than a recommended dose of aspirin (Complaint ¶ 9(B)(8)) and that Excedrin P.M. is a more effective pain reliever than aspirin because it contains three analgesic ingredients (Complaint ¶ 9(B)(10)). CX 233, 235, 236, 241, 243, 244, 760Z007, 761Z007, made the representation contained in Paragraph 9(B)(8). CX 233, 241 and 244 made the representation alleged in Paragraph 9(B)(10).

346. The fact that Excedrin P.M. advertisements made the alleged representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7139–47). Further confirmatory evidence is contained in CX 263 and 264, reports of ASI Audience Reaction tests.

347. In some advertisements (CX 233 and 241), Excedrin P.M. is represented as stronger than aspirin. For example, CX 233 states that Excedrin P.M. gives you “extra-strength,” a claim which consumers would understand as meaning Excedrin was stronger and more effective than aspirin (Ross, Tr. 7140). These advertisements made the representation in Paragraph 9(B)(8) because consumers would understand that an analgesic which is stronger than aspirin would relieve more pain than aspirin (Ross, Tr. 7140; *see also* Ross, Tr. 7066; CX 819).

348. In some advertisements Excedrin P.M. is represented as containing more pain relievers than aspirin. For example, CX 235 states that Excedrin P.M. . . . “has more pain relievers than simple aspirin” (for similar language *see* CX 236). These advertisements made the representation alleged in Paragraph 9(B)(8) because consumers would understand the representation that Excedrin P.M. has more pain relievers than aspirin as claiming that Excedrin P.M. would relieve more pain than aspirin (Ross, Tr. 7140).

349. In some advertisements (CX 233, 241, 244) Excedrin P.M. is represented as containing three pain relievers. For example, CX 243 states that Excedrin P.M. “combines a mild sleeping aid with 3 pain relievers.” These advertisements made the representations alleged in Paragraph 9(B)(8) and 9(B)(10) because consumers would view the representation that Excedrin [91] P.M. contains three pain relievers, *i.e.*, more pain relievers than aspirin, (a) as claiming that Excedrin P.M. would relieve more pain than aspirin (Complaint ¶ 9(B)(8)) (F.

345, *supra*) and (b) as a reason for Excedrin P.M. being a more effective pain reliever than aspirin (Complaint ¶ 9(B)(10)) (Ross, Tr. 7141).

350. Confirmation that these representations were made is found in CX 263 and 264, two ASI Audience Reaction tests of CX 233, an advertisement containing both the "extra-strength" and "three pain relievers" claim. Tabulations in these tests show that the advertisements conveyed the message that Excedrin P.M. was stronger, or more effective (CX 263R; CX 264Y) and contained three pain relievers (CX 263R). A respondent in CX 263 viewed the advertisement as "saying, that [Excedrin P.M.] is three times stronger than daytime aspirin," indicating not only an understanding that Excedrin is being represented as relieving more pain than aspirin, but as being more effective because of the presence of *three* analgesics (Ross, Tr. 7140, 7143).

b. *Complaint Paragraph 9(B)(9)*

351. Respondents have represented that a recommended dose of Excedrin P.M. is more effective for the relief of pain which occurs at night than a recommended dose of aspirin or any other nonprescription internal analgesic (Complaint ¶ 9(B)(9)). This representation was made in the following advertisements: CX 224, 228, 229, 233, 235, 236, 240, 243.

352. The fact that Excedrin P.M. advertisements made the alleged representations is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7133-38). Further confirmatory evidence is contained in the following ASI Audience Reaction tests: CX 260, 262, 263, 264.

353. This representation was made through a variety of express and implied claims of Excedrin's greater ability to relieve pain occurring at night, as distinct from pain generally, than aspirin or any other nonprescription internal analgesic.

