

IN THE MATTER OF
THOMPSON MEDICAL COMPANY, INC.

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

Docket 9149. Complaint, Feb. 5, 1981—Final Order, Nov. 23, 1984

This Final Order requires a New York City pharmaceutical company to cease, in connection with the advertising, sale or distribution of over-the-counter (OTC) health care products, using the brand name "Aspercreme" for any product that does not contain a significant amount of aspirin; or misrepresenting by any other means that aspirin is an active ingredient of such product. TV and radio advertising for "Aspercreme" must include an explicit aspirin disclaimer statement and such disclaimer must also be prominently displayed in print advertising and product labeling. The Order further bars the firm from misrepresenting the contents, validity, results or interpretations of tests or studies; and from representing, without prescribed substantiation, the speed or effectiveness of its products in the relief of minor pain and other symptoms of arthritis, bursitis, rheumatism or other musculoskeletal disorders. Additionally, the Order dismisses Paragraph 12(f) of the Complaint.

Appearances

For the Commission: *Elizabeth T. Guarino, Grace Polk Stern, Melvin H. Orlans, Randell C. Ogg, Nancy W. Warder and Teresa A. Hennessy.*

For the respondent: *Stuart L. Friedel, Joseph M. Burke and Patricia Hatry, Davis & Gilbert, New York City; Stephen Kurzman, Nixon, Hargrave, Devans & Doyle, Washington, D.C.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Thompson Medical Company, a corporation, (hereinafter "Thompson"), and Ogilvy & Mather, Inc., a corporation, (hereinafter "Ogilvy"), hereinafter sometimes referred to as respondents, have violated the provisions of the 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. Thompson is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New

York with its offices and principal place of business located at 919 Third Avenue, New York, New York.

PAR. 2. Ogilvy is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York with its office and principal place of business located at 2 East 48th Street, New York, New York.

PAR. 3. Thompson is now and has been engaged in the business of manufacturing, advertising, offering for sale, sale, and distribution of various over-the-counter health care products, including the products Aspercreme Creme Rub and Aspercreme Lotion Rub (hereinafter "Aspercreme"), products advertised to treat various disorders. In connection with the manufacture and marketing of Aspercreme, Thompson is now and has been engaged in the dissemination, publication, and distribution of advertisements and promotional material for the purpose of promoting the sale of Aspercreme for human use. As advertised, Aspercreme is a "drug" within the meaning of Section 12 of the Federal Trade Commission Act. [2]

PAR. 4. Thompson causes said products when sold to be transported from its places of business in various States to purchasers located in various other States. Thompson maintains, and at all times mentioned herein has maintained, a substantial course of trade in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Ogilvy is now, and for some time past has been, an advertising agency of Thompson. Ogilvy has prepared and placed for publication, advertising material to promote the sale of Aspercreme for human use.

PAR. 6. In the course and conduct of its business, and at all times mentioned herein, Thompson has been and now is in substantial competition in or affecting commerce with corporations, firms, and individuals representing or engaged in the manufacture or marketing of health care products.

PAR. 7. Ogilvy at all times mentioned herein has been and now is, in substantial competition in or affecting commerce with other advertising agencies.

PAR. 8. In the course and conduct of their businesses, respondents have disseminated and caused the dissemination of certain advertisements concerning Aspercreme through the United States mail and by various means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, including the insertion of advertisements in magazines with national circulations and the placement of advertisements with television stations with sufficient power to broadcast across state lines and into the District of Columbia.

PAR. 9. Typical statements and representations in said advertise-

ments, disseminated as previously described, but not necessarily all-inclusive, are the advertisements attached hereto as Exhibits A through H.

PAR. 10. Through the use of the advertisements referred to in Paragraphs Eight and Nine and others not specifically set forth herein, respondents represented and now represent, directly or by implication that:

- a. Aspercreme contains aspirin.
- b. Aspercreme is a recently discovered or developed drug product.
- c. Valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatic conditions, and their symptoms. [3]

PAR. 11. In truth and in fact:

- a. Aspercreme does not contain aspirin.
- b. Aspercreme is not a recently discovered or developed drug product; it has been available for purchase since at least 1971 and its active ingredient has been in existence since at least 1954.
- c. No valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatism, and their symptoms.

Therefore, the representations, set forth in Paragraph Ten were and are false, misleading, or deceptive; and the advertisements referred to in Paragraphs Eight and Nine were and are misleading in material respects, and constituted and now constitute false advertisements.

PAR. 12. Through the use of the advertisements referred to in Paragraph Eight and Nine and others not specifically set forth herein, respondents represented, and now represent, directly or by implication that:

- a. Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.
- b. Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.
- c. Aspercreme is a more effective drug than orally-ingested aspirin for the relief of minor arthritis and its symptoms.
- d. Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms.
- e. Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.
- f. The use of Aspercreme will result in no side effects.

PAR. 13. At the time of the first and subsequent disseminations of the representations contained in Paragraph Twelve respondents did

not possess and rely upon a reasonable basis for making those representations. Therefore, the dissemination of the said representations as alleged constituted, and now constitutes, unfair or deceptive acts or practices in or affecting commerce.

PAR. 14. Through the use of the advertisements referred to in Paragraphs Eight and Nine and others not specifically set forth herein respondents have represented and now represent [4] directly or by implication that they possessed and relied upon a reasonable basis for the representations set forth in Paragraph Twelve at the time such representations were made.

PAR. 15. In truth and in fact, respondents did not possess and rely upon a reasonable basis for the representations set forth in Paragraph Twelve at the time such representations were made. Therefore, the representations set forth in Paragraph Fourteen were and are false, misleading or deceptive.

PAR. 16. Through the use of the trade name "Aspercreme" in advertising, labels and promotional materials, respondents have represented and now represent that the product "Aspercreme" contains aspirin.

PAR. 17. In truth and in fact, "Aspercreme" contains no aspirin. Therefore, the representation in Paragraph Sixteen was and is false, misleading, deceptive or unfair, and the use of the trade name "Aspercreme" to describe a product which contains no aspirin constituted and now constitutes an unfair or deceptive act or practice in or affecting commerce,

PAR. 18. The use by respondents of the aforesaid unfair or 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.

PAR. 19. The acts and practices of respondents, as herein alleged, including the dissemination of the aforesaid false advertisements, 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 or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended.

Complaint

104 F.T.C.

EXHIBIT A

OGILVY & MATHER INC.
 2 EAST 48 STREET NEW YORK 10017
 WILBRAT WILL & SON

Client: THOMPSON MEDICAL
 Product: ASPERCREME
 Title: "RUB VERSION, NO MORTICE"
 Commercial No. QTAI 9013
 Date Approved: 10 25 '78



4. Now with amazing Aspercreme.



3. right where you hurt most.



2. imagine being able to put the strong relief of aspirin



1. PRESENTER (OC) when you suffer from arthritis.



8. with more of aspirin's possible side effects



7. (OC) Strong, penetrating relief which lasts for hours



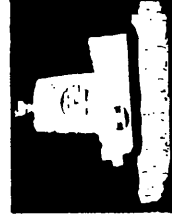
6. of minor arthritis pain



5. You can get the strong relief of aspirin directly at the point.



12. where you hurt. Remarkable



11. (VC) The strong relief of aspirin right



10. No embarrassing odor



9. Aspercreme. Fast-acting

Complaint

EXHIBIT B

OGILVY & MATHER INC.
 2 EAST 48 STREET, NEW YORK 10017
 MURRAY HILL 8-4100

Client:
 Product:
 Title:
 Commercial No.:
 Date Approved:

THOMPSON MEDICAL
 ASPERCROME
 "VISIBLE MEN"
 QTAI 9033
 3/30/79

1. PRESENTER (OC) When you suffer from arthritis,

2. Imagine putting the strong relief of aspirin right where you hurt.

3. Aspircreme is an odorless rub

4. which concentrates the relief of aspirin.

5. When you take regular aspirin,

6. it goes throughout your body like this.

7. But, in seconds,

8. Aspircreme starts concentrating all the temporary relief of two aspirin

9. directly at the point of minor arthritis pain.

10. Strong, concentrated relief.

11. VO: Aspircreme.

12. The strong relief of aspirin right where you hurt

Complaint

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EXHIBIT C

Radio TV Reports

41 East 42nd Street New York N.Y. 10017
(212) 697-5100

PRODUCT
PROGRAM

ASPERCREME
NEWS
WNBC-TV

1/23 80
(NEW YORK)

80-01116
30 SEC.
7:24PM

REVISION OF COMMERCIAL • 7V9635



1. WOMAN: When you suffer from arthritis,



2. imagine being able to put the strong relief of aspirin right where you hurt most.



3. Now with amazing Aspercreme.



4. you can get the strong relief of aspirin



5. directly at the point of minor arthritis pain.



6. Strong penetrating relief which lasts for hours.



7. With none of aspirin's possible side effects.



8. Aspercreme. Fast acting, no embarrassing odor.

CONTAINS NO ASPIRIN[®] SUPER

9. The strong relief of aspirin right where you hurt. Remarkable.

ALSO AVAILABLE IN COLOR VIDEO TAPE CASSETTE

THOMPSON MEDICAL CO., INC.

Complaint

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EXHIBIT D

OGILVY & MATHER INC.
 2 EAST 45 STREET, NEW YORK 10017
 MURRAY HILL 8-8100

Client:
 Product:
 Title:
 Commercial No.:
 Date Approved:

THOMPSON MEDICAL
 ASPERCREME
 "VISIBLE MEN"
 QTAI 9033
 3/30/79

1. PRESENTER (OC). When you suffer from arthritis.

2. Imagining putting the strong relief of aspirin right where you hurt.

3. Asperceme is an odorless rub.

4. which concentrates the relief of aspirin.

5. When you take regular aspirin,

6. it goes throughout your body like this.

7. But, in seconds,

8. Asperceme starts concentrating all the temporary relief of two aspirin

9. directly at the point of minor arthritis pain.

10. Strong, concentrated relief.

11. VO: Asperceme.

12. The strong relief of aspirin right where you hurt.

Complaint

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EXHIBIT E

Radio TV Reports

41 East 42nd Street New York, N.Y. 10017
(212) 697-5100

PRODUCT
PROGRAM

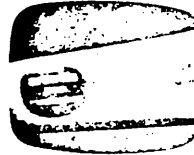
ASPERCREME CREME RUB OH80-08742
STATION BREAK 5/14/80 30 SEC.
WYKW-TV (L CLEVELAND) 10:59 AM



1. ANNCR: Listen to what these people say about Aspercreme for temporary relief of minor arthritis pain.



2. 1ST WOMAN: I really felt like I was rubbing the pain away.



3. ANNCR: Aspercreme.



4. 1ST MAN: The Aspercreme gives me relief without upsetting my stomach.



5. 2ND WOMAN: Aspercreme is free.



6. 2ND WOMAN: It doesn't stain my clothes.



7. 3RD WOMAN: There's no odor.



8. 4TH WOMAN: And look it's greaseless.



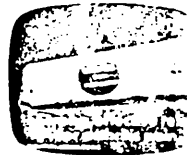
9. 3. Aspercreme.



10. 2ND MAN: I'm saying that I am really pleased with the relief I got from Aspercreme.



11. 5TH WOMAN: The relief lasts for hours.



12. ANNCR: Aspercreme Strong, effective relief for arthritis pain. 6TH WOMAN: It really works.

ALSO AVAILABLE IN COLOR VIDEO-TAPE CASSETTE

EXHIBIT F

At last! A remarkable breakthrough for arthritis pain: Aspercreme.

Aspercreme is an effective arthritis medicine which concentrates all the strong relief of aspirin directly at the point of pain.

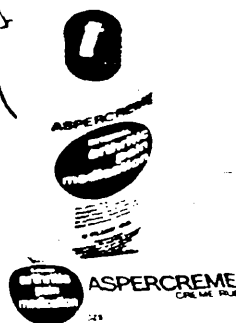
1 Strong concentrated relief. Aspercreme™ pinpoints relief where you hurt. Aspirin tablets go throughout your body. But Aspercreme concentrates the relief of an effective aspirin-like analgesic directly at the point of arthritis pain — where you need it the most.

2 Fast relief for minor arthritis pain. Aspercreme penetrates deep into painful areas — fingers, elbows, knees, back, shoulders. You get deep relief in minutes. Aspercreme works faster than aspirin because you rub it in right where you hurt.

3 No embarrassing liniment odor. Aspercreme, like aspirin itself, has no liniment smell. You can use it any time. Anywhere — without any annoying, embarrassing odor. Relatives, friends, co-workers — nobody but you knows you're using it!

4 No side effects. Aspercreme gives you strong, long-lasting relief. It won't upset your stomach. Use it safely as often as you wish.

Available in creme and lotion



Complaint

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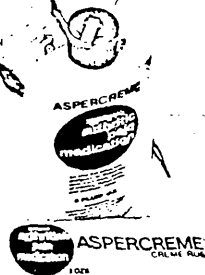
EXHIBIT G

At last! A remarkable breakthrough for arthritis pain: Aspercreme.

Aspercreme is an effective arthritis medicine which concentrates all the strong relief of aspirin directly at the point of pain.

- 1 Strong concentrated relief.**
Persistent, pinpoint relief where you need it. Aspirin tablets go throughout your body. But Aspercreme concentrates the relief of two aspirin directly at the point of arthritis pain—where you need it most.
- 2 No side effects.**
Aspercreme gives you strong, long-lasting relief. I won't upset your stomach. I won't irritate your skin. I won't interfere with your other medications.
- 3 Fast relief for minor arthritis pain.**
Aspercreme penetrates deep into painful areas—fingers, elbows, knees, back, shoulders. You get deep relief in minutes. Aspercreme works faster than aspirin because you rub it in right where you hurt.
- 4 Long lasting relief.**
Aspercreme gives you pain relief that lasts for hours. Long lasting relief during the day—when you're active. Long lasting relief at night when you want to get to sleep and stay asleep.
- 5 No embarrassing liniment odor.**
Aspercreme, like aspirin itself, has no liniment smell. You can use it any time, anywhere—without any annoying, embarrassing odor. Relatives, friends, co-workers, nobody but you know you're using it.
- 6 Non greasy, won't stain.**
Aspercreme Cream Rub and Aspercreme Lotion vanish into your skin. Both forms of Aspercreme are non-greasy, so you won't stain your clothes and bed sheets. And Aspercreme has no unpleasant "burning" sensation.
- 7 Ideal for tendonitis, bursitis.**
Aspercreme reduces pain, swelling and inflammation. That's why Aspercreme is especially effective for tendonitis, bursitis, muscle rheumatism, even tennis elbow.
- 8 Tested by arthritis specialist.**
Aspercreme was tested by a leading arthritis specialist on his patients. His results showed that Aspercreme is actually faster and more effective than aspirin in relieving minor arthritis pain.

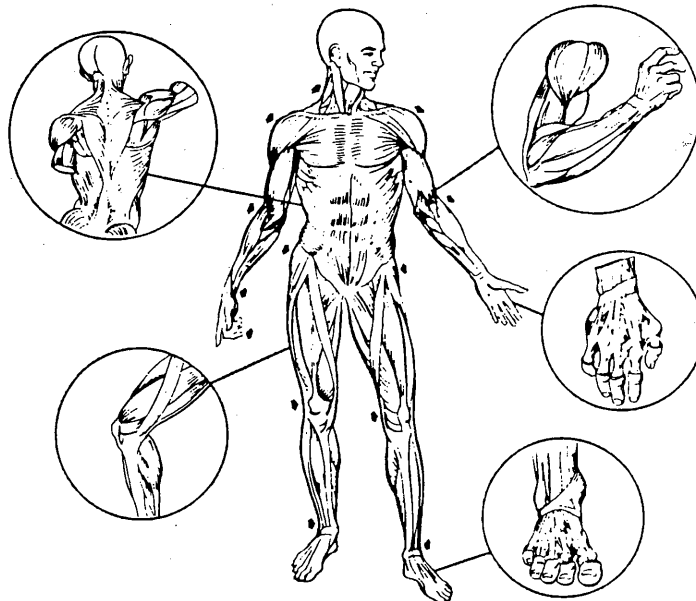
STORE NAME



Available in cream rub or lotion

EXHIBIT H

Minor Arthritis Pain?



There's always been aspirin...

Now there's ASPERCREME

Works faster, safer than aspirin—relieves pain in minutes

Aspirin has been helping sufferers of minor arthritis pain for years. Now there's a different way to get relief. ASPERCREME. An analgesic rub that works from the outside in... to relieve pain with analgesic power and speed. No other leading rub works this way.

RUB ASPERCREME IN... RUB PAIN OUT
Rub ASPERCREME in where you hurt. In just seconds pain starts to fade away. That's because ASPERCREME'S analgesic penetrates, almost instantly, into the area of pain. You get all this relief power without waiting for a tablet to work, and without risk of stomach upset. You just rub ASPERCREME in... rub pain out.

ASPERCREME is ideal for Topical Relief of Temporary Minor Pain of Arthritis, Rheumatism & Muscle Aches.

When pain mounts, minutes count. You can't wait for aspirin to work. Maybe aspirin upsets your stomach. Simply rub ASPERCREME in where you hurt... fingers, knees, shoulders, back, elbows. In seconds, pain starts to fade away.

Aspercreme penetrates into the painful area relieving that pain with its almost instant-working aspirin-like analgesic. It's true—when you RUB ASPERCREME IN you RUB PAIN OUT.

NO LINIMENT SMELL

ASPERCREME has no liniment smell. This means you can use ASPERCREME anytime and any place you need it, without that annoying and embarrassing liniment smell. And ASPERCREME isn't greasy either. Won't stain clothes or linen. There's never been anything like ASPERCREME before. Try it today.

TESTED BY A LEADING DOCTOR

A leading specialist in arthritis and rheumatism tested Aspercreme on his own patients. Many experienced remarkable relief. Results of his controlled clinical test indicate that Aspercreme actually relieves pain faster, safer, better than aspirin. Aspercreme proved especially effective in the treatment of tendonitis, bursitis, muscular, rheumatic and arthritic pains. No side effects were reported.

SOME report ASPERCREME better than anything tried before for pain relief. . . .

"I am a 100% disabled veteran. I have arthritis and ASPERCREME is without a doubt the very best." C.H.—Petersburg, VA

"ASPERCREME is the only one I have found that has given me great relief from my arthritic pain." J.B.—Boessia City, LA

"ASPERCREME is the only medication I have found anywhere that gives me relief." R.A.—Lowell, MA

"Nothing compares to ASPERCREME." P.K.—Garden Grove, AL

"My husband has been getting wonderful relief from ASPERCREME." Mrs. R.C.—Baton Rouge, LA

"My father says ASPERCREME is better than any other medicine he has tried." M.A.—Reading, O



Available in lotion or cream
Try Aspercreme yourself today, for fast, safe, blessed relief from pain.

Thrifty
DRUG AND DISCOUNT STORES

Initial Decision

104 F.T.C.

INITIAL DECISION BY

MONTGOMERY K. HYUN, ADMINISTRATIVE LAW JUDGE

JUNE 24, 1983

PRELIMINARY STATEMENT

On February 5, 1981, the Federal Trade Commission ("Commission") issued an administrative complaint charging Thompson Medical Company, Inc. ("Thompson") and Ogilvy and Mather, Inc. ("Ogilvy") with violation 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 Aspercreme. On March 9 and 17, 1981, respondents filed their answers denying that they violated the Federal Trade Commission Act as charged. On January 4, 1983, the Commission issued its Decision and Order settling the complaint charges against Ogilvy and Mather International, Inc. (the successor corporation of Ogilvy and Mather, Inc.) which agreed to the terms of a consent agreement. *In the Matter of Ogilvy & Mather International, [2] Inc.*, Docket No. 9149, Decision and Order issued January 4, 1983. [101 F.T.C. 1 (1983)]

The parties were allowed extensive pretrial discovery. Several prehearing conferences were held in order to simplify the issues, to resolve disputes related to discovery and generally to expedite the trial preparation of the parties.

Based on the complaint and answer and prehearing conference orders, the following issues are matters for determination in this proceeding:

1. Whether Thompson represented, directly or by implication, in certain advertisements that:

- (a) Aspercreme contains [aspirin].
- (b) Aspercreme is a recently discovered or developed drug product.
- (c) Valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatic conditions and their symptoms.
- (d) Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.
- (e) Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.
- (f) Aspercreme is a more effective drug than orally-ingested aspirin

(g) Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms.

(h) Aspercreme acts by directly penetrating through the skin to the site of the arthritis disorder. [3]

(i) The use of Aspercreme will result in no side effects.

2. Whether, at the time, the above representations were made:

(a) Representations 1 (a) through (c) were false, misleading or deceptive.

(b) Respondent possessed and relied on a reasonable basis for representations 1 (d) through (i) and whether the making of such representations without a reasonable basis was false, misleading or deceptive.

3. Whether, through the use of the brand name "Aspercreme" in advertising, labels and promotional materials, respondent represented that the product "Aspercreme" contains aspirin and whether the use of the brand name "Aspercreme" is false, misleading or deceptive.

4. Whether respondent's use of the aforesaid unfair or deceptive representations and the dissemination of aforesaid false advertisements have the capacity and tendency to mislead consumers into the erroneous belief that these representations are true and into the purchase of substantial quantities of Aspercreme by reason of said erroneous belief and thus constitute unfair methods of competition and unfair or deceptive acts proscribed by Sections 5 and 12 of the Federal Trade Commission Act,

The evidentiary hearings for the presentation of complaint counsel's case-in-chief began on July 5, 1982 and ended on July 23, 1982. Defense hearings began on August 23, 1982 and ended on January 19, 1983, including a recess from September 9 to October 4, 1982. The evidentiary record was closed on [4] March 7, 1983.¹ The parties simultaneously filed their proposed findings of fact, conclusions of law, order and supporting memoranda and replies thereto. Some thirty witnesses, including nineteen expert witnesses, testified. Transcripts of hearings number some 6,500 pages. Some 200 documentary exhibits, including numerous consumer studies and medical-scientific studies, were received into evidence.

The proposed findings and conclusions submitted by the parties and their arguments in support thereof have been given careful consideration by me and to the extent not adopted by this Initial Decision, in the form proposed or in substance, are rejected as not supported by the evidence or as immaterial. Any motion appearing on the record not heretofore or hereby specifically ruled upon either directly or by the necessary effect of the conclusions in this Initial Decision are hereby denied.

¹ By order dated April 5, 1983, the Commission extended the due date of this Initial Decision to June 24, 1983.

Upon consideration of the entire record in this proceeding and having considered the demeanor of the witnesses, I make the following findings of fact and conclusions of law and order based on the record considered as a whole:² [5]

FINDINGS OF FACT

I. RESPONDENT, JURISDICTION AND OTHER GENERAL FINDINGS

1. Thompson Medical Company, Inc. ("Thompson") is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York with its offices and principal place of business located at 919 Third Avenue, New York, New York (Answer of Thompson, Paragraph 1).

2. Thompson is now and has been engaged in the distribution, advertising, offering for sale, and sale of various over-the-counter drug products, including the products Aspercreme Creme Rub and Aspercreme Lotion Rub ("Aspercreme") (Answer of Thompson, Paragraph 3) and certain appetite control drugs (CX 45F, Admission No. 81). In connection with the marketing of Aspercreme, Thompson is now and has been engaged in the dissemination, publication, and distribution of advertisements and promotional material for the purpose of promoting the sale of Aspercreme for human use. As advertised, Aspercreme is a "drug" within the meaning of Section 12 of the Federal Trade Commission Act (Answer of Thompson, Paragraph 3).

3. In the course and conduct of its business, Thompson causes Aspercreme, when sold, to be transported from its place of business to purchasers located in various other States of the United States and the District of Columbia. Thompson maintains, and at all times relevant to this proceeding has maintained, a substantial course of trade in these products, in or affecting commerce, as "commerce" is defined

² For the purposes of this Initial Decision, the following abbreviations were used:

- F. - Finding of Fact in this Decision
- CPF - Complaint Counsel's Proposed Findings
- CB - Complaint Counsel's Memorandum In Support of Proposed Findings
- CRB - Complaint Counsel's Memorandum In Support of Reply Findings
- RPF - Respondent's Proposed Findings
- RB - Respondent's Memorandum In Support of Proposed Findings
- RRB - Respondent's Reply Memorandum
- Tr. - Transcript of hearings, sometimes preceded by the name of the witness
- CX - Complaint Counsel's documentary exhibit
- RX - Respondent's documentary exhibit
- CPX - Complaint Counsel's physical exhibit
- RPX - Respondent's physical exhibit
- Comp. - Complaint
- Ans. - Answer

in the Federal Trade Commission Act. The volume of such business has been substantial (Answer of Thompson, Paragraph 4; F. 74-76, *infra*).

4. In the course and conduct of its business, and, at all times relevant to this proceeding, Thompson has been and is now in substantial competition in or affecting commerce with corporations, firms, and individuals representing or engaged in the manufacture or marketing of health care products (Answer of Thompson, Paragraph 6).

5. In the course and conduct of its business, Thompson has disseminated and caused the dissemination of certain advertisements concerning Aspercreme through the United States mail and by various means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, the insertion of advertisements in magazines with national circulations and the placement of advertisements with [6] television stations with sufficient power to broadcast across states lines and into the District of Columbia (Answer of Thompson, Paragraph 8; F. 73-75, *infra*).

6. Aspercreme is a topical cream or lotion rub, the active ingredient of which is 10% triethanolamine salicylate ("TEA/S") (See RX 276-84; RPX 3-6; CPX 5-7). TEA/S is also known as trolamine salicylate. The package direction for its use advises that the user massage it into painful areas until thoroughly absorbed into skin, three or four times daily (e.g., RX 279).

7. In a report published on December 4, 1979, the Food and Drug Administration's Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products ("FDA OTC External Analgesic Panel") concluded that TEA/S "is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic" for labeling purposes (CX 269, p. 69,856). The Panel placed TEA/S among the Category III ingredients and recommended that during the testing period provided to demonstrate effectiveness, the ingredient TEA/S may bear the labeling provided for topical analgesics (*Id.*).

8. In a notice of proposed rulemaking published on February 8, 1983, the FDA published a tentative final monograph on OTC external analgesic drug products, which in effect adopted the FDA Advisory Panel's conclusions and recommendations regarding TEA/S as a topical analgesic (CX 443).

9. By Citizens Petition dated November 24, 1981 and filed with the FDA (RX 366), Thompson requested the Commission to reopen the administrative record and to receive new data being submitted by Thompson and urged that 10% TEA/S (Aspercreme) be placed by the FDA in Category I as an effective topical analgesic. Although there

has not been a final disposition of Thompson's November 1981 Petition and subsequent correspondence by the FDA, the FDA's proposed rule for OTC external analgesic drug products (CX 443) appears to have considered substantially all of the studies in evidence in this proceeding and to have adopted the OTC External Analgesic Panel's conclusions and recommendations regarding TEA/S. As reflected in this record, it is unlikely that the FDA will reverse its position with respect to topical TEA/S as a result of its review of the pending Thompson submissions (*See* F. 393-400, *infra*). However, respondent states that, under the FDA's monograph procedures for OTC external analgesic drug products, respondent is permitted to continue marketing Aspercreme for an interim period until April 9, 1984, pending development and review of "evidence that will permit final classification of the [7] effectiveness of TEA/S, "presumably including two or more well-controlled clinical trials (RB 18).

II. EXPERT WITNESSES WHO TESTIFIED REGARDING MARKETING AND MEDICAL/SCIENTIFIC ISSUES

10. Complaint counsel called Drs. Joel B. Cohen and Ann Silny on the issues related to advertising, marketing and consumer psychology, and Drs. John Adriani and Sanford H. Roth on the medical/scientific issues in this case.

A. John Adriani, M.D.

11. Dr. John Adriani is a Professor of Pharmacology at Louisiana State University Medical School, and Clinical Professor of Oral Surgery (Anesthesiology) at the Louisiana State University School of Dentistry. He is also Director of Research, in the Department of Anesthesiology, Louisiana State University Medical School and at Charity Hospital, in New Orleans, Louisiana (Adriani, Tr. 1128). Dr. Adriani is a respected researcher in the field of analgesics (O'Brien, Tr. 3736-37; Silverman, Tr. 2340). He previously taught physiology and pharmacology as pertains to anesthetic drugs and did anesthesia research at New York University College of Medicine (Adriani, Tr. 1129). As a practicing physician, Dr. Adriani organized a pain clinic at Charity Hospital in New Orleans. His patients include those suffering from rheumatic and other diseases (Adriani, Tr. 1141). Dr. Adriani is a consultant to the Food and Drug Administration and has served on two advisory panels on OTC drugs, including the OTC External Analgesics Panel which evaluated analgesic, antirheumatic, otic, protectant and sunscreen products, including TEA/S, the active ingredient in Aspercreme (Adriani, Tr. 1130, 1135-36, 1147-48). He is also a consultant to the State of Louisiana Governor's Formulary Committee which admits certain drugs onto a list that the hospitals will stock

and supply to private patients (Adriani, Tr. 1136). Dr. Adriani has served as an advisor and consultant to a number of pharmaceutical companies, including Norwich-Eaton and Cetilyte Laboratories. He also has done consulting work involving the testing of ether and different narcotics and the stability of anesthetics with the presence of soda lime for pharmaceutical firms such as Squibb and Malincradt (Adriani, Tr. 1138-39). Dr. Adriani has also conducted studies which evaluated certain pain-relieving drugs for pharmaceutical firms, including Darvon and Demerol (Adriani, Tr. 1138-40). Dr. Adriani himself has [8] been personally involved in well over 100 clinical studies (Adriani, Tr. 1144).

12. Dr. Adriani is a Fellow in the American College of Clinical Pharmacology and the American Society for Clinical Pharmacology and Therapeutics (Adriani, Tr. 1131-32). He is a Board-certified member of the American Board of Anesthesiology. For 10 years, he was a member of the Council on Drugs of the American Medical Association, serving as Chairman of the Council for a period of three years (Adriani, Tr. 1133). In addition, Dr. Adriani belongs to numerous research societies, including the Southern Society for Clinical Research and the National Society for Medical Research (Adriani, Tr. 1129-31). He has served in both elected and appointed positions on several scientific and educational committees. He is a member of the Society of Experimental Biology and Medicine, the International Congress of Pharmacology, and served on the Advisory Committee to Commissioner Larrick of the Food and Drug Administration from 1963 to 1965. Dr. Adriani was Chairman of the Advisory Committee of the Food and Drug Administration on Anesthetic and Respiratory Drugs, and a member of the Scientific Review Panel on publication of the Book, *Drug Interactions*, published by the American Pharmaceutical Association (Adriani, Tr. 1130).

13. Dr. Adriani has authored thirteen books covering such areas as drugs used for stimulation, anesthesia, and sedation, pain-relieving drugs, drugs given prophylactically, and muscle relaxants (Adriani, Tr. 1143-44). Of the approximately 600 articles he has published, half are scientific papers relating to research work and approximately 200 of them involved the clinical testing of drugs. A great many of these articles have been published in peer-reviewed scientific journals, including *Anesthesia and Anesthesiology*, *Clinical Pharmacology and Therapeutics*, the *Journal of Experimental Medicine and Biology*, and the *Journal of the American Medical Association* (Adriani, Tr. 1146). Dr. Adriani has served as editor and reviewer of articles on pain-relieving drugs or anesthetics for numerous scientific magazines and journals, and has edited over thirty textbooks and resource works on anesthesia (Adriani, Tr. 1142; CX 368W-X). He was Editor-in-Chief of

the *1971 AMA Drug Evaluations* and wrote approximately ten chapters of the book, including sections on strong analgesics and mild analgesics (Adriani, Tr. 1132-35). Dr. Adriani has appeared as an expert witness in a number of legal proceedings and before Congressional committees, and has testified in malpractice and product liability cases as well. Most of these cases involved pain-relieving drugs (Adriani, Tr. 1140). He also served as an expert witness in a product liability case concerning Benzocaine (Adriani, Tr. 1138). [9]

14. Dr. Adriani has received numerous awards and honors. Among these are the Distinguished Service Award of the American Society of Anesthesiologists and the Distinguished Service Award of the International Anesthesia Research Society. He received the Gold Medal For Distinguished Achievements in Medicine of an International Scope, from the Columbia University Alumni Association. He also received the Ralph M. Waters Medal, which in anesthesiology is comparable to the Nobel Prize, and was invited to donate his personal papers and letters to the National Library of Medicine, at the National Institutes of Health (CX 368Q). Dr. Adriani received the highest honor awarded to a civilian by the Italian Government, for his activities in medicine. He also received the Gaston Labat award which is given to physicians who contribute to the development of regional anesthesia. Dr. Adriani received this award in connection with his investigative work in local anesthetics and different techniques in nerve blocking (Adriani, Tr. 1137-38).

15. Based on his background, training, experience and familiarity with the literature, Dr. Adriani is eminently qualified as an expert in clinical pharmacology, topical analgesics, and in the evaluation of the safety and efficacy of analgesic drugs.

B. *Dr. Joel B. Cohen*

16. Dr. Joel B. Cohen is Chairman of the Marketing Department and a Professor of Marketing at the University of Florida where he also serves as Director of the Center of Consumer Research (Cohen, Tr. 82). It conducts theoretical and applied research on consumer behavior, focused primarily on consumer information processing and decisionmaking (Cohen, Tr. 83). Dr. Cohen's teaching responsibilities are almost entirely in the consumer behavior area (Cohen, Tr. 85). Dr. Cohen holds a Ph.D. from U.C.L.A. in Marketing with a minor in Social Psychology. In 1966, he joined the faculty of the University of Illinois where he taught consumer behavior, behavioral science, marketing research and graduate level research design courses (Cohen, Tr. 87). From 1972-1974, Dr. Cohen served as Director of the Social and Behavioral Science Division of National Analysts, a leading marketing research and social science research organization (Cohen, Tr.

93-94). Dr. Cohen has been working in the area of consumer research and information processing for more than seventeen years. His primary areas of expertise are in consumer information processing, the study of consumer attitudes and cognition (what consumers have learned and believe), mass communication, and research design questions and measurement [10] (Cohen, Tr. 92). Over the years, Dr. Cohen has done consulting for both industry and governmental agencies (Cohen, Tr. 93-94). As consultant to the National Academy of Sciences Panel on the Impact of Drug Use and Misuse, he advised the panel regarding research design questions which could be used to evaluate the success of any advertising program which might be developed to combat drug abuse (Cohen, Tr. 95-96). More recently, he did consulting work for R.J. Reynolds relating to the processes through which advertising leads to changed cognitions and attitudes (Cohen, Tr. 96). Dr. Cohen was chief witness on advertising for Senator Packwood's Commerce Committee with respect to how cigarette warning information works. Dr. Cohen has been a consultant to the Federal Trade Commission since 1974.

17. Dr. Cohen is a member of the Association for Consumer Research. He is a member of the American Marketing Association and served as Chairman of their 1975 National Conference. Dr. Cohen is a member of the American Psychological Association and has chaired a number of professional symposia and workshops on consumer information processing (Cohen, Tr. 88-90, 98). While Dr. Cohen's work has concentrated on consumer behavior, he has presented papers at various conferences dealing with advertising, attitude measurement and applied projects in marketing and advertising (Cohen, Tr. 87-88). Dr. Cohen has authored a book, *Behavioral Science Foundations of Consumer Behavior*, and numerous articles and papers in the field of consumer behavior and attitudes (Cohen, Tr. 87-88; CX 36B-F). Dr. Cohen is a permanent member of the editorial boards of the *Journal of Consumer Research* and the *Journal of Marketing*. He is an editorial consultant for other journals in psychology and marketing including the *Journal of Applied Psychology*, the *Journal of Experimental Psychology*, the *Journal of Marketing Research*, *Economic Development and Cultural Change*, and *Population and Environments: Behavioral and Social Issues*. The types of articles Dr. Cohen reviews for the various journals include those in the areas of consumer information processing, advertising issues, measurement of persuasion, and particularly articles on processes through which advertising is supposed to affect a consumer's preferences and subsequent decisions (Cohen, Tr. 90-91). Dr. Cohen is well qualified as an expert in consumer information processing and analysis of consumer research.

C. Sanford H. Roth, M.D.

18. Dr. Sanford H. Roth currently serves as Medical Director of the Arthritis Program at St. Luke's Hospital Medical Center in Phoenix, Arizona, and has extensive experience in the [11] field of rheumatology and has been involved in clinical research relating to analgesic and anti-inflammatory drugs (Roth, Tr. 1488, 1499-1500, 1501-03, 1512). Dr. Roth's experience includes more than seventeen years of clinical practice with patients suffering from rheumatoid diseases, musculoskeletal disorders, and complications of osteoarthritis as well as considerable research in the areas of anti-arthritis, anti-inflammatory, analgesic and immuno modulating drugs (Roth, Tr. 1500-05). Dr. Roth has been involved in multiple research efforts comparing aspirin to nonsteroidal anti-inflammatory drugs (Roth, Tr. 1500). His former association with the Phoenix Arthritis Center focused on the treatment of rheumatic disorders, but also involved clinical investigations (Roth, Tr. 1506-07). He is a well-known and respected rheumatologist (O'Brien, Tr. 3736-37; Ehrlick, Tr. 4038). Dr. Roth has served as a consultant to the FDA and was an expert witness in rheumatology before the Arthritis Advisory Committee (Roth, Tr. 1495). He participated in the development of new FDA guidelines on package inserts, and worked with the National Institute of Health creating the American Rheumatism Association Medical Information System ("ARAMIS") which is now the world's largest repository of rheumatic disease, clinical data. Dr. Roth presently serves as co-director and principal investigator for the Phoenix data bank (Roth, Tr. 1495-97). Dr. Roth has served as a consultant to various pharmaceutical companies including Hoechst-Roussel Company, Pfizer Drug Company, Syntex Drug Company, Perdue Frederick and the MMM RIKER Company (Roth, Tr. 1497-98). This work involved the clinical evaluation of drugs and, in particular, salicylates (including the development of a nonacetylated salicylate for Perdue Frederick), work with teaching programs for the Riker Company in connection with another nonacetylated salicylate, and involvement with Bristol Myers relating to the gastrointestinal safety of a highly buffered aspirin product (Roth, Tr. 1499-1500).

19. Dr. Roth has served as Chairman of the Anti-Rheumatic Drug Therapy Study Group of the American Rheumatism Association and is currently a member of other professional associations with particular interest in rheumatology (Roth, Tr. 1493). He is affiliated with the American Society of Clinical Rheumatology, a peer group limited to twenty members, the American College of Clinical Pharmacology and the American Society of Clinical Pharmacology and Therapeutics (Roth, Tr. 1494). Dr. Roth has been involved in clinical testing and has

published many papers on this subject in peer-reviewed journals, including the *Journal of Rheumatology*, *Excerpta Medica*, and the *Journal of Clinical Pharmacology*. In addition, Dr. Roth has been invited to lecture at many seminars and symposiums (Roth, Tr. 1507-11; CX 369E-O). Dr. Roth has [12] been involved in the editing of various professional journals and books and other resource works on rheumatology (Roth, Tr. 1509-11; CX 369A, P). He is extensively involved in writing and lecturing about clinical evaluations and current work relating to analgesic and anti-inflammatory agents (Roth, Tr. 1513).

20. Dr. Roth's research background and clinical experience, as well as his familiarity with the current literature qualify him well as an expert in rheumatology and in the design, execution and analysis of clinical research regarding analgesic and anti-inflammatory drugs.

D. Ann Silny, Ph.D.

21. Dr. Ann Silny is Vice President of Client Services for ASI Market Research, a Los Angeles firm involved in custom research, syndicated copy testing and program testing for networks (Silny, Tr. 684-85). Dr. Silny holds a Ph.D. in experimental psychology from the University of California, Berkeley, with her primary area of graduate study being in the design and conduct of experiments and the analysis of experimental results with a specialization in behavioral endocrinology (Silny, Tr. 691-92). Throughout her studies at Berkeley, she taught such courses as Introductory Psychology, Cognitive Psychology, Information Processing, and Comparative Psychology (Silny, Tr. 693). During graduate school, she studied under Dr. Leo Postman, a well-known theoretician and recognized authority in the area of learning and memory (Silny, Tr. 694). After receiving her Ph.D. in 1975, Dr. Silny joined the Roosevelt University in Chicago as Assistant Professor of Psychology teaching basic courses in research and methodology and design and quantitative methods (Silny, Tr. 694).

22. In her present position at ASI, Dr. Silny, after conferring with a client to determine their research objectives, recommends a research design using either a standardized copy testing system or designing custom research. She oversees the implementation of that research and then performs data analysis and presentation recommendation to the client. Most of Dr. Silny's time is devoted to the design of custom research which is research design custom tailored to specific research objectives as opposed to standardized research which is done under the same format with the same set of measures (Silny, Tr. 686-87). Dr. Silny has performed attitudinal tracking studies, media evaluation experiments and syndicated copy testing for many major consumer research clients including Alberto-Culver, Firestone,

Arco, Chevron, Home Box Office, and [13] VISA (Silny, Tr. 688-89). In Dr. Silny's previous position with ASI, she was responsible for decisions as to appropriate statistical tests, conducting those tests and evaluation of the data. In addition, she supervised the maintenance of norm systems which are records of how commercials in given categories have tested over a period of time. This system becomes the evaluative benchmark (Silny, Tr. 689-90).

