

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 glycinat 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 Freedman-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