354. In some advertisements, Excedrin is represented as the "extra-strength nighttime pain reliever" specially formulated for pain occurring at night. For example, CX 233 states that Excedrin P.M. is "The extra-strength nighttime pain reliever. Its special formula contains three pain relievers plus a mild sleeping aid." These advertisements clearly make the representation alleged in Paragraph 9(B)(9). Consumers would understand them as representing (1) particularly through the "extra-strength" claim, that Excedrin P.M. is more effective than aspirin or any other nonprescription internal analgesic (Ross, Tr. 7134); and (2) through the representation of a special formula for "nighttime" pain relief that Excedrin P.M. was more effective for pain occurring at night (Ross, Tr. 7134). [92]

355. In some advertisements, pain occurring at night, when the

consumer is going to sleep, is represented as different from pain occurring during the day. Excedrin P.M. is, in turn, represented as better for this type of pain because it is "more than simply a pain reliever." For example:

(a) Merv Griffin: If you sometimes go to bed with aches and pains, the makers of Excedrin have a new idea for you. Excedrin P.M. . . . the nighttime pain reliever. Because aches and pains seem different at night . . . That's when you want more than simply a pain reliever. You also want something to help you get to sleep. That's what new Excedrin P.M. is made for. It combines pain relievers with a special ingredient to help you sleep. So it relieves pain and its tension and helps you get to sleep . . . (CX 224A).

(b) Daytime pain and nighttime pain can be as different as day and night. Because at night, when its quiet, even a tiny pain can hurt a lot. You could take a simple pain reliever. But it doesn't have anything extra to help you sleep. Excedrin P.M. does . . . (CX 228A).

These advertisements clearly make the alleged representation (Ross, Tr. 7135).

356. ASI Audience Reaction tests of some of these advertisements confirms that conclusion (CX 262-264; Ross, Tr. 7135-38). In CX 263 the verbatim comments demonstrate, *inter alia*, that consumers perceived Excedrin P.M. as specially formulated and thus more effective for pain occurring at night (CX 263Z022; Ross, Tr. 7136). The analysis of verbatim comments in CX 264 similarly indicates such a perception (CX 264Y; Ross, Tr. 7137). One participant in CX 264 noted that "there was a definite point that [Excedrin P.M.] was a different thing for nighttime pain than you would use during the day. It was more effective, so you would be able to sleep" (CX 262Z037). Another pointed to the product's seeming unique formulation for pain at night: "I would say that the combined ingredients make it unique, but somehow I had the feeling that it was Excedrin with one of the across-the-counter sleeping medications added, you know . . ." (CX 262Z043). [93]

## 2. Representations of Established Superiority for Excedrin P.M.

357. Bristol-Myers has not expressly claimed that it has been "established" that:

(a) a recommended dose of Excedrin P.M. will relieve more pain than a recommended dose of aspirin (Complaint ¶ 7(B)(8));

(b) a recommended dose of Excedrin P.M. is more effective for the relief of pain which occurs during the night than aspirin or any other nonprescription internal analgesic (Complaint ¶ 7(B)(9)); nor that

(c) Excedrin P.M. is a more effective pain reliever because it contains three analgesic ingredients (Complaint ¶ 7(B)(10)).

However, the cited Excedrin P.M. advertisements make express claims of superiority over other drugs and implies a claim that such superiority has been scientifically established (F. 266, *supra*).

### 3. Representations that Excedrin P.M. Relieves Tension

#### a. *Complaint Paragraph 12(B)*

358. Bristol-Myers has represented that Excedrin P.M. will relieve nervous tension, anxiety and irritability and will enable persons to cope with the ordinary stresses of everyday life (Complaint ¶ 12(B)). This representation was made in CX 216 and 219.

#### b. *Complaint Paragraph 23*

359. Bristol-Myers has represented that the mild sedative or sleep-inducing agent contained in Excedrin P.M. is special and unique (Complaint ¶ 23). These representations were made in the following advertisements: CX 213-222, 224, 228, 229, 233, 234, 238, 239, 241-244, 760Z005, 761Z005, 760Z006, 761Z006, 760Z007, 761Z007, 760Z008, 761Z008.

360. The fact that Excedrin P.M. advertisements made the alleged representation is demonstrated by the advertisements themselves and confirmed by expert testimony (Ross, Tr. 7155-56). The representation alleged in Paragraph 23 was made through statements relating to the special or unique contents of Excedrin P.M. making it a sedative (F. 361, *infra*).