23. Dr. Silny has published in various textbooks and technical journals (Silny, Tr. 695; CX 31B). She is a member of the Advertising Research Foundation, the American Marketing Association and the Association of Consumer Research (Silny, Tr. 695). Dr. Silny has served as an expert witness in cases involving consumer research, including *Vidal Sassoon v. Bristol Myers* and *U-Haul v. Jartran* (Silny, Tr. 696).

24. Dr. Silny is a qualified expert in the design, execution and interpretation of advertising copy research.

25. Thompson called a large number of expert witnesses. Five expert witnesses testified regarding the marketing, advertising and consumer psychology issues. They are Jacqueline Silver, Dr. Ivan Ross, Dr. Roslyn Freudenthal, Dr. Kenneth M. Warwick and Jay Jasper. Ten expert witnesses testified regarding the medical/scientific issues. They are Drs. H.I. Maibach, R.L. Marlin, A.J. Patel, S.L. Altschuler, J.L. Rabinowitz, G.E. Ehrlich, E.L. Golden, W.M. O'Brien, H.I. Silverman and S.I. Heller.

E. Howard I. Maibach, M.D.

26. Dr. Howard I. Maibach's testimony and his qualifications as an expert in dermatology, dermatopharmacology, and the percutaneous absorption of drugs have been stipulated by counsel. Dr. Maibach is a Professor of Dermatology at the University of California Medical School, San Francisco, California. He is a Research Associate at the Cancer Research Institute, is on the active staff of the University of California - H.C. Moffitt Hospitals, and is a Consultant in Dermatology to the Stanford Research Institute and to the State of California Department of Public Health. He is a Diplomate of the American Board of Dermatology (certified in 1961), and is a Fellow of the American College of Physicians. He is a member of the American Academy of Dermatology, the New York Academy of Sciences, the American Federation for Clinical Research, the American Dermatological Association, and the American Society for Clinical Pharmacology and Therapeutics. He is on the Board of Editors of the *International Journal of Dermatology*. He [14] has published over 400 papers on dermatology, including percutaneous absorption or penetration of topical drugs.

F. Robert L. Marlin, Ph.D.

27. Dr. Robert L. Marlin has been a consultant in the field of clinical research since 1972. Most of his clients are pharmaceutical companies. Dr. Marlin advises pharmaceutical companies on the design of clinical studies, helps define the scope of the investigations, initiates and monitors the clinical research, and after the investigation is completed, works with the clinician to review the results (Marlin, Tr. 3150-51).

28. Dr. Marlin received a bachelor's degree in psychology from Syracuse University, a master's degree in administration from the Maxwell School in Syracuse, and a doctorate in information science from Rutgers University. His doctoral research investigated the reliability of the adverse reaction reporting system in the FDA hospital reporting programs. Dr. Marlin has also taken post-graduate courses in pharmacology at Rutgers University (Marlin, Tr. 3154-56).

29. Dr. Marlin's first professional position was with the New York State Department of Mental Hygiene as an assistant in the testing of the patient population at a State facility. His next position was with the Sterling-Winthrop Research Institute, where he later became an assistant to the executive vice president of Winthrop Laboratories. His duties included the evaluation of laboratory data, biological data, pharmacological data, and other clinical information on drugs which were being licensed in the United States or other countries in Europe or the Far East. Concurrently, Dr. Marlin worked in the clinical research department of the company, monitoring the clinical trials conducted by Winthrop Laboratories in the southeast part of the United States, including clinical trials of a parenteral analgesic, an anesthetic, and several radioactive-type drugs used as diagnostic tools. Dr. Marlin's next position was coordinator of medical affairs for Knoll Pharmaceutical. In that position, he was responsible for designing the protocols for the clinical investigations, initiating the studies, monitoring the studies, and evaluating the data and oversaw the submission of the drug to the FDA for approval. While at Knoll, Dr. Marlin supervised the research for various drugs in the analgesic and asthmatic areas. Thereafter, Dr. Marlin was employed by Schering Pharmaceutical as an assistant to the vice president of Research of New Product Development and oversaw the research for new products. Dr. Marlin also worked for Sandoz as the senior clinical research associate, where he remained for [15] six years until 1975 when he opened a consulting business. Dr. Marlin has been involved in clinical research on both ethical and OTC preparations for some twenty pharmaceutical companies. His work with OTC drugs has

involved mostly analgesics such as aspirin, acetophenetidin, and other salicylates (Marlin, Tr. 3156-63).

30. Dr. Marlin is a member of the Drug Information Association, The American Association for the Advancement of Science, The New Jersey Academy of Science, The American Statistical Association, and The Biometric Society (Marlin, Tr. 3163-66). Dr. Marlin is qualified as an expert in clinical trials for the evaluation of the safety and efficacy of drug substances.

G. Professor Alain Jacques Patel

31. Professor Alain Jacques Patel is a French physician and is chief surgeon and head of the orthopedic and traumatologic surgery department at the Raymond Poincare Hospital, Paris, France, a teaching hospital connected with the University of Paris, where he is a professor of medicine. The orthopedic and traumatologic surgery department with 144 beds provides both in-patient and out-patient care. The majority of patients in the department suffer from musculoskeletal problems. Professor Patel treats many patients with rheumatic disease (Patel, Tr. 1805-06, 1812). Dr. Patel divides his time among treating patients, teaching graduate and post-graduate refresher courses in medical treatment and surgery, and doing research. He conducts research at the Institute of Research in Orthopedics, connected with the University of Paris. He has been president of the Institute for approximately ten years (Patel, Tr. 1815-17).

32. About twelve years ago, the French Ministerial of Health designated Professor Patel as a national expert on drugs. In this capacity, Professor Patel conducts tests on the efficacy and safety of new drug products. In order for a drug to be put on the French market and qualify as an approved drug for Social Security purposes, it must first be tested and approved by designated experts of the French Ministerial of Health. He has conducted about twenty-four clinical tests. Because his specialty involves musculoskeletal and bone disease of which pain, swelling, and limitation of movement are the primary symptoms, many of the drugs that Professor Patel has tested have been analgesics (Patel, Tr. 1817-20). Professor Patel is also associated with the French Foreign Office as the medical coordinator for all medical affairs for [16] Southeast Asia. Until he became a designated national expert on drugs, he had published about 175 papers on such topics as orthopedic lesions, congenital or rheumatological lesions, traumatologic cases, research on trauma, and research on drugs (Patel, Tr. 1822-23, 1835-36).

33. Professor Patel has received many honors for his work in orthopedics and traumatology, including the Croix du Merite National from the French Ministerial of Health, which is regarded as the high-

est honor the French government bestows on a civilian of his age (Patel, Tr. 1836-37). Professor Patel is qualified as an expert in osteoarthritis, rheumatoid arthritis, and cases involving bone, muscle, and ligament difficulties.

H. Stanley L. Altschuler, M.D.

34. Dr. Stanley L. Altschuler is a physician licensed to practice in New York, New Jersey, and Pennsylvania. He is a board-certified specialist in internal medicine and pulmonary diseases. In addition to a private practice, Dr. Altschuler is on the staff of the Medical College of Pennsylvania, Frankfort Hospital, Nazareth Hospital, and the Albert Einstein Medical Center, all of Philadelphia. He has teaching responsibilities in internal medicine and pulmonary disease at Frankfort Hospital, the Medical College of Pennsylvania, and the Albert Einstein Medical Center. He also makes medical rounds with the hospital staff. Dr. Altschuler is a member of the American College of Physicians, the American Thoracic Society, and the Pennsylvania Lung Association (Altschuler, Tr. 2990-91, 2993-94, 3003).

35. Dr. Altschuler attended medical school at Upstate Medical Center in Syracuse, New York. He interned at Monmouth Medical Center in New Jersey and did his medical residency at the Veterans Administration Hospital at the Medical College of Pennsylvania, which was followed by a two year fellowship in pulmonary disease at Temple University. Thereafter, Dr. Altschuler joined the staff of the Philadelphia VA Hospital, where he remained for approximately eight years and began a private practice. In 1979, he resigned from the staff of the VA Hospital for full-time private practice. Approximately 20% of Dr. Altschuler's patients have rheumatic difficulties (Altschuler, Tr. 2990-92, 2994).

36. Dr. Altschuler has conducted some ten clinical tests on drug products for pharmaceutical companies. Generally, the agents that he has tested have been for use in the field of internal medicine. Dr. Altschuler is also the author of several [17] articles in the fields of his specialties (Altschuler, Tr. 2994, 2995-96; RX 575). Dr. Altschuler is qualified as an expert in internal medicine, pulmonary disease, and the conduct of clinical trials for the testing of drugs.

I. Joseph L. Rabinowitz, Ph.D.

37. Dr. Joseph L. Rabinowitz is a biochemist who specializes in the field of lipid isotopes. His work consists of using radioactive isotopes to discover how the body utilizes fat and how it metabolizes nutritional products and drugs. Many of his projects involve an analysis of drug absorption and he has been using radioactive carbon (carbon 14) in his biochemical and pharmacological research for thirty years. He

has conducted research for a number of pharmaceutical companies in the area of radioactive tracers and drug absorption testing (Rabinowitz, Tr. 3481, 3491-92).

38. Dr. Rabinowitz is currently chief of radioisotope research at the VA Hospital in Philadelphia and a professor of biochemistry at the University of Pennsylvania. His responsibilities at the University consist of teaching biochemistry and radioisotope courses to medical and dental students at the graduate level and overseeing the radioisotope research conducted at the University. As chief of radioisotope research at the VA Hospital, he functions as an advisor to investigators on the feasibility and desirability of using isotopes in their research. In addition, Dr. Rabinowitz serves as a reviewer and/or a member of the editorial boards of several professional journals, including the *Journal of Medicinal Chemistry*, the *Journal of Lipid Research*, and the *Journal of Nuclear Medicine* (Rabinowitz, Tr. 3482-83; RX 563).

39. Dr. Rabinowitz received his Master of Science degree in chemistry and his doctorate in organic chemistry from the University of Pennsylvania. He has done postdoctoral work in biochemistry, chemistry, and physiology at the University of Pennsylvania; Carlsberg Laboratory in Copenhagen, Denmark; Milstead Enzyme Laboratory in England; and Orsay Physiology Laboratory in Paris, France. With respect to radioisotope research, Dr. Rabinowitz has taken several physics and radiation safety courses at the University of Pennsylvania, has received on-the-job training in the handling and use of radioisotopes, and has taken courses in isotope technology at the College of Pharmacy at the University of Pennsylvania. He has been licensed for many years by the Atomic Energy Commission to use and possess radionuclides (radioactive atoms) (Rabinowitz, Tr. 3481-82; RX 563). [18]

40. Dr. Rabinowitz is a member of a number of professional societies, including the American Society of Biological Chemistry. Membership in this society is considered difficult to achieve. Dr. Rabinowitz has been honored for his work in radionuclides with many awards, including the Doctor Honoris Causa from the University of Bordeaux, France; the Harrison Award in Chemistry from the University of Pennsylvania; the Fulbright Professor Award in Biochemistry at the Carlsberg Laboratory, Denmark; The Silver Medal of the City of Bordeaux, France; and the Medal of the City of Nancy, France (Rabinowitz, Tr. 3484-85; RX 563). Dr. Rabinowitz has published some 200 books, articles, and abstracts, including many that discuss radioactive materials and their interrelationships with drugs. He has co-authored a book on radioisotope methodology which is used in many universities throughout the world (Rabinowitz, Tr. 3490-92).

Dr. Rabinowitz is well qualified to give testimony as an expert in radioisotope testing.

J. George E. Ehrlich, M.D.

41. Dr. George E. Ehrlich is currently a professor of medicine and director of the Division of Rheumatology of Hahnemann Medical College, Philadelphia, Pennsylvania and specializes in rheumatology. At Hahnemann, he provides a teaching program for medical students, health professionals, and graduate physicians specializing in rheumatology, provides patient care programs in rheumatology and helps guide research in rheumatology (Ehrlich, Tr. 3980-82). He is also on the associate staff of Albert Einstein Medical Center and the Moss Rehabilitation Hospital (Ehrlich, Tr. 3980-82).

42. Dr. Ehrlich received his undergraduate degree from Harvard University and his bachelor of medicine and doctor of medicine degrees from Chicago Medical School. He did his internship at Michael Reese Hospital in Chicago. He followed his internship with several residencies: Francis Delafield Hospital of Columbia Presbyterian Medical Center, New York City (soft tissue pathology and surgery); Beth Israel Hospital, Boston (internal medicine); and Tufts New England Medical Center, Boston (senior residency in medicine). After his residencies, Dr. Ehrlich did two fellowships in rheumatology, the first at the National Institute of Arthritis and Metabolic Diseases of the National Institute of Health, and the second at a hospital for special surgery at the New York Hospital Medical Center Complex of Cornell University. Concurrently with this second fellowship, he held a special fellowship in research at the Sloan-Kettering Institute. Prior to joining the faculty at [19] Hahnemann College, Dr. Ehrlich was a professor of medicine and rehabilitative medicine at Temple University School of Medicine and director of the Section of Rheumatology at the Albert Einstein Medical Center and Moss Rehabilitation Hospital (Ehrlich, Tr. 3980-82).

43. Many awards and honors granted to Dr. Ehrlich for his work in rheumatology include the distinguished alumnus award from Chicago Medical School, the Phillip Hench award of the Association of Military Surgeons, several Distinguished Service Awards from the Arthritis Foundation, two official citations from the City of Philadelphia, The Order of the Star with the rank of Cavaliere from the Italian Solidarity, the Phillip Hench lectureship from the American College of Physicians (twice), and the William K. Ishmael lectureship at the University of Oklahoma (Ehrlich, Tr. 3982-84).

44. Dr. Ehrlich is a former consultant on inflammatory drugs to the FDA Bureau of Drugs. He is currently a consultant to the American Medical Association Directory of Drugs, and serves as a consultant to

pharmaceutical companies on the development of testing for new inflammatory drugs. He is a member of numerous professional organizations and holds fellowships in various organizations including the American College of Clinical Pharmacology, the American Congress of Rehabilitation Medicine, and the American College of Physicians (Ehrlich, Tr. 3985-87; RX 135). Dr. Ehrlich's publications on rheumatology numbering some 150, includes papers concerned with the clinical testing of drugs, as Dr. Ehrlich has participated in more than thirty clinical trials in the past twenty years (Ehrlich, Tr. 3987-88).

45. Dr. Ehrlich has testified at many proceedings as an expert. He was invited by the Food and Drug Administration to give testimony as to the value of studies that were submitted as efficacy evidence for salicylate drugs and related inflammatory drugs. He has also testified at the Department of Health, Education and Welfare regarding the federal licensing program for physical therapists. He has been an expert witness in a variety of litigation involving malpractice cases and compensation cases (Ehrlich, Tr. 3989-90). Dr. Ehrlich is qualified as an expert in the design, execution, and analysis of clinical trials and is well qualified as an expert in rheumatology (Ehrlich, Tr. 3990-91).

K. Emanuel L. Golden, M.D.

46. Dr. Emanuel L. Golden is a specialist in internal medicine and rheumatology. He has practiced in internal [20] medicine since 1956 and in rheumatology since 1960. His current practice is approximately 75% rheumatology and 25% internal medicine, and he sees between 100 and 125 patients a week. He is certified as a Diplomate of the American Board of Rheumatology, and as a Fellow of the American College of Physicians. He is affiliated with the North Broward Hospital and the Boca Raton Community Hospital in Florida. Dr. Golden is a member of the American Rheumatism Association, the Arthritis Foundation, the Broward County Arthritis Foundation, and the American Medical Association. He is an accredited lecturer in rheumatology for the Palm Beach Arthritis Foundation and the Broward County Arthritis Foundation, and he lectures at the hospital staff training programs for nurses and therapists at North Broward Hospital and Boca Raton Community Hospital. Dr. Golden is also a visiting physician at the Jackson Memorial Hospital at the University of Miami (Golden, Tr. 2647-49, 2663-68; CX 327).

47. Dr. Golden received his medical training at the Chicago Medical School, interned at Brooklyn Jewish Hospital, and did a three year medical residency at Kingsbridge Veterans Hospital in New York City. Prior to attending medical school, Dr. Golden received one year

of post-graduate training in bio-chemistry and endocrinology. From 1960 to 1963, Dr. Golden trained with Dr. Steinbrocher at the Joint Disease Hospital in New York City, where he received further training in joint diseases from a clinic which was run by the school. After spending three years at the Joint Disease Hospital, Dr. Golden was appointed by the director of medicine at Mt. Sinai Hospital to the position of director of the arthritis clinic at Greenpoint Hospital, a city hospital which was at that time affiliated with Mt. Sinai Hospital. From here, he moved to Elmhurst City Hospital, a teaching hospital affiliated with Mt. Siani, and became an associate professor of medicine at Mt. Sinai Hospital School of Medicine. He stayed at Elmhurst City Hospital for ten years during which time he taught interns and residents in the field of rheumatology, acted as a consultant to the hospital, and directed both the Regular Arthritis Clinic and the Combined Arthritis Rehabilitation Clinic. As director of the Regular Arthritis Clinic, Dr. Golden set up a treatment program for outpatients with arthritis, ran the clinic, and supervised a staff of three rheumatologists. Approximately 100 patients a week were treated on a regular basis at this clinic. The Combined Arthritis Rehabilitation Clinic was created by Dr. Golden in collaboration with a doctor in rehabilitative medicine. The object of this clinic was to tailor a treatment program for chronic arthritics to meet all of their medical needs. This combined treatment clinic was a new concept at this time, but has since been adopted by other hospitals. Dr. Golden [21] served as the director of the Combined Clinic and oversaw the activities of the entire staff of physicians, residents, therapists, and paramedics (Golden, Tr. 2648-61). In 1975, when the American College of Physicians formally recognized rheumatology as a special field of medicine, Dr. Golden took the required examination and became a Diplomate of the American Board of Rheumatology (Golden, Tr. 2649). Dr. Golden is well qualified as an expert in internal medicine and rheumatology.

L. William M. O'Brien, M.D.

48. Dr. William M. O'Brien is a physician and a specialist in rheumatic diseases. Dr. O'Brien is an attending physician at the University of Virginia Hospital and Blue Ridge Sanitarium and a professor of internal medicine at the University of Virginia Medical School. In his capacity as a professor, he runs four clinics a week, one for patients with rheumatoid arthritis, two for patients with general rheumatic disease, and one for patients with lupus erythematosus (O'Brien, Tr. 3642-43).

49. After graduating from Yale Medical School, Dr. O'Brien trained in internal medicine at Massachusetts General Hospital and at Harvard. He did a Fellowship at the National Institute of Arthritic and

Metabolic Diseases at the National Institute of Health. At the Manchester Royal Infirmary in England, he served as Senior Registrar in rheumatology. For three years, he was Senior Clinical Investigator at the Arthritis Institute of the National Institute of Health. He was an assistant professor in internal medicine for three years at Yale Medical School. He has held his present position as a professor of medicine at the University of Virginia for eleven years (O'Brien, Tr. 3642).

50. Dr. O'Brien has been accorded many honors for his work. He is a member of the Heberden Society in England, a society limited to 100 experts in rheumatology. He is a member of the Academy of Medicine in Chile, and has received an award from the American Epidemiology Society. As an adviser to the chief of medicine of the Veterans Administration, he served for four years on the committee that designs the long-term clinical trials for the Veterans Administration. The many clinical trials Dr. O'Brien was involved in included the trials to discover the role of aspirin in preventing myocardial infarction. He also served as medical consultant to the Consumers Union of the United States for three years and has assisted for many years in the publishing of a medical letter on clinical trials established by the Consumers Union. Recently, he published two letters criticizing the use of the arthritis prescription drugs Oraflex and Feldine (O'Brien, Tr. 3643-44). [22] The professional societies to which Dr. O'Brien belongs include the American Rheumatism Association and the Anti-Inflammatory Drug Study Group. In his association with the former he designed and directed, for six years, all of the clinical trials run by the association. These trials, through the association's cooperating clinic committee of which Dr. O'Brien was chairman, focused on anti-rheumatic drugs. This year he was made co-president of the Anti-Inflammatory Study Group which provides for discussion among physicians about clinical trials (O'Brien, Tr. 3644-45).

51. Dr. O'Brien has published numerous articles, books, and lectures. Most of these are in the field of rheumatology and most concern the testing of drugs. While he was chairman of the cooperating clinic committee of the American Rheumatism Association, Dr. O'Brien published in the *New England Journal of Medicine* and in *Clinical Pharmacology and Therapeutics* a series of articles on trials which he conducted on aspirin and aspirin-like drugs (O'Brien, Tr. 3645-46). He has appeared before the Federal Trade Commission, the FDA Internal Analgesic Advisory Panel, and the United States Senate. Many drug companies have requested him to render opinions on analgesics and anti-inflammatory drugs (O'Brien, Tr. 3646-48). Dr. O'Brien is well qualified as an expert in rheumatology; internal medicine; and the design, execution, and analysis of clinical trials.

M. Harold I. Silverman, Ph.D.

52. Dr. Harold I. Silverman is a professor of pharmacy and executive director of Pfeiffer Pharmaceutical Sciences Laboratories at the Massachusetts College of Pharmacy and Allied Health Sciences, Boston, Massachusetts. He is also a member of the faculty at Boston University Medical School and the New England College of Optometry. He is a registered pharmacist in Massachusetts, New Jersey, and Pennsylvania. Dr. Silverman has been the executive director of Pfeiffer Pharmaceutical Sciences Laboratories since its inception approximately five years ago. In this role, Dr. Silverman helps plan, design, and execute the research at the laboratory and is responsible for all the reports it issues. The staff also provides teaching for Massachusetts College of Pharmacy and Allied Health Sciences of which the laboratory is a part. Dr. Silverman has taught courses in biopharmaceutics (the development, design, and analysis of a pharmaceutical product), product development, industrial pharmacy, physical pharmacy, and OTC drug products. All of these courses have touched upon FDA rules and regulations and the toxicology, safety, and efficacy of drug substances (Silverman, Tr. 2070-76, 2086-89, 2090-92). [23]

53. Dr. Silverman began his education as a pharmacist at the Philadelphia College of Pharmacy and Science, graduating with a baccalaureat degree in 1951, a masters degree in 1952, and a doctorate in 1956. Thereafter, he went to Long Island University as a professor of pharmacy and taught basic pharmaceutics, veterinary pharmacy, physical pharmacy, and dosage form development. During part of this time, he also worked as a senior scientist at Warner Lambert Research Institute. Following his teaching at Long Island University, Dr. Silverman worked for Knoll Pharmaceutical Company for several years, attaining the position of vice president in charge of pharmaceutical research and development. He left Knoll Pharmaceutical to begin work at the Massachusetts College of Pharmacy as a professor of pharmacy and chairman of the Department of Pharmacy. After a time, he became the associate dean and executive director of the Pfeiffer Pharmaceutical Sciences Laboratories. Throughout most of his career, he has remained in touch with the practical side of his field by working part-time as a registered pharmacist (Silverman, Tr. 2076-77, 2079, 2092).

54. In addition to belonging to numerous societies, holding various appointments as a lecturer or visiting scientist, serving as an advisor to the Food and Drug Administration, and having been honored with many awards including the Newcomb Award for original research in pharmacognosy, Dr. Silverman is the author of numerous publications. At the present time, his major areas of interest are the develop-

ment of drugs, the evaluation of the dosage form, and improvement of the bioavailability of drugs. Dr. Silverman has studied topically creams and barriers, and the absorption of chemical substances through the skin (Silverman, Tr. 2099-101; RX 578). Dr. Silverman is qualified as an expert in pharmacy, pharmacokinetics, drug absorption, drug stability, bioavailability, and the safety, efficacy, and mode of action of topical and oral drugs as seen from the perspective of a pharmaceutical expert.

N. Saul I. Heller, M.D.

55. Dr. Saul I. Heller is a physician licensed to practice medicine in New York and Connecticut and specializes in psychiatry, neurology, and acupuncture and is certified as a Diplomate of the American Board of Psychiatry and Neurology. Throughout his years of practice, Dr. Heller has been interested in the treatment of pain. He received the first license in New York State for the practice of acupuncture, and was instrumental in developing the legislation which established the [24] acupuncture licensing program. Dr. Heller has been engaged in private practice for fifty years. In his practice, he has treated over 25,000 patients for pain-related problems and disorders. The most common disorder that he sees in his patients is headache pain of various types, but he also sees patients with spinal symptoms, neuralgia, bursitis, and tendonitis. As most of his patients suffer from arthritis from time to time, it is not uncommon for him to treat arthritis-related pain (Heller, Tr. 2565-66, 2571-72, 2579-81).

56. Dr. Heller received his Bachelor of Arts degree from Cornell University and His Doctorate of Medicine from Cornell Medical College. Following his graduation, Dr. Heller interned at Lenox Hill Hospital and did his residency at the New York State Psychiatric Institute, a division of Columbia Presbyterian Medical Center. He thereafter served as a research fellow at Bellevue Hospital in New York. Throughout his practice, Dr. Heller has served on the attending staff of several major New York hospitals, including Bellevue Hospital, New York University College of Medicine, Riverside Hospital, LeRoy Hospital, Gracie Square Hospital, Mid-Island Hospital, and Nassau County Medical Center. For five years, he was a member of the faculty of New York University College of Medicine and taught courses in psychiatry. He served for ten years as the director of the Neurology and Psychiatry Departments at Cabrini Hospital (Heller, Tr. 2566-67).

57. Dr. Heller has held many government appointments, including that of medical advisor to the director of the Selective Service System. He was president of the New York State Board of Medicine and president and founder of the New York Society of Acupuncture for

Physicians and Dentists. He has served on the Insurance Committee of the American Psychiatric Association, the Medical Malpractice Panel of the New York State Supreme Court, and the Medical Grievance Committee of the New York State Board of Regents. Dr. Heller was appointed to the Rockefeller Commission to study the uses, efficacy, and regulations of acupuncture. He has been vice president and trustee of both the American College of Acupuncture and the International College of Acupuncture (Heller, Tr. 2469-70). Dr. Heller is the author of two publications that discuss his studies on the use of Sedac electrical current in acupuncture to relieve pain. He has received many honors for his professional work including a Congressional Medal of Honor (Heller, Tr. 2572-74; 2578-79). Dr. Heller is qualified as a specialist in neurology, psychiatry, and the diagnosis and treatment of pain-related problems. [25]

O. Roslyn Freudenthal, Ph.D.

58. Dr. Roslyn Freudenthal is a statistical consultant specializing in biomedical trials and psychological research. She received her bachelor of science degree in chemistry with minors in mathematics and physics from New York University in 1931. In 1933, she obtained a master's degree in microanalysis, and in 1940, a doctorate in organic synthesis with a minor in biochemistry, both from New York University. Her studies were supplemented by a year at Pregl Institute at the University of Graz, Austria where she studied microanalysis, and by a year at Fordham University, where she took a graduate course in statistical applications in experimental science.

59. Dr. Freudenthal began her career as a research chemist in 1937, but taught herself statistics by reading recognized works on the subject. Realizing the extent of the demand for biostatisticians, she decided to go into the field. In 1940, she left the Psychiatric Institute to work at Killian Research Laboratory in New York City. Although hired as a chemist, she continued to do statistical work, analyzing the results of the studies conducted at the laboratory. After three years, she went to the Food Research Laboratory in Long Island City as a biometrist and the director of research and became a full-time statistician. Dr. Freudenthal designed and interpreted bioassays and acted as a statistical consultant for clients. In 1947, Dr. Freudenthal left the Food Research Laboratory and became a private consultant (Freudenthal, Tr. 4869-74; RX 88).

60. Over the years, Dr. Freudenthal has performed consulting work for many physicians in connection with their clinical research. She has also worked for Thompson Medical Company for over twenty years and has been involved with approximately thirty projects. In the past thirty to forty years, Dr. Freudenthal has participated in

approximately 300 research projects and clinical trials and approximately 125 clinical trials. On these 125 trials, roughly twenty have involved analgesic medications such as Aspercreme, aspirin, sodium salicylate, and methyl salicylate (Freudenthal, Tr. 4878-90; RX 88). Dr. Freudenthal has contributed to many published papers, and her name appears on about twenty of them. She is a member of Phi Beta Kappa, the New York Academy of Sciences, the American Statistical Association, Sigma Xi, and the Biometric Association (Freudenthal, Tr. 4891-92; RX 88). Dr. Freudenthal is qualified as an expert in the evaluation of medical research data and the setting up of codes for clinical trials.

61. Respondents called the following advertising and consumer research experts. [26]

A. Jacqueline Silver

62. Ms. Jacqueline Silver is a senior vice president of Needham Harper & Steers ("NH&S"), a major international advertising agency ranked among the top twenty advertising agencies in the world (Silver, Tr. 5583). Her responsibilities include the Research Department of NH&S's New York office (Silver, Tr. 5584), the chairing of the important Strategy Review Board and the Advertising Review Board of NH&S (Silver, Tr. 5584-85). The Strategy Review Board reviews research strategies developed for its advertising campaigns (Silver, Tr. 5586-87). The Advertising Review Board reviews the advertising plans developed by the account groups and the advertising created in accordance with the strategies approved by the Strategy Review Board (Silver, Tr. 5587-88). Ms. Silver's duties also include the design, implementation and analysis of research programs developed for NH&S clients (Silver, Tr. 5588-89). She is directly responsible for all research, including studying the marketplace, positioning the product within the competition, assessing the attitudes of consumers, establishing the product's primary benefits and profiling the consumer in terms of psychographic dimensions (Silver, Tr. 5588-89). The agency regularly conducts strategic studies, copy tests, tracking studies and product tests which Ms. Silver oversees (Silver, Tr. 5592-93). NH&S also conducts the "Lifestyle Study," on an ongoing basis as a current source of information with respect to consumer behavior and attitudes (Silver, Tr. 5626-27). Prior to joining NH&S in 1976 as Director of Research, Ms. Silver was vice president-executive research director at Grey Advertising, Inc. where she conducted research for clients, including drug companies such as Sandoz, Bristol-Myers, Richardson, Merrill, A.H. Robbins, Sterling Drug, Whitehall Laboratories, and Merck, Sharpe & Dome (Silver, Tr. 5602). Ms. Silver has also assisted clients in the development of product packaging and

labeling, the creation of brand names and their positioning within the product category (Silver, Tr. 5602-03). She has conducted approximately fifty studies with respect to brand names and approximately 200 studies on product packaging (Silver, Tr. 5603) and has been involved in some ten strategic studies of analgesic products, including a research project for internal analgesics for arthritis (Silver, Tr. 5606-07). Recently, Ms. Silver conducted a study for the USDA on nutrition in which her role included the design, execution and presentation of the research (Silver, Tr. 5608).

63. Ms. Silver has an Associate of Arts Degree from the University of California at Berkley and a Bachelor of Science in [27] Mathematics from New York University. Ms. Silver has since taken courses in experimental design, statistics, computer sciences and psychology at New York University and The New School. After beginning her career as an interviewer at age fifteen, she has been employed by many market research organizations including Opinion Research Corporation, Market Facts, National Analysts, Mervin Fields, Human Factors, Marketing Impact, Oxtoby Smith, and Daniel Starch (Silver, Tr. 5611-12). At Marketing Impact and Oxtoby Smith, (research suppliers), she was a field director (Silver, Tr. 5613), at Data Decision, a computer company, a group head in charge of processing and analyzing copy tests for Colgate-Palmolive, among other client companies (Silver, Tr. 5613-14) and at Market Facts, Inc., senior study director (Silver, Tr. 5614).

64. Ms. Silver regularly reads the important journals which focus on advertising, market research and consumer behavior (Silver, Tr. 5631). Ms. Silver is a member of the American Marketing Association, Advertising Women of New York, the Advertising Research Foundation (being a member of the latter's Copytesting Practices Committee and the Public Opinion Committee), the American Association of Advertising Agencies (Silver, Tr. 5627) and the Association of Advertising Research Directors. Ms. Silver has given courses, seminars and presentations in marketing research, strategy development and techniques (Silver, Tr. 5629). Ms. Silver has a broad range of practical experience in the design, execution and analysis of consumer and market research (Silver, Tr. 5620). Ms. Silver is qualified as an expert in market and consumer research, advertising strategy and evaluation, including packaging and brand names, consumer behavior, and the design, implementation and analysis of market and advertising research.

B. Ivan Ross, Ph.D.

65. Dr. Ivan Ross is a Professor of Marketing at the University of Minnesota School of Management and former Chairman of the Mar-

keting Department. He is a member of the Graduate Faculty of the College of Business Administration and the Department of Psychology of the University (RX 570). Dr. Ross has a doctorate in Industrial and Consumer Psychology and teaches courses in Consumer Behavior, Advertising and Sales Promotion, Marketing Research and Marketing Communications (RX 570). Dr. Ross is a licensed Consulting Psychologist. His areas of specialization include consumer behavior, marketing and advertising research, motivation research, and the design and analysis of consumer and marketing surveys and experiments, including the construction of questionnaires (RX 570). [28]

66. Dr. Ross has published many papers on consumer psychology and attitudes, marketing analysis and research and the selection and meaning of brand names (RX 570F-I) and has spoken before professional associations and societies dealing with consumer behavior and decisionmaking (RX 570). Dr. Ross has been a consultant to the United States Public Health Service and to the FDA Bureau of Drugs from 1976 to 1977 with respect to package inserts and consumer information to be placed on OTC and prescription products (Ross, Tr. 5947, 5949-50). He has served as a consultant to advertising agencies with respect to advertising strategy, marketing, advertising and consumer research matters and has conducted many focus group interviews (RX 570).

67. Since 1974, Dr. Ross has been a member of the Minnesota Advertising Review Board, acting as an arbitrator of advertising complaints (Ross, Tr. 5947-48), the American Council for Consumer Interest and the Society of Consumer Affairs Professionals ("SOCAP,") and a member and former President of the Division of Consumer Psychology of the American Psychological Association (Ross, Tr. 5948-49). He is an advisor to the State of Minnesota Office of Consumer Services with respect to consumer legislation and consumer protection issues (Ross, Tr. 5949) and has served as Vice Chairman of the Minnesota Advertising Review Board.

68. Dr. Ross has appeared in behalf of the Federal Trade Commission in administrative hearings as an expert in consumer psychology, consumer behavior and marketing research and gave testimony regarding various marketing and advertising issues, including the meaning of advertisements, the consumer perceptions of the messages in advertisements and their impact on the consumer (Ross, Tr. 5053-54). Such cases include the Federal Trade Commission's recent internal analgesic cases (*In the Matter of American Home Products Corporation*, Docket No. 8918 [98 F.T.C. 136 (1981)], *aff'd in part and mod. in part*, 695 F. 2d 681 (3rd Cir. 1982 [101 F.T.C. 698 (1983)]); *In the Matter of Bristol-Myers Company*, Docket No. 8917 [102 F.T.C. 21 (1983)]; and *In the Matter of Sterling Drug, Inc.*, Docket No. 8919 [102

F.T.C. 395 (1983)]. He has also testified as an expert in trademark infringement litigations and has served as a consultant in many trademark cases (Ross, Tr. 5962; RX 570). Dr. Ross is qualified as an expert in consumer psychology and consumer behavior, marketing research, and evaluation of advertising and trademarks.

C. Dr. Kenneth M. Warwick

69. Dr. Kenneth M. Warwick is the President of Ken Warwick & Associates, Inc. (a marketing research consulting firm) and [29] has been in the marketing research business for over twenty years. He graduated from Queens University in Ireland with a Bachelor of Arts degree in Psychology. In 1963, Dr. Warwick received a Doctorate in Psychology and Statistics from the University of London. He has taught courses in Experimental Psychology, Consumer Psychology, Research Design, Methodology and Analysis, and Statistics at London University, Northwest University, Columbia University and New York University. He has been a reviewer of faculty research proposals for the City University of the City of New York for the past five years. In the United Kingdom, he was a partner in an advertising research firm, DRC, Limited. In this country, Dr. Warwick has served as a consultant in marketing and consumer research to two advertising agencies, Foote, Cone & Belding and Kenyon & Eckhardt. He was employed as Executive Vice President of Grudin, Appel & Haley, a market research company (which performed marketing and advertising research for such companies as Warner-Lambert, ITT, American Cyanamid and the Lorillard Corporation) and supervised the Statistical Analysis Group and the researchers and project directors engaged in the ongoing research projects and assisted in designing the execution and the analysis of market research (Warwick, Tr. 5281-82). Dr. Warwick was also employed at Grey Advertising, Inc. as a Vice President and Associate Research Director in charge of research projects for such clients as Ford Motor Company, United States Steel and General Electric (Warwick, Tr. 5280-81). In his own company, Dr. Warwick provides consulting services with respect to advertising and market research, including the design, execution and evaluation of research projects. His clients include AT&T, RCA, American Cyanamid, Warner-Lambert, and major advertising agencies such as BBD&O, Backer & Spielvogel, Scali, McCabe & Sloves, and McCann Erickson. He also provides consulting advice to law firms and market research companies and suppliers such as Simmons Market Research and Data Developing Corporation. Dr. Warwick has been involved in some 200 copy test and sixty research studies (Warwick, Tr. 5291).

70. Dr. Warwick has testified in trademark litigations and litigations involving deceptive advertising as an expert on advertising and

marketing research (Warwick, Tr. 5279-80). Dr. Warwick has published and presented numerous papers dealing with marketing research and consumer research. Among his publications is the "Statistical Data Processing in Market Research" chapter in the *Standard Handbook in Marketing Research* published by the American Marketing Association (Warwick, Tr. 5288-89; RX 577).

71. Dr. Warwick is a member of the American Psychological Association, American Statistical Association, American [30] Marketing Association, the New York Academy of Science and the Royal Statistical Society (Warwick, Tr. 5291), and is the Computer Science Editor and a member of the editorial review board of the *Journal of Marketing Research* (Warwick, Tr. 5290). Dr. Warwick is qualified as an expert in consumer psychology and the design, implementation, review and evaluation of marketing and advertising research (RX 577).

D. Jay Jasper

72. Mr. Jay Jasper is a Senior Vice President and Creative Director of Ogilvy and Mather International, Inc. where he has been employed for fourteen years (Jasper, Tr. 4698). As Creative Director, Mr. Jasper is responsible for supervision of the writers, art directors and producers who create advertising (Jasper, Tr. 4698-700). After graduating magna cum laude from Brandeis University, Mr. Jasper attended Yale University, the College de France and the Sorbonne (on a Fulbright Scholarship) (Jasper, Tr. 4703). He frequently lectures on advertising to advertising and trade groups as well as to management personnel of O&M throughout the world (Jasper, Tr. 4703-04). Mr. Jasper is an expert in the creation and evaluation of advertising and advertising strategy.

III. THE MARKETING AND ADVERTISING OF ASPERCREME

73. Thompson first began to market Aspercreme in 1976 after purchasing it from the Sperti Drug Company (CX 45E (Admission No. 79)). Prior to acquisition of Aspercreme by Thompson, Sperti advertised the product on a live, local television program in Ohio and part of Indiana. Thompson continued this advertising until August of 1979 (RX 285B). Spot market television advertising was first disseminated in October of 1978. Aspercreme advertising was first aired on network television in September of 1979 (RX 285C). Network, spot and syndicated television advertising for the period 1978 through 1981 included the following:

CX 1, disseminated 2,814 times from October 1978 through February 1980.

CX 2, disseminated 1,443 times from April through December 1979.

CX 3, disseminated 1,890 times from January through June 1980. [31]

CX 4, disseminated one time in December of 1979.

CX 5, disseminated 492 times in April to June 1980.

CX 9 and 21, disseminated 130 times from November 1980 through April 1981 on a combined basis.

CX 12 through 20, disseminated 253 times during the 1976 through 1979 time frame on a combined basis (CX 25).

Print advertising for the period 1978 through 1981 including the following:

CX 6 was disseminated twice in the *Readers Digest* in March and April of 1979 and once in the *Saturday Evening Post* in May of 1979 (CX 25).

CX 7, 8, 10 and 11 are co-op advertisements for which there are no specific dissemination data available: however, they were disseminated (Tr. 47-49; Paragraph 9 and Exhibits G and H of the Complaint and Paragraph 9 of the Answer).

74. For the years 1976 through 1981, Thompson's net annual sales, net sales of Aspercreme and Aspercreme advertising expenditures were as follows:

	Annual Sales	Aspercreme Sales	Aspercreme Ad Expenditures
	(000)	(000)	(000)
1976	\$18,385	\$ 68	\$ 1
1977	29,092	289	10
1978	27,243	589	95
1979	45,847	3,188	1,768
1980	92,275	5,860	2,230
1981	N.A.	5,931	1,595
1982 (Thru July)	N.A.	4,452	2,056

(CX 45E-F (Admission No. 80); RX 573) [32]

75. From 1976 through 1981, annual consumer sales of Aspercreme averaged about \$2.5 million. In promoting Aspercreme by advertising from 1976 through 1981, Thompson spent at least \$5 million. Thus, annual advertising expenditures for Aspercreme from 1976 through 1981 have averaged approximately \$950,000. The average advertising-to-sales ratio for Aspercreme for the 1976 through 1981 period was about 36%.

76. For the years 1976 through 1981, the share of the topical analgesic market accounted for by Aspercreme was as follows:

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1976	.8%	(CX 45Z-017)
1977	.8%	(CX 45Z-017)
1978	1.4%	(CX 45Z-017)
1979	7.4%	(CX 45Z-017)
1980	16.8%	(RX 286D)

During the same time period, the market share held by Ben-Gay has remained at about 40% and that of Mentholatum, at about 9%. The market share held by Aspercreme has grown steadily from virtually nothing to 7.4% in 1979 and to 16.8% in 1980 (RX 286D).

IV. MEANING OF ASPERCREME ADVERTISEMENTS AND
THE BRAND NAME "ASPERCREME"

A. *Standards For The Determination Of
The Meaning Of Advertisements*

77. In determining whether an advertisement made a particular representation, the appropriate standard is whether, taking the advertisement as a whole, the representation constitutes a reasonable interpretation of that advertisement. The question is whether the representation at issue is an interpretation of the advertisement to which more than an insubstantial number of consumers would adhere. Since more often than not several reasonable interpretations of a given advertisement are possible (Ross, Tr. 5969-70), it is not necessary that the claim found to have been made be the only or the most reasonable interpretation of the advertisement.

78. The primary evidence with respect to the meaning of the advertisements in the record consists of the advertisements [33] themselves. The record also contains extrinsic or secondary evidence regarding the meaning of the advertisements, namely, expert testimony, consumer research, and evidence of how the networks and other expert bodies interpreted the advertisements.

79. In determining the meaning of individual advertisements, I have primarily relied on my knowledge and experience to determine what impression or impressions an advertisement as a whole is reasonably likely to convey to a consumer. When my initial determination is confirmed by the expert testimony of complaint counsel or respondent, I rested. When my initial determination disagreed with that of expert testimony, which was often conflicting, I reexamined the advertisement in question, and further considered other record evidence such as copy tests and other consumer research before reaching a final determination. I have not relied on such extrinsic evidence when, after careful study and reflection, I found it to be unpersuasive and contrary to the weight of evidence.

*B. Respondent Has Made Certain Representations
Alleged In The Complaint*

*(1) Complaint Paragraph 10 (a): The claim that
Aspercreme contains aspirin.*

80. Thompson has respresented, expressly or impliedly, that Aspercreme contains aspirin. This representation was made in varying degrees in all of the TV and print advertisements in evidence in this proceeding. They include CXs 1-22 and 37.

81. For example, CXs 1 and 2, the earlier TV ads in evidence, unmistakably suggested that Aspercreme is an aspirin rub, which enables a user to put the relief of aspirin directly at the point of pain. CX 1, a TV commercial aired some 2,814 times from October 1978 through February 1980 (CX 25A), states in part:

When you suffer from arthritis, imagine being able to put the strong relief of aspirin right where you hurt most.

Now with amazing Aspercreme, you can get the strong relief of aspirin directly at the point of minor arthritis pain. [34]

The strong relief of aspirin right where you hurt (both voice and video super).

CX 2, another TV commercial, aired some 1,400 times during 1979 (CX 25A), states in part:

When you suffer from arthritis, imagine putting the strong relief of aspirin right where you hurt.

Aspercreme is an odorless rub which concentrates the relief of aspirin.

When you take regular aspirin, it goes throughout your body like this. (Video shows how regular aspirin tablets dissolve in the stomach, are absorbed in the blood and circulate throughout the body to reach the pain site in the left shoulder.)

But, in seconds, Aspercreme starts concentrating all the . . . relief of two aspirin directly at the point of minor arthritis pain. (Video shows Aspercreme "concentrating all the temporary relief of two aspirin directly at the point of . . . pain" in the shoulder without going through the stomach and throughout other parts of the same body).

82. CX 9, a TV commercial which was aired in 1980 and 1981 (CX 25A), is an example of Aspercreme ads which do not contain "no-aspirin" video super or other aspirin disclaimer statements but state instead that "Aspercreme contains salycin, a strong non-aspirin pain reliever which penetrates right to the point of pain." CX 9 contains no other references to "aspirin." CX 9 is of some importance for the reason that it was copy tested by the parties separately for use in this litigation (CX 26, the ASI Theatre Test; CX 35/RX 520, the FRC Test; and CX 32/RX 500, the Lieberman Test) and was the subject of exten-

sive discussion by marketing expert witnesses of both parties at the trial.

83. Most of the more recent TV commercials for Aspercreme in evidence contain a short video super "contains no aspirin" (CX 3), or "relief without aspirin" (CX 4), or a phrase "aspirin [35] free" (CX 5). Several others contain, a statement "Aspercreme contains salycin, a strong non-aspirin pain reliever" without a "no-aspirin" video super of any type (CXs 9, 21-22). Still others contain a statement "it delivers an aspirin-like formula right in the lotion" (CX 19).

84. Several Aspercreme advertisements include affirmative statements to the effect that Aspercreme does not contain aspirin (See CXs 3-5, 9, 21-22, 37). These disclosure statements were added because the networks required them (Jasper, Tr. 4739, 4746), and this fact indicates that the Aspercreme ads were construed as communicating an aspirin content message. Moreover, the disclosures in these particular advertisements were shown to be ineffective. With respect to CX 3 and CX 4, the "video super" is too brief in duration and disclosures obscure when compared to the repeated audio and video phrases such as "the relief of aspirin" (Cohen, Tr. 213-15; Ross, Tr. 6194). This conclusion is confirmed by CBS and the National Association of Broadcasters ("NAB"), both of which advised Thompson that a video super was insufficient to counter the net impression of these ads (See CXs 79-80, 88D). In fact, Thompson's own advertising agency had reached the same conclusion regarding the ineffectiveness of the video super (See CX 66B). The disclosure in the other advertisements were shown to be insufficient to overcome the aspirin content message conveyed by the brand name and the comparison to oral aspirin (Cohen, Tr. 218-22, 226-27; see CX 27). Moreover, some of these ads (*i.e.*, CXs 9, 21-22, 37) state that Aspercreme "contains salycin, a non-aspirin pain reliever." This phrase is ambiguous because it does not negate the impression that "Aspercreme" may also contain aspirin in addition to "salycin" (Ross, Tr. 6205-06; Silver, Tr. 5715, CX 92A).

85. In addition to the use of brand name "Aspercreme," most of the advertisements contain statements which may lead the consumer to conclude that Aspercreme is an aspirin rub. For example, a majority of the ads compare and contrast Aspercreme with pills (*i.e.*, aspirin tablets) (CXs 1-11, 21-22, 37). This direct comparison tends to lead consumers to conclude that Aspercreme contains aspirin and that Aspercreme is another form in which aspirin can be taken, that is, in cream form as opposed to pill form (Cohen, Tr. 558; Ross, Tr. 5985-87, 5988-89, 5991).

86. Another way in which the ads suggest that Aspercreme contains aspirin is to repeat the words "Aspercreme" and "aspirin" in the same

commercial (Cohen, Tr. 207). *See, e.g.*, CXs 1-4, 6-8). The two things viewers are likely to recall most from such ads are the name Aspercreme and the word "aspirin" (*Id.*). [36]

87. Many of the Aspercreme advertisements in evidence state more than once that Aspercreme provides "the strong relief of aspirin" (*See, e.g.*, CXs 1-4, 6-7, 10-11). In the print ads (CXs 6-7, 10-11), this statement appears in the subheadline, which is more prominent than the test (Cohen, Tr. 223; Ross, Tr. 6199). The phrase "relief of aspirin" is, of course, provided by aspirin (Ross, Tr. 6179-80). Indeed, Mr. Jasper indicated that, in creating ad copy, he would consider the phrase "aspirin's relief" to be an excellent way of communicating aspirin content (*See* Jasper, Tr. 4738). Even if "relief of aspirin" is understood to mean the relief of tablets containing aspirin (*See* Ross, Tr. 6181-82), the fact remains that the relief provided by such tablets comes from the aspirin they contain (Ross, Tr. 6182). Consequently, the phrase "relief of aspirin" may be reasonably understood to mean that Aspercreme provides the ingredient aspirin (*i.e.*, that Aspercreme's relief comes from aspirin) (CXs 60B, 79A).

88. Other phrases used in the ads which suggest aspirin as an ingredient include "like aspirin itself" (*See* CXs 6-7) and a comparison between Aspercreme, a topical rub, and "regular" aspirin (CXs 2, 4). These phrases may reasonably be construed to mean that Aspercreme is a form of aspirin rub (Cohen, Tr. 210-12, 223-24).

89. Some Aspercreme ads use visual images to reinforce the aspirin content suggestion. For example, in CXs 1-4, a woman holds two aspirin tablets while saying that Aspercreme enables you to put the "strong relief of aspirin right where you hurt." The aspirin tablets in the woman's hand are then replaced by a tube of Aspercreme. Two images are evoked: a product which places aspirin tablets at the point of the pain, and a product which contains aspirin tablets in a cream form.

90. The determination that the brand name "Aspercreme" is capable of suggesting to a consumer that the product is a form of aspirin rub is reasonable. When an advertisement, obviously addressed to a target audience of arthritics and rheumatics, touts "Aspercreme" as a new rub which enables them to concentrate the "strong relief of two aspirin" right where you hurt most without upsetting your stomach, its clear, dominant message is that "Aspercreme" is, as the name suggests, a form of aspirin rub which relieves minor pains of arthritis and rheumatism without the stomach upset you get from taking aspirin in a tablet form.

91. The determination that the Aspercreme ads discussed above contain express or implied claims that the product is a form of aspirin

rub is supported by the advertisements [37] themselves viewed as a whole and is confirmed by expert testimony (*e.g.*, Cohen, Tr. 206-29, Silny, Tr. 771-72, 814-16; Ross, Tr. 5985-86, 5991, 6197-98), consumer research, other documents showing how self-regulatory bodies (the National Association of Broadcasters and CBS) and Thompson's own advertising agency viewed the ads (CXs 79, 80, 92, 116).

92. The copy tests and other consumer research regarding the ingredient inferences viewers are likely to draw from the brand name "Aspercreme" and some of the Aspercreme commercials is confirmatory of the foregoing determinations. Such consumer research includes:

- a. The ASI Interlock Experiment (CX 26)
- b. The ASI Theatre Test (CX 27)
- c. The Mapes and Ross Test (CX 50)
- d. The FRC Test (CX 35/RX 520)
- e. The Lieberman Test (CX 32/RX 500)
- f. The Video Storyboard Test (CX 51)
- g. The Schneider Focus Groups (CX 52)
- h. The Nicholas Focus Groups (CX 53)

Of the above, the two ASI Tests (CXs 26 and 27) were conducted for the FTC counsel, and the FRC Test (RX 520/CX 35) and Lieberman Test (RX 500/CX 32), for Thompson. All of these four tests were designed and conducted for use in this litigation. Generally speaking, these copy tests and other research show that a significant number of viewers took the Aspercreme commercials to suggest that Aspercreme contained aspirin.

93. The Mapes and Ross Test (CX 50), is a copy test on CXs 1 and 2 conducted in May 1979 for Ogilvy and Mather, Thompson's advertising agency for Aspercreme, and is the only copy test which predated this litigation and sheds some light on the ingredient issue.

94. Ogilvy and Mather, Thompson's advertising agency, concluded from the Mapes & Ross Test (CX 50) that a substantial number of respondents who viewed CXs 1 and 2 had misinterpreted the commercials to mean that Aspercreme contained aspirin. Specifically, the verbatim comments were reviewed by several Ogilvy and Mather employees who marked the comments as showing "confusion" regarding the ingredients in Aspercreme (*See*, CXs 45B-C, 93, 94, 95, 96, 97, 98 (Admissions No. 24-27)). In September 1979, Barbara Thompson, an employee from Ogilvy's research department, sent a memo (CX 116) to the head of Ogilvy's legal department detailing the percentages of viewers who had "misinterpreted" the ads to mean Asper-

creme contains [38] aspirin. According to CX 116, of those viewers who confirmed they had seen the ads, 30% who saw CX 1 ("Stand-Up Presenter") and 21% who saw CX 2 ("Visible Men") "misinterpreted" the ads to mean Aspercreme contains aspirin (CXs 45B, 116 (Admission No. 15)). *Also see* CPF 112)

95. Thompson's criticisms of the reliability of the Mapes and Ross Test (CX 50) during this trial are somewhat undermined by the fact that representatives of Thompson had discussed the Mapes and Ross Test during a meeting with its advertising agency, Ogilvy and Mather, and based on that discussion, Thompson decided which commercial to air (CX 99A). Thus, Thompson has relied on the Mapes and Ross Test to make an important business decision.

96. The ASI Interlock Experiment (CX 26) was designed specifically to measure consumers' ingredient inferences from the brand names of three products in the topical analgesics product class, Aspercreme, Ben Gay and Mobisyl (a TEA/S cream similar to Aspercreme). The responses to an open-ended question "What ingredient or ingredients, if any, are suggested by the brand name?" are summarized below:

	Ingredient Mentions			
	(in percentage)			
	Aspercreme	Mobisyl	Ben Gay	Total Sample
	(N=120)	(N=66)	(N=73)	(N=259)
Aspirin	78%	8%	3%	39%
Crema	31	2	10	17
Mobil Oil/Gas/Motor Oil	-	12	-	3
Camphor	-	-	5	2
Heat	-	-	5	2
Penicillin	-	3	-	1
Silicone	-	3	-	1
Pain killer	-	-	4	1
Nengol	-	-	1	0
Benvereen	-	-	1	0
Benzedrine	-	-	1	0
Sedative	-	2	-	0
Benzoyl peroxide	-	-	1	0

(CX 26G, Table II).

97. The following tabulation of the ASI Interlock Experiment data demonstrates the ability of brand names of the [39] test products to suggest specific ingredients and dramatically confirms what common sense and daily experience would tell us about the brand name "Aspercreme":

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Ingredient Type Mentions

	(in percentage) <u>Aspercreme</u>	<u>Mobisyl</u>	<u>Ben Gay</u>
	(N=120)	(N=66)	(N=73)
Aspirin mentioned	78%	8%	3%
Other active ingredients without aspirin mentioned	0	5	19
Cream or other inactive ingredients without aspirin mentioned	5	17	11
No ingredient mentioned (Don't Know, None or Declined to Answer)	17	74	73

(CX 26J, Table IV).

98. Another conclusion suggested by the CX 26 data is that the product category (analgesic rub) alone does not generate an inference that the product contains aspirin or that the pain relieving ingredient in the product is aspirin. These results clearly show that the brand name "Aspercreme" produced a remarkably high level of aspirin mentions, while the names Ben Gay and Mobisyl showed low levels of aspirin mentions and that the name "Aspercreme" is capable of suggesting to many that the product contains aspirin (Cohen, Tr. 161-63; Silny, Tr. 771-72).

99. The purpose of CX 27, the ASI Theatre Test, was to investigate the effects of an Aspercreme commercial which contains an affirmative ingredient disclosure statement on viewers' perception of the products' ingredients, and specifically to determine whether such an advertisement (CX 9) effectively overcame the aspirin-content suggestion conveyed by the brand name "Aspercreme" (Cohen, Tr. 163-64; Silny, Tr. 773; CX 27B-C). In response to an unaided question, 17% of the survey respondents who remembered seeing CX 9 stated that CX 9 represented that Aspercreme contained aspirin. When an aided question was put, the proportion increased to 38% (CX 27F-H). [40]

100. The CX 27 data show that, in response to the unaided recall question ("what ingredient or ingredients, if any, did the commercial say Aspercreme [or Mobisyl] contained"), of the people who saw the Mobisyl commercial, only 1% thought Mobisyl contained aspirin, while 17% who saw the Aspercreme commercial containing an ingredient disclosure statement thought Aspercreme contained aspirin. In response to the aided recognition question (which read a list of ingredients to respondents and, as each ingredient was read, asked them whether that particular ingredient is contained in the product) only 5% of those in the Mobisyl group thought the product contained

aspirin, whereas 38% of respondents in the Aspercreme group thought Aspercreme contained aspirin. For every ingredient except aspirin, the recognition levels were statistically the same between the Aspercreme and Mobisyl groups (Cohen, Tr. 188-90; Silny, Tr. 814-15; CX 27G).

101. Thus, the ASI Theatre Test (CX 27) clearly shows that the tested commercial (CX 9) led more viewers to state that Aspercreme contains aspirin, despite the affirmative disclosure to the contrary, than did a competitive product in the same category. Significantly, more people thought Aspercreme contained aspirin (an ingredient the commercial says it does not have) than thought it contained salycin (an ingredient the commercial says it has). This indicates that the brand name Aspercreme creates a strong perception that the product contains aspirin and the affirmative ingredient disclosure statement is not effective in overcoming that perception (Cohen, Tr. 194-95; Silny, Tr. 814-16, 1068-69).

102. Respondents in the ASI Theatre Test (CX 27) were not limited to users of topical rubs or arthritis sufferers because it was a perception test. In such a test, there is no reason to believe that users and non-users of the product class would differ in their perceptions (Silny, Tr. 749, 778). Thompson's chief marketing witness, Dr. Ross, agreed that as a general principle of marketing research, usage or non-usage of the product category has no measurable impact on respondents' perceptions of what is represented in the test ad, and that in this study there were, in any event, no substantial differences between users and non-users in terms of their responses to the perception questions (Ross, Tr. 6234-35, 6240-42).

103. Thompson's other criticisms directed to the design and execution of CX 27 do not diminish the essential import of this ASI copy test (See RB 129-36; CPF 92-102).

104. Thompson, through its counsel (Davis and Gilbert), commissioned two copy tests of CX 9 for the purpose of this [41] litigation: The FRC Test (RX 520/CX 35) and the Lieberman Test (RX 500/CX 32). Davis and Gilbert retained Dr. Kenneth Warwick to design and execute the tests (Warwick, Tr. 5296). CX 9 contains an ingredient disclosure statement "Aspercreme contains salycin, a strong non-aspirin pain reliever." Dr. Warwick was aware of the possibility that the tests may be used in litigation and that he might be requested to appear as a witness (Warwick, Tr. 5364-71). Before the design and execution of the studies, counsel for Thompson showed Dr. Warwick a document that outlined the complaint allegations in this proceeding (*i.e.*, that the Aspercreme advertising implies that the product contains aspirin) (Warwick, Tr. 5371-73).

105. In the FRC Test (RX 520), while 2.9% of the respondents an-

swered "aspirin" in response to the unaided Question 1, "What was the name of the ingredient in the product you just saw advertised?", the aspirin ingredient answers increased to 22% in response to the aided Question 2, "Based on the commercial you just saw, does the product in the commercial contain aspirin?".

106. Question 2 is a straightforward and reasonable aided recall question and appropriate in light of the objective of the study. Although it suggests to a respondent that the product may contain aspirin and it can be answered in a yes/no fashion, it is not "leading" in the sense of signalling what the desired answer is.

107. The FRC Test (RX 520) shows that CX 9, an Aspercreme advertisement containing an affirmative ingredient disclosure statement, and shown under fairly optimal conditions for communication (respondents were told to pay attention, the ad was shown twice, and respondents were questioned immediately thereafter) led 3-22% of the respondents to say the product contains aspirin, and left an additional 10% confused as to whether the product contains aspirin (Cohen, Tr. 281-82; Silny, Tr. 841-42).

108. The Lieberman Test (RX 500) is the second copy test on CX 9 designed by Dr. Warwick, who also designed the FRC Test (RX 520). It was administered by Lieberman Research Suburban, Inc. ("Lieberman"). The reasons for conducting two copy tests on CX 9, both designed by Dr. Warwick, are not clear in this record. However, Dr. Warwick had not intended to do two tests in the outset (Warwick, Tr. 5401; CX 45Z-019 (Admission No. 46)). The decision to do the Lieberman Test was made after FRC was completed and after Dr. Warwick communicated the FRC results to Davis and Gilbert. The Lieberman Test was then done at the request of Davis and Gilbert (CX 45Z-030 (Admission No. 64); Warwick, Tr. 5403). [42]

109. Dr. Warwick did not include in the Lieberman questionnaire a direct aspirin ingredient question which he had included in the FRC Test. Although Dr. Warwick testified that this was an improvement over the FRC Test design, which he characterized as "flawed," the evidence is also consistent with the conclusion that the direct ingredient question was dropped because it had produced results unfavorable to Thompson in the FRC Test.

110. A major defect in the Lieberman questionnaire is that the open-ended question ("What was the name of the ingredient in the Aspercreme—the product advertised?") was not followed by a probe or any aided question (in contrast to the FRC Test which had the direct, close-ended ingredient question) (CX 34B).

111. Also, as in the FRC Test (RX 520), the question in Lieberman was biased in that it suggested that there was only one ingredient. so

that respondents were permitted to answer with only one ingredient (Cohen, Tr. 263-64; Silny, Tr. 839).

112. Considering the fact that the test audiences had just twice seen CX 9 which states "Aspercreme contains salycin, a strong non-aspirin pain reliever," it is somewhat surprising that only 25% of the respondents named salycin (RX 500E). In any event, a probe would have made it possible for respondents to mention aspirin as well, since a salycin response does not negate the possibility that respondents may have thought the product also contained aspirin (Silny, Tr. 834). It is accepted in marketing research that an open-ended question is not representative of everything stored in respondents' minds (Silny, Tr. 835). As Dr. Ross, Thompson's marketing witness, stated, open-ended questions lead most respondents to play back only one theme or point. They do not draw out a complete or exhaustive list of all the things respondents may have on their minds. Rather, respondents will play back the dominant theme or primary impression and, having done that, will probably stop (Ross, Tr. 6260).

113. In the final analysis, there is no way to test whether a consumer does or does not take a certain meaning from an ad other than putting that direct question to the consumer and asking the consumer to affirm or deny that the claim was made (Ross, Tr. 6260-63). In other cases, Dr. Ross has relied on aided, close-ended, ultimate questions, such as the question in a *Sterling Drug* study which read, "Did the advertisement suggest or did it not suggest that Bayer worked better than any other aspirin" (Ross, Tr. 6264). And another Thompson witness agreed [43] that a probe following an open-end question is common and accepted in marketing research (Silver, Tr. 5941). The initial reasoning regarding questionnaire design that occurred to Dr. Warwick, a marketing researcher with 20 years' experience, was that since he was interested in aspirin, he should ask a direct question about aspirin (Warwick, Tr. 5457-58, 5470).

114. An aided or close-ended question (as in the FRC Test) may well have cleared up the confusion caused by the wording of Question 1, and would have given respondents a further opportunity to say whether aspirin as well as salycin was an ingredient (Silny, Tr. 834-35). Because no aided or close-ended question was asked, there is no way of knowing how much information respondents had in their minds that was not revealed in response to Question 1 (Cohen, Tr. 276).

115. In any event, the Lieberman Test (CX 32/RX 500) shows that CX 9, an Aspercreme commercial which contains a non-aspirin ingredient disclosure statement led, on the basis of an unaided question, about 3% of the test audience to name Aspirin as an ingredient in Aspercreme (RX 500C). This is substantially lower than the 17% level

produced by an unaided question in the ASI Theatre Test (CX 27), which also tested CX 9.

116. In sum, the three copy tests on CX 9 in evidence (CX 27, RXs 500 and 520), taken together, are generally confirmatory of my view that the non-aspirin ingredient disclosure statement contained in CX 9 is woefully insufficient.

(a) *The Video Storyboard Test (CX 51)*

117. CX 51, the Video Storyboard Test, was a copy test conducted for Thompson to measure the relative persuasiveness of CX 1 and CX 2. The methodology involved a shopping mall intercept approach in Bridgeport, Connecticut. The sample consisted of 100 persons selected from among the shoppers. Respondents were shown one of the test commercials, and the questionnaire was administered immediately thereafter (CX 51N).

118. The Video Storyboard Test does not shed any light on the issue whether there is an aspirin content representation in the tested ads. It was designed specifically to find out what main idea in the ad is of most interest to viewers (Cohen, Tr. 229-30; Ross, Tr. 6310-11). The questionnaire primarily asked respondents how interested the ad made them in trying Aspercreme, and what the main idea in the ad was (CX 51N). The study did not ask whether or not the advertisements suggested [44] that the product contains aspirin. It is obvious that the main idea of the Aspercreme ads is relief of arthritis pain (Cohen, Tr. 231). People might have given that answer on this test and still thought that a secondary idea of the ad was that the product contains aspirin (Cohen, Tr. 229-30).

119. Thompson's marketing witness Dr. Ross asserted that if respondents had perceived aspirin as an ingredient in Aspercreme as a result of seeing CX 1 or CX 2 in this test, the questionnaire afforded them opportunities to express this (Ross, Tr. 6002-03). However, in order to make the statement that Aspercreme contains aspirin, the respondent would have to believe that that was the one main idea the commercial was trying to get across (Cohen, Tr. 231). It cannot be determined from the responses to this test whether the ads led these respondents to the inference that aspirin is an ingredient in Aspercreme. To answer that question, a direct ingredient question must be included as was done in the ASI and FRC tests (Cohen, Tr. 232; CX 27 and RX 520).

(b) *The Schneider Focus Groups (CX 52)*

120. CX 52, entitled "An Analysis of Group Sessions on Aspercreme" (the Schneider focus groups), is a report of two focus group

sessions conducted for Thompson by David L. Schneider, Ph.D. (CX 52).

121. Qualitative research (such as the focus group), while lacking the "representativeness" of other types of marketing studies such as surveys, copy tests, and controlled experiments, is a widely used form of marketing research today. Trained moderators probe in very careful ways to elicit answers to the research questions (Cohen, Tr. 106).

122. The respondents in CX 52 had been given Aspercreme for a two week period of trial. All suffered from arthritis or some form of muscular aches or pains on a continuing basis (CX 52B-C). They were not shown any advertisements for Aspercreme, but had the Aspercreme package during the trial period. After the two week trial period, a number of people either thought the product they used contained aspirin or were confused as to the product's aspirin content (Cohen, Tr. 197-99, 552; CX 52K-N).

123. For example, CX 52 noted that respondents had relief expectations based on the idea that the product contained aspirin (CX 52M). Among the quotes cited were the following: "I wondered if it would be able to work since aspirin is [45] something you swallow"; "I figured they'd ground it up and mixed it with cream till it was smooth"; "When I saw it and saw 'Asper', I right away thought it must also have aspirin in it" (CX 52L).

(c) *Nicholas Research Focus Groups (CX 53)*

124. CX 53 is a report by Nicholas Research on three focus group sessions conducted for Thompson involving Aspercreme. No advertisements were shown to respondents, but they had been given Aspercreme packages to use for a ten-day trial period (CX 53F). The objectives of the study were to gain insight regarding respondents' arthritis symptoms, and the products they currently used for arthritis, and to determine their reactions to Aspercreme vis-a-vis other over-the-counter remedies after use (CX 53D).

125. A number of respondents in CX 53 believed that the product contained aspirin (Cohen, Tr. 552). For example, the moderator observed that respondents "were attracted to the name Asper/Aspercreme because it has aspirin in it, or it is full of aspirin" (CXs 53Z, Z-056). The moderator also reported that several respondents felt since Aspercreme contained aspirin they could substitute it for aspirin (CXs 53Y, Z-053). One respondent said, "I didn't take any aspirin [during the trial period]—the name—Aspercreme—I said to myself, 'Maybe it has aspirin in it—I'd be applying the aspirin to the localized area instead of taking it internally.'" And another respondent noted, "Don't need to take aspirin, since this contains aspirin in it" (CX 53Z-053; Cohen, Tr. 200).

(2) *Complaint Paragraph 10 (b)*: The claim that Aspercreme is a recently developed drug product.

126. Thompson has represented, directly or by implication, that Aspercreme is a recently discovered or developed drug product. This representation was made in CXs 6-8, 10-11. The fact that Aspercreme advertisements made this representation is evidenced by the advertisements themselves and is corroborated by expert testimony (See CXs 6-8, 10-11; Cohen, Tr. 249-50).

127. The representation that Aspercreme is a newly developed product is made through the use of a bold headline which states "At last! A remarkable breakthrough for arthritis [46] pain: Aspercreme" (CXs 6-7, 10-11; Cohen, Tr. 250). If Aspercreme is a "remarkable breakthrough" which has "at last" been achieved, then consumers would reasonably conclude that it is newly discovered (Cohen, Tr. 250).

128. In CX 8, the headline states that "There's always been aspirin ... Now there's Aspercreme." This headline suggests that the product is newly developed, and the message is reinforced in the first paragraph of the test, which reads: "Aspirin has been helping sufferers of minor arthritis pain for years. Now there is a different way to get relief. Aspercreme" (Cohen, Tr. 250).

(3) *Complaint Paragraph 10(c)*: The claim that valid scientific studies have proven that Aspercreme is more effective than orally-ingested aspirin for the relief of minor pain of arthritis or rheumatic conditions.

129. Thompson has represented, expressly and by implication, that valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of minor pain of arthritis and rheumatic conditions. This representation was made in CX 7 and CX 8, a fact which is evidenced by the advertisements themselves (See CXs 7-8).

130. CX 8, a print ad, explicitly states that Aspercreme was "tested" and "proved" more effective than oral aspirin in treating tendonitis, bursitis, muscular, rheumatic and arthritic pains. CX 8 goes on to discuss a particular test done by "a leading specialist in arthritis and rheumatism," and describes that test as a "controlled clinical test" (See CX 8). From these statements, consumers could reasonably understand the "test" to be valid scientific proof of the proposition asserted in the ad—that Aspercreme is faster and better than aspirin. CX 7, another print ad, similarly represents that Aspercreme has been "tested," and that its superiority demonstrated by scientific tests conducted by "a leading arthritis specialist."

- (4) *Complaint Paragraph 12(a)*: The claim that Aspercreme is an effective drug for the relief of minor pain of arthritis and its symptoms.

131. Thompson has represented, expressly or by implication, that Aspercreme is an effective drug for the relief of minor [47] pain of arthritis and its symptoms such as inflammation. This representation was made in all of the advertisements in evidence, including CXs 1-22 and 37. Respondent does not dispute that it made this claim (See RB 142). However, none of the Aspercreme ads in evidence contain a claim that Aspercreme cures arthritis.

- (5) *Complaint Paragraph 12(b)*: The claim that Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor pain of arthritis and its symptoms.

132. Thompson has represented, expressly or by implication, that Aspercreme is as effective a drug as orally-ingested representation was made in all of the Aspercreme ads in evidence, including CXs 1-22 and 37. Respondent does not dispute that it made this claim (See RB 142-43). However, none of the ads in evidence contain a claim that Aspercreme cures arthritis.

- (6) *Complaint Paragraph 12(c)*: The claim that Aspercreme is a more effective drug than orally-ingested aspirin for the relief of minor pain of arthritis and its symptoms.

133. Thompson has represented, expressly or by implication, that Aspercreme is more effective than aspirin tablets because it works faster than aspirin tablets, or it works without aspirin's side effects such as stomach upsets, or both. Aspercreme ads in evidence which made such a claim include CXs 1-11, 21-22, and 37.

134. Many of the Aspercreme advertisements in evidence represent that Aspercreme provides the same relief as oral aspirin, only faster and/or with fewer side effects (Ross, Tr. 6164. See Cohen, Tr. 251, 253, 254; CXs 6-8). Consumers are interested in the end benefit of a product like Aspercreme (Ross, Tr. 6200), and the end benefit of a product which provides faster relief with fewer side effects is that it is more effective (Ross, Tr. 6164-65; Cohen, Tr. 254). Clearly, then, a claim of faster relief or fewer side effects is a claim of greater effectiveness.

135. In CX 8, the subheading states that Aspercreme "Works faster, safer than aspirin." This assertion of superior speed [48] and safety is a representation of superior effectiveness (Cohen, Tr. 254). The text of the ad then goes on to reinforce this message by explicitly stating

that "Aspercreme actually relieves pain, faster, safer, better than aspirin" (CX 8).

136. The claim of superior speed, which would be perceived as superior effectiveness (*See* F. 134, *supra*), is also made in CXs 2, 4, 6-7 (Cohen, Tr. 251, 253-54). CXs 6 and 7 both contain the direct statement that Aspercreme works faster than oral aspirin (Cohen, Tr. 253-54; CXs 6-7). Moreover, CX 7 explicitly states that Aspercreme was found to be "faster and more effective than aspirin" (Cohen, Tr. 254; CX 7). In CXs 2 and 4, Aspercreme's superior speed is demonstrated by the video portion of the commercials. In both instances, the video suggests that Aspercreme reaches the point of pain faster than oral aspirin since it goes directly to the point of pain instead of having to work its way through the body (CXs 2, 4; Cohen, Tr. 251).

137. Another element in Thompson's advertising that communicates superior effectiveness is the claim that Aspercreme, in contrast to oral aspirin, provides "concentrated relief" (Cohen, Tr. 252, 254-55; CXs 78A, 88C. *See* CXs 2, 4, 6-7, 10-11). A number of Thompson's advertisements represent that Aspercreme concentrates the drug directly at the point of pain, as opposed to regular aspirin which diffuses throughout the body (Cohen, Tr. 252, 254-55; CX 78A, 88C). Such a representation could reasonably create the impression that the relief provided at the point of pain by a concentrated product (*i.e.*, Aspercreme) would be superior to that provided by a product which travels throughout the body (*i.e.*, regular aspirin).

138. Confirmatory evidence that CX 2 conveyed a superiority message is found in the Mapes and Ross copy test (Cohen, Tr. 252-53; CX 50). The copy test showed that 44% of the participants who saw "Visible Men" (CX 2) played back a theme relating to the comparative superiority of Aspercreme over tablets (Cohen, Tr. 252-53; CX 50). Many of these responses went to efficacy, with 27% of the respondents playing back "faster than tablets," 5%, "better than tablets," and 10%, "more effective than tablets" (CXs 50P, V-Z-031).

139. Further confirmation that the challenged superiority claims were made is provided by letters from NBC and the NAB (*See* CXs 78A, 88C). Both of these specialists in the field of communications wrote to Thompson to indicate that a claim of superiority to aspirin was being made (*Id.*).

140. Dr. Ross, Thompson's expert witness, agreed that a claim of faster relief, or relief with fewer side effects, is a [49] superiority claim. He stressed, however, that the superiority claim in these Aspercreme ads referred not to the product ingredients or formulation but to the modes of product application—topical versus oral (*See* Ross, Tr. 6165). However, to the consumer, what is important is the end benefit of the product (pain relief), not how that benefit is achieved

(Ross, Tr. 6201), and a superiority claim in these Aspercreme ads will be understood to mean that Aspercreme is a superior pain reliever than aspirin tablets. By the same token, an ad claim which compares Aspercreme with aspirin and says Aspercreme is faster or safer than aspirin tablets is a "comparative claim" in a real sense, although it does not name the aspirin tablets being compared by brand name.

(7) *Complaint Paragraph 12(d)*: The claim that Aspercreme is an effective drug for the relief of minor pain of rheumatic conditions.

141. Several Aspercreme advertisements in evidence represented, expressly or by implication, that aspercreme is an effective drug for the relief of minor pain of rheumatic conditions. They include CXs 7-8, 13-14, 16-20. Respondent does not dispute that some Aspercreme ads contain a claim that Aspercreme is effective for the relief of minor pain of rheumatic conditions (RB 142-43). However, none of the Aspercreme ads in evidence suggests that Aspercreme cures rheumatic diseases.

(8) *Complaint Paragraph 12(e)*: The claim that Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.

142. Many Aspercreme ads in evidence represented, expressly or by implication, that Aspercreme acts directly by penetrating through the skin to the site of arthritic pain. They include CXs 1-4, 6-11, 21-22, 37. Respondent does not dispute that it has represented that Aspercreme penetrates directly from the skin to the point of arthritic pain (RB 143-44). [50]

(9) *Complaint Paragraph 12(f)*: The claim that Aspercreme has no side effects.

143. It is true that several Aspercreme advertisements expressly represented that Aspercreme has "no" side effects (CXs 6-8, 10-11). However, when viewed as a whole, each ad was clearly saying no more than Aspercreme does not cause stomach upsets as oral aspirin is known to do. In my view, these ads can be reasonably construed to say (1) that Aspercreme is a topical rub and does not cause stomach upsets and other side effects associated with aspirin tablets, or (2) that Aspercreme is a safe product and does not have any side effects to worry about. In the context of these ads, a claim of "no side effects" will be taken to mean "no *significant* side effects."

(10) *Complaint Paragraph 14*: The claim that Thompson possessed and relied upon a reasonable basis for the efficacy and safety claims contained in Aspercreme advertisements.

144. Thompson has represented, directly or by implication, that it possessed and relied on a reasonable basis for Aspercreme's efficacy and safety claim contained in the advertisements in evidence, including CXs 1-22 and 37. This determination is evidenced by the advertisements themselves and supported by expert testimony (Cohen, Tr. 256-59; Ross, Tr. 6461).

145. Consumers generally believe that there must be a basis for efficacy and safety claims for OTC drugs or advertisers would not be allowed to make them (Cohen, Tr. 256-59; Ross, Tr. 6461). Consumers assume that this basis would be the kind of support or proof that would be acceptable to the medical/scientific community or the FDA (Cohen, Tr. 256-57; Ross, Tr. 6462). Hence, all Thompson's advertisements which made efficacy or safety claims implied that there is an appropriate scientific basis for these claims.

146. Several Aspercreme ads in evidence also reinforce the reasonable basis representation through the use of various trappings of scientific support. These trappings include explicit representations of "controlled clinical test" (CX 8), and other clinical proof (CXs 7, 20, 37), references to support in the medical community (CXs 7-8), and the use of a scientific model (CXs 2, 4). [51]

*C. The Use Of The Brand Name "Aspercreme" In Advertisement:
Complaint Paragraph 16*

147. It is found that through the use of the brand name "Aspercreme" in advertisements, labels and promotional material, Thompson represented, directly or by implication, that Aspercreme contains aspirin as alleged in Paragraph 16 of the complaint. This determination is based on the advertisements and related consumer research in evidence and expert testimony regarding the use of the "Aspercreme" brand name.

148. The determination that many consumers are likely to take from the brand name "Aspercreme" a meaning that the product contains aspirin is reasonable and conforms to our common sense and daily experience. This view is also confirmed by the record evidence pertaining to this issue.

149. The brand name is the most salient part of a commercial (Cohen, Tr. 549). Consumers are more apt to be aware of and recall brand names than specific copy points made in advertising (Ross, Tr. 6317-19). The brand name is a more powerful stimulus and will be

remembered by consumers far longer than any specific advertising or copy points (Cohen, Tr. 559; Ross, Tr. 6319).

150. Respondent's expert witnesses do not dispute that a brand name is not only capable of communicating information about product ingredients but also capable of playing a role in creating beliefs about a product (Ross, Tr. 6315-17), especially during the product's introductory phase (Ross, Tr. 6341). However, they testified that most consumers will not construe "Aspercreme" to mean that the product contains aspirin (Ross, Tr. 5970, 5983-85; Silver Tr. 5797-99, 5804, 5815).

151. Dr. Ross suggested that a brand name immediately acquires a "secondary meaning" (which he defined as simply identifying or standing for the particular product), and that when it does, any associations the brand name may originally have triggered are immediately lost (*See* Ross, Tr. 5963, 6083).

152. Dr. Ross also took the position that a brand name is not deceptive where the consumer can, through information or experience, determine for him or herself whether or not the association suggested by the name is true (*See* Ross, Tr. 6333). This approach confuses the issue of whether a given advertisement is deceptive with the issue of whether the initial deception can be cured by other information or consumer's use [52] experience. In this connection, Dr. Ross agreed that the consumer will not generally search for further ingredient information in order to verify what he or she has been told in advertising (Ross, Tr. 6370. *Also see*, F. 179-86, *infra*).

153. On the other hand, Dr. Ross agreed that the brand name Aspercreme, in the context of an ad for an analgesic product, may convey to some consumers that the product contains aspirin, as distinguished from an ad where the brand name was "X" (Ross, Tr. 6197-98). Dr. Ross also recognized that if a consumer is in an "ingredient" frame of mind and comes upon the brand name Aspercreme in an analgesic context, "Aspercreme" would be associated with aspirin (Ross, Tr. 6231, 6277-78).