361. Some advertisements prominently feature the label of Excedrin P.M. which contains the statements "The Night-time Pain Reliever. Special Formulation." Advertisements also refer to Excedrin P.M.'s "special formula" or "special night-time [94] ingredient," when representing the product as a mild sedative. These advertisements clearly made the representation alleged in Paragraph 23 (Ross, Tr. 7155-56).

#### c. *Complaint Paragraph 19*

362. A review of the Excedrin P.M. advertisements in evidence shows that none of them mentioned in any way the presence of aspirin in that product. Bristol-Myers' Excedrin P.M. ads did not disclose that Excedrin P.M. contains aspirin (Complaint ¶ 19).

363. All advertisements received in evidence were disseminated to the public. CX 800, 801 and 802 contain a listing of all advertisements offered by complaint counsel and, where available, information on the dates of dissemination and number of disseminations.



V. THE SCIENTIFIC EVIDENCE SUPPORTS THE ALLEGATIONS  
OF THE COMPLAINT

A. *Evidence Necessary To Establish Absolute Or  
Comparative Analgesic Performance*

1. Well-Controlled Clinical Studies Are Necessary To  
Establish Comparative Efficacy of Analgesics

364. In order to say any scientific or medical proposition is established, experts in the pertinent field require that the proposition be supported or proven by a type and quality of scientific evidence that reduces the chance for error to an acceptable level and is unlikely to be due to chance (Azarnoff, Tr. 9178; Moertel, Tr. 5529-31). Experts apply a set of basic methodological and analytical criteria to determine whether a body of evidence is sufficient to establish a proposition (Forrest, Tr. 8952, 8908-12, 8986; Moertel, Tr. 5533-45; Grossman, Tr. 7767-69; Azarnoff, Tr. 9178-82). Bristol-Myers itself considered and used the terms "established" and "proven" interchangeably in its statements dated November 14, 1967 and filed with the Federal Trade Commission *in the Matter of a Proposed Trade Regulation Rule for Non-Prescription Systemic Analgesic Drugs*. In discussing the shortcomings of a report of a clinical analgesic study, Bristol-Myers there charged that, "The authors themselves do not claim to have proven, or to have established, the tentatively couched conclusions" (CX 908 for identification, p. 31; Lanman, Tr. 12033). *Also see* Bristol-Myers' Supplemental Comments, dated February 7, 1968 (CX 907 for identification), p. 14.

365. It is generally agreed by scientists that the only type of evidence sufficient to establish the comparative efficacy of drugs is well-controlled clinical (or therapeutic) testing, using real patients with real symptoms (Azarnoff, Tr. 9179; [95] Moertel, Tr. 5528-29; Grossman, Tr. 7767; Forrest, Tr. 8952, 8908-09; CX 514, pp. 35371, 35444).

366. The criteria for evaluating the reliability and validity of clinical studies used to establish the comparative efficacy of drugs include: (a) where analgesics are involved, an appropriate pain model (F. 368, 374-80), using subjective responsive methodology (F. 369, *infra*); (b) replication of results (F. 370, *infra*); (c) an experienced, unbiased investigator (F. 371, *infra*); (d) adequately trained personnel and appropriately instructed subjects (F. 372, *infra*); (e) a written, and sufficiently detailed protocol (F. 373, *infra*); (f) random assignment of patients to treatments (F. 384-87, *infra*); (g) double-blinding (F. 388, *infra*); (h) where pain is being measured, use of a placebo control (F. 389, *infra*); (i) use of appropriate statistical techniques determined in advance of tests (F. 390, *infra*); (j) use of a recognized level of statisti-

cal confidence (the 5% level) (F. 391, *infra*); (k) application of appropriate judgment as to the clinical significance of results (F. 392-93, *infra*); and (l) subjecting the study to peer review (F. 394, *infra*).

367. Other methods which purport to measure comparative efficacy, or other techniques which try to assess comparative efficacy without actual measurement, have not been shown to be sufficiently reliable for this purpose (F. 400-04, *infra*).