154. Mr. Jasper of Ogilvy and Mather testified about the creation of advertising for respondent. When asked upon cross-examination what name he would choose to indicate to consumers that a product was an aspirin-containing cream, Mr. Jasper felt that the most effective, straightforward name would be Aspirincream, or Jay's Aspirincream (Jasper, Tr. 4838-39). He then conceded that it would be reasonable for an advertiser/marketer to use a phonetic or alphabetic variation of the name Aspirincream to convey the aspirin content message, and that the name Aspercreme could be viewed as such an alphabetic or phonetic variation (Jasper, Tr. 4839-40). Thompson's witnesses generally agreed that the name Aspercreme might sound

like aspirin to consumers (*See* Jasper, Tr. 4838-40; Ross, Tr. 6350; Silver, Tr. 5689, 5793-95).

155. Complaint counsel's expert witnesses, Drs. Cohen and Silny, both testified that the name Aspercreme strongly implies that the product contains aspirin (Cohen, Tr. 161-62, 549; Silny, Tr. 771-72). These opinions are based on their experience and the consumer research in evidence, including CX 26.

156. In the ASI Interlock experiment (CX 26), a controlled study designed to measure the impact of the brand name, some 78% of the respondents answered an open-ended question about ingredients by stating that the name Aspercreme suggested or implied that aspirin was in the product (CX 26G, F. 96, *supra*). By contrast, when the same generic product description was given to the Ben Gay and Mobisyl groups, only 3% and 8% responded that aspirin was suggested by those names. Thus, the generic product category, which was identified in the experiment by the description "for the relief of arthritis pain," does not generate the inference that aspirin is an ingredient. Although respondent's experts dismissed CX 26 as a word association game, it is reasonable to conclude that it is the name Aspercreme which led to the strong inference of aspirin content (Cohen, Tr. 161-63; Silny, Tr. 771, 1084). [53]

157. Two reports of focus group sessions (CXs 52 and 53) also support the proposition that the brand name Aspercreme is capable of leaving some consumers with the impression that the product contains aspirin. CX 52, a report of two focus groups done by David Schneider (*See* F. 120, *supra*), notes that "In a number of instances the name made one especially eager to try it, *for the aspirin association was evoked*" (CX 52K (emphasis in original)). The importance of the name's aspirin association is repeatedly emphasized in the report (*See* CXs 52K, M, N). Specific comments made by a number of consumers during the focus group sessions lends support to the conclusion that the brand name Aspercreme suggests aspirin to some consumers (*See* CX 52L). For example, a consumer stated: "When I saw it and saw 'Asper', I right away thought it must also have aspirin in it . . ." (CX 52L). The focus group participants had used Aspercreme for two weeks prior to the focus group sessions.

158. CX 53 is a focus group report by Nicholas Research (*See* F. 124, *supra*) and it provides further support for the conclusion that the name Aspercreme leads to the inference that the product contains aspirin (Cohen, Tr. 199). This focus group study was conducted at a different time and by a different moderator than CX 52, again with people who had used the product. CX 53 concludes that "others [*i.e.*, other respondents] were attracted to the name 'Asper/Aspercreme' because it has 'aspirin' in it" (CX 53Z 7, 958). The report also contains

the comments of several consumers who felt that, since Aspercreme had aspirin in it, they could take it instead of oral aspirin (CX 53Z-053).

159. Further evidence of the brand name's impact is provided by CX 27, the ASI Theatre Test. This study showed that the Aspercreme commercial tested (CX 9) led more viewers to state that Aspercreme contains aspirin than did a commercial for a competitive product, despite the presence of an affirmative ingredient statement "Aspercreme contains salycin, a strong non-aspirin pain reliever" in CX 9. It is also noteworthy that more people thought Aspercreme contained aspirin than thought it contained salycin, the very ingredient named in CX 9 (Cohen, Tr. 194-95).

160. The determination that the name Aspercreme suggests aspirin content is also confirmed by the fact that Thompson's own advertising agency recognized that the name would be so interpreted (See CXs 54Z, 55B-E, 60B). For example, in one agency memorandum discussing the aspirin content claim, it was noted that altering the "relief of aspirin" phrase would do nothing about "possible rub-off from the brand name" (CX 60B). Another agency strategy document refers to the "the 'aspirin' component of Aspercreme" (CX 54Z). [54]

161. From all of the foregoing, it is found that the brand name "Aspercreme" for an analgesic product is likely to mislead a significant segment of the target group (consumers of OTC analgesic drugs) into believing that the product contains aspirin.

D. The Presence Of Aspirin Is A Material Fact In Advertisements Of An OTC Topical Analgesic Product Directed To Consumers Who Suffer From Minor Pains Of Arthritis And Rheumatism

162. The presence of aspirin in an over-the-counter analgesic product is a material fact to consumers, particularly to arthritics, because aspirin is a commonly known pain reliever and widely associated with the relief of minor pain and other symptoms of arthritis. Many arthritics know that aspirin is a drug of choice for the treatment of minor arthritic pain and also that orally-ingested aspirin can cause stomach discomfort and other side effects. A topical product which provides aspirin relief by the external route without undesirable side effects of orally-taken aspirin would be highly material to those who suffer from minor pain and other symptoms of arthritis and who desire to avoid side effects of aspirin tablets. Essentially, Thompson does not dispute the foregoing proposition (e.g., Ross, Tr. 6370-71, 6373; Silver, Tr. 5694, 5841-42; Warwick, Tr. 5323, 5390-91, 5395; CXs 54D, Z-005, Z-007).

163. The Lieberman Study (RX 500) and the FRC Study (RX 520), both conducted for respondent for use in this litigation, also contain

data which show a significant portion of the test subjects, and a majority of arthritics, preferred an aspirin product over a non-aspirin product for pain relief. In FRC, some 39% said they preferred aspirin products (Warwick, Tr. 5333-34), while in Lieberman, which tested only arthritics, some 53% expressed a preference for an aspirin product (Warwick, Tr. 5333-34; CX 32F). These are substantial magnitudes (Ross, Tr. 6371-72). Other consumer research evidence in the record also confirms the importance of aspirin content in analgesic products to consumers in general and arthritics in particular (CXs 50Z-005, Z-016, 52I-J, 53Z-025-29, 590).

164. The opinion of Ms. Silver, Thompson's advertising expert, that the materiality of aspirin content is limited to internally-taken products and does not extend to a topical drug such as Aspercreme because consumers generally take topical products less seriously than orally-taken products (Silver, Tr. 5844-45) is contrary to the weight of evidence in this record. [55]

E. Respondent's Argument That The Various Ingredient Statements Printed On Aspercreme Packaging Would Have Effectively Disabused Consumers Of Any Notion They May Have Taken From Aspercreme Advertisements That Aspercreme Is An Aspirin Product Is Contrary To The Evidence And Is Insufficient As A Matter Of Public Policy Against False Or Misleading Advertising

165. Respondent suggests that since all Aspercreme packages from 1976 to the present, in one form or another, informed the purchaser that Aspercreme does not contain aspirin, consumers were not misled by the advertisements challenged in this proceeding (See RPF 304-15).

166. The law is long-settled that when the initial contact between a seller and buyer occurs through a deceptive drug advertisement, Sections 5 and 12 of the Federal Trade Commission Act are violated even if the truth is subsequently made known to the purchaser through information given on the label. *Carter Products, Inc. v. FTC*, 186 F. 2d 821 (7th Cir. 1951). In my view, the proposition that a marketer may mislead consumers in advertising provided the truth is disclosed to the purchaser at the time of purchase is utterly incompatible with any notion of truthful advertising and is unacceptable.

167. In any event, the information printed on Aspercreme packages was at best confusing and did not say unequivocally that Aspercreme does not contain aspirin until December 1982, almost two years after the administrative complaint was issued in this proceeding (See F. 169-78, *infra*).

168. Furthermore, the evidence is clear that consumers generally obtain their product information from advertising and that a large

portion of consumers do not read packaging information for ingredient information (See F. 180-82, *infra*).

169. RX 276 shows an Aspercreme package used in 1976, when Aspercreme was acquired from Sperti Drug Products, Inc. A two-line statement in small print at the bottom of the front panel states: "Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin" (RX 276A). The ingredient statement on the back panel states: "Active ingredient: 10% Triethanolamine Salicylate." In a large circle just below the ingredient statement, the following statement is printed: [56]

Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin. This externally applied analgesic works as effectively in giving temporary relief as many internal pain relievers without stomach upset or other undesirable side effects. Aspercreme produces its amazing results without the unnecessary sensation of heat.

170. RX 277 shows an Aspercreme package used by Thompson after January 1977. A printed statement on the front side (the lower half of RX 277B) and placed below the prominent "ASPERCREME" logo reads "An effective, deep-penetrating aspirin-like analgesic for temporary relief of occasional minor pains of ARTHRITIS, RHEUMATISM, BACK & MUSCULAR ACHES." At the bottom of the same panel, another statement in smaller print states: "Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin."

171. On the top side of the package (the middle segment of RX 277B), a prominent statement covering almost one half of the panel reads:

delivers an aspirin like*
analgesic directly
to the point of pain
*Salicylate

172. The upper 5/6 of RX 277B shows the back of the display panel and package forming a large, single panel. The statement shown on the top side of the package and quoted in the preceding F. 169 is repeated in smaller type. This statement is followed by (in much smaller type):

An effective, deep-penetrating aspirin-like analgesic for temporary relief of occasional minor pains of ARTHRITIS, RHEUMATISM, BACK & MUSCULAR ACHES.

On the bottom side of the package (the middle portion of RX 277B);

a statement appearing above the ingredient statement reads in part:
[57]

Aspercreme manifests its activity through absorption of an accepted analgesic chemically similar to aspirin . . .

173. RX 278 shows an Aspercreme package bearing an expiration date "EXP APR 82" (RX 278B). The phrase "aspirin-like analgesic" appears four times: once prominently on the front display panel (top third of A), once in smaller type on the front side of the package (bottom third of A), and twice on the back panel (upper two-thirds of B). The phrase "an accepted analgesic chemically similar to aspirin" appears twice: once on the top side in small type, and once in much smaller type on the back panel.

174. RX 279 is an Aspercreme package bearing an expiration date "EXP 1/85" and is said to have been created in February 1981 (RPF 307). The front of the display panel ("fifth display panel") states prominently in red:

ARTHRITIS RELIEF
without aspirin

On the front side of the package, "relief without aspirin" is repeated in white print on brown background, to the right of which appears a statement "contains SALICYN, a strong non-aspirin pain reliever."

On the back panel, "RELIEVES PAIN FAST DOES NOT CONTAIN ASPIRIN" appears in white print on brown background in an oval inset, to the right of which appears a statement "Aspercreme delivers an effective non-aspirin analgesic directly to the point of pain." ". . . its strong, effective non-aspirin pain reliever" appears again in a smaller print.

The statement "Arthritis Pain Medication RELIEF WITHOUT ASPIRIN" appears on the bottom panel as well as on both the top and bottom closures of the package. Thus, the phrase "relief without aspirin" appears five times on RX 279.

175. RX 280 is an Aspercreme package for the 1.25 ounce size and was adopted in early 1981. The printed statements are almost identical to those of RX 279 in content and layout.

176. CPXs 5, 6 and 7 are Aspercreme packages which were purchased by complaint counsel in local drug stores during 1982. The printed statements contain such phrases as "Arthritis [58] relief without pills," "contains Salycin, a strong non-aspirin pain reliever," and/or "aspirin-like analgesic." However, none of them contain the phrase "Arthritis relief without aspirin," "Relief without aspirin," or "Does not contain aspirin" which were printed on RXs 279 and 280.

177. RPXs 3 through 6 are current Aspercreme packaging for the full line (the 3 ounce, 1 1/4 ounce and 5 ounce cream and the 6 ounce lotion (RX 286C)). RPX 3 was filed in the Thompson production department in August 1982 and appeared on some retail shelves as early as December 1982. RPXs 3 through 6 are expected to replace Aspercreme packaging on the retail shelves as existing product is exhausted (RX 286C).

178. RPXs 3 through 6 state in bold letters on the front and back of the package, including the fifth display panel: "without aspirin"; "aspirin-free"; "does not contain aspirin"; and "non-aspirin."

179. Respondent's principal advertising and consumer psychology expert witnesses, Dr. Ivan Ross and Ms. Jacqueline Silver, both testified that the package information would be read by those consumers who are interested in ingredients and that those who read it will understand that Aspercreme is not an aspirin product from the clear and prominent disclaimer statements printed on the package (See Ross, Tr. 6069-80; Silver, Tr. 5668-69, 5737-60, 5895-96, 5916-20).

180. Dr. Joel Cohen, complaint counsel's principal marketing expert, testified that, as a general principle, product labels are not an important source of product information for consumers and that advertising is a more important and dominant source of such information (Cohen, Tr. 244-45). In support of his expert opinion on the relative roles of advertising and labeling, Dr. Cohen relied on a FDA study entitled "Consumers and Medication." That study, based on a national probability survey, showed that in response to a question asking where people get their information on over-the-counter medicines and remedies, 43% replied advertising, while only 13% said labels (Cohen, Tr. 244-45). The survey also shows that older people are less likely to read labels than younger people (Cohen, Tr. 249). Arthritis are more likely to be older people. Older people are also likely to have a harder time reading labels, and may avoid reading labels in stores (Cohen, Tr. 247-48, 319; Silver, Tr. 5743). There is also a growing trend in the country to sell over-the-counter drugs in supermarkets. When people go to the supermarket they are not likely to spend time reading package labels because they generally would have a large number of items to buy (Cohen, Tr. 247). [59]

181. Thompson's witness, Dr. Ross, referred to another FDA study, and discussed the responses to two questions. The first asked "do you read the label for ingredients" and the second asked "whether label reading is necessary or important" (Ross, Tr. 6384, 6386-87). Although people view it as socially desirable to read labels (Ross, Tr. 6384-85), and such questions tend to bias the data by stimulating affirmative responses (Ross, Tr. 6392-93), 38% of the respondents

answered "no" or only "sometimes" to the question on the importance of label reading (Ross, Tr. 6385).

182. In another study referred to by Dr. Ross (the Houston and Rothschild study) label-reading behavior was observed and timed in a store environment (CX 407G). The study concluded that consumers do not read labels, even when advertising encouraged them to do so. The study found that consumers' knowledge about the product was enhanced only when they were provided with information in advertising (Ross, Tr. 6393-94; CX 407N-O). Dr. Ross also agreed that unless consumers have a special interest or concern, they are not apt to attend to what is on a package (Ross, Tr. 6358).

183. Dr. Cohen also testified that if a consumer is convinced by the advertising that the product has a certain ingredient, he or she is less likely to read the label for ingredient information (Cohen, Tr. 419). Since aspirin is among the most familiar OTC drugs, to the extent a consumer is led by advertising to think that a product contains aspirin, he or she is less likely to read the label for ingredient information (Cohen, Tr. 260-61, 326).

184. Dr. Cohen also testified generally that, even to those who do take the time to read the package information, such phrases as "aspirin-like," "similar to aspirin" or "contains Salycin, a strong non-aspirin pain reliever" do not specifically and unequivocally say that Aspercreme does not contain aspirin and merely tend to confuse the consumers (Cohen, Tr. 317-19, 323-24, 5743-44).

185. Ms. Silver, respondent's expert witness, agreed that the phrase "without pills" (CXP 5), is not a statement regarding ingredients (Silver, Tr. 5899) and that those packages which do not contain clear aspirin disclaimers like "without aspirin" or "does not contain aspirin" are less likely to convey a no-aspirin message to a reader (Silver, Tr. 5903-04). And, as Dr. Ross admitted, the phrase "contains Salycin, a strong non-aspirin pain reliever" does not negate the proposition that the product may contain aspirin as well (Silver, Tr. 6205-06). [60]

186. Further evidence that Aspercreme packaging information does not overcome impressions that the product contains aspirin is seen in the Schneider (CX 52) and Nicholas (CX 53) focus groups (F. 120-25, *supra*). There, respondents had Aspercreme packages during a trial period of ten days and two weeks. After presumably seeing the package information, a number of them felt that the product contained aspirin (CXs 52, 53; Cohen, Tr. 552; *also see* Cohen, Tr. 552-53; CX 34B).

V. CERTAIN MEDICAL CHARACTERISTICS OF RHEUMATIC DISEASES AND
ARTHRITIS AND CONSUMER INJURY WHICH MAY RESULT FROM
MISLEADING OR DECEPTIVE ADVERTISEMENTS TARGETED TO ARTHRITICS

A. Rheumatic Diseases And Arthritis

187. Rheumatic diseases cause pain and stiffness of the musculoskeletal system (Golden, Tr. 2681-82; CX 268, p. 35,454). The symptoms of the more common rheumatic diseases are joint and muscular aches, pain and stiffness, and joint inflammation (CX 268, p. 35,453).

188. Arthritis is a rheumatic disease which may be defined as inflammation of the joints (Roth, Tr. 1526; Ehrlich, Tr. 3991-92; O'Brien, Tr. 3733; Altschuler, Tr. 3014). The term "arthritis" may be broadly used as an umbrella for more than 100 rheumatic conditions involving discomfort around the joints (O'Brien, Tr. 3929-30; Ehrlich, Tr. 3991; CX 268, p. 35,454). Other types of rheumatic diseases involve muscles, tendons, ligaments, or bursae (a small sac of tissue between muscle and joint (Adriani, Tr. 1281-82)) and are referred to as rheumatism (CX 268, p. 35,454). A non-articular rheumatic condition is one which does not involve the joint, while an arthritic condition is one which involves the joint (CX 45M, No. 240).

189. About 90% of all arthritis is either rheumatoid or osteoarthritis (O'Brien, Tr. 3927-30; CX 268, pp. 35,455-57). Osteoarthritis (degenerative joint disease) is a very common disease, especially among the elderly. Rheumatoid arthritis, which occurs in both adults and juveniles, is a systematic disease, but is characterized by inflammation of the synovial joints (movable joints which have a cavity and are lined by a synovium, or joint lining which is a specialized connective tissue) (Adriani, Tr. 1271-72; Ehrlich, Tr. 3992-93; CX 268, p. 35,457). According to the Arthritis Foundation, osteoarthritis afflicts some sixteen million persons, and rheumatoid arthritis, seven million (O'Brien, Tr. 3930). [61]

190. It is a misconception to view arthritis as minor aches and pains, a non-lethal disease of old age for which nothing can be done (O'Brien, Tr. 3928-29; CX 268, p. 35,454). Arthritis is a serious public health problem. Arthritis, particularly rheumatoid arthritis, causes lost work time and money. About twenty-seven million work days are lost annually because of arthritis (Roth, Tr. 1536-37; CX 268, p. 35,455). Osteoarthritis is an aging population like ours is an increasing problem in terms of medical costs (Roth, Tr. 1536-37).

191. Many arthritic diseases interfere with a normal life by changing the quality and productivity of life (Roth, Tr. 1537-38). Arthritis and rheumatism are second only to heart disease as a cause of chronic limitation of major activity. About one in every five chronically housebound invalids has arthritis. Although arthritis cripples a large

number of persons each year, it kills relatively few. There is no other group of diseases which causes so much pain and suffering by so many for so long. Because of the tendency to cripple without killing, arthritis and rheumatism head the list of chronic diseases from the standpoint of social and economic importance (CX 268, p. 35,455).

192. The FDA OTC Internal Analgesic Advisory Panel concluded that accepted OTC antirheumatic agents, such as aspirin and other salicylate products, "should be used in the treatment of rheumatic diseases only under the advice and supervision of a physician" for the reason that "basically, each person with symptoms of the more common rheumatic diseases, e.g., joint and muscular aches, pains and stiffness, and joint swelling should seek the advice of a physician for proper diagnosis of the specific cause of the symptoms and for identification of the exact rheumatic disease involved." The Panel concurred with the National Institute of Arthritis, Metabolism and Digestive Diseases ("NIAMD") which advised "If you have arthritis, do not try to treat yourself. All forms of arthritis must be treated by a qualified physician" (CX 268, p. 35,453).

193. More money is spent on unproven remedies and quackery than on arthritis research in the United States because people with arthritis are desperate and looking for cures (Roth, Tr. 1537).

194. Aspercreme is a topical rub promoted by Thompson for use as an analgesic for relief of various types of musculoskeletal pain. The active ingredient in Aspercreme is 10% triethanolamine salicylate (TEA/S). Aspercreme does not contain aspirin (Ans. at 4). Accordingly, the advertising representations that Aspercreme contains aspirin as alleged in Paragraph 10(a) and Paragraph 16 (the use of the brand name Aspercreme) is false. [62]

195. Strictly speaking, Aspercreme is not a recently discovered or developed drug product: Aspercreme has been available since 1971 and TEA/S, its active ingredient, has been in existence since at least 1954 (Ans. at 3). Strictly speaking, therefore, the implied representation that Aspercreme is a recently discovered drug is false. However, common sense argues that a relatively obscure product, such as Aspercreme in the late 1970's, should be allowed some leeway during the initial ad campaign in claiming novelty.

B. Consumers Are Unable To Evaluate The True Pharmacological Effects Of OTC Analgesic Drugs Such As Aspercreme

196. There is an important difference between a consumer's ability to perceive his pain relief and his ability to evaluate the true pharmacological efficacy of an OTC analgesic drug (Ross, Tr. 6426-29). See *Warner-Lambert Co.*, 86 F.T.C. 1398, 1495 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied* 435 U.S. 950 (1978).

197. Most arthritis and rheumatism pain is characterized by peaks and valleys and spontaneous remissions and will often subside with the mere passage of time and without treatment (Adriani, Tr. 1271; Altschuler, Tr. 3072-73; Ehrlich, Tr. 4092-93; Golden, Tr. 2905-07; O'Brien, Tr. 3732-33, 3768-69; Silverman, Tr. 2334). Under these circumstances, consumers who use Aspercreme cannot evaluate whether any pain relief they perceived was the result of pharmacologic action of the product or due to mere passage of time (Ross, Tr. 6443-44). Nevertheless, they would attribute the perceived pain relief to Aspercreme (Ross, Tr. 6443-44; *see also*, Ehrlich, Tr. 4225; O'Brien, Tr. 3778).

198. A large number of the users of Aspercreme (and other TEA/S products) use other medications as well (Ehrlich, Tr. 4013, Ross, Tr. 6126; Tr. 2636 (Myoflex recommended for use as an adjuvant). *See* CX 45Z-016-17 (Admission No. 5); Golden, Tr. 2768). These consumers cannot evaluate whether the relief they perceived came from Aspercreme or from the other products they were taking (Ross, Tr. 6442).

199. Consumers are directed to apply Aspercreme by rubbing or massaging it into painful areas until it is well absorbed (*See* RX 282-83; RPX 3-6). Since rubbing alone is well-known to have a soothing effect in treating musculoskeletal pain (Ehrlich, Tr. 4060-61; Golden, Tr. 2768; Heller, Tr. 2622; Roth, Tr. 1630, 1750, 1753-54; CX 269, pp. 69,783-84), consumers are [63] unable to evaluate whether any relief they perceived came from the rubbing or from the pharmacological effect of Aspercreme (Ehrlich, Tr. 4088; Golden, Tr. 2768; Ross, Tr. 6442).

200. Placebo response refers to the relief perceived from a pharmacologically inert agent (placebo), and, therefore, not attributable to the agent's pharmacological effect (Altschuler, Tr. 3096; Ehrlich, Tr. 4107; Roth, Tr. 1549; CX 268, p. 35,444). Placebo response is a commonly observed phenomenon, particularly in situations involving analgesia (pain relief) (CX 268, p. 35,444). This is because the subjective nature of pain makes it particularly amenable to suggestion (Ehrlich, Tr. 4092, 4150-51). A drug must provide significantly greater relief than a placebo to be considered effective (Ehrlich, Tr. 4153-54; Roth, Tr. 1629; CX 268, p. 35,444).

201. The placebo response rate averages around 35% (Ehrlich, Tr. 4095-97, 4116-17; O'Brien, Tr. 3790), and may range as high as 60% (O'Brien, Tr. 3773; Roth, Tr. 1550). Placebo response has been extensively investigated by experts in the field of analgesics (O'Brien, Tr. 3790). In a frequently cited 1955 survey article, entitled "The Powerful Placebo," Dr. H. K. Beecher reported that placebos were highly effective, having produced an average response rate of 35.2% in over 1,000 patients in fifteen different clinical studies encompassing a wide

variety of conditions, including post-operative pain, headache pain, angina pain, nausea, cough, anxiety and tension, and the common cold (Ehrlich, Tr. 4095-97, 4116-17; O'Brien, Tr. 3790). The placebo effect is substantial in the case of arthritis (Silverman, Tr. 2337). For example, a published study on rheumatoid arthritis reported a placebo response rate of 50% to placebo pills (Ehrlich, Tr. 4127-29).

202. The placebo response is not just a short-term phenomenon. In the case of arthritis, placebo relief can last for as long as twenty to thirty months (Ehrlich, Tr. 4127-29; O'Brien, Tr. 3774-75). In a study of the placebo response in patients with rheumatoid arthritis, 31% of the patients experienced relief for a period ranging from two to twenty months (Ehrlich, Tr. 4127-29).

203. Consumer expectations also have a significant impact on the perceived performance of a product. Perceptions of performance are heavily influenced by expectations, and these expectations can carry through to consumers' evaluation of the product's performance. In other words, the higher the expectation of performance is, the higher will be the perception of performance (Ross, Tr. 6430-31, 6433). Studies have shown that, despite the fact that one cake was preferred in a blinded test as more moist, labeling the other cake as the preferred brand for moistness can lead consumers to perceive that the [64] other brand was more moist (Ross, Tr. 6431). Similarly, in a drug study where a placebo was given to two groups, one of which was told it was an energizer and the other told it was a tranquilizer, both groups responded in accordance with what they were told (Ehrlich, Tr. 4151-52).

204. Advertising can play a major role in creating expectations of relief for an analgesic product (Ross, Tr. 6435). And the impact of advertising is particularly significant on arthritics (Roth, Tr. 1539-40). Aspercreme's advertising created consumer expectations that the product would provide relief (Adriani, Tr. 1238; Ross, Tr. 6435; Roth, Tr. 1615-17). Hence, most Aspercreme purchasers buy the product with the expectation of relief (Ross, Tr. 6435). Thus, Aspercreme advertising may have significantly increased the placebo effect on Aspercreme users (Adriani, Tr. 1238; Roth, Tr. 1615-17).

205. The perception that a treatment is new results in enthusiasm and heightened expectations (Ehrlich, Tr. 4109; O'Brien, Tr. 3770-72, 3775-76; Roth, Tr. 1540). This, in turn, can lead to an exaggerated perception of the treatment's effectiveness (Ehrlich, Tr. 4109; O'Brien, Tr. 3770-72, 3775-76). Hence, the well-known comment that "we must use new drugs quickly before they lose their power to heal" (O'Brien, Tr. 3775-76; *see also*, Ehrlich, Tr. 4109; O'Brien, Tr. 3770-72). To the extent the ads claimed Aspercreme to be a newly developed

drug, consumers' expectations and perceptions of its value may well have been enhanced.

206. The effect of expectations on perceived product performance can be negated if expectations are disconfirmed by experience with the product (Ross, Tr. 6430-31, 6446-47). However, because of the self-limiting nature of rheumatic pain, the placebo response, the effect of concomitant medications, and the rubbing effect, consumers cannot accurately evaluate the true efficacy of Aspercreme (F. 197-99, *supra*). Under these circumstances, there is in fact no opportunity for usage to disconfirm consumer expectations, and each time consumers use Aspercreme they are reinforcing expectations they had when they came to the product in the first place (Ross, Tr. 6446-47).

C. The Use Of An Unproven OTC Remedy May Cause Significant Physical And Economic Harm To Consumers Who Suffer From Rheumatic Diseases Including Arthritis

207. The use of an OTC drug product, which is not significantly different from placebo, for self-medication to [65] treat rheumatic pain poses a real danger to the consumer (O'Brien, Tr. 3722; Roth, Tr. 1538-39). As indicated by Dr. Altschuler, a physician called as an expert by Thompson, in treating patients with rheumatic pain it is appropriate to address the underlying problem directly, rather than using a placebo for pain relief (Altschuler, Tr. 3043-44; see F. 190-92, *supra*). It is not true for patients with rheumatic pain that a placebo is helpful and safe to apply (Altschuler, Tr. 3093). A person with a disease (such as rheumatic disease) should not take an inert substance as therapy (O'Brien, Tr. 3935).

208. The failure to promptly diagnose and treat rheumatic diseases with effective medication can have serious effects upon the individual. Not all musculoskeletal pain is the same (Roth, Tr. 1767; CX 268, p. 35,454). The pain due to overexertion is different from the persistent, although not severe, pain of early rheumatoid arthritis, where the harm of not seeking timely evaluation and treatment is great (*Id.*). In some instances, relatively minor pain can be the first warning of very serious conditions (Roth, Tr. 1636).

209. There is significant harm to consumers when patients in early stages of a rheumatic disease use Aspercreme for minor pain and fail to seek effective therapy (Roth, Tr. 1615-17). Moreover, because of the consumer's inability to evaluate the true efficacy of OTC analgesic drugs, such usage may continue over a long period of time. If not diagnosed and treated properly and at an early stage, rheumatic diseases can lead to progressive degeneration and debilitation (CX 268, pp. 35,454-56). And although the pain associated with rheumatic diseases can sometimes be relieved by antirheumatic OTC analgesics,

the more serious underlying features of the disease, which often lead to progressive degeneration and the prospect of permanent physical disability, may go untreated (*Id.*). Thus, Thompson's own expert, Dr. O'Brien, agreed that it would be inappropriate for an arthritic to self-medicate with a product which in fact is not significantly better than placebo because he or she may thus substitute an ineffective and unproven remedy for a truly effective drug (O'Brien, Tr. 3722).

210. In terms of economic costs, a therapeutically inactive medication, no matter how inexpensive, is a costly drug to the consumer (Silverman, Tr. 2440-41), and to society as well. Not only is the consumer wasting his money (Roth, Tr. 1538-39) by the initial purchase, but because of his inability to evaluate drug efficacy the consumer can also be expected to make repeat purchases of the product. In the aggregate, expenditures for such products represent a waste of societal resources. There is more money spent on unproven remedies and quackery than arthritis research in the United States because people with [66] arthritis are desperate and looking for cures (Roth, Tr. 1536-37). Indeed, Ogilvy and Mather International, Inc., Thompson's ad agency which created the challenged Aspercreme advertising, has pointed to a \$400 million industry in fraudulent arthritis remedies (CX 54C). The Arthritis Foundation has expressed its concern about ineffective remedies that burden society with their cost (O'Brien, Tr. 3952). The failure to treat rheumatic diseases with effective drugs can lead to lost work time and money by disease victims (Roth, Tr. 1536-37). Additionally, there is the problem of evolving medical costs where the disease progresses unchecked (*Id.*). For these reasons, an unproven remedy such as Aspercreme can cause significant economic harm to the consumer and to society as a whole.

*D. Costs And Benefits Of Requiring Thompson To
Have A Reasonable Basis Of Support For Its Advertising
Claims For Aspercreme*

211. For the reasons discussed herein above, there are substantial benefits to both individual consumers and society as a whole in requiring Thompson to have a scientifically acceptable and legally sufficient substantiation for its efficacy claims for Aspercreme. Although a pain study is not among the simplest, the costs to Thompson associated with such a requirement are relatively modest. Expert opinion in this case placed the cost of conducting a well-controlled clinical trial to demonstrate analgesic efficacy in the range of \$10,000 - \$15,000 per test (Adriani, Tr. 1175-76; Roth, Tr. 1562). Because one ideal study that would not require replication might well be more expensive than two acceptable clinical tests, requiring two adequate tests may be

more practical, even viewed from a purely economic standpoint (Roth, Tr. 1562-63).

212. It is apparent that the requirement for clinical trials is not burdensome when one considers the modest cost of conducting clinical testing in light of the costs associated with the marketing and advertising of an unproven drug product. In any event, on the basis of this record, imposition of the relatively modest cost of two clinicals cannot be reasonably expected to have a significant adverse effect on a manufacturer's plans to bring such an OTC analgesic drug product to the market.

213. For all of the foregoing reasons, the benefits of requiring Thompson to possess and rely upon the acceptable level of scientific substantiation for its Aspercreme efficacy claims clearly outweigh the costs involved in meeting that requirement. [67]

VI. ADEQUATE SUBSTANTIATION OF OTC ANALGESIC DRUG EFFICACY
REQUIRES WELL-CONTROLLED CLINICAL TRIALS

A. *It Is Well Settled That Adequate And Well-Controlled Clinical Trials Are Required To Show The Effectiveness Of Drugs, Including OTC Analgesic Drugs*

214. It is well settled that well-controlled clinical trials are required to establish analgesic efficacy of a drug (Adriani, Tr. 1156; Roth, Tr. 1541-42; 46 FR 47,731 (1979)). *Also see, American Home Product Corp.*, 98 F.T.C. 136, 201, 376-81 (1981), *modified*, 696 F. 2d 681 (3rd Cir. 1983). [101 F.T.C. 698 (1983)]

215. The 1962 amendments to the Food, Drug and Cosmetic Act explicitly incorporated the requirement of "adequate and well-controlled" "clinical investigations" for drug efficacy in general. 21 U.S.C. 355(d) (1976). The FDA regulations promulgated to implement the 1962 amendments set forth the essential elements of adequate and well-controlled clinicals. 21 C.F.R. 314.111(a)(5)(ii) (1982). The FDA has also determined that the 1962 Act's requirement for "clinical investigations" means that at least two adequate and well-controlled clinicals are required. 44 FR 51,512, 51,518 (1979).

216. The FDA's 1972 OTC drug review procedure provided by regulation that the same level of clinical evidence to show the effectiveness of a new drug be required to document the efficacy of an OTC drug on the market "unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the value of the investigation." 21 C.F.R. 330.10(a)(4)(ii) (1982). In this connection, the FDA has expressly rejected the contention that the standards for new drug approval are inappropriate for OTC drugs that have been on the market for a substantial period of time and

noted that they represent "what medical scientists today consider to be adequate proof of effectiveness." See FDA OTC Drug Review Policy Statement; 46 FR 47,729, 47,731 (1979).

217. The FDA's OTC Internal Analgesic Panel and OTC External Analgesic Panel have adopted similar requirements for adequate and well-controlled clinicals to show efficacy for OTC analgesic drugs (CX 268, pp. 35,444-45, CX 269, pp. 69,857-58).

218. Other corroborative evidence, such as long-term use of a drug in the market and reports of clinical experience with a drug is not an acceptable substitute for well-controlled [68] clinicals to show drug efficacy (Adriani, Tr. 1439-40; Roth, Tr. 1765-66; 46 FR 47,731 (1979)).

219. Thompson does not seriously dispute the general requirement that adequate and well-controlled clinicals are needed to establish drug efficacy. However, it has maintained that in the case of a mild and harmless topical analgesic drug (such as Aspercreme) that requirement should be greatly relaxed or dispensed with (Ehrlich, Tr. 4085-86; O'Brien, Tr. 3968-72; Steinberg, Tr. 5205-07, 5218-19). This position is contrary to the prevailing and accepted view of the medical scientific community and has been rejected by the FDA (F. 216, *supra*).

220. There is no adequate substitute for clinical trials to demonstrate the efficacy of a drug for pain relief. The FDA panels on internal and external analgesics both noted that pain is a subjective experience (CX 268, p. 35,444, CX 269, p. 69,857). When a clinical trial involves subjective reports such as pain, the elements of a well-controlled clinical trial are crucial. Hence, the efficacy of an analgesic drug cannot be shown simply by producing a number of positive studies if they are not adequate and well-controlled studies (O'Brien, Tr. 3784-85).

221. The FDA Internal Analgesic Panel and External Analgesic Panel also explicitly rejected animal screening tests, experimental pain, bioavailability studies, and other artificial measures as substitutes for clinical trials to show drug efficacy (CX 268, p. 35,444, CX 269, p. 69,857). Both panels concluded that efficacy of analgesic drugs must be appraised by accepting the subjects' own reports on indices of pain experiences (CX 268, p. 35,444, CX 269, p. 69,857).

222. The medical scientific community requires replication of the results of a clinical test involving an analgesic drug (Adriani, Tr. 1438; O'Brien, Tr. 3796-97; Roth, Tr. 1541). The FDA panels on internal and external analgesics both require a minimum of two positive well-controlled trials by different investigators or laboratories to demonstrate the effectiveness of an analgesic drug (CX 268, p. 35,445, CX 269, 69,858). Replication is necessary because there is a potential for systematic bias and random error in any clinical trial; the methodology

gy may be insensitive, or the wrong conclusion may be reached by sheer chance (O'Brien, Tr. 3798). Moreover, even an experienced investigator may use an aberrant methodology, or some unexpected flaw or anomaly in the randomized population may bias the test results (Roth, Tr. 1561). Other possible sources of systematic bias include the geographic location of the trial and idiosyncracies in the way the data are collected (Adriani, Tr. 1174, 1333). [69]

B. *Elements Of A Well-Controlled Clinical Trial*

223. Over a period of years, a number of standards for an adequate and well-controlled clinical trial have been developed by the medical scientific community. In regulation promulgated under the 1962 amendments to the Food, Drug and Cosmetic Act, the FDA has codified these standards. 21 C.F.R. 314.111(a)(5)(ii) (1982). The FDA has expressly adopted these same standards for proof of effectiveness of OTC drugs. 21 C.F.R. 330.10(a)(4)(ii) (1982). The record shows that the standards set forth in these FDA regulations are those accepted by the medical/scientific community as a whole (Adriani, Tr. 1158; Ehrlich, Tr. 4066-67; O'Brien, Tr. 3745; Roth, Tr. 1541-42). The reports of the FDA panels on internal (CX 268) and external analgesics (CX 269) also reflect the testing standards the medical/scientific community would apply in the case of analgesic drugs (Adriani, Tr. 1159).

224. The standards commonly used to evaluate the adequacy of a clinical trial for establishing the efficacy of a drug include: (1) a written protocol or plan for the study; (2) a suitable control; (3) adequate blinding of subjects and investigators to minimize bias; (4) randomization of treatments; (5) qualified investigators; (6) an appropriate patient population; and (7) appropriate statistical methods to evaluate the results (*E.g.*, CX 269, pp. 69,857-58).

225. A written protocol which defines the study's objectives and methods is a critical element of a well-controlled trial (Adriani, Tr. 1167; Ehrlich, Tr. 4067-68; O'Brien, Tr. 3754-55; Roth, Tr. 1551). The protocol should be written before the study is conducted (Adriani, Tr. 1167-68; CX 45I (Admission No. 147)). It should describe the essential elements of the study design as well as the analysis plan, including the scoring system to be used in evaluating the results (Adriani, Tr. 1169, 1199-200; Roth, Tr. 1551-52, 1555-56, 1591-92; CX 269, p. 69,858). Departures from the protocol should be minimized to insure the validity of the ultimate analysis (Ehrlich, Tr. 4067-68; O'Brien, Tr. 3754-55). Any major change or amendment to the protocol should be in writing (Adriani, Tr. 1169; O'Brien, Tr. 3753-55; Roth, Tr. 1551). Data for a subject who breaches the protocol in a meaningful manner, by not taking the drug as directed or by otherwise acting inconsistently with the protocol's directions, should be discarded (Ehrlich, Tr.

4067-68; O'Brien, Tr. 3759-60). Including the analysis plan in the protocol is essential to protect the integrity of the study (Adriani, Tr. 1199-200; Roth, Tr. 1591-92). Selecting the statistical analysis and scoring system in advance guards against conscious or unconscious bias on the part of the investigator. [70]

226. In order to minimize bias, a well-controlled clinical trial should incorporate at least one of four types of controls that are generally recognized as providing a comparison of treatments in a way that permits quantitative evaluation of the results. A study may incorporate a placebo control that compares the result of a test drug with an inert substance designed to resemble the test drug. When objective measurements of effectiveness are available and the placebo effect is negligible, comparison of treated and untreated subjects may be appropriate. In circumstances involving diseases with high and predictable mortality and uniform symptoms, an historical control may be used, whereby the results of a new treatment are compared with case histories in similar patient populations. An active treatment control (use of an effective therapy for comparison) may be appropriate in some circumstances, such as a condition where withholding treatment of administering a placebo would be against the interest of the patient. 21 C.F.R. 314.111(a)(5)(ii)(a)(4) (1982).

227. In an analgesic trial, it is not appropriate to use "no treatment" as a control. Pain is a subjective sensation (Adriani, Tr. 1160-61; CX 269, p. 69,857). And the placebo effect is known to be substantial. Also, the use of an historical control is not appropriate because there is no reason not to use a current control (O'Brien, Tr. 3750-51). Moreover, since all pain is subjective and musculoskeletal pain fluctuates, use of an historical control for a drug like TEA/S is inappropriate.

228. A placebo control is commonly required for a clinical trial of an analgesic drug in order to provide a consistent variable to determine whether a drug has a pharmacological effect (Adriani, Tr. 1423-24; Roth, Tr. 1549). A placebo control is particularly important in a study involving a drug for relief of pain because administration of a placebo produces a response that resembles the response to a mild analgesic (Adriani, Tr. 1164-65; Roth Tr. 1550; CX 45J (Admission No. 165), CX 268, p. 35,444). Establishing the sensitivity of the methodology used is important in the case of a clinical trial of a mild analgesic (Adriani, Tr. 1441-44; O'Brien, Tr. 3801-02; CX 268, p. 35,445). Accordingly, a clinical trial comparing a known analgesic to a test drug should incorporate a placebo control if the effectiveness of the test drug has not been established (Adriani, Tr. 1441-44; Roth, Tr. 1563-65). Especially in the case of rheumatoid arthritis and osteoarthritis, an uncontrolled trial is not reliable because the placebo effect may account for the good results (O'Brien, Tr. 3926-27). [71]

229. An analgesic trial should be double-blinded (CX 268, p. 35,444, CX 269, p. 69,857). An effective double-blind is critical in analgesic studies because they record patient's subjective responses. Effective blinding requires that neither the bottles, the physical characteristics of the test substance (such as taste and smell), nor the data sheets give any clue as to the identity of the substances used in the trial (Roth, Tr. 1548). Blinding both the subjects and the investigators is required to minimize bias (Adriani, Tr. 1162-63; Golden, Tr. 2959; O'Brien, Tr. 3782-83; Silverman, Tr. 2404). Single-blind studies are not acceptable for mild to moderate analgesics (Adriani, Tr. 1422). 21 C.F.R. 314.111(a)(5)(ii)(c) (1982).

230. In a well-controlled clinical trial, test subjects should be assigned to treatment groups in a manner that reduces bias, yet seeks to assure comparability of the test and control groups in terms of relevant variables such as sex, age, severity of condition, and the like. 21 C.F.R. 314.111(a)(5)(ii)(2) (1982). Therefore, an appropriate randomization procedure should be used so that these variables balance out (Adriani, Tr. 1165-66; Roth, Tr. 1543-44; CX 268, p. 35,444, CX 269, p. 69,857).

231. A clinical trial should be conducted by an experienced investigator with an appropriate background in the disease being evaluated (Roth, Tr. 1558; Silverman, Tr. 2311). The personnel who administer the test should also be experienced, as well as properly trained and instructed in using the measures involved in the clinical trial (Adriani, Tr. 1172; Roth, Tr. 1558-59).

232. In an analgesic trial of a drug intended for relief of various types of pain, a sufficient number of subjects with each of the appropriate types of pain should be studied (Silverman, Tr. 2311; CX 269, p. 69,857). The number of subjects should be sufficient to permit statistical analysis of the data, eliminate bias, and take the placebo effect into account. The subjects should be of both sexes and should be within the age range that would use the test drug (CX 269, p. 69,857). For clinical studies of OTC analgesics, each treatment group should contain between thirty and sixty subjects. *See American Home Products Corp.*, 98 F.T.C. at 202-03.

233. For a test of an antirheumatic drug, patients with suitable inflammatory rheumatic diseases should be selected (Adriani, Tr. 1159-60; CX 268, p. 35,468). Subjects should be grouped and studied by disease category (CX 268, p. 35,468).

234. An analysis of the results of a clinical trial is usually reported in terms of statistical significance so that the degree of confidence in the results can be assessed. In biomedical trials, 95% confidence level (or P value not greater [72] than of 0.05) is the accepted standard for statistical significance (Adriani, Tr. 1170; Ehrlich, Tr. 4068-69; Freu-

denthall, Tr. 4983; Roth, Tr. 1556-57; Silverman, Tr. 2317; CX 45Y (Admission No. 148)). In a clinical trial to determine whether treatments are significantly different from each other, a finding of statistical significance at the 95% confidence level means that there is a chance of only one in twenty that the difference observed may be due to chance alone.

235. When the results of a clinical trial have been determined to be statistically significant, the next question is whether the results are also clinically important. Statistically significant results may be clinically so small that the choice between two treatments may lack therapeutic significance (Adriani, Tr. 1171; Roth, Tr. 1557). Accordingly, statistically significant differences can be clinically insignificant.

236. For observed differences between treatments to be clinically significant, the differences must be real. A finding of statistical significance verifies that the observed differences are in fact real (Ehrlich, Tr. 4080-82). Thus, to be clinically significant, the observed differences between two treatments must be statistically significant in order to rule out the possibility that the differences are due to chance alone (Adriani, Tr. 1171-72; Roth, Tr. 1557-58).

237. In a comparative drug trial, the hypothesis being tested is that there is no difference between the two drugs (Freudenthal, Tr. 5007). Since it is not possible to prove a null hypothesis, one can only measure the differences between two treatments and assess whether or not the data are inconsistent with the null hypothesis (Ehrlich, Tr. 4169-70; Freudenthal 5008-09). A danger in evaluating clinical trials is to misinterpret a failure to demonstrate a difference between two treatments as meaning that the treatments are in fact the same. When differences are statistically significant, the results can be said to be due to essential differences in the drugs. When differences are statistically insignificant, however, this does not rule out the possibility that real differences may not exist (Ehrlich, Tr. 4170-72; Freudenthal, Tr. 5009-12; O'Brien, Tr. 3800).

238. Although pain relief cannot be objectively measured, there are appropriate objective measures of inflammation that can be used in a trial of an antirheumatic drug. These measures include grip strength, flexion, ring size, and walking time (Adriani, Tr. 1476; Ehrlich, Tr. 4017-18; Roth, Tr. 1545-47). Objective measures are useful in a clinical trial because multiple measurements can corroborate one another (O'Brien, Tr. 3781-82; Roth, Tr. 1553). Moreover, a subject's global [73] evaluation of the level of his pain may be difficult to interpret (Roth, Tr. 1668). Accordingly, a clinical trial incorporating objective measures, where possible, is preferable to a study based exclusively on subjective judgments (Silverman, Tr. 2402, 2411-13; CX 45Y, Tr. 148). In the example of Dr. Ehrlich, respondent's witness has

incorporated objective measures in clinical trials he conducted (Ehrlich, Tr. 4017-18).

239. In a clinical trial, the use of the test drug should conform to reality. The test subjects should use the drug in the same manner as a consumer would in terms of dosage level, method of application, and the like (Adriani, Tr. 1170; Roth, Tr. 1552; Silverman, Tr. 2312). Accordingly, patient subjects should be instructed to use the product correctly. Insuring that the subjects follow instructions is also important (Silverman, Tr. 2312). For example, oral instructions may be reinforced in writing; pill counts may confirm that subjects followed instructions; and urine and blood tests may demonstrate that the subjects actually used the medications (Roth, Tr. 1559-61).

240. The record is clear that the FDA requires, for OTC drug labeling purposes, two or more well-controlled clinical trials to show efficacy. In particular, the FDA OTC External Analgesic Panel and the FDA's Tentative Final Monograph on OTC Analgesic Products have applied the "well-controlled clinicals" rule to TEA/S and concluded that there was insufficient evidence to show TEA/S analgesic efficacy (F. 393-95, *infra*).

241. The obvious need for regulatory harmony and uniform standards governing the issue of OTC drug efficacy dictates that the same level of scientific evidence required by the FDA for OTC drug labeling/marketing be demanded by the FTC for OTC drug advertising with respect to the issue of efficacy.

242. The need to require adequate scientific evidence of efficacy is greater in cases where, as here, a relatively obscure topical product is being touted as a proven effective pain reliever for arthritis sufferers, a group singularly disposed to grasp at new promises of relief (F. 193, *supra*).

VII. THE CLINICAL TRIALS AND OTHER MATERIAL AND INFORMATION IN EVIDENCE FALL SHORT OF AN ADEQUATE SUBSTANTIATION FOR THE EFFICACY CLAIMS CONTAINED IN ASPERCREME ADVERTISEMENTS

243. The clinical trials Thompson relies on in this proceeding as evidence of efficacy are deficient in several important respects and none of them can appropriately be relied [74] on as an adequate and well-controlled trial which shows Aspercreme's effectiveness as an analgesic drug.

244. The most that can be said for Aspercreme is that it is being promoted as a topical analgesic for relief of mild pain and, *if shown to be effective*, can offer a topical alternative to OTC internal analgesic products, many of which are known to have significant adverse side effects especially at high arthritic dose levels. The record evidence clearly shows that the analgesic efficacy of Aspercreme remains to be

shown, although there is a modicum of evidence of some skin-penetration of salicylate molecules (bioavailability) (*See* F. 315-25, *infra*). Until the analgesic efficacy of TEA/S is established, however, much more than evidence of *bioavailability* is required. What is required is adequate evidence of *bioactivity*. This was precisely the reason why the FDA's External Analgesics Panel (CX 269) and the FDA's proposed rule governing OTC external analgesic products (CX 443 - Tentative Final Monograph dated February 8, 1982) both concluded that there is yet insufficient evidence to show the analgesic efficacy of TEA/S for labeling purposes under the Food, Drug and Cosmetic Act.

245. The clinical trials relied on by Thompson include the following purportedly well-controlled trials: the Golden study (RX 49/CX 200); the Golden-Altschuler study (RX 50/CX 214); and the so-called French studies by Drs. Patel and Chappelle (RX 34/CX 209; RX 35/CX 208; RX 36/CX 210; RX 37/CX 253 and RX 38/CX 266). *See* RB 39-49.

A. *The Golden Study (RX 49/CX 200)*

246. In 1976, Thompson asked Dr. Robert Marlin, its consultant, to design and set up a clinical study for Aspercreme (Marlin, Tr. 3183-85). Dr. Marlin knew that Dr. Golden was a board-certified rheumatologist and that Dr. Golden possessed the proper credentials to conduct the study (Steinberg, Tr. 5149-50).

247. Dr. Golden first did a pilot study to test the reaction of five patients to this product. He then wrote to Dr. Steinberg of Thompson and reported his preliminary finding that the product worked very well on patients with nonarticular rheumatic problems, that four out of the five patients experienced pain relief, but the fifth, who had severe osteoarthritis of the knee, was not helped (RX 47). Dr. Golden was encouraged by the results of the pilot study and agreed to conduct a full-fledged controlled clinical study (Golden, Tr. 2684-85; Steinberg, Tr. 5150-51). [75]

248. Dr. Marlin conferred with Dr. Golden and drafted a protocol for the study, with twenty patients in each group for a total of forty patients. In the opinion of Drs. Marlin and Golden, forty patients was a significant number of subjects from which to derive meaningful data (Golden, Tr. 2687-89; Marlin, Tr. 3183, 3186-87, 3452). Dr. Marlin recommended that Aspercreme be tested against aspirin because aspirin is known as the comparison drug in tests of nonsteroidal inflammatory drugs (Marlin, Tr. 3188, 3452). The study was set up as a double-blind trial with two groups of twenty patients, each group approximately equal in distribution of age, sex, and types of rheumatic pain (Golden, Tr. 2691).

249. In his capacity as coordinator and monitor, Dr. Marlin took

care of getting the test drug, the aspirin, and the placebo products from the manufacturer to Dr. Roslyn Freudenthal, a biostatistician. Dr. Freudenthal packaged the aspirin, placebo, and test medication in boxes that were unmarked except for a code number (Freudenthal, Tr. 4899). When Dr. Freudenthal had completed randomizing the medication to eliminate any possibility of bias, Dr. Marlin arranged for the medication to be sent to Dr. Golden's office (Marlin, Tr. 3209; Steinberg, Tr. 5151-52). The subjects in the study were primarily drawn from a pool of Dr. Golden's regular patients. After Dr. Golden had determined that the subject was acceptable under the study's protocol, the patient was given tablets and cream and instructed in the use of the medication (Golden, Tr. 2693). Dr. Marlin monitored the study by visiting Dr. Golden approximately once every week to ensure that the protocol was being followed. At that time, he also reviewed the case report forms with Dr. Golden (Marlin, Tr. 3124-25). It was Dr. Golden who collected the raw data (Golden, Tr. 2687-88). Dr. Marlin reviewed the data and forwarded the data to the biostatistician, who broke the code and analyzed the results (Golden, Tr. 2696).

250. The Golden study compared the pain relief achieved by the two groups; one group took aspirin tablets and rubbed a placebo cream into the painful area four times a day, the other group ingested a placebo and rubbed Aspercreme into the painful area four times a day (Golden, Tr. 2687-88). Dr. Freudenthal set up the code in such a manner that the study was completely blind. No one except Dr. Freudenthal had access to the code (Freudenthal, Tr. 4899-901). After the study was completed, Dr. Freudenthal conducted her analysis, wrote her report, and sent her report to Thompson (Freudenthal, Tr. 4904-08; RX 83).

251. Dr. Freudenthal's statistical analysis of the data showed that the group receiving the placebo tablets and Aspercreme rub did as well as and sometimes better than the group receiving aspirin tablets and the placebo rub (RX 82). There was a statistically significant greater number of patients [76] in the aspirin group that experienced adverse reactions. The report also showed a somewhat faster pain relief for the Aspercreme group (Freudenthal, Tr. 4908-09; Golden, Tr. 2698-700; Marlin, Tr. 3223-24; Steinberg, Tr. 5155-56; RX 49). The Golden Study was the test (or controlled test) referred to in CXs 7 and 8, print ads for Aspercreme. Dr. Marlin analyzed the data and reached conclusions similar to those of Dr. Freudenthal (Marlin, Tr. 3224, 3226).

252. The Golden study, however, failed to show a statistically significant difference between the experience of the aspirin and Aspercreme groups in terms of pain relief (Erhlich, Tr. 4165-66; Freudenthal, Tr. 5015-16; Steinberg, Tr. 5252-53; RX 83F-G). Also,

the Golden study does not show that Aspercreme is *more* effective than aspirin for pain relief (O'Brien, Tr. 3792). Nor did the Golden study measure or show that Aspercreme is effective as an anti-inflammatory drug (Ehrlich, Tr. 4164-65; O'Brien, Tr. 3793-94).

253. A failure to demonstrate statistically significant differences between drugs, however, does not mean that there are no real differences between them (F. 237, *supra*). It is not unusual for a clinical study to fail to distinguish between aspirin, a known active drug, and placebo. Thus, in a single clinical trial, the failure to show a difference between the two tested drugs does not mean that the two drugs are equally effective (O'Brien, Tr. 3798). Errors can occur; the methodology can be insensitive; or the wrong conclusion may be reached by sheer chance (*see* Ehrlich, Tr. 4188-89; Freudenthal, Tr. 4890-91, 4897-98).

254. In clinical trials of mild analgesics, it is important to insure the sensitivity of the test methodology (O'Brien, Tr. 3101-02). A comparison of two drugs, one known to be effective, is termed a positive control (Roth, Tr. 1563-65). If efficacy has not yet been established for the second drug, a placebo must be incorporated into the study design in order to demonstrate the sensitivity of the study's methodology (*Id.*). The Golden study tested Aspercreme against an active control (aspirin), but it did not employ a third group using only placebo pills and placebo cream, and thus was not placebo-controlled (Ehrlich, Tr. 4185; Freudenthal, Tr. 5013-14; Steinberg, Tr. 5252-53; *also see*, F. 228, *supra*). Since there was no placebo control, there is no way to evaluate whether the methodology of this study was sufficiently sensitive to pick up even the known difference between aspirin and a placebo (Ehrlich, Tr. 4187; Freudenthal, Tr. 5014). Accordingly, there is no way to determine whether the study failed to show a difference between aspirin and Aspercreme because no real difference exists or because the methodology used was not sensitive enough to show a difference between the [77] two (Ehrlich, Tr. 4178-79). For this reason, the Golden study's failure to distinguish between Aspercreme and aspirin cannot be considered meaningful in evaluating Aspercreme's analgesic efficacy.

255. Another reason for limiting the import of the Golden study is the truism that a clinical study which fails to show a difference between two drugs does not prove the null hypothesis (*see* F. 234, 237, *supra*). A test of statistical significance at the 95% confidence level enables us to determine whether or not we can reject the null hypothesis (Freudenthal, Tr. 5008). The null hypothesis can be disproven or rejected, but it cannot be proven that the null hypothesis is true (Freudenthal, Tr. 5008-09). Thus, a study which fails to show a statistically significant difference and fails to reject the null

hypothesis does not prove that the two drugs are equal (Freudenthal, Tr. 5012; *see* Freudenthal, Tr. 5009–12). Hence, the Golden study does not show that aspirin and Aspercreme are equally effective.

256. In her addendum to the Golden study (RX 83H), Dr. Freudenthal purported to calculate the type 2 (or beta) error—that is, the likelihood that aspirin is better than Aspercreme—and concluded it was less than .05 (Freudenthal, Tr. 4912–14, 5016–17, 5019–20). However, in calculating the beta error, Dr. Freudenthal did not use the formula that the power of a test is one minus the beta error (Freudenthal, Tr. 5017). Yet, this is the formula set forth by Dr. Mainland, the recognized statistical expert whose word Dr. Freudenthal accepts as authoritative (Freudenthal, Tr. 5008, 5017–19). Dr. Freudenthal's approach to beta error thus differs from Dr. Mainland's (*Id.*). Also, Dr. Freudenthal's results and conclusions are inconsistent with those found in an article by another well-recognized expert, Dr. Freireich (*see* Freudenthal, Tr. 5020–23). In calculating beta error, Dr. Freudenthal did not use any tables referring to the power of a test or to beta error; rather, she referred to tables of confidence intervals (Freudenthal, Tr. 5025–26). Yet, she did not know whether confidence intervals were used to evaluate alpha (type 1) error, rather than beta (type 2) error (Freudenthal, Tr. 5026–27). In later testimony, she defined confidence levels in terms of the likelihood of accepting a chance difference as real (*i.e.*, a type 1, or alpha error) (Freudenthal, Tr. 5033–34). Finally, Dr. Freudenthal did not know whether or not the method she used was the accepted method for calculating beta error (Freudenthal, Tr. 5025). Under these circumstances and for the foregoing reasons, Dr. Freudenthal's calculation of beta error and conclusions based thereon must be rejected as unreliable.

257. The failure of the Golden study to show a difference between aspirin and Aspercreme in terms of pain relief is [78] not surprising in view of its small sample size (twenty in each group). One indication of the consequences of inadequate sample size in the Golden study is that subjects with moderate osteoarthritis who were randomly assigned to the aspirin pills/placebo cream group did not experience pain relief (CX 200D). This result is clearly at variance with other studies of aspirin (Roth, Tr. 1582–83), and would tend to support the conclusion that the Golden study methodology was insensitive. This result may also be attributable in part to the small number of subjects in the study (Roth, Tr. 1767–68).

258. As acknowledged by respondent's own witnesses, and by authorities whose competence and views they acknowledged and respect, the smaller the number of subjects in a study, the more likely it is that the results will show no statistically significant differences between the drugs being tested (Ehrlich, Tr. 4220–22; Freudenthal,

Tr. 5013). As expounded by Dr. Emil Freireich, a recognized authority on the evaluation of clinical trials (Ehrlich, Tr. 4180-81; Marlin, Tr. 3418), comparative studies with small numbers of patients (*i.e.*, twenty-five patients or less in the active treatment group, and the same in the control group) will nearly always produce results showing no significant difference between the two groups (RX 383L). Indeed, Dr. Freireich termed comparative studies using twenty-five subjects or less in each treatment group as "pernicious" (*Id.*). Dr. Marlin conceded that in the Golden study (CX 200), all of the calculations involved sample sizes of twenty or less for each test group (Marlin, Tr. 3419-20).

259. The FDA's Internal Analgesic Panel and External Analgesic Panel recommended sample sizes of at least twenty-five in each group (active treatment and control groups) (Marlin, Tr. 3469-70; CX 268, pp. 35,444-45, CX 269, p. 69,862). In another FTC analgesic proceeding, experts agreed that a sample size of between thirty and sixty in each treatment group was appropriate in analgesic trials (F. 232, *supra*).

260. Dr. Marlin agreed that in analgesic studies (which employ subjective response methodology) one generally needs larger numbers of subjects in order to produce results showing a statistically significant difference between the test group and the control group. The reason is that when one is dealing with subjective responses, the variability is great. In contrast, in studies employing an objective rating methodology, a smaller number of subjects will suffice (Marlin, Tr. 3279-80).

261. The problem of small sample size in the Golden study was exacerbated by the fact that, as reflected in the published report (CX 200), the study data was broken down, after the study was completed, into a large number of smaller subgroups. As [79] explained by Dr. Roth, an expert called by complaint counsel, having conducted the study with twenty subjects each in the Aspercreme and aspirin cells, a number well below the recommended sample size, the results were further broken down into subsets that are so small as to make comparisons among them meaningless (Roth, Tr. 1580-81, 1584-85). For example, Table III at CX 200D shows that for patients who were experiencing severe pain at the start of the study, 14% of the subjects in the aspirin pills/placebo cream group subsequently rated their pain relief as "poor," while the same percentage (14%) of the subjects in the TEA/S cream/placebo pills group self-rated their pain relief experience as "excellent." The number of subjects involved in the table is seven in all, five in the TEA/S group and two in the aspirin group (who were experiencing severe pain at the start of the study). Thus, the 14% figures in fact mean *one* subject who experienced

"excellent" pain relief and another subject who experienced "poor" pain relief. Use of percentages based on cells of one or three patients is a breach of the accepted way in which comparisons are made, distorts the degree of difference in the test and control subjects' responses to the test substances and may lead to misleading conclusions (Roth, Tr. 1574-77, 1583). Respondent's own expert, Dr. Ehrlich, conceded that because of the sample sizes, the results do not constitute scientific, statistical proof and are merely suggestive (Ehrlich, Tr. 4164-65).

262. Complaint counsel's experts also criticized the *composition* of the small sample—specifically, that there was an unacceptably wide array of conditions and diseases among the subjects (Adriani, Tr. 1188). The forty subjects were experiencing pain from one or more of the following diverse diseases or conditions: osteoarthritis, rheumatoid arthritis, bursitis, tendinitis, myositis, fibrositis, muscle spasms, myalgias, sprains and strains (CX 213F-Z-057). According to rheumatologist Dr. Roth, it is inappropriate to compare arthritis of the hip to a strain in a non-weightbearing area (Roth, Tr. 1579). If there were subpopulations of significant size in the Golden Study, comparisons could appropriately have been made about the effect of the different treatments on persons suffering the same or similar conditions. As it is, however, the study is "comparing apples, oranges, tomatoes and peanuts" (Roth, Tr. 1579). In order to show a product's efficacy for arthritic pain, the study must have an adequate number of patients of each type of arthritis as subjects in the study (Adriani, Tr. 1189; CX 269, p. 69,862). Because the Golden study did not have sufficient number of subjects in the treatment group and in the control group of each type of syndrome represented among them, the study does not provide a reasonable basis for making analgesic efficacy claims as to particular medical conditions (Adriani, Tr. 1198). [80]

263. There were other flaws in the methodology of the Golden study. One of the more important is the fact that the study did not screen out aspirin non-responders (Golden, Tr. 2805; Roth, Tr. 1581). For this reason alone, the FDA rejected the Golden study, indicating that the inadequate history of aspirin use among the test subjects, and the study's failure to screen out non-responders to aspirin, preclude acceptance of the treatment comparison because of the potential bias against aspirin in treatment responses and adverse reactions (Adriani, Tr. 1191; Roth, Tr. 1582; CX 443; see CX 342B).

264. Another significant problem with the Golden study concerns the data forms completed for each of the study subjects: the Background and Clinical Data form and the Patient Reporting Card form. These forms were defective in that, with respect to the substantial number of patients having multiple areas of pain, it was impossible

tics are comparable to shipment patterns and can be used as an indicator of the boundaries of the geographic market.

b. *San Luis Obispo County*

The patient flow statistics have two aspects: first, they show that hospitals in San Luis Obispo County draw almost all of their patients from the county, and second, they show that the vast majority of county residents are served by hospitals located within the county. Taken together, these two aspects of patient flow, "inflow" and "outmigration," are strong indicators that the county is the broadest area constituting a relevant market in this case.

The inflow statistic was determined from 1980 patient origin data from the five hospitals in the county (French, Sierra Vista, SLO General, Twin Cities and Arroyo Grande). These data show that over 90 percent of persons hospitalized at these hospitals were residents of the county (*i.e.*, there is very little inflow). Studies conducted by AMI corroborate this finding.

While outmigration cannot be ascertained with the same degree of precision as the inflow statistic, the evidence is clear that the degree of outmigration from the county is small and that most county residents do not leave the county to obtain hospital services. For example, official government statistics show that only 14.5 percent of Medicare beneficiaries aged 65 and over who were residents of San Luis Obispo County and were hospitalized in 1977, were hospitalized outside the county. Similarly, only 13 percent of county residents receiving Medi-[135]Cal benefits who were hospitalized in 1977 were discharged from hospitals outside the county.

AMI has attempted to show that outmigration was much higher than these government statistics indicate. One of AMI's witnesses, Robert E. Mittelstaedt, Jr., a Vice President of AMI's subsidiary, Friesen International, Inc., prepared for trial and testified concerning a chart estimating that 30 percent of the county residents who were hospitalized were hospitalized outside the county. This estimate is inconsistent with other, more reliable, evidence in the record concerning outmigration, including not only the official government data cited above, but also an earlier study prepared by Mr. Mittelstaedt. Mr. Mittelstaedt's estimate prepared for this litigation is based on assumptions whose validity is subject to serious question. In particular, Mr. Mittelstaedt calculated his outmigration estimate based on an assumption that residents of the county utilize hospitals at the same rate as residents of California in general. In fact, record evidence shows that persons residing in the health systems area ("HSA") that encompasses San Luis Obispo County utilize hospitals at a substantially lower rate than do Californians on average. When Mr.

Mittelstaedt's estimate is recalculated using the local HSA utilization rate instead of the much higher California rate, the result is an estimate that is consistent with the Medicare and Medi-Cal data in the record.

Thus, while precise data on outmigration is unavailable, the record evidence is sufficient to show that at most it is approximately 14 percent. Since Mid-Coast Health Systems Agency, the planning body for the area in which San Luis Obispo county is located, estimates that outmigration from the designated health systems area amounts to only five percent of inpatient days, outmigration from the county could well be lower than 14 percent. French and Sierra Vista are high-quality hospitals that offer a broad range of services, and there are three other hospitals in the county. These facts suggest that it is unlikely that outmigration would be much higher in San Luis Obispo County than in the HSA as a whole. Outmigration may therefore be as little as five percent.

These outmigration percentages actually overstate the extent to which hospitals in San Luis Obispo County face effective competition from hospitals outside the county. For example, some residents hospitalized outside the county presumably became ill while traveling. More importantly, some county residents must travel to hospitals in other areas in order to receive specialized, sophisticated services that are not available in San Luis Obispo County. (See, e.g., F. 70) Other than these two basic reasons for outmigration, there is little [136] indication of competition between county hospitals and hospitals outside the county.

It is not surprising that there is little "inflow" and "outmigration" of patients. First, for reasons of convenience and limited mobility, patients prefer to go to a hospital near home where their family and friends can visit them. Second, the location of the admitting physician is a major factor in determining where patients are admitted. Both complaint counsel's and AMI's physician witnesses stated that it is impractical for a physician to make daily rounds at hospitals distant from the physician's office. The record is clear that virtually all admissions (99.7% in 1980) to San Luis Obispo County hospitals were made by physicians whose offices are located in the county. (F. 65) These physicians actively practice only in San Luis Obispo County and there is no evidence whatsoever that these physicians will rapidly shift their office locations to another site in response to fluctuations in the price and quality of hospital services. This makes it likely that patients will continue to be hospitalized in the county. While residents of the county could theoretically shift to other hospitals by seeking out physicians located outside the county, doctor-patient relationships are often highly personal, and based on habit, custom, and

convenience, making rapid shifts to hospitals outside the county unlikely.

Industry participants view San Luis Obispo County as a relevant geographic market. Officials of AMI in planning documents look upon the county as a separate market and point to only county hospitals as competitors. Hospital administrators also look upon county hospitals as their only competition. Efforts to attract patients are not directed outside the county because it is believed there is little hope of getting patients from those areas. Specialists who received patients through referral stated that most doctors that refer patients to them are located in San Luis Obispo County. Furthermore, it is very rare for doctors in the county to refer patients to doctors outside the county. When it was done, it is usually patients with unusual medical problems who are referred to major medical centers in the Los Angeles or San Francisco areas, and at Stanford University.

AMI contends that northern Santa Barbara County should be included in the relevant geographic market based largely on the fact that the two hospitals in the town of Santa Maria (Valley Community Hospital and Marian Medical Center), located in northern Santa Barbara County, draw approximately 9 and 11 percent of their patients, respectively, from San Luis Obispo County. [137]

Analysis of the patient origin data by ZIP code shows that most of the county residents who use Santa Barbara hospitals live in Nipomo, a town close to the county border that accounts for only 3.4 percent of the population of the County of San Luis Obispo. Bureau of the Census, U.S. Dept. of Commerce, *1980 Census of Population, General Population Characteristics - California* 6-31, 6-34, 6-36, 6-40. As the Supreme Court has recognized, some crossover along the fringe of a relevant geographic market is inevitable. "To be sure, there is still some artificiality in deeming the four-county area the relevant 'section of the country' so far as businessmen located near the perimeter are concerned. But such fuzziness would seem inherent in any attempt to delineate the relevant geographical market." *United States v. Philadelphia National Bank*, 374 U.S. 321, 360 n. 37 (1963). The small crossover here does not negate the basic soundness of San Luis Obispo County as the relevant geographic market.

The Supreme Court has stressed that the relevant market area is the area in which the designated product is "marketed to a significant degree by the acquired firm." *United States v. Marine Bancorporation*, 418 U.S. 602, 621 (1974). The evidence shows that the hospitals in San Luis Obispo County draw very few patients from northern Santa Barbara County. None of the San Luis Obispo County hospitals drew more than 4 percent of its patients from northern Santa Barbara County. Examination of physician admitting patterns confirms this

conclusion. With rare exception, physicians whose offices are located in northern Santa Barbara County do not admit patients to hospitals in San Luis Obispo County. Similarly, physicians who practice in San Luis Obispo County almost never admit patients to hospitals outside the county.

c. *The City of San Luis Obispo*

When assessing the competitive effects of a merger, it is necessary to focus on the area where "the effect of the merger on competition will be direct and immediate." *United States v. Philadelphia National Bank*, 374 U.S. 321, 357 (1963). The evidence shows that AMI's acquisition of French Hospital has its most direct effect on competition in the city of San Luis Obispo. Thus, whether described as a "market" or a "submarket," the city and its immediate environs are also an appropriate geographic area to use in determining the legality of the French acquisition.

Examination of the patient flow statistics indicates that residents of the city and environs go almost exclusively to hospitals located in the city. Residents of the city of San [138] Luis Obispo and the surrounding area¹⁴ accounted for less than one percent of the 1980 admissions at Twin Cities Hospital, and less than two percent of Arroyo Grande's admissions. (F. 80) The statistics show that the three hospitals in the city do draw a substantial number of patients from other sections of the county. 1980 patient origin data indicate that these patients accounted for approximately 41 percent of the admissions at Sierra Vista, 44 percent at French, and 51 percent at SLO General. (F. 79)

The fact that patients come to hospitals in the city is not surprising since French and Sierra Vista are larger hospitals and better equipped than the hospitals in the north county area and the south county area. Twin Cities and Arroyo Grande hospitals do not offer services such as CAT scan, cardiac catheterization, and open heart surgery. Arroyo Grande does not have an obstetrics department. SLO General is the hospital of choice for obstetrics and has a renal dialysis unit. Thus, patients from the outlying areas come to the city for services not available locally.

One of the most significant "commercial realities" affecting competition in the market for inpatient hospital services is the role that doctors play in competition among hospitals. Since doctors are responsible for admitting patients to hospitals, hospitals necessarily compete for physicians in order to capture their admissions. The effective area of competition for these physicians is limited, however, because doctors, for reasons of practical necessity, admit patients to hospitals

¹⁴ The environs of San Luis Obispo City include the towns of Los Osos, Morro Bay, and Baywood Park.

located near their offices. Physician witnesses with offices in the city of San Luis Obispo confirmed that they do not admit patients to hospitals outside the city, because commuting times make it highly impractical, and because if patients were at distant hospitals they would be unable to provide proper medical supervision. (F. 77)

Statistics on physician admitting patterns confirm that the location of a physician's office is a substantial factor in determining where patients are admitted. Approximately 98 percent of all admissions to the three hospitals in the city of San Luis Obispo were by physicians whose offices are located in the city and its environs. (F. 75) Similarly, 99 percent of admissions to Twin Cities were by physicians with offices in the North County cities of Templeton, Atascadero, and Paso Robles. [139] (F. 76) The South County hospital, Arroyo Grande, drew over 92 percent of its admissions from doctors located in that area of the county. (F. 76)

Thus, while city hospitals draw a significant number of their patients from the North and South County areas, virtually all of the admissions of these patients are made by physicians located within the designated submarket, the city and its environs, because Twin Cities and Arroyo Grande were too far away and because they offered no services that were not available in the city. Twin Cities and Arroyo Grande Hospitals are served by two separate medical staffs, and these hospitals do not make any effort to attract patients from the city area.

The Supreme Court has stressed that practical "commercial realities" govern when defining relevant geographic markets. *See, e.g., Brown Shoe Co. v. United States*, 370 U.S. 294, 336 (1962); *United States v. Phillipsburg National Bank & Trust Co.*, 399 U.S. 350, 362 (1970). The commercial realities of the hospital services market in which French and Sierra Vista operate are reflected in a variety of evidence demonstrating that those involved in the hospital services market view the city and its environs as a distinct geographic market. For example, on numerous occasions prior to this litigation, AMI officials observed that county hospitals outside the city provide little competition to the hospitals in the city. A relevant illustration is a 1978 AMI planning study of Arroyo Grande which stressed the relative lack of competition between this hospital and the three hospitals located in the city of San Luis Obispo:

It is important to reiterate that our findings clearly pointed to the fact that there is no definable competition for Arroyo Grande Community Hospital. The hospitals south of Arroyo Grande are geographically located too far away to be competition and the facilities, Sierra Vista and French and County [SLO General] in the north likewise are geographically too far away to be considered direct competition.

(CX 197N) [140]

In addition, testimony by hospital administrators and physicians supports defining the city and environs as a separate submarket. For example, the former administrator of French testified that he regarded Sierra Vista and, to a lesser extent, SLO General as his competition for patients and physicians. Neither Twin Cities nor Arroyo Grande were viewed as competitors because of their location and because they offered no services not available in the city.

French, Sierra Vista and SLO General are in direct competition for patients located in the city and its environs. They also compete for patients in the outlying county areas who need services only available in the city, or who come to see physicians located in the city. These patients cannot "practicably turn" to hospitals outside the city, unless their physician's office location changes or they select a new physician whose office is located outside the city. Doctors obviously cannot promptly change their office locations to another city in response to moderate changes in price or quality levels at the city hospitals. Physician-patient relationships, while perhaps more practicably adjusted in most cases than the city of a doctor's office, are also unlikely to be rapidly altered, since personal preferences, habit, and trust often play a significant role in an individual's choice of a physician. Furthermore, patients may not always be aware of reductions in certain categories of service most noticeable to physicians. These factors serve to insulate hospitals within the city from competition by Twin Cities and Arroyo Grande and strongly indicate that the city and its environs constitute a separate geographic market.

D. Competition In The Hospital Market

1. Hospital Competition Nationally

In 1981, health care expenditures in this country were \$286.6 billion, or 9.76 percent of the gross national product. *U.S. Department of Commerce, Statistical Abstract of the United States*, 102, 418 (1982-1983). The largest component of this expense was hospital care; \$118 billion in 1981, up from \$9.1 billion in 1960. *Ibid.*

Congress recognized in 1974 that the health care industry does not respond to classic marketplace forces:

[T]he health care industry does not respond to classic marketplace forces. The highly technical [141] nature of medical services together with the growth of third party reimbursement mechanisms act to attenuate the usual forces influencing the behavior of consumers with respect to personal health services. For the most part, the doctor makes purchasing decisions on behalf of the patient and services are frequently reimbursed under health insurance programs, thus reducing the patient's immediate incentive to contain expenditures.

S. Rep. No. 1285, 93d Cong., 2d Sess. 39 (1974), *reprinted in* 1974 U.S. Code Cong. & Ad News 7842 at 7878.

In connection with hospital services, the 1974 Senate Report stated:

Investment in costly health care resources, such as hospital beds, coronary care units or radioisotope treatment centers is frequently made without regard to the existence of similar facilities or equipment already operating in an area. Investment in costly facilities and equipment not only results in capital accumulation, but establishes an ongoing demand for payment to support those services. There is convincing evidence from many sources that overbuilding of facilities has occurred in many areas, and that maldistribution of high cost services exists.

(*Ibid.*)

In 1979 Congress amended the 1974 National Health Planning and Resources and Development Act in part as follows:

The Congress finds that the effect of competition on decisions of providers respecting the supply of health services and facilities is diminished. The primary source of the lessening of such effect is the prevailing methods of paying for health services by public and private health insurers, particularly for inpatient health services and other institutional health services. As a result, there is duplication and excess supply of certain health services and facilities, particularly in the case of inpatient health services.

42 U.S.C. 300k-2(b)(1) (Supp. IV 1980) [142]

Price plays a less significant role as a competitive variable in the hospital market than in most other industries. Most transactions for hospital services are covered by third-party financing arrangements. The largest third-party payor is the federal government's Medicare and Medicaid programs. State governments, via their share of the Medicaid program, are also significant purchasers of hospital care. Through the traditional system of city and county hospitals, local governments also function as third-party payors. About 55% of hospital charges are paid by governmental bodies. (Derzon, 1978) The next largest third-party payors are nongovernmental insurance organizations. The largest of these is Blue Cross. Following Blue Cross in terms of magnitude of hospital services purchased are commercial insurance carriers. The least significant purchasers of hospital care are individual consumers without insurance, called "self-pay" patients. The best available evidence indicates that approximately 90 percent of all hospital charges are borne by third-party payors. (F. 95)

The effect of third-party payment is to render patients somewhat insensitive to the prices charged for hospital services. While consumers predictably do from time to time express an interest in hospital charges, the evidence is clear that patients seldom choose among hospitals based on their prices. Under the third-party payor arrange-

ments, neither the patient nor the physician is under financial pressure with respect to hospital charges.

Another significant feature affecting competition in the hospital market is that the largest third-party payors—Medicare, Medicaid and Blue Cross—do not pay on the basis of hospital charges; rather, these payors reimburse hospitals on the basis of costs. Thus, a cost-reimbursed hospital increases its revenue by spending more; the result of incurring fewer costs is revenue reduction.

Because most patients come into contact with the system so infrequently and because of the rapid technological advances in this field, the consumer lacks information about his own need for medical care, and about the appropriateness of the care he receives. Thus, it is the doctor who makes the basic decisions about the course of care. Both patients and doctors do not have complete knowledge about the prices of the care which is sought. Partly this is because the pricing of hospital services involves thousands of individual items. More importantly, consumers and doctors lack an incentive to become aware of exact prices because they know that third-party payors will pay the vast majority of the bill. Thus, doctors do not “price shop” for their patients. [143]

Although the hospital industry has some unusual competitive characteristics, both price and nonprice competition among hospitals clearly exist, and price competition in particular is growing. Competition has been sharply stimulated by the recession, the general state of excess capacity that prevails in the hospital industry, and the increasing sensitivity of purchasers of hospital care to high hospital charges, particularly governmental and group purchasers.

Hospitals compete in a variety of ways to fill their beds and increase their revenues. First, hospitals compete indirectly for patients through their physicians, who often act as fiduciary agents for patients in the selection of a hospital. Hospitals seek to encourage physicians to admit patients to their hospital by offering the equipment, facilities, services, amenities, and support staff that physicians want for themselves and for their patients. A hospital risks losing physician admissions to competing hospitals if it does not respond in some way when more advanced technology, services, or amenities are offered by other hospitals. The existence of viable hospital alternatives gives physicians leverage when they seek improvements in hospital services. Aside from aiding in the assurance of quality service across-the-board, competition for medical staff physicians gives hospitals added incentive to carve out areas of special expertise, niches in the market where they can excel. There is considerable room for service competition to work over and above the floor set by regulatory bodies.

Second, hospitals compete directly for patients on a nonprice and

price basis. They compete on a nonprice basis for patients by providing high quality services, amenities, and innovative care options and by educating potential patients through advertising and public relations activities. Since many hospitalizations involve elective surgery or other nonemergency treatment or tests which allow for scheduling in advance, patients consider and act upon the reputation and service choices of hospitals in deciding where to be hospitalized. A survey conducted by AMI's subsidiary, Friesen, in Tampa, Florida, for example, indicated that 35 percent of the persons surveyed would ask to go to the hospital which they preferred and another 54 percent would ask their doctor to admit them to a specific hospital, but would go where their doctor preferred. (CX 1055F) Doctors with privileges at more than one hospital usually try to honor patient preferences.