368. Experts who study the performance of analgesics in clinical pain have found several "pain models" amendable for their evaluations. Surgical pain, orthopedic pain, post-operative pain, cancer pain, post-partum pain, pain from dental extraction, and headache pain have all been used in well-controlled clinical studies that have assessed the comparative efficacy of analgesics (Forrest, Tr. 8911; Beaver, Tr. 6045; CX 514, p. 35382).

369. Since pain is a personal and subjective experience, the best way to establish the comparative efficacy of OTC analgesics is to elicit the subject's own report of the pain experienced and the degree of relief obtained after administration of the drugs under study—the subjective response methodology (Forrest, Tr. 8908-10; Moertel, Tr. 5534; CX 514, pp. 35377, 35444). There are no objective measures of pain relief in the clinical situation (Forrest, Tr. 8916).

370. 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 studies on the drugs in question are required (Brown, Tr. 4878, 8160-61; Forrest, Tr. 8917; Grossman, Tr. 7769; Moertel, Tr. 5530, 5850-51; Azarnoff, Tr. 9180, 9185-86; CX 514, pp. 35371, 35445). Replication of results in the hands of separate, competent investigators reduces the likelihood that the original [96] results were due to chance (Azarnoff, Tr. 9185; Brown, Tr. 8161; Moertel, Tr. 5850; Grossman, Tr. 7769) and avoids the possibility that errors or artifacts in the design or execution of any one study are carried over into the next (Moertel, Tr. 5851; Brown, Tr. 8161). As Dr. Brown said:

You don't want two studies, neither of which are convincing. You want two studies that, by themselves—each study should stand by itself. Then the question is, if you can replicate a persuasive study in several laboratories, then you are really persuaded that it isn't a fluke of the laboratory or fluke of the investigator (Brown, Tr. 8161).

371. A threshold requirement for an adequate and well-controlled study is an experienced investigator (Forrest, Tr. 8921; Moertel, Tr. 5533-34). Moreover, the motivation of an investigator is a possible source of bias, and it is therefore important to ensure that the investigator is truly independent (Moertel, Tr. 5534).

372. Whereas nurses or other persons are used to administer treat-

ments, and to observe and record the subjective responses of patients under study, it is of course important that they be adequately trained and experienced to guard against distortion of the information provided by patients (Brown, Tr. 4976-78; Forrest, Tr. 8921; Moertel, Tr. 5541-42). In out-patient clinical studies, where patients are ambulatory and record their own responses to treatment, the chance for distortion in recording responses by a nurse or other third party is virtually eliminated; but the patients themselves must be instructed to properly record their responses (Moertel, Tr. 5541; Forrest, Tr. 9123-24; Beaver, Tr. 5965; Azarnoff, Tr. 9231-33).

373. A written protocol which sets down in detail the objectives of the study and how those objectives are to be met before the study begins is essential if the study is to be well-controlled (Moertel, Tr. 5537). Such a protocol should cover not only features of study design, but also a plan for its analysis (Moertel, Tr. 5542; Azarnoff, Tr. 9180, 9183; F. 390, *infra*). Strict adherence to such a protocol provides a reader with an additional opportunity to judge whether there was an opportunity for uncontrolled bias to enter into the conduct of the study (Moertel, Tr. 5542-43).

374. The clinical study must employ a pain model that is appropriate for the conclusions sought to be drawn from it (Moertel, Tr. 5537). In general, the best pain model is the type(s) of pain for which use of the drug is intended or for which a claim of efficacy may be made (Moertel, Tr. 5535-37; Azarnoff, Tr. 9185; Forrest, Tr. 8911; Evans, Tr. 6352-53). [97] Where a claim relates to comparative efficacy for headache pain, at least one of the well-controlled studies required to establish such claim should be in headache pain (Smith, Tr. 5442; Forrest, Tr. 8911; Moertel, Tr. 5537). The need for at least one study to focus on the type of pain for which a claim is made, *i.e.*, headaches, is especially acute where the product involved is a combination of ingredients, like Excedrin, which may act differently in different pain models (Beaver, Tr. 6048-51).