Direct price competition for patients is most commonly reflected in such visible hospital charges as room and board. Other visible items on which hospitals compete on price include emergency room charges and obstetrics. Although consumers do [144] not generally know the detailed hospital charges for various ancillary services, they learn the range of the more visible charges from the local media and from their personal experiences and those of their family and friends. AMI's own studies show it will lose patients if these visible charges are too much higher than the competition's. Hospital administrators, therefore, check the visible charges of nearby hospitals to make sure their hospitals are not out of line for fear of loss of patients if their hospital gets a reputation for exorbitant prices.

Current economic conditions are causing consumers to become increasingly more price conscious about their medical care. Long-term unemployed persons are losing the health insurance coverage offered by their former employers. Financially pressed patients are postponing elective surgery. Because of escalating hospital costs, insurance companies are raising their deductible and co-payment levels¹⁵ and broadening exemptions to their policies, and similar proposals are being considered for federal and state programs. Insured patients often have to pay substantial amounts of their hospital bill out of their own pockets, for example, 20 percent under typical commercial health insurance plans. Where even a relatively small proportion of consumers are sensitive to price differences among hospitals, their presence helps constrain hospital pricing for all patients.

Third, hospitals compete for the volume business of group purchasers by offering competitive rates and discounts to health maintenance organizations ("HMOs"), self-funded employer plans, private insur-

¹⁵ A deductible is a sum which the patient must pay before the third-party payor will begin to pay for medical care. A co-payment is an arrangement under which the insured must pay a certain percentage of the bill for his medical services.

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ance companies, and government programs. California is in the forefront of this competitive activity. There, the state's Medi-Cal program is actively engaging in competitive price negotiations with hospitals for the business of Medi-Cal patients. (F. 117-122) The State of California expects to achieve savings of \$200 million a year under this new program. The California Blue Cross Plan has announced that it will sponsor a preferred provider program under which subscribers will receive financial incentives to obtain treatment at those hospitals which give a substantial discount. Other insurers and employee benefit plans are also setting up preferred provider plans, placing increased reliance on price competition among hospitals. Group purchasers have greater [145] leverage in playing off one hospital against another for a discount in areas where hospitals are experiencing excess capacity. In California, hospitals on average are operating at only 64 percent of licensed capacity.

Fourth, hospitals also compete with each other for certificates-of-need ("CONS"). Since CONs often confer exclusive or nearly exclusive rights to offer particular services, hospitals try to gain competitive advantages over other hospitals in filing for CON applications.

To sum up, competition can and does play a valuable role in the hospital industry. It fosters innovation and high quality service; it ensures that adequate service and technology alternatives will be available to patients and physicians; it places some constraint on charges to individual patients; and it helps private and public third-party payors to restrain price increases and sometimes to secure discounts.

The record contains specific examples of both price and nonprice competition. Mr. Robert A. Derzon, one of respondents' expert witnesses, was co-director of a project conducted by the consulting firm of Lewin & Associates to compare the economic performance of investor-owned and not-for-profit hospitals. The project produced a study entitled "Two Case Studies of Competition Between Hospitals," published in 1981. (CX 1030; see F. 100) The Lewin Report is based on case studies of two different communities, each of which was initially served by a single non-profit hospital, but which became two-hospital towns with the entry of a new hospital operated by an investor-owned group. The Lewin Report reported how one hospital sought to forestall creation of a competing hospital by dissident physicians on its medical staff by beginning planning for an intensive care unit. The dissident physicians proceeded to open a new hospital because, in the words of one dissident, the board and administrator of the existing hospital "were not thinking about modern medicine," and provided "second-rate" medical care. When the new hospital was established, the existing hospital made service additions of the sort desired by specialists.

The Lewin Report also detailed another situation where the new for-profit hospital provided physicians with spacious, quiet, and well-lit physician dictation and chart review areas, which contrasted with a general lack of quiet space for physicians at its non-profit competitor. The new hospital also assigned blocks of operating room time to its most active surgeons, so that the surgeons could minimize preparation time and work with nurses familiar with their procedures. This policy was responsive to the complaints of surgeons about the [146] "first come, first served" rule for scheduling operations at the existing non-profit competitor. The Lewin Report discussed hospitals' use of loans, subsidized office space, and income guarantees for physicians as competitive strategies. The Lewin Report discussed "conscious price competition" between the two hospitals in "Lee County," as evidenced by the new for-profit hospital's policy of holding its room and board charges below those of the established non-profit hospital, and of keeping the differences between the two hospitals' ancillary charges per patient day unusually low. The Lewin Report discussed the strategy of the for-profit hospital to promote usage of its new emergency room by announcing publicly that its emergency room rates would "compare favorably" with its competitor's rates. (F. 110)

There is record evidence concerning AMI's application for a certificate-of-need to build a new hospital in Yuma, Arizona, where there was already an existing hospital. In connection with the hearing process on the application, which was opposed by the existing hospital, AMI made statements indicating that competition between hospitals would occur and would be helpful. AMI argued that:

[A] review of YRMC's [Yuma Regional Medical Center] rate increases indicates that YRMC has difficulty in managing hospital cost without a second hospital in Yuma. Perhaps, a second hospital in Yuma will make YRMC more conscious of the need to contain hospital costs.

(CX 1051M) Mr. Victor Kolodziej, AMI Vice President and Financial Director for AMI's Pacific Southwest Region, argued that price competition would occur in Yuma if AMI were permitted to build a new hospital there to compete with the established hospital:

What we are talking about is a deescalation in the build up of rates in the future; that what should happen within the competitive mold is that rates will not increase as they have in the past. It's not the reduction of rates themselves; it's a deescalation in the inflation of rates.

They will not cut rates. We would not cut rates, but rates would not increase as rapidly in the future.

(CX 1072W)

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Mr. Ronald Porter, Group Vice President of AMI and Regional [147] Director for AMI's Pacific Southwest Region also emphasized that price competition would exist if AMI were permitted to build a new hospital in Yuma:

We believe that if efficiency is introduced into the marketplace, into our facility, it will allow us the opportunity to have rates which are lower or at the top end to be that of Yuma Regional Medical Center and that we believe that competition in this case will force both facilities to be very mindful. I think it will force both facilities to become efficient.

(CX1072V) Mr. Porter also expressed succinct evaluation of the benefits of competition: "Competition is good. Competition is healthy for the Yuma community." (CX 1072T) Mr. Kenneth Ono, an Operations Assistant with AMI's Pacific Southwest Region, and a former administrator of a hospital in Hawaii, in connection with AMI's Yuma application, described how physicians in Hawaii felt about competition between hospitals:

[T]here were two hospitals there, and one of the comments physicians used to make was, "oh, it's really a hassle going back and forth". . . . [O]n the other hand, they said, "we like it when there's competition" because . . . they can indicate to the administrator about the progressive new things that are being done in one hospital and why can't they be done in another. . . .

(CX1072M)

There is other record evidence that AMI hospitals have engaged in various forms of price and nonprice competition. An example of competition for physicians is the "Selective Centers of Excellence Strategy" proposed by AMI subsidiary Friesen, and adopted by AMI management, for AMI's Brookwood Medical Center. This plan called for the development of OB/GYN, oncology, cardiovascular surgery, and private psychiatry—specialties in which Brookwood already provided high-quality services—into "premier" services. (CX 1060I) Friesen anticipated that the "premier" OB/GYN service would attract physicians dissatisfied with Brookwood's major competitors.

Friesen discussed competitive pricing by hospitals in the strategic plans it prepared for AMI's Community Hospital of Santa Cruz, in Santa Cruz, California, and AMI's Circle City Hospital, in Corona, California. In the Santa Cruz situation, Friesen noted that AMI's hospital lost money on room and board, and earned subnormal profits on ancillary services. Friesen [148] attributed AMI's inability to set rates sufficient to cover its costs and achieve its profit objectives to "the two hospitals competitive situation in Santa Cruz which does not permit Community [Hospital of Santa Cruz] to adjust rates as easily as other region hospitals." In the Circle City strategic plan, Friesen

examined the rates of Circle City in comparison to those of other local hospitals and other AMI Western Region hospitals. One conclusion Friesen drew from that data is that "Circle City is approaching the 'rate ceiling' at which its growth in market share could be impeded by overly aggressive rate increases," which would cause patients to use competing hospitals. (See F. 111)

Friesen's strategic plan for AMI's Palm Beach Gardens (Florida) Community Hospital noted that Pratt and Whitney, a large area employer that is self-insured for health benefits, was asking its employees' physicians not to admit them to the hospital, in part because Pratt and Whitney's medical director believed the hospital's rates were excessive. Friesen recommended that the hospital seek to repair its relationship with Pratt and Whitney, and, upon the company's request, consider giving it a discount in return for a higher volume of patients. (See F. 116) Another Friesen study suggested that AMI's El Cajon (California) Valley Hospital pursue a strategy of developing similar relationships with local employers. (CX 1057B)

Since planning authorities may limit the number of certificates-of-need to be awarded for any particular program or for expansions of bed capacity, hospitals compete to identify the kinds of facilities and services their communities need, and to apply for and obtain certificates-of-need to build and operate those facilities and services. In its strategic plan for AMI's Community Hospital of Santa Cruz, Friesen urged AMI to oppose the application of Dominican Hospital, Community's sole competitor for a certificate-of-need for additional beds. Friesen warned that "[i]t is necessary to show that [AMI is] directly addressing community needs, not simply objecting to Dominican's analysis," and suggested that AMI might do so by offering new or expanded services. (CX 1054B)

At least three AMI hospitals in California engaged in price discounting for the business of HMOs. The "Health Net" HMO received discounts of between 10 and 15 percent of charges from those three hospitals, and another HMO received a discount ranging from 26 to 28 percent (depending upon volume of HMO patient days) from one of the hospitals. (See F. 114) Friesen's strategic plan for AMI's El Cajon (California) Valley Hospital recommended that the hospital seek the business of HMOs that do not have their own hospitals. (CX 1057B) [149]

2. Hospital Competition in San Luis Obispo County

Prior to AMI's acquisition of French Hospital, San Luis Obispo County presented a situation in which many of the types of competition previously described could and did exist. The county was well-supplied with physicians who could practice at any one of the five

hospitals in the county. In addition, there was substantial excess hospital capacity throughout the period preceding the acquisition. In 1978, for example, the average occupancy rate for all five hospitals in the county was only 54.2 percent. Furthermore, the hospitals had particular strengths and weaknesses, so patients and physicians were presented with a number of choices among the hospitals.

The city of San Luis Obispo contained the largest hospitals in the county, Sierra Vista with 172 acute care beds, and French with 138 acute care beds. Both hospitals offered a wide range of services. Sierra Vista, which was considered one of AMI's finest hospitals (CX 307), had an active emergency room and offered CAT scanning, nuclear medicine and ultrasound. French also offered a number of specialized services, including CAT scanning, cardiac catheterization, and pediatrics. In addition, it was recognized for the quality of its nursing staff and the quality of food served to patients. SLO General, which was heavily subsidized by the county, was the choice of people without health insurance and those who relied on the county to pay for their health care. It was not as modern as French and Sierra Vista and was considered by many doctors as inferior to French and Sierra Vista. SLO General is the hospital of choice for obstetrics since it was the first hospital to offer facilities for natural childbirth. Periodically, there had been discussions concerning closing SLO General.

Prior to AMI's acquisition, competition between the hospitals in the county took place primarily between French and Sierra Vista. First, the hospitals competed to attract doctors to admit to their facility. There was pressure on each hospital to satisfy the needs of the doctors who were already admitting there, since they could always admit patients to one of the other hospitals. Hospitals in San Luis Obispo purchased equipment physicians needed in order to ensure that they would continue to use their facilities. There are several examples of hospitals purchasing new equipment and updating existing equipment to attract and keep physicians. (F. 135-139)

This competition for doctors through the provision of equipment and services, especially between French and Sierra Vista, resulted in the hospitals' purchasing needed equipment and improving the quality of services. For example, such [150] competition had a major impact on how the present French Hospital was equipped when it was built. The equipment in the original French Hospital was described as "very poor" (Boyd, 354), and the hospital generally was considered by doctors to be the worst of the three hospitals in the city. (Boyd, 351) The equipment at Sierra Vista, on the other hand, was described as "superior." (Boyd, 352) When the new French Hospital was built in 1972, the administration "tried to furnish the necessary instruments and the equipment that would encourage physicians to use French

Hospital." (Anderson, 232) For example, special equipment for neurosurgery was provided so that a neurosurgeon in the city would use French for his surgery. (Anderson, 233)

The hospitals competed on the quality of nursing care offered patients. French had excellent nursing care prior to the acquisition, a fact acknowledged by an AMI official (Loftin, 1481), which gave French a competitive advantage. (F. 140-41) French also competed for physicians through its pediatric department, considered "outstanding" and "the best pediatric department in town." (Boyd, 376) In addition, French competed by virtue of its CAT Scanner which was superior to the one at Sierra Vista. (Boyd, 355) In 1975, French Hospital, which was still owned by Dr. French at that time, set up a heart catheterization laboratory, enabling cardiologists to diagnose heart disease. This program was viewed by French as a way of competing with Sierra Vista since it was a source of referrals. A few years after the heart catheterization program was instituted, French also instituted a heart surgery program. Mr. Anderson, a former administrator at French, noted that they regarded the service as one which would give the hospital increased census since it was not available elsewhere. (Anderson, 222) AMI recognized that such a program was advantageous to French. In noting the advantages of buying French, for example, one AMI memorandum states that the acquisition "would remove the need for Sierra Vista to develop a competitive service." (CX 38C)

During the period that the physicians owned French Hospital, they brought a number of new specialists into the French Clinic. In bringing in these physicians, the French Clinic doctors were interested "in the expertise they would bring to our role as being as complete as possible in the practice of medicine." When French Hospital was purchased from Dr. French, offers were made to physicians from outside the French Clinic group. In early 1978, three physicians accepted limited partnerships in the facility. In October, 1978, offers were made to eight other physicians, and two accepted. The loss of physicians to French concerned Mr. Carlson, the administrator of Sierra Vista. After the first offering of French partnership shares in 1978, Mr. Carlson reported to AMI that "[a]n unknown [151] factor in physician utilization of the hospital is the increasing number of physicians who have been invited to buy into French Hospital." (CX 317B) By October 1978, when the second offering was made, Mr. Carlson was even more concerned: He wrote that:

A problem of major concern is that of competition from French Hospital. Because of doctor ownership, past increases in the number of physicians and possible future

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additions to the Clinic makes that hospital an increasingly formidable competitor for the limited number of patients in the area.

(CX 318B)

The hospitals in San Luis Obispo were careful about their rates in those areas where patients were likely to be most knowledgeable. Hospital administrators and AMI officials checked room rates both within the county and in other areas. Mr. Friedmann, who was in charge of pricing at French Hospital prior to the French acquisition, kept track of room rates at hospitals in the county and throughout the state. Mr. Friedmann suggested that such examinations had a competitive purpose. He testified:

There is natural tendency to examine these rates in the sense that certainly you don't want to be terribly out of line or competitively out of line in the sense of, if I were overly high, I would know that maybe I have a problem within my facility as to my costs that had to be examined. Plus from a public relations standpoint, you don't want to be the highest priced show possibly in town.

(Friedmann, 1580) Documents show that AMI also was concerned with room rates in the county. An Arroyo Grande planning document includes a survey of room rates, but only those in the county. (CX 191H-I) A memorandum analyzing the upcoming French acquisition similarly noted only those rates at hospitals within the county (CX38N), the same hospitals that are referred to as French's competition. (CX38M) Another AMI memorandum suggests that there was room for Sierra Vista to adjust its rates, based on a study of room rates at hospitals in the county. (CX 479; *see also* CX480)

Evidence indicates that competition also had an effect on other charges that were likely to be "visible" to consumers, the operating room and the emergency room fees. In the Spring of [152] 1978, the installation of a new computer allowed French to change from a per-hour operating room charge to a unit pricing system. As a result, operating room charges were changed so that the "front-end charge" was reduced but, due to various "weighting factors," total revenue could be increased. This change, however, did result in lower operating room fees for some patients. The reduction in the "front-end charge" would become known to patients, because that was "the actual visible fee . . . that would normally be published, for instance in the paper." (Friedmann, 1583) French reduced another visible charge to patients, the emergency room charge. Doctors used the French emergency room on weekends and off-hours instead of opening up their offices. Usually there was a charge for the use of the emergency room, but it was waived when doctors saw patients under these circumstances. There was concern at Sierra Vista about the competitive

moves of French Hospital. In a letter to Mr. Loftin, a local physician who practices at Sierra Vista noted the changes in fee schedules, and stated: "It is . . . becoming apparent that this hospital [French] is attempting to generate competition . . . and thus is become [sic] extremely competitive with Sierra Vista Hospital." (CX 737) The doctor went on to state that AMI should consider a decrease in its emergency room fees "to be competitive. . . ." (*Id.*) Mr. Loftin replied on February 12, 1979, while AMI was considering the acquisition of French Hospital (CX 738; *see* CX 38): "We have been aware of the competitive moves of French Hospital and will most certainly work to counteract these." (CX 738)

Other services offered by Sierra Vista faced competition from French. Sierra Vista operated a reference lab prior to the acquisition. The lab was slow to get business, however, due to "a number of factors including prices from both local competitors and the major labs in Los Angeles." (CX 452B) One such "local competitor" was French Hospital, which subsequently established a price schedule lower than Sierra Vista's. (CX 319B) In January, 1979, Mr. Carlson noted that Sierra Vista would "need to take action soon to combat this development." (CX 319B)

French Hospital hired a public relations manager who began a series of educational seminars on health issues. Mr. Friedmann, financial administrator at French and also a partner, stated that he believed that this would increase the number of patients for the medical clinic group and that "a direct derivative would be . . . that the hospital would get maybe additional census because the physicians now saw a greater number of patients than they did previously. . . ." (Friedmann, 1586) Sierra Vista had an auditorium which was used by a number of organizations for educational programs, and started its own series of programs [153] similar to those at French. In one report, Mr. Carlson noted that the hospital was beginning "a series of educational programs for the community under the direct sponsorship of the hospital. The majority of programs held in the hospital have been sponsored by the various agencies putting on the programs, however, I feel that additional areas of interest to the public should be addressed by the hospital." (CX 318B)

Although few doctors from outside the city of San Luis Obispo regularly used the city hospitals, the possibility that these doctors might admit some patients there imposed some competitive pressure on hospitals in the outlying areas. The existence of French as an independent hospital provided a way of bringing pressure to bear on the Arroyo Grande [AMI] administration when new equipment was needed. Dr. Schwam, who practiced at Arroyo Grande, testified:

[M]odernizing Arroyo Grande Hospital and stimulating administration to get what we though was adequate equipment has always been a problem. . . .

* * * * *

So the medical staff had a certain amount of leverage in a sense because we could always point to French Hospital in terms of equipment that we felt that we needed and that we were not getting. Some members of the medical staff even stated that they would take their patients to French Hospital if certain basic equipment was not forthcoming.

(Schwam, 585) Dr. Schwam did not generally admit patients to French, but he used that option as a way of "alerting administration that we wanted progressive changes." (Schwam, 585-86) AMI recognized this competitive pressure. In a report prepared by the staff of AMI Vice President Norman Loftin (Loftin, 1492) concerning Arroyo Grande, it was noted that "among the physicians in the community, French is used over Sierra Vista, another American Medical International Hospital, because of the philosophy that subtly suggests to the corporation that it invest in the same quality and level of care in both Arroyo Grande and Sierra Vista." (CX 197G)

Respondents contend that due to physician polarization in the city of San Luis Obispo, there was no substantial nonprice competition between French and Sierra Vista. (See RB, pp. 91-98) The effects of physician polarization, to the extent it existed in San Luis Obispo, was minimal. Much of the so-called polarization was normal rivalry, a result of intense competition [154] among physicians for patients. (See F. 148-151) As the evidence cited above demonstrates, there was substantial price and nonprice competition between French and Sierra Vista, the physician polarization notwithstanding.

Respondents also contend that the absence of normal economic incentives in the hospital industry results in an "uncontrolled spiral of duplicative and wasteful purchasing" of expensive equipment, and that this is condemned by the Planning Act. (Resp. Reply Brief, p. 38) Yet, respondents also argue that there are substantial non-market constraints on hospitals regarding decisions on hospital costs and charges. (RB, pp. 56-59) The record establishes that while there might be some excesses in catering to physicians, countervailing considerations outweigh the excesses. Some equipment which was purchased by San Luis Obispo hospitals was relatively inexpensive and easy to obtain. French and AMI had procedures whereby they reviewed doctors' requests for equipment to ensure that it was necessary, financially feasible, and useful to more than one individual. Furthermore, such requests were reviewed by committees so that there is "a consensus

before we expend significant amounts of money. . . ." (Carlson, 1324) Each hospital balanced its need to keep physicians satisfied with other financial considerations, including the return to the hospital. (See Friedmann, 1575) Finally, the health planning laws further inhibit unnecessary expenditures by hospitals since some equipment cannot be purchased without a certificate-of-need, and such certificates will not be granted if unnecessary duplication or low utilization will result. Third party payors, especially Medicare, Medicaid, Medical and Blue Cross, take a close look at hospital expenditures since they reimburse based on costs.

Dr. Lave, complaint counsel's expert witness, expressed a very relevant view of the benefits and costs of nonprice competition:

There are always adverse effects of competition. When anybody looks at it, when a Soviet planner looks at competition, he sees excessive capacity being built in one place, some other capacity sitting idle in another place, he sees luxury here that need not be present and so on.

There is always something in competition that gets people who don't understand it irritated because it always looks as if this could be done more efficiently if we had somebody in charge who could give the orders. The fact is that over time these [155] relatively minor excesses that come about because of competition are disciplined by the marketplace and help to keep the competitors on their toes and to lead to a greater efficiency.

So that this is just as true with respect to hospitals as it is with other areas of the economy. I think that on balance this kind of nonprice competition is extremely productive both in terms of the quality of patient care that one would see as defined by health professionals and the quality of patient care as patients would view it, which is probably just as important as the quality of care as defined by health professionals.

(Lave, 839-40)

E. Competitive Effects of the Acquisition

AMI's acquisition of French Hospital has produced extremely high concentration in the hospital market in both the city and county of San Luis Obispo. By making the French acquisition, AMI increased its market share, measured by inpatient days, from 55.6 percent to 75.5 percent in San Luis Obispo County and from 57.8 percent to 87.2 percent in the city of San Luis Obispo. For market share measured by gross hospital revenues, the comparable figures are an increase from 52.2 percent to 71.3 percent in the county and from 53.3 percent to 82.4 percent in the city. The Herfindahl-Hirschman Index based on inpatient days increased from 3818 to 6025 in the county and from 4370 to 7775 in the city; based on gross hospital revenues the increase was from 3518 to 5507 in the county and from 3996 to 7097 in the

city.¹⁶ (Appendix D)

The concentration statistics do not reveal the full extent of AMI's dominance of the market. AMI's only competitor in the city of San Luis Obispo is SLO General. It is not a formidable competitor because it is relatively old, smaller than either French or Sierra Vista, and, with the exception of its obstetrics department, lacks the modern and sophisticated equipment, and in some areas the high quality nursing services, [156] necessary to attract doctors, and is preferred by fewer patients than French or Sierra Vista. (F. 132, 135; Boyd, 358) The only other non-AMI hospital in San Luis Obispo County is Twin Cities. This hospital is small, does not offer the range of services offered by French or Sierra Vista, and is inconveniently located for many residents of the county. (F. 14, 24, 133) As a result, neither SLO General nor Twin Cities offers effective competition to AMI's hospitals in San Luis Obispo County. Because of the substantial barriers to the construction of new hospitals in San Luis Obispo County, particularly by firms not already operating in the area, it is very unlikely that AMI will face any competition for the foreseeable future other than that offered by SLO General and Twin Cities.

Further, there are no practical substitutes for the "cluster of services" offered by AMI's hospitals. Also, governmental regulatory apparatus in no way constrains AMI's use of market power to raise prices, restrict output, or diminish the quality of the services it provides; instead, such planning laws as exist serve as barriers to new entry. Thus, evidence of extremely high market shares, high entry barriers, great disparity in size between the top firm and the other hospitals in the market, excess capacity and a relatively stagnant demand for hospital services, all confirm that AMI's dominant market power will persist.

The power which AMI has over acute care hospital services in San Luis Obispo County and the city is best expressed by Dr. Lave, complaint counsel's expert witness:

AMI has tremendous power to maintain its prices, to get its prices and say to other people, well, of course you can always travel many miles at great inconvenience to [you] and to your family and be hospitalized somewhere else but in the meantime we have this hospital here.

There is quite a substantial price premium that would be associated with their ability to be able to control these three hospitals in the county.

(Lave, 901-02)

AMI was aware of the control over health care in San Luis Obispo

¹⁶ The Justice Department's Merger Guidelines indicate that the Department is likely to challenge mergers increasing the Herfindahl-Hirschman Index more than 100 points where the post-merger index is above 1800 points. (47 FR 38493-38497 (June 30, 1982))

County, which the French acquisition would confer. This is revealed by a memorandum recommending the French acquisition from AMI Vice President Dennis Danko to AMI's Contract Development Committee. Mr. Danko's responsibilities at AMI were the identification and analysis of community hospitals throughout the United States for purposes of acquisition. [157] Mr. Danko was a major participant in the negotiations for the purchase of French Hospital and signed the letters of intent for the transaction on AMI's behalf. His memo states:

[W]ith the French acquisition, AMI would become the prime, if not the only, provider of health care services in the area. . . . While it is true that if we do not acquire French, our health care centers in the San Luis Obispo County region will continue to operate on a viable basis; however, we face a choice of paying a premium price, thus controlling health care services, while meeting our earnings expectations, or continue to struggle to capture basically the same patient load with French, or another operator such as N.M.E. [National Medical Enterprises], who may purchase French. It would be my recommendation that we proceed with the acquisition as outlined.

(CX 41C-D)

While Congress has "remained convinced that competition does not operate *effectively*" in the hospital field, *National Gerimedical Hospital & Gerontology Center v. Blue Cross*, 452 U.S. 378, 392 (1981) (*emphasis supplied*), the record establishes that there are substantial areas of competition in the hospital market in general, and San Luis Obispo County in particular.¹⁷ While this competition might not be termed [158] "effective," as the term was used by the Congress, it is beyond doubt of sufficient significance to warrant protection.

Prior to the acquisition, AMI hospitals and French Hospital engaged in various forms of nonprice competition to attract physicians and their patients, or to retain the patronage of those physicians and patients already using their facilities. These activities have already been set forth in detail. With the French acquisition, these hospitals no longer compete against each other in this way. Mr. Danko stated in his memorandum that if the acquisition did not occur, AMI would have to "continue to struggle to capture basically the same patient load with French, or another operator such as [National Medical Enterprises]. . . ." (CX 41D) The administrator of French after the

¹⁷ Respondents argue that the prerequisites for a competitive market are absent from the hospital industry. (See RB, pp. 23-33) As complaint counsel points out, respondents are relying on conditions for a textbook model of perfect competition (Complaint counsel's Reply Brief, pp. 3-9), "but the pure model must never be mistaken for that 'competition' we wish to preserve." R. Bork, *The Antitrust Paradox* 60. Respondents also characterize the record evidence of actual competition between hospitals as "gossamer and anecdotal" (Resp. Reply Brief, p. 2), "unsupported fragments of testimony and uninterpreted excerpts from documents" (Resp. Reply Brief, p. 16), and "occasional wisps of language." (Resp. Reply Brief, p. 18) The substantial evidence relied upon in this opinion demonstrating areas of actual competition between hospitals consists of statements by credible witnesses, some of whom were respondents' officials, and contemporaneous documents written by respondents' officials. This evidence is not easily denigrated. At a minimum, the competitive effects which AMI represented would occur in Yuma, Arizona if a second hospital were to enter the market (see pp. 146-147 *supra*), should exist in San Luis Obispo if French Hospital were to remain an independent entity.

acquisition, Mr. Lauran Bowytz, recognized that competition with French had ended with the acquisition. In 1980, he was interviewed by a representative of AMI subsidiary Friesen. He noted that he cannot compete along traditional lines, such as by recruiting doctors, or "steal[ing] from S[ierra] V[ista]" because "competition is AMI." (CX 295W) An AMI Quality Assurance Report for Sierra Vista also recognized that competition between Sierra Vista and French would be curtailed:

For many years Mr. Carlson and his forces have challenged the French Hospital and won the battle, now *that* activity has to be curbed and a balance of cooperation mixed with healthy competitiveness has to be reached whilst retaining hard earned standards of care.

(CX 425F) (Emphasis in original) This report also recognized that AMI hospitals in San Luis Obispo find themselves in a "politically sensitive arena" because of the "monopoly of the hospital market." (CX425F) Mr. Danko stated that with the French acquisition, AMI "would become the prime if not the only provider of health care services in the area. . . ." (CX 41C)

AMI took steps to make charges uniform at all of its hospitals in the San Luis Obispo area after it acquired French. In 1980, for example, a memorandum to administrator Mr. Lauran Bowytz at French Hospital recommended that the charges for certain items be changed. It noted that "these price changes [159] will establish uniformity for the San Luis Obispo area." (CX 301A; *see also* CX 302A) In the Friesen report for French Hospital, Friesen noted as an "action item" to "standardize fee structure for AMI hospitals." (RX 5435Z69) On another occasion, Mr. Bowytz took advantage of the lack of restraint on AMI's pricing conduct by raising charges in order to compensate for a low patient census. (RX 5378AA) In another instance, Mr. Bowytz noted that he was implementing increases for purposes other than to cover certain costs. (CX 51A)

Thus, price competition for patients on the basis of room and board and other visible rates has been foreclosed between the two largest hospitals in the market, leaving little, if any room for price competition in the city or county. Whereas previously, doctors and patients knew that they had a viable and acceptable independent hospital to go to if they were dissatisfied with the service or price of either French or Sierra Vista, that choice no longer exists. The need for this choice is especially important in the city of San Luis Obispo since the remaining nearby alternative, SLO General, does not have the range and quality of services that the majority of physicians and fee-paying patients in the community prefer, and lacks the money to substantially upgrade its facility. Before the acquisition, the administrators of

French and Sierra Vista knew that patients and doctors had a choice nearby and this leverage increased their sensitivity to physician and patient needs.

Group purchasers of hospital services, or third-party payors, have become more aggressive in recent years in seeking lower hospital costs. (F. 183-185) Actual and potential price competition for the business of third-party payors has been restricted by the acquisition. Third-party payors have lost competitive leverage in playing off French against the AMI hospitals in the market to obtain the best price possible for their insureds. The magnitude of potential savings in this area is substantial since Blue Cross, Medi-Cal, and charge-based payers account for a substantial portion of the hospital revenues in San Luis Obispo County. Recent California legislation has provided impetus for competitive bidding, both in the public and private health insurance sectors, and Medi-Cal, Blue Cross, and preferred provider plans have already begun to engage in this process. HMOs also seek competitive bids for their hospital requirements. By acquiring its leading competitor, AMI has foreclosed independent competitive bids from French, a hospital that had a tremendous economic incentive to cut prices because of low patient census. The testimony of Mr. William Guy, the Medi-Cal Negotiator for the State of California, illustrates the competitive impact of the French acquisition on group purchasers of hospital services seeking competitive bids: [160]

Well, if the major facilities which you need in order to meet the terms of the law are owned by a single entity, you hardly have an opportunity for competition. Competition is what we need within the negotiating environment to drive the most cost-effective rate for the state.

(Guy, 666)

AMI's defense relies heavily on the alleged pervasiveness of regulation and absence of price competition in the hospital industry.¹⁸ The premise implicit in AMI's arguments is that preexisting noncompetitive conditions in an industry are a reason for upholding an acquisition against antitrust challenge. Not only does this argument fail in the face of the evidence noted above documenting the existence of competition that is worth preserving and enhancing, but it is also at odds with cases upholding the validity of Clayton Act challenges in

¹⁸ Some post-acquisition evidence was received relating to rate of charge growth at French and Sierra Vista since the acquisition, the purchase of new and additional equipment, and improvements in the quality of care since the acquisition, including nursing care and food services. (See RB, pp. 102-109) Much of this evidence is subjective in nature, inconclusive, and entitled to little weight as post-acquisition evidence within the control of respondents. It is not possible to compare what AMI has done at French with what would have been done by the previous owners during this same period if the acquisition had not occurred, or what would have happened if National Medical Enterprises had acquired French.

other industries where government regulation has attenuated price and other forms of competition. *United States v. Philadelphia National Bank*, 374 U.S. 321, 368-369 (1963); *California v. Federal Power Commission*, 369 U.S. 482 (1962); *Maryland and Virginia Milk Producers Ass'n v. United States*, 362 U.S. 458 (1960); *United States v. Pacific Southwest Airlines*, 358 F.Supp. 1224 (C.D. Cal. 1973), *cert. denied*, 414 U.S. 801 (1974); *see also Federal Maritime Commission v. Seatrain Lines, Inc.*, 411 U.S. 726 (1973). The failure to protect the price and nonprice competition which exists in the hospital market by strict enforcement of the antitrust laws leaves no alternative but to abandon the market to monopolists or cartels.

The regulatory environment for hospitals in California leaves more room for effective price and service competition [161] than existed in many of the cases where an antitrust violation was found despite the fact that competition had been affected by comprehensive "public utility" or "rate" regulation. At the time of the *Philadelphia National Bank* decision, banks were regulated much more heavily than hospitals are now in California. Entry, branching, interest rates, and the investment and lending practices of banks were regulated to varying degrees by state and federal governments. 374 U.S. at 327-330. Service, rather than price, was the principal focus of competition among banks. *Id.* at 368.

Even when an industry is heavily regulated, any actual and potential competition that exists should be preserved and nourished by eliminating private restraints so that competition can operate to the maximum extent possible. *See Philadelphia National Bank*, 374 U.S. at 372, ("fact that banking is a highly regulated industry . . . makes the play of competition not less important but more so"). Preservation of the potential for price competition in San Luis Obispo County is especially important since California, rather than relying on government price regulation, is actively seeking to stimulate price competition among hospitals. (F. 117-122)

Service competition, like price competition, is protected by the anti-trust laws. To the extent that price competition is weak or sometimes nonexistent, there is all the more reason to protect the nonprice competition that does exist. *See Northern Pacific Railway Co. v. United States*, 356 U.S. 1, 12 (1958), where it is stated: "All of this [foreclosure of competition] is only aggravated . . . here in the regulated transportation industry where there is frequently no real rate competition at all and such effective competition as actually thrives takes other forms."

Finally, other antitrust cases have recognized the need to protect competition in the health care field, despite the fact that in some respects health care market forces operate in unusual ways. *E.g.*,

Arizona v. Maricopa County Medical Society, 102 S.Ct. 2466 (1982); *American Medical Ass'n*, 94 F.T.C. 701 (1979), *aff'd as modified*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided court*, 455 U.S. 676 (1982); *United States v. Hospital Affiliates International, Inc.*, 1980-81 Trade Cas. (CCH) ¶ 63,721 (E.D. La 1980).

F. Attempt to Monopolize

Count II of the complaint charges that AMI has, with specific intent to exclude competitors and maintain the power to control delivery of hospital services, attempted to monopolize and has otherwise engaged in unfair methods of competition in the market for general acute care hospital services in San Luis [162] Obispo County or parts thereof. (Complaint ¶ 15) Specific acts in furtherance of this alleged conduct engaged in by AMI include the acquisition of French Hospital and the foreclosure of a competing hospital chain from purchasing French.¹⁹ (Complaint ¶ 16)

"Monopoly power" means the power to control prices and exclude competition. *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966) An attempt to monopolize is illegal whether or not it is successful. *Lorain Journal Co. v. United States*, 342 U.S. 143, 153 (1951). The three basic elements of the offense are (1) exclusionary or anticompetitive conduct (2) prompted by a specific intent to monopolize, (3) coupled with a dangerous probability that monopoly will result. *Swift & Co. v. United States*, 196 U.S. 375, 396 (1905); *E. I. du Pont de Nemours & Co.*, 96 F.T.C. 653, 725 (1980). Complaint counsel contend that all three elements are present in this case, and I agree.

Complaint counsel argues that the French acquisition is anticompetitive conduct designed to further AMI's attempt to monopolize, and that an anticompetitive acquisition can be the basis for a finding of attempt to monopolize. *Heattransfer Corp. v. Volkswagenwerk, A.G.*, 553 F.2d 964, 981 (5th Cir. 1977), *cert. denied*, 484 U.S. 1987 (1978); *Bergjans Farm Dairy Co. v. Sanitary Milk Producers*, 241 F.Supp. 476, 486 (E.D. Mo. 1965), *aff'd*, 368 F.2d 679 (8th Cir. 1966). *See also United States v. Grinnell Corp.*, 384 U.S. at 570-71 (monopolization). Respondents point out that evidence of anticompetitive conduct other than acquisitions was present in the above cases. (See Resp. Reply Brief, pp. 147-148) Respondents also reference two Commission opinions where it was held that an illegal acquisition was not sufficient, standing alone, to infer an intent to monopolize. *United Fruit Co.*, 82 F.T.C. 53, 158-59 (1973), *enforcement granted in part and denied in part sub nom. Harbor Banana Distributors, Inc. v. FTC*, 499 F.2d 395 (5th Cir. 1974), *modified*, 88 F.T.C. 981 (1976); *Golden Grain Macaroni*

¹⁹ The allegation that AMI directed its three hospitals in San Luis Obispo County to take a united position in refusing to compete with each other by offering price and other concessions to a local HMO was dropped by complaint counsel before trial. (Tr. 74; see Complaint ¶ 16(c))

Co., 78 F.T.C. 63, 165 (1971), *order enforced in part*, 472 F.2d 882 (9th Cir. [163] 1972), *cert denied*, 412 U.S. 918 (1973), *modified*, 82 F.T.C. 1824 (1973).²⁰

The acquisition in the present matter was made under entirely different conditions and with a significantly greater competitive impact than the acquisitions considered by the courts and the Commission in the cited cases. In San Luis Obispo County, AMI had a 55.6 percent share of inpatient hospital days and 52.2 percent of gross hospital revenues in the county at the time of the acquisition. The acquisition increased these market shares to 75.5 percent and 71.3 percent respectively. The market shares for the city were 57.8 percent of inpatient hospital days 53.3 percent of gross hospital revenues prior to the acquisition. AMI acquired its largest and most direct competitor increasing its market share percentages to 87.2 percent and 82.4 percent. An acquisition that eliminates the principal competitor in a market and increases market share to this degree is sufficient, in my view, to infer an attempt to monopolize the market. See *E. I. du Pont de Nemours & Co.*, 96 F.T.C. 653, 727 (1980); *Heattransfer Corp.*, 553 F.2d at 981; *American Tobacco Co. v. United States*, 328 U.S. 781, 797 (1946).

There is other credible evidence to support AMI's intent to monopolize. The exclusionary effect of the acquisition and the market power it gave AMI was clearly anticipated by the top AMI officials involved in the decision to make the French acquisition. On January 25, 1979, AMI Vice President Loftin recommended to AMI's Contract Development Committee that it authorize a letter of intent to purchase French Hospital. Mr. Loftin sought the letter of intent, at least in part, because he believed that National Medical Enterprises ("NME"), a national hospital chain which owned Twin Cities Hospital in northern San Luis Obispo County, also was interested in the hospital. In his memo he wrote:

We do know that National Medical Enterprises is also currently interested in French and that preliminary discussions have been held. Due to his fact, we would like to proceed as soon as possible.

(CX 38B) [164]

On February 9, 1979, AMI Vice President Danko wrote to the AMI Contract Development Committee recommending the French acquisition:

[W]ith the French acquisition, AMI would become the prime, if not the only, provider

²⁰ In *United Fruit*, the hearing examiner [ALJ] found lawful competitive business motives for the challenged acquisition (82 F.T.C. at 158), and in *Golden Grain Macaroni*, the Commission considered that the acquisition was motivated in part by a desire to replace the loss of production facilities. (78 F.T.C. at 165)

of health care services in the area. This may be viewed by some in the medical community and others negatively. However, in the long run the positives would overcome the negatives. There also exists a real possibility that with or without French, the local county-owned hospital (114) beds may close. Currently, one-half of its bed complement is not in operation; it has lost its JCAH accreditation; and the county is supposedly subsidizing the hospital in excess of \$1.0M/yr. Note that this hospital is predominately providing O.B. services at this point, plus hemo.

While it is true that if we do not acquire French, our health care centers in the San Luis Obispo County region will continue to operate on a viable basis; however, we face a choice of paying a premium price, *thus controlling health care services*, while meeting our earnings expectations, *or continue to struggle to capture basically the same patient load with French, or another operator such as N.M.E., who may purchase French.* It would be my recommendation that we proceed with the acquisition as outlined.

(CX 41C-D) (emphasis supplied)

These contemporaneous business documents written prior to the acquisition by the relevant AMI officials intimately involved in evaluating the acquisition clearly establish a specific intent to monopolize. These documents are entitled to much greater weight than after-the-fact explanations offered at trial by interested AMI witnesses.²¹ See *United States v. United States Gypsum Co.*, 333 U.S. 364, 395-96 (1948); *National Commission on Egg Nutrition*, 88 F.T.C. 89, 177-178 (1976), *aff'd*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Adolph Coors Co.*, 83 F.T.C. 32, 185 (1973), *aff'd in part and rev'd in part on other grounds*, [165] 497 F.2d 1178 (10th Cir. 1974), *cert. denied*, 419 U.S. 1105 (1975).

It is concluded that AMI engaged in exclusionary and anticompetitive conduct that was prompted by a specific intent to foreclose competitors and control hospital services in the city of San Luis Obispo and San Luis Obispo County. Further, there was a dangerous probability that AMI would be successful in monopolizing the markets. In fact, it can be concluded that success was achieved. A quality assurance report, written in April 1980, made reference to the "monopoly of the hospital market" in respect to Sierra Vista and French. (CX 425F) As a result of the acquisition, AMI achieved over 80 percent of the city market and over 70 percent of the county market for hospital services. Judge Learned Hand, in *United States v. Aluminum Co. of America*, 148 F.2d 416, 424 (2d Cir. 1945), stated that 33 percent of a market does not constitute a monopoly and it is doubtful whether 760 or 64 percent would be enough. He probably would have agreed that in excess of 70 percent or 80 percent would be enough. I believe it is enough to indicate a strong probability of achieving monopoly, especially when the barriers to entry are high and the remaining competition is very weak. See *Heattransfer Corp.*, 553 F.2d at 981; *United*

²¹ See F. 164 n. 15, n. 16.

States v. Grinnell Corp., 384 U.S. at 571; *United States v. American Tobacco Co.*, 328 U.S. at 797.

Complaint counsel also asserts that there is other evidence of AMI's intent to monopolize. (CB, pp. 62-65) Complaint counsel cites evidence that AMI was aware of and concerned about competitive moves by French, and stated an intent to counter these moves. This evidence may reflect reasonable competitive efforts to meet competition, or at least it can be interpreted in that manner, and it will not be considered as evidence of an intent to monopolize.

Complaint counsel also contends that AMI paid a "premium price" for French Hospital, relying upon Mr. Danko's memorandum of February 9, 1979, quoted above, that "we face a choice of paying a premium price, thus controlling health care services, while meeting our earning expectations. . . ." (CX 41D) According to complaint counsel, the short of the matter is that AMI was eager to eliminate actual competition from French and potential competition from National Medical Enterprises and was willing to pay a premium price in order to control the market. Complaint counsel thus attaches great significance to the former phrase (premium price) while apparently ignoring the latter (earning expectations).

The evidence concerning whether or not AMI paid a premium price for French is set forth in detail in the findings of fact. (F. 163-173) The evidence does not establish whether or [166] not AMI paid a premium price for French, or if a premium price was paid, whether any part of that price was attributable to a design to foreclose competitors and control the market. Contemporaneous AMI documents indicate that some AMI officials believed the price was a premium; these same documents also indicate that the officials believed that at the price paid AMI expected to meet its profit objectives: "In summary, the acquisition of [French] appears to be a unique opportunity for AMI. It would be immediately profitable, achieve our rate of return objective and provide additional growth." (CX 38G; *see also* F. 173) It is therefore plausible to assume that the price that AMI paid was a reasonable price based on legitimate profit concerns. Accordingly, the issue of whether AMI paid a premium price for French Hospital, and whether any part of that price was attributable to AMI's monopolistic intentions, has not been proved by substantial evidence.

G. AMI's Efficiencies Defense

1. A Factual Analysis

Respondents offered evidence that the acquisition of French has created the potential for far-reaching cost savings which could be affected by implementation of recommendations set forth in a study

entitled "Cost Savings Expected From Consolidation of French and Sierra Vista Hospitals." (RX 5614A-S) The study indicates that this consolidation could result in annual operating cost savings of at least \$1,238,000 and capital cost savings of at least \$12,200,000. In addition to these monetary savings, an enhancement in the quality of care is expected. The study was prepared in connection with this proceeding by employees of AMI and its wholly-owned subsidiary, Friesen, under the direction of Mr. Mittelstaedt, a Vice President of Friesen. AMI's counsel helped formulate the questions to be addressed by the study.

The study estimated the operating cost savings of consolidation by comparing the unit costs of particular ancillary and support services provided at both hospitals, then assuming that the services could be provided at one location for both hospitals at the lower unit cost. The study also estimated the costs of personnel whose positions would be eliminated upon consolidation. The largest portion of savings would result because of capital expenditure savings made possible by consolidation. This figure was arrived at by comparing the cost of the capital improvements needed to maintain Sierra Vista as a "first-rate hospital," should there be no consolidation, with the capital costs of consolidating French and Sierra Vista. Further, respondents contend the \$1.238 million per year operating cost savings does not include savings which possibly will be achieved from increased patient volumes arising out of [167] consolidation, because there will be no need in the future for two departments to purchase the same equipment where the consolidated patient volume only justifies one.

The record indicates that consolidation of services between hospitals is unlikely to be achieved without common ownership. As a practical matter hospitals simply are not willing to give up services to other independently-owned hospitals. The fact that hospitals attempt to preserve their revenue flows and physician loyalties precludes consolidation of important services between noncommonly-owned hospitals. According to AMI, this matter of consolidation has not been put to the Executive Committee of AMI because of the present litigation. Disentangling the two hospitals in the event they were consolidated and AMI subsequently ordered to divest French would be costly. Further, it would disrupt the community; in particular, it would disrupt the physicians who would have oriented their practices in accord with the distribution of services recommended by Friesen, and would then have to readjust in the event of divestiture.

Friesen recommended the "consolidation of the two facilities under common management while retaining the operation of the two separate physical facilities." (Mittelstaedt, 1027) Under this strategy, the operations of French and Sierra Vista would be merged under a single administrator and a single hospital name, the medical staffs would be

unified into a joint medical staff, and services would be divided between the two facilities. Among the services which would be located exclusively at French are pediatrics, obstetrics, clinical laboratory, ophthalmology, cardiology, and pathology. Among the services which would be located exclusively at Sierra Vista are trauma, orthopedics, neurosurgery and oncology. Both facilities would continue to provide medical/surgical services as well as intensive care and coronary care services.

It is not clear that consolidation of French and Sierra Vista will occur, even assuming AMI is permitted to keep French Hospital. Consolidation of French and Sierra Vista, as recommended by Friesen, would require the preparation of detailed implementation plans and formal approval of the Executive Committee of AMI's Board of Directors. There, is no assurance that those individuals and committees at AMI who would have to authorize the over \$8 million for the consolidation would act to do so. AMI management does not always agree with the conclusions of Friesen (Loftin, 2497), nor necessarily [168] follows Friesen's recommendations.²² (Loftin, 2492) Consent of the hospitals' local boards also will have to be obtained.

A number of practical barriers stand in the way of a consolidation of the scope Friesen recommends. No consolidation on this scale had even been done before. (Derzon, 2075) A number of doctors told Friesen that it was their belief that AMI did not have the "guts" to tackle some of the tough issues associated with a consolidation.²³ Doctors who currently practice at one hospital will fight the idea of their specialty being moved to the other. Finally, AMI would have to obtain approval from the local HSA and the state before making most of the capital expenditures required to consolidate the hospitals. Government approval is subject to a number of contingencies beyond AMI's control, including how much delay there might be before government approval is granted or denied. Since consolidation is one of Mid-Coast HSA's goals, it can be expected that Mid-Coast HSA will work with AMI at some plan of consolidation, but not necessarily that proposed by Friesen, since the consolidation plan does not contemplate the elimination of excess hospital beds. (See F. 202)

It is questionable whether economies of scale, such as the \$1.238 million in operating expenses envisioned by RX 5614, actually can be

²² Testimony elicited from AMI's top officials, Mr. Weisman and Mr. Loftin, was to the effect that they would recommend implementation of the Friesen consolidation plan. (Weisman, 1746; Loftin, 1534) Mr. Weisman testified that he would "unequivocally and enthusiastically" support the proposal. (Weisman, 1747) However, it is only logical to assume that the "Friesen proposal" might undergo substantial revision prior to any actual approval and implementation.

²³ At the August, 1981 presentation of Friesen's findings and recommendations to the French and Sierra Vista medical staffs, some support was expressed by local physicians for the concept that French and Sierra Vista be consolidated. The specialties of Drs. Stahl and Harvey, two of the physicians expressing support for the consolidation, would benefit from the proposed consolidation, and their testimony must be weighed in that vein.

gained through consolidation. Dr. Schramm, respondents' economic expert, has noted that there is inconsistent evidence concerning whether economies of scale exist for hospitals. He has noted that "[w]hen combined, existing research suggests that the economies of scale attached to hospital size and, presumably, to the size of any hospital entity however formed, may be illusive." (CX 1048P) [169] Dr. Schramm also has written:

[C]onsolidations undertaken to achieve efficiency, economic security, operating surpluses and improved capabilities for meeting future demands may be ill-advised. The consolidation process itself is complicated, costly and uncertain. Those contemplating a merger should recall that the return-to-scale efficiencies expected in many mergers are never realized.

(CX 1048T)²⁴

AMI did not take any significant steps toward consolidation of French and Sierra Vista services during the 17 months between AMI's acquisition of French and the time it learned of the Commission's investigation of the acquisition. After the acquisition was completed, Friesen reported to AMI that consolidation would produce "somewhat, not enormously, potential lower costs," and "modest" increased profitability. (RX 5435C, Z61; Mittelstaedt, 1109) The administrator of Sierra Vista, in an August 1981 memorandum, also indicated that he did not expect major cost savings to be achieved through consolidation: [170]

It was my hope that our long range plans would permit consolidation of some services with the eventual objective of at least a slight decrease in the rate at which expenses are increasing. Even though such cooperative efforts would not necessarily be of major dollar savings, they would have been at least symbolic of our united efforts to hold down costs.

(CX 1063A)²⁵

Mr. Mittelstaedt made a number of questionable assumptions and omissions in his study which affect his results. To calculate the oper-

²⁴ Dr. Schramm also cautioned that consumers may see less of the benefits of consolidation than of its costs:

[T]he merger movement [in the hospital industry] must be seen in the light of consumer satisfaction. Clearly, absolute consumer choices suffer as consolidations advance. This is traditionally rationalized by citing reductions in unit prices that follow consolidation. Interestingly, however, prices do not always reflect the savings of consolidation and artificial price settings must be controlled through regulation. The apparent risk in consolidation from the consumer perspective is that prices may not reflect true savings. The costs of consolidation are expressed as both higher market prices and lost flexibility in the market. Moreover, consumers generally are deprived of product choice even though, as is often argued, the quality of products and services may improve.

²⁵ AMI has listed possible savings already realized from use of a mobile van with echocardiography and ultrasound equipment, a joint system for maintenance of biomedical equipment, a joint reference laboratory for physicians at French, sharing of computer services, and joint hiring of an anesthesiologist. (See F. 224-230) These purported savings are minimal at best, and most could be realized without any consolidation such as is proposed by the Friesen study.

ating cost savings resulting from consolidation, Mr. Mittelstaedt compared the unit costs of particular services provided at each hospital, then assumed that the service could be provided at one location for both hospitals at the lower unit cost, even though in some instances the service would be moved from the lower cost hospital to the higher cost hospital. (See F. 214) In addition, a portion of the savings are due to more effective purchasing arrangements. Consolidation is not necessary to achieve these savings; joint purchasing involving separately-owned hospitals is fairly common in California.

RX 5614 ignores the cost of capital for the expenditures required to consolidate French and Sierra Vista. Approximately \$8.7 million in renovations and new construction (in 1982 dollars) is required to effect the consolidation set forth in RX 5614. If AMI financed the consolidation project at 10%, the average cost of capital to AMI, the annual cost of capital for the consolidation would be at least \$870,000. RX 5614 also does not consider the cost of depreciation on newly-constructed facilities and renovations built in the course of consolidation. Depreciation is usually treated as an expense. (See CX 38H, J-K-Depreciation on the \$2,103,400 of new construction over 40 years would be approximately \$52,585 per year. (See 38J) If the renovations were also depreciated on the same basis, then there would be an additional expense of almost \$165,000. [171]

RX 5614 assumes that consolidation of the emergency rooms at French and Sierra Vista would eliminate the need for French's contract with a physician group to provide medical coverage at its emergency room, and thereby save \$204,000. This savings assumes that the physician group covering Sierra Vista's emergency room, which is also under contract, could handle an increase in the number of emergency room visits of more than 50%, and would handle this increase without insisting on greater compensation for its services. RX 5614 also states that consolidation would make it unnecessary to have certain supervisory personnel at both Sierra Vista and French (for example, two administrators or two directors of nursing), and so permit the elimination of 12 supervisory positions, with annual savings of approximately \$419,000. It also assumes that each supervisor in charge of activities at both hospitals (for example, the director of nursing or the x-ray chief) will have an assistant who can routinely exercise responsibility for on-the-spot decisions when the supervisor is not present. This projected cost savings would be diminished to the extent that the supervisors and assistants whose responsibilities are increased as a result of the elimination of supervisory positions, ask for, and receive, increased compensation for their efforts—a possibility acknowledged by Mr. Mittelstaedt. (Mittelstaedt, 1129-31) Finally, even if successfully implemented, the annual cost savings through

elimination of supervisory positions would be less than the projected \$419,000 in the first three years following consolidation, since RX 5614 assumes it would take at least three years to implement the personnel reductions.

The projected operating cost savings for laboratory tests ignores the need to maintain two laboratories even after consolidation. RX 5614 projects annual costs savings of \$160,000 on the assumption that all laboratory test performed at French and Sierra Vista could be performed at one laboratory facility located at French. Mr. Mittelstaedt predicted that switching Sierra Vista's lab work to French will achieve those savings even though French's per unit cost for lab work is much higher than Sierra Vista's. (See RX 5614H) Also, as Mr. Mittelstaedt acknowledged in his testimony, it would still be necessary to have a "stat" laboratory at Sierra Vista to perform tests where results are needed immediately. (Mittelstaedt, 1057) Mr. Mittelstaedt's testimony about the economies of increased volume at a centralized facility (Mittelstaedt, 1048) suggests that "stat" tests performed at Sierra Vista will be more expensive after consolidation than before. This added expense offsets some or all of whatever savings might occur by having the remainder of Sierra Vista's [172] laboratory tests performed along with French's tests at French.²⁶

RX 5614 concludes that consolidation will permit AMI to save \$38,000 per year by consolidating the contracts with outside laundry firms of the hospitals. This assumes, without explanation, that the same volume of laundry would cost less under one contract for both French and Sierra Vista than under two separate contracts with the same laundry. There is nothing in the record explaining why it is necessary for both French and Sierra Vista to be owned by AMI to gain whatever advantages there may be to joint purchasing of laundry services, nor is there any explanation why this savings already has not been realized by AMI since institution of joint purchasing of laundry services would be simple to commence and to terminate, if necessary. RX 5614 also concluded that, through consolidation, \$89,000 could be saved through purchasing of food supplies for French at the price paid by Sierra Vista. This conclusion does not take into account the possibility that French used food supplies of higher quality than those Sierra Vista uses, or offers a menu requiring more expensive food than Sierra Vista uses.

There would be a great number of decisions AMI would have to make to perform the variety of tasks required by consolidation. Mr. Mittelstaedt asserted that there would be no costs to AMI involved in

²⁶ The joint laboratory may prove impractical, much like the mobile van service instituted by AMI, which was questioned in the beginning by knowledgeable AMI officials (see F. 225), and which lasted only two years before each hospital went back to using its own equipment. (See F. 224)

the administrative expense of the employees making those decisions. French and Sierra Vista are two miles apart. RX 5614 does not take into account the costs of transporting personnel and goods between French and Sierra Vista after consolidation. The supervisors listed on RX 5614, some of whom would be in charge of activities at both French and Sierra Vista after consolidation, periodically might have to shuttle back and forth between the facilities. It would also be necessary to transport specimens between the Sierra Vista and the consolidated clinical laboratory and pathology department at French, and to deliver supplies from the central inventory facility at one hospital to the other hospital.

In short, it is unlikely that the consolidation of French and Sierra Vista, should it occur, will result in the cost savings projected by AMI. If one includes only the cost of [173] capital expense and the depreciation expense, the annual potential savings drop from \$1.2 million to about \$160,000. Other assumptions and omissions noted above will reduce these savings even further.

Most of the savings projected by Friesen are from capital cost savings, which it suggests, will be in excess of \$12.7 million. This figure represents the difference between the \$20.9 million in capital improvements required to maintain Sierra Vista as a first-rate independent hospital if consolidation does not occur, and the \$8.1 million required to consolidate services at both facilities.²⁷ In addition to the obstacles to any consolidation which may prevent its being completed, there are a number of reasons why AMI may not spend \$20 million plus to renovate Sierra Vista. First, there is no proof that such expenditures are necessary. Of the \$20.9 million in capital expenditures, over \$17 million are expenditures which AMI claims are needed at once. All of these problems existed before AMI acquired French, but AMI has not found it necessary to make such expenditures up to this time. Sierra Vista is already a first-rate hospital, and Mr. Mittelstaedt admitted that more modest changes could be instituted which would maintain the status quo at Sierra Vista. The suggested changes might improve the facility, but one may reasonably question how dire the need for such changes really is. Secondly, assuming *arguendo* that such changes are needed, AMI may not be willing to spend almost \$21 million to make them in a market area that "does not present an ideal situation in terms of market growth and development" and where "[g]rowth in the community is not expected to be high enough to justify major capital expenditures across the board of AMI hospitals." (RX 5435Z66) In fact, AMI could probably build a new hospital for less

²⁷ Whether consolidation or capital improvements occur, the costs associated with the capital improvements will be added to the hospitals' basis for computing costs and passed on to patients. (See F. 33) Thus, one could question whether any "efficiencies" have been realized for consumers.

than \$20.9 million. In April 1981, AMI Executive Vice President R. Bruce Andrews told a group of security analysts: "We are still building hospitals at costs averaging \$50,000 - \$60,000 per bed, fully equipped, particularly in rural or semi-rural areas." (CX 430Q) Using Mr. Andrews' figures, AMI could build a new Sierra Vista, from the ground up—with the 50 bed addition contemplated by RX 5614—for approximately \$13 million, or \$7 million less than the proposed renovation of Sierra Vista. [174]

AMI would need a certificate-of-need to make the changes envisioned by RX 5614. California's health planning authorities will closely scrutinize such a large proposed capital expenditure (Johns, 1879-1883), both as to whether the improvements are really necessary and whether more modest improvements would be sufficient. In addition, more than \$3.1 million of the proposed capital expenditures, for addition of 50 beds in the late 1980's, may not be approved. San Luis Obispo County is overbedded and is likely to remain so for some time in the future. Thus, California's health planning authorities are unlikely to approve additional beds in the area. The original Friesen reports for San Luis Obispo noted that the HSA "did not see a need for additional beds in the San Luis Obispo County planning area. . . . Any program involving the addition of beds will be difficult." (RX 5435U)

To the extent that AMI spends less than \$20.9 million to renovate Sierra Vista, the alleged savings realized by consolidating are correspondingly reduced. It is in AMI's interest to make these capital costs appear as high as possible to accentuate the supposed savings to be realized from consolidating with French. This would explain some of the inconsistencies between the \$20.9 million figure and other evidence in the record. For example, AMI has already applied for a certificate-of-need for a more spacious emergency room at Sierra Vista. (Carlson, 1344-45) This project may obviate the need for part of the construction program outlined at RX 5614R-S, particularly the \$900,000 temporary relocation of the emergency room and the \$11,500,000 for new construction. Also, most of the \$20.9 million would go for new construction which would cost \$160 (in 1982 dollars) per square foot. (RX 5614N)²⁸ The Friesen reports, which were also overseen by Mr. Mittelstaedt, projected the cost of new construction at \$120 per square foot (in 1981 dollars). (RX 5435Z65) It seems unlikely that the \$40.00 per square foot difference is due entirely to one year of inflation.

²⁸ This is the price for new construction needed as part of the consolidation with French. (RX 5614N) It is assumed that the cost is the same for new construction required under the plan to renovate Sierra Vista.

2. Legal Analysis

The Commission recently stated the position that efficiencies resulting from a merger cannot be used to justify a merger whose legality has been challenged under the antitrust laws: [175]

While [evidence of some types of efficiencies] is appropriate for consideration by the agency in the exercise of its prosecutorial discretion at the pre-complaint stage, the Commission believes that there are too many analytical ambiguities associated with the issue of efficiencies to treat it as a legally cognizable defense.

Statement Of Federal Trade Commission Concerning Horizontal Mergers, at 9. Chairman Miller dissented on this point, stating that he "believes that scale-type efficiencies should be considered as part of the legal analyses. . . ." *Id.* at 9 n.22.

Cases decided over the years are generally interpreted as rejecting efficiency arguments in merger cases. In *FTC v. Procter & Gamble Co.*, 386 U.S. 568 (1967), the Supreme Court stated: "Possible economies cannot be used as a defense to illegality. Congress was aware that some mergers which lessen competition may also result in economies but struck the balance in favor of protecting competition." *Id.* at 580. The Court reached this conclusion despite the existence of internal Procter & Gamble memoranda which predicted that the merger would lead to large cost savings in promotion, sales, and distribution. See *Procter & Gamble Co.*, 63 F.T.C. 1465, 1541-42 (1963).

This holding in *Procter & Gamble* followed logically from the Court's earlier reasoning in *United States v. Philadelphia National Bank*, 374 U.S. 321 (1963):

We are clear, however, that a merger the effect of which "may be substantially to lessen competition" is not saved because, on some *ultimate reckoning of social or economic debits and credits*, it may be deemed beneficial. A value choice of such magnitude is beyond the ordinary limits of judicial competence, and in any event has been made for us already, by Congress when it enacted the amended § 7.

Id. at 371 (emphasis added).

Further, in *Ford Motor Co. v. United States*, 405 U.S. 562, (1972), the Supreme Court stated: "It is argued, however, that the acquisition has some beneficial effect in making Autolite a more vigorous and effective competitor . . . than Autolite had been as an independent. But what we said in *United States v. Philadelphia National Bank* . . . disposes of that argument." *Id.* 569-570 [176]

Other considerations militate against accepting at face value an efficiency defense. It is extremely difficult for the fact finder to measure the existence and magnitude of claimed efficiencies because they often involve assumptions, overstatements, speculations, and ques-

tionable methodology offered by an interested party who has control of the supporting information. Judge (then Professor) Posner has termed efficiencies in merger cases "an intractable subject for litigation." R. Posner, *Antitrust Law* 112 (1976) The illusive nature of alleged efficiencies and resulting cost savings has been clearly stated by respondents' expert, Dr. Carl Schramm, in writings published prior to this litigation. (See p. 168-169 *supra*; see also F. 211) It is also difficult to ascertain with reasonable certainty which asserted savings can, or cannot, be effectuated through other means much less anticompetitive than a merger.

It also is extremely difficult to measure how much increased efficiency is needed to outweigh the expected effects of a merger in terms of an increase in market power. Concerning the trade-off between market power and efficiency, Judge (then Professor) Bork concluded that "[p]assably accurate measurement of the [required information] is not even a theoretical possibility; much less is there any hope of arriving at a correct estimate of the hypothetical situation." R. Bork, *The Antitrust Paradox* 125 (1978).

The difficulties which some learned authorities have posited in attempting to accurately gauge the efficiencies of a merger are present in this proceeding. Attempting to balance alleged cost savings versus an anticipated increase in market power (the anticompetitive effects of which are demonstrated in this record) and a possible loss of consumer satisfaction,²⁹ together with the Commission's policy decision in its Statement Of Federal Trade Commission Concerning Horizontal Mergers, make it unwarranted based on the record and inappropriate under legal precedent to sustain respondents' attempted efficiencies defense. [177]

H. *The Planning Act Does Not Confer an Antitrust Exemption*

Respondents contend that the challenged acquisition is not subject to the antitrust laws. The National Health Planning and Resources Development Act ("NHPRDA"), 42 U.S.C. 300k-300s (1976 & Supp. IV 1980), depends for its effectiveness on voluntary actions by providers to reduce excess hospital capacity. The local implementing agency, the Mid-Coast Health Systems Agency, had advocated mergers of hospitals in order to alleviate over-capacity and duplicative hospital services in San Luis Obispo. AMI further contends that its acquisition of French and its plans to merge that facility with Sierra Vista were intended and reasonably calculated to advance that goal. Thus, ac-

²⁹ Dr. Schramm, respondents' expert, has noted this possibility: "Interestingly, however, prices do not always reflect the savings of consolidation and artificial price settings must be controlled through regulation. The apparent risk in consolidation from the consumer perspective is that prices may not reflect true savings. The costs of consolidation are expressed as both higher market prices and lost flexibility in the market." (CX 1048S)

cording to respondents, an antitrust exemption in this case is necessary to make the Planning Act work. (RB, p. 1)

The current system of health planning was established by Congress in 1974 when it enacted NHPRDA.³⁰ This legislation set up a series of mandatory Health Systems Agencies (HSAs) which cover every area in the country. HSAs are responsible for health planning within each area and are private, rather than governmental organizations. Congress required that the HSAs be made up of both providers and consumers, with consumers being the majority and adequately reflecting the various groups represented in the local population. In NHPRDA, Congress required HSAs to perform certain specific functions. (42 U.S.C. 300k-1, 300l-4(c)(1)(A) (1976 & Supp. IV 1980) These functions are to produce health systems plans; to conduct project reviews, including certificate-of-need reviews; to do "Proposed Uses of Federal Funds" reviews; and to conduct other reviews as requested by other agencies. California has fourteen HSAs. (CX 533B) HSA 8, the Mid-Coast HSA, includes the counties of San Luis Obispo, Monterey, San Benito and Santa Cruz. (RX 5466F-G, T, Z7)

A Health Systems Plan is a document prepared by the HSA which discusses the health care needs and goals of the health systems area. It is approved at the state level and then by federal officials who review it for "scope, quality, and consistency with federal planning policies." (Johns, 1973) Health systems plans often make general recommendations [178] concerning how certain goals should be achieved; however, the HSA has no power to enforce these recommendations. Furthermore, plans do not make recommendations about specific institutions.

HSAs are also required to produce documents called Annual Implementation Plans ("AIPs"). The AIPs are supposed to take the recommendations contained in the health systems plan and discuss when and how they should be implemented. "These recommendations [in the AIP] usually take the form of committees should be formed, meetings should be held, studies should be undertaken and so forth." (Johns, 1915) Like the Health Systems Plans, AIPs do not specify which hospitals should undertake any of the steps specified in the plans. (*Ibid.*)

Another major function of HSAs is making recommendations on certificates-of-need ("CON") applications. Each state is required to have a CON program; before a provider can undertake certain projects, it must first receive a CON. The granting of a CON represents a judgment by the state that a proposed project is consistent with local needs and state policies. Projects requiring CONs (except in excep-

³⁰ See *National Gerimedical Hospital & Gerontology Center v. Blue Cross of Kansas City*, 452 U.S. 378 (1981) for a succinct discussion of the federal health planning laws.

tional circumstances) include new hospitals, expansion of bed capacity at existing hospitals (except for small increases by hospitals with high occupancy rates), transfer of beds from one license classification to another, and other major capital expenditures for a hospital. (See F. 84-86) Federal law does not compel states to require a CON for a change of ownership not also involving changes in services or bed capacity. (42 U.S.C.A. 300m-6(d)(1) (West Supp. 1982)) California law expressly exempts acquisitions of hospitals from CON review of capital expenditures. (*Cal. Health & Safety Code* Section 437.10 [Deering Supp. 1983]; see also RX 5821Z5; Johns, 1915)

In California the state planning agency, required by NHPDA, is the Office of Statewide Health Planning and Development ("OSHDP"). This office passes on CON applications and produces a statewide health plan which makes policy recommendations concerning health care needs of the state. This office has no power to enforce its recommendations. California also has an Advisory Health Council which performs the functions which the NHPDA specifies are to be performed by a Statewide Health Coordinating Council (SHCC).

The OSHDP and other organizations have consistently noted that extensive excess capacity exists throughout California. According to one estimate, there are about 10,000 excess beds in the state. In addition, it was also determined that there were excesses in "nearly every conceivable type of service in the state." (Johns, 1912-13) Nearly every HSA in its health systems plan notes the existence of excess capacity and makes some general recommendations concerning its elimination. [179]

Prior to the acquisition of French, the Mid-Coast HSA had determined in the 1978-1983 Health Systems Plan and the 1979-1984 Health Systems Plan that excess beds existed and would exist in the future. The 1978-1983 Plan, for example, noted that by 1983, San Luis Obispo County would have an excess of 169 medical-surgical beds (RX 5466Z178); 12 perinatal beds (RX 5466Z275); and 19 intensive care/coronary care beds. (RX 5466Z260) The 1979-1984 Health Systems Plan also found an excess in medical/surgical beds (RX 5467Z190); pediatric beds (RX 5467Z225); intensive care/coronary care beds (RX 5467Z280); and perinatal beds. (RX 5467Z295) Mid-Coast HSA has long considered consolidation of services as a solution to the problem of excess capacity. (See e.g., RX 5460Z39, Z42; RX 5461Z1-Z6, Z11-Z14; Z30; RX 5462Z11, Z12, Z15, Z17; RX 5466P, Z57, Z181, Z209-Z211, Z265-Z266, Z283-Z285, Z290-Z291)

Although Congress allowed the planning authorities veto power over the addition of unneeded new health care facilities through the CON process, reductions in unneeded existing facilities and services were to be implemented through the voluntary efforts of providers:

The apparently modest initial means of implementing health plans, seeking the assistance of individuals and entities in the health service area to do so, is in fact the most important method available. . . . [T]he agency must be willing to seek the cooperation of established health entities in the community including physicians, hospitals, and HMOs.

H.R. Rep. 1382, 93d Cong., 2d Sess. 60. *See* Conf. Rep. No. 1640, 93d Cong., 2d Sess. 69, 73 (1974), *reprinted in* 1974 U.S. Code Cong. & Ad. News 7971 at 7979, 7983.

AMI did not consult with the Mid-Coast HSA concerning its plans for the acquisition of French Hospital, nor did AMI consult with the HSA concerning its plans for consolidation of French and Sierra Vista. Since acquiring French Hospital, AMI has not closed any hospital beds. The consolidation of French and Sierra Vista set out in the study prepared by Mr. Mittelstaedt for this proceeding also would not result in any reduction in beds. Further, no individual service will experience a net reduction in beds; the excess beds simply will be shifted from one hospital to another. For example, in 1985 San Luis Obispo County will have an excess of 116 medical/surgical beds. The proposed consolidation of French and Sierra Vista contemplates reducing the number of [180] medical/surgical beds at French by 18 and increasing them by the same amount at Sierra Vista. In 1985 there will be an excess of nine perinatal or obstetric beds. AMI proposes to move the 12 existing obstetric beds at Sierra Vista to French. In 1985 there will be an excess of 10 pediatric beds; AMI plans to supplement the 10 beds at French with 6 additional beds now at Sierra Vista. Finally, in 1985 there will be an excess of 15 ICU/CCU beds. (RX 5469Z21) AMI plans no change in the 8 ICU/CCU beds which exist at each hospital. (RX 5614L-M)

In addition to being concerned about excess beds, the Mid-Coast HSA also was concerned with unnecessary duplication of services. Rather than act consistently to reduce duplicative services where ever possible, AMI in its consolidation plan for French and Sierra Vista has decided selectively which HSA goals it wishes to advance and which it does not. Again, its actions suggest that it is not concerned initially or primarily with furthering the HSA's goals.

Thus, respondents' position that the acquisition of French was "intended" to advance the goals of the local HSA (RB, p. 1) is not supported by the record. AMI's concern was entirely profit-motivated, to make an acquisition that would meet its profit objectives,³¹ while

³¹ Prior to making a commitment to purchase French, AMI officials wrote:

In summary, I view French as a viable, productive acquisition. The \$11.0 million purchase price for the hospital equates to nearly \$80,000/bed, a premium price. However, the necessary bottom line can be met and exceeded.

(CX 41C)

(footnote cont'd)

enabling it to control health care services in San Luis Obispo County.³² [181]

The Supreme Court has determined that NHPDA does not provide a blanket antitrust exemption for conduct alleged to be consistent with the plans of an HSA; nor is such conduct immunized from antitrust scrutiny because it is intended to aid implementation of an HSA plan. In *National Gerimedical Hospital & Gerontology Center v. Blue Cross of Kansas City*, 452 U.S. 378 (1981), the court held that although Blue Cross may have acted with only the highest motives in seeking to implement the plans of the local HSA, it cannot defeat an antitrust claim by the assertion of immunity from the requirements of the Sherman Act. The court further noted that implied antitrust immunity can be justified only by a convincing showing of clear repugnancy between the antitrust laws and the regulatory systems. Even when an industry is regulated substantially, this does not necessarily evidence an intent to repeal the antitrust laws with respect to every action taken within the industry. An intent to repeal the antitrust laws is much clearer when a regulatory agency has been empowered to regulate the type of conduct under antitrust challenge.

The action challenged in *National Gerimedical Hospital* was neither compelled nor approved by any governmental regulatory body. Instead, it was a "spontaneous response" to the finding of only an advisory planning body, the local HSA, which, under the NHPDA, had no regulatory authority over health-care providers. The court held that the application of the antitrust laws to the Blue Cross conduct would not frustrate a particular provision of NHPDA or create a conflict with the orders of any regulatory body; nor is NHPDA so incompatible with antitrust concerns as to create a "pervasive" repeal of the antitrust laws as applied to every action taken in response to the health-care planning process. 452 U.S. at 393. [182]

National Gerimedical Hospital governs AMI's claim of immunity in this case. Like Blue Cross's policy, AMI's acquisition was neither compelled nor approved by any governmental, regulatory body. No regulatory system applied to the acquisition because neither state nor federal law required or provided for issuance of a certificate-of-need for hospital acquisitions. The HSA did not review or approve of the

In summary, the acquisition of [French] appears to be a unique opportunity for AMI. It would be immediately profitable, achieve our rate of return objective and provide additional growth.

(CX 38F)

³² Mr. Dennis Danko, an AMI Vice President concerned with the French Hospital acquisition, wrote:

[W]e face a choice of paying a premium price, thus controlling health care services, while meeting our earnings expectations, or continue to struggle to capture basically the same patient load with French, or another operator such as N.M.E., who may purchase French. It would be my recommendation that we proceed with the acquisition as outlined.

(CX 41C-D)

acquisition, nor was it consulted in connection with the acquisition. As a result, as was the case in *National Gerimedical Hospital*, application of the antitrust laws to AMI's acquisition would not "frustrate a particular provision of NHPRDA or create a conflict with the orders of any regulatory body." 452 U.S. at 390. Since nothing in NHPRDA required or authorized AMI to acquire French Hospital, there is no "clear repugnancy" between NHPRDA and the antitrust laws with respect to the acquisition. *Id.* at 391.

The doctrine of implied repeal is a mechanism for reconciling the antitrust laws and a subsequently enacted regulatory system. In fact, however, NHPRDA does not create a regulatory system that even applies to the acquisition at issue in this case. As the Supreme Court ruled in *National Gerimedical Hospital*, nowhere does the Act direct or authorize private conduct designed to implement HSA plans. *Id.* at 391. It is clear that the Mid-Coast HSA, like other HSAs, does not have regulatory power over hospitals or other health care providers. *Id.* at 385. Neither the HSA nor any other regulatory body possessed authority to approve or require the acquisition. As a result, as was the case in *National Gerimedical Hospital*, there can be no direct conflict between NHPRDA and the antitrust laws with respect to the acquisition, and implied immunity is not necessary to make the Act work. Since both statutory schemes can coexist without direct conflict, both will apply. At most, NHPRDA only directs HSAs "to the extent practicable" to seek to implement their plans "with the assistance of individuals and public and private entities." 42 U.S.C. 3001-2(c)(1). There is no basis in the Act for inferring a Congressional intent to immunize AMI's independent, private conduct from the antitrust laws, even if that conduct is arguably consistent with the objectives of the HSA or of NHPRDA.³³ [183]

The acquisition in question was a profit-motivated, unilateral, voluntary act that may incidentally have been consistent, to some extent, with Mid-Coast HSA's goals. On this slim straw AMI is now, for the purposes of this litigation, attempting to hide behind the skirts of NHPRDA. If AMI's argument is accepted, then virtually all voluntary, noncoercive behavior that arguably furthers the goals of an HSA would be exempt from the operation of the antitrust laws. Under this reasoning the rule of restricted applicability of implied repeal established by *National Gerimedical Hospital* and earlier cases would be

³³ To the extent AMI seeks immunity from the antitrust laws based on footnote 18 in *National Gerimedical Hospital & Gerontology Center v. Blue Cross of Kansas City*, 452 U.S. 378, 393 n. 18 (1981) (see RB, p. 21; Resp. Reply Brief, p. 12), such reliance is misplaced. Footnote 18 suggests that the court did not intend to foreclose future claims of antitrust immunity in other factual contexts. The court indicates that immunity might be appropriate for HSAs and State agencies in the exercise of their authorized powers, and where an HSA has expressly advocated a form of cost saving cooperation among providers where it is necessary to make NHPRDA work. Here we do not have an expressly advocated form of cooperation among providers that is necessary to make NHPRDA work; instead, this proceeding concerns the unilateral, profit-motivated act of AMI in eliminating its principal competitor.

pervasively abrogated. AMI has failed to meet the test for implied immunity from the antitrust laws set out by the Supreme Court. In addition, it is concluded that AMI's acquisition of French Hospital was not intended or reasonably calculated to advance the goals of the HSA. AMI's argument that its acts are exempt from Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act is rejected.

I. The Remedy

The Notice of Contemplated Relief served with the complaint included, but is not limited to (1) a requirement that AMI divest the assets acquired in the French Hospital acquisition, and (2) a requirement that for a period of ten years, AMI obtain prior Commission approval before making any future acquisition of any general acute care hospital located within the marketing area of a hospital owned or operated by AMI or one of its subsidiaries. In complaint counsel's post-trial brief, the prior approval provision has been limited to thirteen "sunbelt" states where AMI presently owns hospitals. Complaint counsel also would require the prior approval in the thirteen "sunbelt" [184] states of an acquisition where AMI leases or manages a hospital. (See F. 242)

AMI points out that the purpose of divestiture relief is to restore prior competition to a market; citing *Ford Motor Co. v. United States*, 405 U.S. 562, 573 (1972); *United States v. E. I. du Pont de Nemours and Co.*, 366 U.S. 316 (1961); *Retail Credit Co.*, 92 F.T.C. 1, 161 (1978), *vacated and remanded on other grounds sub. nom.; Equifax, Inc. v. FTC*, 618 F.2d 63 (9th Cir. 1980). Where divestiture will not have this effect, such relief constitutes a penalty rather than a remedy and is therefore impermissible.

According to AMI, divestiture would not be appropriate in this case because it would not restore any appreciable competition that existed prior to the acquisition. Due to the prevalence of third-party hospitalization coverage in San Luis Obispo, meaningful price competition among AMI and French Hospital would not arise following divestiture. Furthermore, it is not possible to restore significant competition for physicians among hospitals in San Luis Obispo since little existed prior to the acquisition due to physician polarization in the community. In any event, this latter form of "competition" is precisely that which Congress has determined leads to duplicative equipment and excess hospital capacity. Thus, at best, divestiture would have the effect of fostering a form of business rivalry that Congress has sought to discourage because it results in costly excess and waste. (See RB, p. 157)

AMI also opposes any prior approval requirement on the grounds

that complaint counsel has not established the prerequisites for such a remedial provision. According to AMI the record does not contain any support for a prior approval requirement that would apply to proposed acquisitions in markets other than those alleged by complaint counsel to constitute the relevant markets in this action [San Luis Obispo City and County]. There is no showing that AMI deliberately violated the antimerger laws by acquiring French, that AMI is likely to disregard the antimerger laws in the future, or that there is a "merger trend" in the industry necessitating such broad relief. The proposed prior approval requirement would unfairly handicap AMI's ability to participate in the competitive market that exists for the right to acquire hospitals that are looking for new owners. This lessening of competition is not justified by any legitimate enforcement need of the Commission. (*See Resp. Reply Brief*, p. 193)

AMI also argues that a prior approval clause would not serve any reasonable purpose since the Commission can readily monitor [185] AMI's acquisitions by means of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a (1976). (*See RB*, 166)

It has already been concluded that AMI's acquisition of French Hospital violated the Clayton and Federal Trade Commission Acts, and that substantial actual and potential competition has been restrained and eliminated. Consequently, an appropriate remedy must be determined. It is well-settled that the Commission has wide discretion in framing an order deemed adequate to cope with the violation of law found to exist. *FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 392-93 (1959); *L. G. Balfour Co. v. FTC*, 422 F.2d 1, 23 (7th Cir. 1971). In cases where a violation of Section 7 is found, the most effective remedy to correct the injury to competition is generally held to be divestiture. *Ford Motor Co. v. United States*, 405 U.S. 562, 573 (1972); *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 326-35 (1961). A ban on future acquisitions usually is ordered to prevent repeat violations. *Liggett & Meyers, Inc.*, 87 F.T.C. 1074, 1140, 1183 (1976), *aff'd*, 567 F.2d 1273 (4th Cir. 1977). As Commissioner Pertschuk recently stated in *Damon Corporation*, Dkt. C-2916, Order to Show Cause Why Order Requiring Commission Approval For Certain Acquisitions Should Not Be Modified (Dissenting Statement), March 29, 1983 [101 F.T.C. at 693]:

Prior approval provisions, of course, have been a common fencing-in feature in decades of Commission orders. By requiring firms who have engaged in illegal mergers to get Commission approval before making future acquisitions, a prior approval provision serves both as a prophylactic measure designed to prevent future law violations by the same firm and as a deterrent to other firms which might violate the antitrust laws. As such, a prior approval provision is a modest and sensible restraint on firms that have demonstrated a propensity to violate the law.