375. Bristol-Myers apparently agreed—at least as of early 1968—with the proposition that clinical studies must focus on headache pain if they are to be used as a basis for claims concerning superiority in headache. In Supplemental Comments, dated February 7, 1968, filed before the Federal Trade Commission in *the Matter of a Proposed Trade Regulation Rule for Nonprescription Systemic Analgesic Drugs*, Bristol-Myers asserted that OTC analgesics will function differently in different kinds of headaches, and that, therefore, their performance in pain models far removed from headaches, such as post-partum and post-surgical pain, are not transferrable to ordinary headaches (Lanman, Tr. 12013-14). Bristol-Myers also quoted Dr. John Seed, an

expert recognized in the field of analgesics, and a co-author with such analgesics experts as Drs. Houde, Beaver and Bellville, who stated:

If one wants to claim that [an] analgesic relieves menstrual cramps, one has to test it on patients with menstrual cramps. If one wants to claim it relieves tension headache, one has to test it on tension headaches. If one wants to claim that it acts faster on tension headache than some other preparation, one should be required to prove that it acts faster; *i.e.*, by interviewing people under the proper conditions and finding out how soon the headache goes away (Lanman, Tr. 12020-21).

376. Throughout its February 7, 1968 Comments, Bristol-Myers also cited the opinions of numerous recognized experts in clinical analgesia to support its position that an analgesic may be effective against one type of pain and not against another, or that the comparative efficacies of analgesics may differ depending upon the particular pain model studied (Lanman, Tr. 12020-27). For example, Bristol-Myers cited Dr. Max Sadove, an expert who had published widely in the field of analgesics, who stated, *inter alia*:

one merely gets a hint in any of the usually done studies of what might be expected of the drug. Even if one designs it with placebo controls and cross over design and a sufficient number of [98] patients. *The reason is that the drug may be effective against one type of pain and not against another.* (Lanman, Tr. 12021-22, underscoring by Bristol-Myers).

Bristol-Myers also cited Dr. Louis Lasagna, who was Chairman of the NAS/NRC Panel responsible for CX 511 (F. 23, *supra*), who stated:

If a drug is shown superior to another drug, or to a placebo, in three or four different clinical studies accompanied by pain, and the results are in general agreement, then it would be a reasonable assumption to guess that these same relationships will occur in other kinds of pain that have not been studied. *This is, however, a matter of opinion and educated guessing rather than established fact.* (Lanman, Tr. 12024; underscoring by Bristol-Myers).

377. Bristol-Myers also cited Dr. Walter Modell, former professor of pharmacology at Cornell and current, long-time editor of the *Journal of Clinical Pharmacology and Therapeutics* (Lanman, Tr. 12025-26). Dr. Modell stated that the particular factors responsible for headache pain—which (1) operate within the cranium, in tissues outside but adjacent to the skull, and in certain cranial and cervical nerves and which (2) related to vascular distension, traction and pressure, local tissue inflammation and muscular spasms—are so different from mechanisms centered in other areas of the body involving different nerve pathways that pharmacological data gathered with respect to these other areas would not be reliable with respect to analgesics' performance in headaches (Lanman, Tr. 12025).

378. Regarding Bristol-Myers' February 7, 1968 Comment to the Commission (CX 907 for identification), Dr. Lanman, Bristol-Myers Product's Medical Director for the past 17 years, testified on cross-examination that he "would have to assume responsibility" for the views stated in the documents (Tr. 12028). However, upon redirect examination Dr. Lanman testified that in fact he had not seen a copy of CX 907 or 908 until the previous day's examination when they were handed to him by complaint counsel (Tr. 12183-84). The documents (CX 907 and 908 for identification) do not bear the signature of Dr. Lanman but bears that of Gilbert H. Weil, Bristol-Myers' counsel. Dr. Lanman himself believed, at least in the 1960's, that a clinical analgesic study limited to subjects in normal post-partum pain could not be used as a basis for generalizations about the effectiveness or side effects of an analgesic (Lanman, Tr. 12027; CX 909). [99]

379. Respondents' expert, Dr. Sunshine, testified that the FDA requires submission of at least two studies on new drugs that purport to be analgesics, and he stated that proposed FDA guidelines require that the second study be performed in a different kind of pain than that studied in the first because one could not be sure that the mechanism of action may be the same in another pain model (Sunshine, Tr. 9823-25). In fact, Dr. Sunshine was involved in preparing the guidelines which called for studies in different kinds of pain for new drugs (Sunshine, Tr. 9824-25).

380. Bristol-Myers' position with headache pain studies is that "subjective response clinical studies cannot be done using headache as the pain model" (RPF 964-982). However, the record as a whole does not show that superior effectiveness of Excedrin for headache pain cannot be demonstrated. It simply shows that a subjective response study of headache pain is more difficult than a similar study of some other pain, for example, post-partum pain (Tr. 6057, 6060).

381. Dr. Lanman, Bristol-Myers' Medical Director, testified that a methodology has not been developed for a satisfactory study of headache pain. Bristol-Myers has approached two recognized investigators in the headache pain study field and they have declined to conduct headache pain studies for Bristol-Myers. However, according to Dr. Lanman, Bristol-Myers is trying to develop new methods and techniques for headache pain study (Tr. 11729-31).

382. The record shows that in a headache pain study there are more factors that must be controlled than in other pain studies. However, it is a matter of degree only and does not show that a headache pain study is not feasible (RPF 964-967, 973-76, 980-82). The FDA Analgesic Panel Report lists six reported headache studies using aspirin, one of which appeared in 1967 (CX 514, pp. 35382-83).

383. Studies of comparative analgesic efficacy for simple headache

pain must necessarily be conducted in an outpatient setting (Sunshine, Tr. 9651-52). While attention must be directed towards careful control and instruction of the patients involved in outpatient studies, such research has been successfully conducted with respect to headaches, other kinds of pain (*e.g.*, oral surgery, angina pectoris) and other measures of drug performance besides pain (*e.g.*, anti-emetics) (Beaver, Tr. 5965, 6073; Forrest, Tr. 8985-86, 9140-42; Brown, Tr. 8115-17; Azarnoff, Tr. 9184-85; 9232-33; Sunshine, Tr. 9652, 9751-53). In this proceeding, Bristol-Myers itself relied on two outpatient studies on pain, one of which examined headache pain, in an attempt to support its position that caffeine adds to the analgesic effect of aspirin and acetaminophen (Lanman, Tr. 11512-17, 12066-67, 12083-84). [100]

384. It is essential in any well-controlled study for subjects to be randomly assigned to the various treatment groups under study (Brown, Tr. 4858-60, 4911; Forrest, Tr. 8912; Azarnoff, Tr. 5543; Laska, Tr. 10166; CX 514, p. 35444). The randomization process is necessary to balance out those variables in the subject population and in the design and conduct of the study itself that cannot be identified and controlled directly by the investigator (Forrest, Tr. 8916; Azarnoff, Tr. 9180; Beaver, Tr. 6019-21; Sunshine, Tr. 9684). The randomization process is the prerequisite for concluding that the uncontrolled variables inherent in all research is fairly balanced across the treatment groups (Laska, Tr. 10585-86). It is, therefore, fundamental to the validity of the study and the interpretation of its results (Forrest, Tr. 9114-15; Laska, Tr. 10585-86; Brown, Tr. 4911, 4994-95, 5008, 5083-84). Unless a particular study is properly randomized, the validity of that study is questionable and all analyses of its results are compromised (Forrest, Tr. 9114-15, 9121; Brown, Tr. 5083-84, 8038; Laska, Tr. 10270).

385. A technique to assure that important, identifiable variables are balanced fairly across treatment groups is to stratify all subjects on such variables (*e.g.*, level of initial pain) and then randomly assign subjects within each stratification to the various treatment groups (Azarnoff, Tr. 9180; Sunshine, Tr. 9725-26). Such a procedure will ensure that these critical variables will be represented fairly equally in all treatment groups (Azarnoff, Tr. 9180; Moertel, Tr. 5544; Sunshine, Tr. 9716, 9725-26).

386. A failure to randomize properly may actually be similar to not having attempted randomization in the first place (Forrest, Tr. 8921). That is, the results of inadequately randomized studies may be as attributable to factors which have unequal impact on the treatment groups as they may be to the actual performance of the treatments themselves (Forrest, Tr. 8918-21).