In 1980 there were 5,830 community hospitals in the United States with a total of 988,000 beds. Seventy percent of these beds are owned by private, non-profit entities. Another 21 percent are owned by state or local government bodies. In 1972, 6.5 percent of the beds in community hospitals were controlled by for-profit entities. In 1980, that had grown to 8.8 percent. (RX 5719) That 8.8 percent includes all hospitals owned by for-profit organizations, such as doctor or other investor groups, as well as hospitals owned by for-profit multi-hospital systems such as AMI. (RX 5718, RX 5719) The five largest proprietary hospital chains, Hospital Corporation of America, Humana, AMI, National Medical Enterprises, and Lifemark [186] acquired a total of 192 general acute care hospitals in the years 1975-1981. (CX 608; Silvia, 794-95) During their fiscal year 1975, these firms acquired a total of three hospitals; in their fiscal year 1981, they acquired a total of 80 hospitals. To the extent that this acquisition pace cannot be termed a merger trend, the industry does appear to present conditions that are conducive to mergers.

AMI currently owns, operates or has under construction 75 hospitals in the United States. Nearly all of these hospitals were obtained through acquisition. AMI has acquired 19 general acute care hospitals since 1980. Furthermore, AMI will continue to grow by acquiring hospitals. In 1980, AMI's President stated that the objective of the company was to acquire between four and six hospitals a year, but that it might make acquisitions at a more rapid rate if the right opportunities presented themselves. (CX 430A, C, L, W) Charles P. Reilly, AMI's Senior Vice President responsible for supervising activities directed toward development of new hospitals and the acquisition of hospitals, testified that because of health planning legislation which seeks to limit the expansion of bed capacity and physical plant investment and equipment investment, there are substantially more opportunities to buy hospitals than there are to initiate and charter new ones.

Hospitals typically are owned by one of three groups: a government entity, a non-profit religious or charitable organization, or a for-profit investor group. Because of advances in hospital technology and increases in construction costs required for renovating or replacing an aging facility, establishing and operating a hospital of state-of-the-art quality is quite expensive. Local governmental agencies, religious groups or small investor groups, sometimes cannot obtain the capital necessary to provide needed health care services and therefore decide to sell the hospital. Multi-hospital systems compete to purchase these hospitals by offering financial terms and commitments to provide health services and management expertise which meet the communi-

ty's needs. This competition among multi-hospital systems for acquiring hospitals is intense.

AMI contends that the prior approval order sought by complaint counsel is likely to substantially lessen competition among multi-hospital systems for acquisition of hospitals. The bidding and negotiation involved in hospital acquisitions proceed at a rapid pace and effective participation in that process requires the ability to make a firm commitment in a relatively short period. A prior approval requirement would undermine AMI's ability to put forth a firm offer in a timely fashion. This would be fundamentally different from the Hart-[187]Scott-Rodino filing requirement, or a requirement under state law to obtain CON approval, because such requirements are equally applicable to all purchasers. The prior approval remedy, in contrast, would apply only to AMI and would place a unique condition upon AMI's offer. Mr. Reilly also testified that a perception by hospital sellers that AMI is subject to special conditions may cause them not to contact AMI initially, even where the order does not by its terms apply, and thus AMI would not have the opportunity to compete. (Reilly, 1851)

In contrast to the testimony of AMI officials in this proceeding, AMI stated in its 1981 Form 10-K, filed with the Securities and Exchange Commission, as follows: "In the opinion of the Company's management, divestiture of French Hospital and a reasonable preacquisition screening mechanism would not have a material adverse effect on the Company's business or financial condition." (CX18M)

The divestiture of French Hospital is the most appropriate remedy to restore competition in the general acute care hospital services market in the city and county of San Luis Obispo. Further, a prior approval remedy also is appropriate. The evidence establishes that AMI in the past has grown largely through acquisitions, and because of health planning laws which limit opportunities for the development of new hospitals, AMI will continue to seek to grow through acquisitions in the future. Thus, a prior approval clause is a necessary remedial provision.

Restoring competition that has been eliminated by an illegal merger, once it is consummated, is a time-consuming and difficult process, often taking years of litigation and additional years to secure compliance with a final divestiture order. Even then, the divested entity may never regain the competitive vigor and strength that it had before being acquired. During the lengthy delay from an illegal acquisition until a successful divestiture, the public has suffered from the loss of competition. The Commission, therefore, has regularly used a prior approval clause remedy, with respect to corporations that have already made anticompetitive acquisitions, to obtain a better opportuni-

ty to prevent future anticompetitive acquisitions before they take place and cause injury to the public. As the Commission stated in *Beatrice Foods Co.*, 68 F.T.C. 1003 (1965), "Prophylactic relief, not merely the after-the-fact remedy of divestiture, is essential if the Congressional policy expressed in Section 7 of the Clayton Act is to be effectively carried out. . . ." *Id.* at 1006.

Although the analysis used in merger cases has evolved over the years, the Commission consistently has utilized prior [188] approval as a remedial tool in merger law enforcement. Since January of last year, the Commission has issued final orders in seven merger cases,³⁴ and two consent agreements involving mergers have been accepted but are not yet final.³⁵ All nine contain prior approval relief. In three of the four, where the relevant geographic market was local or regional, prior approval is required for all horizontal acquisitions anywhere in the country.³⁶

The Hart-Scott-Rodino Antitrust Improvements Act of 1976 is a reporting act, not an approval requirement. Not only may the Act's reporting requirements not reach some anticompetitive acquisitions,³⁷ but the Act does not prevent unlawful acquisitions. The reporting party can proceed with an acquisition unless the Commission takes affirmative legal action to prevent the acquisition, or if the acquisition is permitted to proceed, lengthy litigation is necessary to correct the violation. The fact that the Commission has continued to include prior approval clauses in merger orders is clear indication the Commission does not believe Hart-Scott-Rodino offers sufficient protection.

AMI's contention that the prior approval requirement will severely handicap it in its competition for hospitals seem overblown, as starkly revealed in its Securities and Exchange Commission filing. Because of the lengthy negotiations that [189] take place before a hospital is acquired (*see* RPF 16.44-16.45, 16.48), possible certificate-of-need and Hart-Scott-Rodino requirements, time is not as significant in the acquisition process as AMI posits. Further, where time is of the essence, AMI can request an early determination. The Commission has honored such requests under the Hart-Scott-Rodino Act on numerous

³⁴ *Gulf & Western Industries, Inc.*, Dkt. No. 9153 (FTC Apr. 14, 1983) [101 F.T.C. 707]; *ConAgra, Inc.*, Dkt. No. C-3103 (FTC Feb. 16, 1983) [101 F.T.C. 50]; *Canada Cement Lafarge Ltd.*, Dkt. No. C-3100 (FTC Dec. 21, 1982) [100 F.T.C. 563]; *Batus, Inc.*, Dkt. No. C-3099 (FTC Dec. 6, 1982) [100 F.T.C. 553]; *General Electric Co.*, Dkt. No. C-3088 (FTC May 4, 1982) [99 F.T.C. 422]; *Gifford-Hill-American, Inc.*, Dkt. No. C-3085 (FTC Feb. 23, 1982) [99 F.T.C. 372]; *Xidex Corp.*, Dkt. No. 9146 (FTC July 1, 1983) [102 F.T.C. 1].

³⁵ *Coca-Cola Co.*, File No. 821-0100 (FTC Apr. 26, 1983) [102 F.T.C. 1102]; *Allied Corp.*, File No. 811-0191 (FTC Dec. 8, 1982) [101 F.T.C. 721].

³⁶ *Canada Cement Lafarge Ltd.*, Dkt. No. C-3100 (FTC Dec. 21, 1982) [100 F.T.C. 563]; *Batus, Inc.*, Dkt. No. C-3099 (FTC Dec. 6, 1982) [100 F.T.C. 553]; *Gifford-Hill-American, Inc.*, Dkt. No. C-3085 (FTC Feb. 23, 1982) [99 F.T.C. 372].

³⁷ The Commission has a request for comments on a proposal to raise the Hart-Scott-Rodino threshold requirement for filing a premerger report from \$15 million to \$25 million. 47 FR 29181 (July 2, 1982).

occasions, and there is no reason to suppose the Commission would not honor AMI's request for a speedy determination under a prior approval clause.

Complaint counsel seeks to include in the prior approval provision of the order hospitals which AMI leases or manages. This provision appears appropriate and will be included in the Order. AMI has managed hospitals in the past, and may do so in the future. A management contract can give the management firm responsibility for running the hospital's day-to-day operations, including decisions as to staffing levels and other personnel policies, and supply and equipment purchases. In at least some cases, key hospital employees (such as the administrator, controller, and director of nursing) are employed by the management firm rather than by the hospital's owners. Even in areas for which the hospital's owners may be responsible, the management firm may make recommendations to the owners, and therefore exercise some influence over those decisions. The anticompetitive consequences of an acquisition by AMI where it already has a management arrangement in existence could create the same anticompetitive problems as if the hospital were owned outright.

Complaint counsel has proposed limiting the prior approval requirement to 13 states located in the "sunbelt" where AMI currently owns hospitals. Under complaint counsel's proposal the prior approval clause would not apply in the remaining 37 states. This is substantially less coverage than the Commission usually requires. Under a nationwide prior approval requirement, the order would become effective only *after* AMI acquires its first hospital in an area. If AMI does acquire a hospital in the remaining 37 states, then the public at that time requires the same protection as in the states where AMI now operates. While Complaint counsel has failed to offer a convincing basis for this proposed narrowing of the prior approval requirement, especially in view of past Commission precedent, I will not enlarge the relief beyond that which complaint counsel seeks.

The remaining proposals by complaint counsel to narrow the prior approval provision of the Order appear appropriate and also will be adopted. [190]

CONCLUSIONS OF LAW

1. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding, and of respondents American Medical International, Inc. and AMISUB (French Hospital).
2. American Medical International, Inc. was, at all times relevant herein, a corporation engaged in commerce, as "commerce" is defined in the Clayton Act, as amended.

3. French Hospital Corporation was, at all times relevant herein, a corporation engaged in commerce, as "commerce" is defined in the Clayton Act, as amended.

4. French Medical Clinic, Inc. was, at all times relevant herein, a corporation engaged in commerce, as "commerce" is defined in the Clayton Act, as amended.

5. The challenged acquisition and other challenged methods of competition of respondents are in and affect commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended.

6. The product market within which to evaluate the competitive effects of the challenged acquisition and the other challenged methods of competition of respondents is general acute care hospital services.

7. The geographic markets within which to evaluate the competitive effects of the challenged acquisition and the other challenged methods of competition of respondents are San Luis Obispo County, California, and the city of San Luis Obispo, California.

8. The effect of the acquisition by respondents of French Hospital Corporation, including the stock and assets acquired from Central Coast Hospital Company and the assets acquired from French Medical Clinic, Inc., has been or may be substantially to lessen competition, or to tend to create a monopoly, in the relevant product and geographic markets, in violation of Section 7 of the Clayton Act, as amended and as applicable on the date of the acquisition, July 19, 1979.

9. The effect of the acquisition of French Hospital Corporation by respondents, including the stock and assets acquired from Central Coast Hospital Company and the assets acquired from French Medical Clinic, Inc., has been or may be substantially to lessen competition, or to tend to create a monopoly, in the relevant product and geographic markets, and so constitute an unfair method of competition in or affecting commerce, in violation of Section 5 of the Federal Trade Commission Act, as amended. [191]

10. Respondents have attempted to monopolize the relevant product and geographic markets. This attempt to monopolize constitutes an unfair method of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended.

11. The Order entered hereinafter is appropriate and necessary to remedy the violations of law which have been found to exist.

ORDER

I

Definitions

It is ordered, That for purposes of this Order the following definitions shall apply:

A. *Acquire any hospital* means to directly or indirectly acquire all or any part of the stock or assets of any hospital, or enter into any arrangement by which AMI obtains ownership, management, or control of any hospital, including the right to lease or manage any hospital.

B. *AMI* means American Medical International, Inc., a corporation organized under the laws of Delaware with its principal executive offices at 414 North Camden Drive, Beverly Hills, California, and its directors, officers, agents, and employees, and its subsidiaries, divisions, affiliates, successors, and assigns.

C. *AMISUB (French Hospital)* means the wholly-owned subsidiary corporation of AMI which was established for the purpose of acquiring and operating French Hospital located in San Luis Obispo, California.

D. *County* also means a county equivalent such as a parish in Louisiana.

E. *General acute care hospital*, herein referred to as *hospital(s)*, means a health facility, [192] other than a federally-owned facility, having a duly organized governing body with overall administrative and professional responsibility and an organized professional staff which provides 24-hour inpatient care, and whose primary function is to provide inpatient services for medical diagnosis, treatment, and care of physically injured or sick persons with short-term or episodic health problems or infirmities.

F. *Operates a hospital* also means to own, manage or lease a general acute care hospital.

G. *SMSA* means a Standard Metropolitan Statistical Area as defined on June 19, 1981, or as may be hereafter amended, by the Office of Management and Budget, Office of Information and Regulatory Affairs.

II

It is ordered, That within twelve (12) months from the date this Order becomes final, AMI shall divest, absolutely and in good faith, all assets, properties, licenses, leases, and other rights and privileges,

tangible and intangible, that AMI acquired from Central Coast Hospital Company, French Hospital Corporation and French Medical Clinic, Inc., together with any subsequent improvements. The purpose of the divestiture is to reestablish French Hospital as a viable competitor in San Luis Obispo County. The divestiture shall be subject to the prior approval of the Federal Trade Commission.

Pending divestiture, AMI shall take all measures necessary to maintain French Hospital in its present condition and to prevent any deterioration, except for normal wear and tear, of any of the assets to be divested so as not to impair French Hospital's present operating abilities or market value. [193]

III

It is further ordered, That for a period of ten (10) years from the date this Order becomes final, AMI shall not, without the prior approval of the Federal Trade Commission, directly or indirectly acquire any hospital located in the states of Oregon, California, Texas, Oklahoma, Missouri, Arkansas, Louisiana, Mississippi, Alabama, Georgia, Florida, South Carolina, or North Carolina, if:

A. The hospital to be acquired is within a Standard Metropolitan Statistical Area ("SMSA") in which AMI already operates a hospital and in which AMI, immediately after the acquisition, would operate hospitals that combined have a twenty (20) percent or more share of the licensed general acute care hospital beds within that SMSA; or

B. The hospital to be acquired is not within an SMSA but is within a county in which AMI already operates a hospital and in which AMI, immediately after the acquisition, would operate hospitals that combined have a twenty (20) percent or more share of the licensed hospital beds within that county; or

C. The hospital to be acquired is (1) not within an SMSA or a county in which AMI already operates a hospital, but is within thirty (30) miles of a hospital which AMI already operates in another SMSA or county, and (2) the hospital to be acquired and any hospital(s) that AMI operates combined have a twenty (20) percent or more share of the licensed hospital beds in the area within thirty (30) miles of the midpoint between the hospital to be acquired and any hospital operated by AMI.

Provided, however, That no acquisition shall be subject to this Section III if the consideration to [194] be paid for the hospital, including assumption by AMI of liabilities of its present owners, does not exceed one million dollars (\$1,000,000).

IV

It is further ordered, That AMI shall, within sixty (60) days after the date this Order becomes final and every sixty (60) days thereafter until it has fully complied with the provisions of Section II of this Order, submit a report in writing to the Federal Trade Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with these provisions.

Such compliance reports shall include a summary of all contacts and negotiations with potential purchasers of the stock and assets to be divested under this Order, the identity and address of all such potential purchasers, and copies of all written communications to and from such potential purchasers.

AMI also shall submit such further written reports as the staff of the Federal Trade Commission may from time to time request in writing to assure compliance with this Order.

V

It is further ordered, That AMI shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed [195] corporate change, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation of dissolution of subsidiaries, or any other change in the corporation which may affect compliance with the obligations arising out of this Order.

MAP OF HOSPITALS IN AND NEAR
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APPENDIX B

TRANSACTIONS OF AMI'S HOSPITALS IN SAN LUIS OBISPO COUNTY, 1978-1981

Payments for Hospital Services

	Medicare	Medi-Cal (Federal share only)*	Other Federal programs**	Selected private insurers***	Interstate purchases****	Total
French	\$10,801,014	\$1,015,309	\$ 518,345	\$1,149,768	\$1,622,315	\$15,106,751
Sierra Vista	23,683,597	1,304,242	652,947	2,445,744	3,327,346	31,413,876
Arroyo Grande	12,196,968	692,601	237,039	587,824	1,781,738	15,496,170
Total:	\$46,681,579	\$3,012,152	\$1,408,331	\$4,183,336	\$6,731,399	\$62,016,797

All amounts are reasonable estimates.

* Figures for French and Sierra Vista are for period from July 1, 1977 to June 30, 1980. Figures for Arroyo Grande are for period from December 1, 1977 to November 30, 1980.

** Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Veterans Administration, and Department of Labor (Federal workmen's compensation).

*** Aetna Life & Casualty Co., the Equitable Life Assurance Society of the United States, Metropolitan Life Insurance Co., Prudential Insurance Co. of America, Republic National Life Group Insurance Co., the Travelers Insurance Companies, and Union Mutual Life Insurance Co.

**** Interstate purchases of drugs, devices, equipment, or supplies. Figure for French includes only purchases from time hospital was acquired by AMI through 1981.

Sources: CX 703; CX 729B-C; CX 734; CX 735.

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APPENDIX C
Inpatient Origin by
ZIP CODES
Calendar Year 1980

	Sierra Vista		French		San Luis		Arroyo Grande		Twin Cities		Total	
	Admissions	%	Admissions	%	Admissions	%	Admissions	%	Admissions	%	Admissions	%
San Luis Obispo Co. ZIP Codes*	6963	92.5%	3314	90.5%	4674	92.4%	2412	91.7%	3577	92.2%	20940	92.0%
No. Santa Barbara Co. ZIP Codes	256	3.4	147	4.0	133	2.6	50	1.9	—	—	586	2.6
Selected Monterey County ZIP Codes	—	—	—	—	—	—	—	—	61	1.6	61	0.3
All Other Areas	307	4.1	199	5.4	254	5.0	167	6.4	241	6.2	1168	5.1
Totals	7526	100%	3660	99.9%	5061	100%	2629	100%	3879	100%	22755	100%

Source: CX 614 through CX 618.

NOTE: Some columns may not add up to 100% due to rounding.

* There were a number of inpatient admissions from ZIP Codes for post office boxes, government, and educational institutions in San Luis Obispo County. These inpatient admissions have been excluded from the San Luis Obispo County totals and are included in the category "All Other Areas."

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APPENDIX D

HOSPITAL MARKET CONCENTRATION STATISTICS BEFORE AND AFTER
FRENCH HOSPITAL ACQUISITION

	AMI Market Share			Two-firm Market Share			Herfindahl-Hirschman Index	
	Before	After	%	Before	After	%	Before	After
CITY OF SAN LUIS OBISPO	Amount	Amount	%	Amount	Amount	%		
1979 Inpatient days	45,090	68,085	87.2	68,085	78,035	100	4370	7775
1979 Hospital beds	172	310	79.9	310	388	100	3634	6788
1980 Gross inpatient revenues	\$19,721,081	\$30,257,621	85.8	\$30,257,621	\$35,273,159	100	4219	7561
1980 Gross hospital revenues	\$21,956,648	\$33,950,550	82.4	\$33,950,550	\$41,210,244	100	3996	7097
SAN LUIS OBISPO COUNTY								
1979 Inpatient days	64,524	87,519	75.5	87,519	106,004	91.4	3818	6025
1979 Hospital beds	251	389	70.6	389	473	85.8	3135	5417
1980 Gross inpatient revenues	\$28,928,448	\$39,473,988	73.3	\$39,473,988	\$48,851,618	90.7	3657	5760
1980 Gross hospital revenues	\$32,877,322	\$44,871,224	71.3	\$44,871,224	\$55,711,240	88.5	3518	5507

Note: None of the above statistics include beds, inpatient days or revenues attributable to the 14 bed psychiatric unit at SLO General Hospital, since that unit does not provide general acute-care hospital services.

The figures for 1980 gross inpatient revenue and gross hospital revenue are calculated from 1981 data contained on CX 572Z118. Each hospital's 1980 gross hospital revenue is computed by dividing its 1981 gross revenue by the sum of 100% and the "% change from prior year" for gross revenue at that hospital. A similar procedure is followed to compute each hospital's 1980 gross inpatient revenue.

Sources: CX 572Z118; CX 600; CX 601; CX 602; CX 606.

OPINION OF THE COMMISSION

By CALVANI, *Commissioner*:

I. INTRODUCTION

Respondent American Medical International, Inc. ("AMI") appeals Administrative Law Judge Ernest G. Barnes' Initial Decision finding that AMI's acquisition in 1979 of French Hospital in the city of San Luis Obispo, California, through its wholly-owned subsidiary, AMI-SUB (French Hospital), violated Section 7 of the Clayton Act, as amended, 15 U.S.C. 18 (1976), and Section 5 of the Federal Trade Commission Act, as amended 15 U.S.C. 45 (1976).¹ Judge Barnes ordered that AMI divest the [3] acquired assets, including all subsequent improvements, and that AMI is prohibited for a period of ten years, without prior approval of the Federal Trade Commission, from acquiring general acute care hospitals in areas where it already owns or operates such a hospital.

AMI's appeal consists of six principal arguments. First, AMI argues that there is no appreciable price competition among hospitals because of the absence of price-sensitive buyers and sellers of hospital care, and that hospitals do not compete in the antitrust sense on nonprice terms, such as service and quality, because hospitals are not restrained by a functioning price mechanism. Second, AMI contends that the antitrust laws do not apply to this acquisition because of the absence of traditional competition between hospitals and because Congress, in enacting the National Health Planning and Resources Development Act, Pub. L. No. 93-641, 88 Stat. 2225 (1975), *codified at* 42 U.S.C. 300k-300s (1976), intended to immunize acquisitions such as this from antitrust scrutiny. Third, AMI maintains that the acquisition was not likely to lessen actual competition substantially in any

¹ Count I of the Complaint alleged that the effects of the acquisition may be to lessen competition substantially or tend to create a monopoly in the general acute care hospital market in San Luis Obispo County, California, and/or parts thereof, in the following ways:

- (a) actual and potential competition among French, Arroyo Grande Community and Sierra Vista hospitals has been eliminated;
- (b) concentration has been substantially increased;
- (c) existing high barriers to entry have been increased and new entry into the market has been foreclosed;
- (d) respondents have acquired a dominant market position; and
- (e) patients, physicians, and group purchasers of hospital services, such as health maintenance organizations, may be denied the benefits of free and open competition based on price, quality, and service in choosing among hospitals.

(Complaint, ¶13) Count II of the Complaint alleged that AMI attempted to monopolize and has otherwise engaged in unfair methods of competition in this market by:

- (a) acquiring French Hospital;
- (b) preventing a competing national proprietary hospital chain from purchasing French Hospital and offering competition to AMI's two hospitals located in San Luis Obispo County; and
- (c) authorizing its three hospitals in San Luis Obispo County to refuse to compete with each other by offering price and other concessions to Los Padres Group Health, a health maintenance organization.

(Complaint, ¶16)

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relevant market because there was no significant pre-existing price or nonprice competition among hospitals there. Fourth, AMI asserts that recent changes in financing of health care, particularly legislation in the state of California that requires group purchasers of hospital care to negotiate with hospitals for favorable rates, may not be relied upon as a basis for retroactively applying the potential competition doctrine to this transaction. Fifth, AMI disputes Judge Barnes' finding that by acquiring French Hospital AMI attempted to monopolize the general acute care hospital services market in San Luis Obispo County and/or the City of San Luis Obispo, arguing that its intent in acquiring French Hospital was to make a profitable investment that met the goals of the local health planning agency, a legitimate business purpose, and not a specific intent to monopolize. And sixth, AMI contends that the broad prior approval remedy ordered by Judge Barnes is unwarranted because it had the reasonable, good faith belief that the antitrust laws did not apply to the transaction and because [4] it did not act in disregard of the antitrust laws. More particularly, AMI argues that there has been no showing that AMI has a "propensity to violate the law" so as to necessitate prior approval as a means of preventing unlawful transactions in the future. AMI contends that the prior approval requirement would in effect prevent it from competing for the acquisition of other hospitals. We address each of these arguments below.

We disagree with the Initial Decision in several respects. First, although we affirm liability under Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, we do not decide whether AMI has engaged in attempted monopolization. Second, we find that the requirement that AMI obtain prior approval of the Federal Trade Commission for the acquisition of general acute care hospitals in the future eliminates AMI as a potential competitor in the hospital acquisition market to the detriment of sellers of such facilities, thereby necessitating the elimination of this requirement. Instead, we will require AMI to notify the Commission in advance of its intention to make an acquisition of the variety contemplated by Judge Barnes' order. We affirm Judge Barnes' Initial Decision in all other respects.

II. PRICE AND NONPRICE COMPETITION IN THE HEALTH CARE INDUSTRY

A. Price Competition:

AMI vigorously argues that because the economic incentives of physicians, hospitals, and patients are "wholly unlike those of buyers and sellers in typical markets," the hospital industry did not at the time of AMI's acquisition of French Hospital "function in anything

resembling a competitive fashion.” (RAB 6)² AMI cites to specific Congressional findings accompanying [5] passage of the National Health Planning and Resources Development Act, Pub. L. No. 93-641, 88 Stat. 2225 (1975), *codified at* 42 U.S.C. 300k-300s (1976) [hereinafter cited as the “Planning Act”], the Health Planning and Resources Development Amendments of 1979, Pub. L. 96-79, Section 103, 93 Stat. 593, *codified at* 42 U.S.C. 300k-2(b)(1), (2) (Supp. V 1981) [hereinafter cited as the “1979 Amendments”], and the Health Planning Amendments of 1983, as well as to numerous scholarly commentaries, *see, e.g.*, J. Newhouse, *The Economics of Medical Care* 63 (1978). (RAB 6-9) AMI contends that three factors prevent the hospital industry from operating in a competitive fashion: (1) nearly all hospital transactions are covered by some form of third-party payment, reducing the importance of price as a competitive variable; (2) hospitals are paid on a cost-reimbursement basis, and cost-based reimbursement removes incentives for efficiency; and (3) patients lack price information that is needed to make choices about their care and instead rely on their physician, who is no more price-sensitive than the patient. (RAB 8) AMI argues that Judge Barnes’ acknowledgment of “the unique economics of health care” in his Initial Decision (RAB 10-11)³ contradicts his conclusion that competition exists among hospitals in various “attenuated” forms that warrant protection from the anti-trust laws. (RAB 11) Moreover, AMI alleges that although Complaint Counsel asserts that co-payment and deductible provisions encourage hospital selection on the basis of price, there is no evidence that any appreciable number of persons subject to such provisions in fact chose hospitals on that basis. (RAB 12)

Before determining whether price competition exists among hospi-

² The following abbreviations are used in this opinion:

- ID - Initial Decision page number
- IDF - Initial Decision finding number
- Tr. - Transcript page number
(designated by the name of the witness
followed by the transcript page number(s))
- CX - Complaint Counsel’s exhibit number (followed
by referenced page(s))
- RX - Respondents’ exhibit number (followed by
referenced page(s))
- RAB - Respondents’ Brief on Appeal From Initial
Decision
- CAB - Complaint Counsel’s Answering Brief
- RRB - Respondents’ Reply Brief on Appeal From
Initial Decision

³ AMI cites to several specific findings in this regard: that “most all transactions for hospital services are covered by third-party financing arrangements,” that “under private insurance, Medicare, and Medi-Cal, neither the patient nor the physician is under pressure with respect to hospital charges,” and that “patients seldom choose among hospitals based on their prices” (IDF 93); “that [c]onsumers and doctors lack an incentive to become aware of the exact prices because they know that third-party payers will pay the vast majority of the bills” (IDF 98); and that “it is the doctor who makes the basic decisions about the course of care [, and] . . . doctors do not ‘price shop’ for their patients” (IDF 98). *See also* IDF 33, 75, 92, 97, 105.

tals in San Luis Obispo, we feel compelled to comment on the thrust of AMI's argument. AMI appears to be arguing that its acquisition of French Hospital should be exempt from antitrust scrutiny because there presently is no price competition in this industry and because encouraging price competition in this industry by requiring, *inter alia*, the divestiture of French Hospital, will not enhance consumer welfare. Even if we were to accept AMI's contention that price competition does not exist in this industry, which we do not, we could not accept AMI's [6] argument that this fact inescapably leads to the conclusion that a hospital acquisition such as the one at bar is *de facto* exempt from antitrust scrutiny. It is the role of Congress, not the Commission, to legislate exemptions from the antitrust laws, and Congress has not done so in the hospital industry. This applies equally to AMI's argument, discussed below, that the nonprice competition that exists among hospitals in the San Luis Obispo area does not constitute competition in the antitrust sense and does not merit protection of the antitrust laws.

AMI grossly overstates the impact of industry-specific practices on the issue of price competitiveness in the health care industry. As Judge Barnes correctly concluded below, although competition in the hospital industry may not be as vigorous and intense as in other industries, competition nonetheless exists and produces salutary effects in that industry. A fair reading of the record establishes that even AMI has repeatedly acknowledged the existence of this competition in the San Luis Obispo area. For instance, one doctor complained to AMI Vice President Loftin and Mr. Carlson, the administrator of Sierra Vista Hospital:

It is also becoming apparent that [French Hospital] is attempting to generate competition in the way of decreased surgery operating room fees, decreased hospital room fees and decreased laboratory and emergency room fees, and thus it become[s] extremely competitive with Sierra Vista Hospital.

(CX 737) This same doctor urged that AMI consider "the possibility that [a] decrease in fees [by Sierra Vista] to be competitive would be in order" (CX 737) Mr. Loftin acknowledged the competitive situation: "I share the concerns outlined in your letter," and "[w]e have been aware of the competitive moves of French Hospital and will certainly work to counteract these." (CX 738) This is credible evidence of the existence of competition that cannot be ignored. The record also documents AMI's acknowledgment that, in the abstract, competition among hospitals constrains their ability to raise rates and that, in practice, price competition between hospitals in San Luis Obispo County did constrain hospital charges. Friesen International, Inc., an AMI subsidiary, concluded that AMI's Community Hospital of Santa

Cruz was earning below normal profits because of "the two hospital competitive situation in Santa Cruz which does not permit Community to adjust rates as easily as other region hospitals." (CX 1054N; *see also* CX 1059H, 1072 W-X). Regarding an AMI proposal to build an additional hospital in Yuma, California, Mr. Victor Kolodziej, AMI Vice President and [7] Financial Director of AMI's Pacific Southwest Region, stated that such competition would constrain the rate at which hospital charges could increase:

What we are talking about is a deescalation in the build-up of rates in the future; that what should happen within the competitive mold is that rates will not increase as they have in the past. It's not the reduction of rates themselves; it's a deescalation in the inflation of rates.

(CX 1072 W-X; *see also* CX 1030 at 2.38, 3.18). Sensing the existence of competition, AMI kept a constant eye on the more visible aspects of their charges, *e.g.*, room rates and operating room rates. (*See* CX 191 H-i; CX 38 M-N; CX 479; CX 480; Tr. Friedmann 1583). And on at least one occasion AMI responded in the classic manner to the competition that it perceived to exist, by reducing prices. French Hospital waived the fee for the use of its emergency room during "off-hours," which was intended to serve as a "patient-getting technique" for members of the French Clinic. (Tr. Friedmann 1585; Bernhardt 1249-50).

AMI makes a persuasive argument that third-party payment practices, cost-based reimbursement practices, and the relative unavailability of information needed by consumers to make decisions based on price all contribute to reduce the effect of competition in the health care industry. The impact of these factors on competition in the health care industry is well-documented. *See, e.g.*, J. Newhouse, *The Economics of Medical Care* 63 (1978). AMI also cites Congressional findings accompanying the passage of the Planning Act in 1975 and amendments thereto.⁴ (RAB 6-7) Notwithstanding this, price [8] com-

⁴ Thus, one report concluded:

... In the view of the Committee the health care industry does not respond to classic marketplace forces. The highly technical nature of medical services together with the growth of third party reimbursement mechanisms act to *attenuate* the usual forces influencing the behavior of consumers with respect to personal health services. For the most part, the doctor makes purchasing decisions on behalf of the patient and the services are frequently reimbursed under health insurance programs, thus reducing the patient's immediate incentive to contain expenditures.

S. Rep. No. 1285, 93d Cong., 2d Sess. 39, *reprinted in* 1974 Code Cong. & Ad. News 7842 at 7878 (emphasis added). And in 1979, Congress reported:

The Congress finds that the effect of competition on decisions of providers respecting the supply of health services and facilities is *diminished*. The primary source of the lessening of such effect is the prevailing methods of paying for health services by public and private health insurers, *particularly for inpatient health services* and other institutional health services

The Health Planning and Resources Development Amendments of 1979, Pub. L. 96-79, Section 103, 93 Stat. 593, 594-95, *codified at* 42 U.S.C. 300k-2(b)(1), (2) (Supp. V 1981) (emphasis added). The report on the Health Planning Amendments of 1983 states:

(footnote cont'd)

petition does exist in the health care industry, although these factors may operate to reduce its impact, and, as Judge Barnes correctly found, price competition, whether real or perceived, does exist in San Luis Obispo County to the benefit of residents of that locale. Congressional findings do not say that competition does not exist but only that the competition that does exist may be hampered by industry-specific practices such as third-party payment and cost-based reimbursement. To use the [9] terms employed by Congress in these findings, competition in the health care industry may be "attenuate[d]," "diminished," or "significantly reduced."⁵ This is not to say that competition is non-existent or that the competition that does exist does not merit protection by the antitrust laws. Whether real or perceived, hospitals in San Luis Obispo, including AMI's Sierra Vista Hospital, sense the existence of price competition between hospitals there and, on some occasions, respond to that competition in ways that benefit consumers. This conclusion is entirely consistent with Judge Barnes' findings that hospitals engage in "some" price competition (IDF 99) and that "competition" among hospitals exists in various "attenuated" forms that warrant protection by the antitrust laws (ID at 160-61).

B. Nonprice Competition:

AMI mounts a two-prong attack on Complaint Counsel's claim that AMI's acquisition of French Hospital lessened nonprice competition among hospitals in San Luis Obispo County. First, AMI disputes Judge Barnes' finding that hospitals engage in competition on the basis of "nonprice considerations" (IDF 101-105, 108, 112, 127-29), and contends that conduct of this kind "is not competition in the economic sense because it is not disciplined by an effective price mechanism." (RAB 12) As proof that the hospital industry is not a "functioning market," AMI asserts that neither doctors, hospitals, nor patients balance the benefits of additional services and equipment against their costs. (RAB 12-13) Second, AMI argues that the "rivalry" that exists among hospitals cannot be equated with "competition" for purposes of antitrust analysis (RAB 16), since the "competition" that the antitrust laws is intended to encourage "is a process by which

One commonly cited cause of hospital overinvestment is third-party payment. Extensive coverage for hospital services by public and private insurance has created a situation in which patients and their physicians have little concern for the costs of care. The typical insurance policy pays the entire cost of hospital room and board and ancillary services. In the aggregate, only 9 percent of hospital costs were paid out-of-pocket by patients in 1980. Since hospitals encounter little resistance to increased prices, incentives to hold down costs are significantly reduced. This tends to protect hospitals from [the] penalties of excess capacity normally borne by businesses. With extensive third-party payments, *competition for patients is often based on amenities rather than price*, which in turn leads to increased investment.

H.R. Rep. No. 218, 98th Cong., 1st Sess. 3 (1983) (emphasis added; footnote omitted).

⁵ See footnote 4, *supra* at pages 7-8.

rivalry among firms results in low prices and efficiency,” and in the hospital industry “economic analysis demonstrates that the conduct in question has no such tendencies . . .” (RAB 17) AMI argues that Judge Barnes placed undue reliance on various pieces of evidence in which the term “competition” was used in a non-technical, colloquial sense, such as in what AMI labels “the Yuma documents” and “the Lewin Report.”⁶ (RAB 17–19)

We reject AMI’s argument that the nonprice “rivalry” that exists in the hospital industry is not “competition” for antitrust purposes that warrants protection by the antitrust laws. We note as a starting point that Congress, even in the Congressional findings cited by AMI, has found that hospitals compete on nonprice dimensions. For instance, the House Committee on Energy and Commerce report on H.R. 2934, the Health [10] Planning Amendments of 1983, states that “[w]ith extensive third-party payments, *competition for patients* is often based on amenities rather than price, . . .” (RAB 7 (emphasis added)). This same report also noted:

Because physicians making decisions on behalf of their patients create the demand for hospital services, *hospitals compete for patients indirectly by competing for physicians.*

(RAB 7 (emphasis added)) This is fully consistent with Complaint Counsel’s claim that hospitals compete by appealing to the nonprice preferences of patients and the physicians who admit those patients. (CAB 18; *see also* ID at 183) The record clearly establishes that, contrary to AMI’s assertion, economic constraints do affect hospitals’ willingness to engage in nonprice competition.⁷ AMI has acknowledged this on several occasions. For instance, French and AMI balanced physicians’ requests for equipment against the costs associated with those requests. (Tr. Carlson 1324, Loftin 1489, Friedmann 1574–1575; *see also* IDF 146) Moreover, various factors have forced hospitals to consider costs in deciding whether to compete on the nonprice dimension by instituting new patient and physician services. Many insurance companies will not reimburse hospitals for unreasonably high charges. (Tr. Loftin 1498) This sets an upper limit on the amount that can be charged by a particular hospital. Medicare and Medicaid reimbursement systems constrain hospital spending in a similar fashion. (Tr. Derzon 1994, 1999; RX 5828; *see also* Tr. Derzon 2005) There is also evidence in the record that hospitals compete vigorously on

⁶ See description at pages 11–12 *infra*.

⁷ AMI contends that the testimony of Complaint Counsel’s economist, Dr. Lester Lave, should be dismissed “because his analysis fails to account for the absence of an effective price mechanism”. (RAB 15; *see also* RAB 19–21) We reject this contention because we find above that hospitals’ conduct is subject to various economic constraints.

nonprice dimensions. As a general matter, hospitals compete for physician patronage "by offering the equipment, facilities, services, amenities, and support staff that physicians want for themselves and for their patients." (Tr. Lave 826-27) Specifically, hospitals compete for physicians by maintaining high nursing levels (Tr. Boyd 374; Collins 1442; *see also* IDF 141), offering educational programs (Tr. Collins 1442; *see also* IDF 157), seeking certificate-of-need approval for new programs (Tr. Anderson 222, Lave 831), purchasing desired equipment (Tr. Lave 826, Schramm 2299), and providing favorable working conditions (CX 1030 at 3.6). Hospitals provide high quality services and offer new services in order to compete for patients (Tr. Lave 829; CX 1030 at 1.16, 1.20-1.21, 2.16-2.17, 2.47, 3.16-3.17; IDF 112), such as innovative obstetrical services and policies (Tr. [11] Lave 836-37). Friesen's study of Brookwood Medical Center, an AMI hospital, described how nonprice competition operated through adoption of the "Selective Centers of Excellence Strategy." (*See* IDF 101) AMI employed the same strategy in French and Sierra Vista hospitals—French set up a cardiac catheterization and surgery program (Tr. Anderson 221-22; IDF 156) and an advanced pediatrics program (Tr. Boyd 376; IDF 142), and Sierra Vista established a strong emergency program (*see* RX 5436Z46 & 5436Z53). These benefits resulted from increased competition between hospitals:

I think that the primary effect of nonprice competition is to keep institutions on their toes, to keep them from becoming ossified in what it is that they are doing; to try and look for new opportunities, and to try and take a look for new ways of serving physicians and patients; to keep them from simply sitting back and responding when physicians or people in the community say that they need something but instead to aggressively go out and try to find out what the market looks like, what people will want. That is very good for the whole community.

(Tr. Lave 835) There is no doubt that consumers in the health care industry benefit substantially from the nonprice competition that exists between hospitals located in San Luis Obispo County. AMI's own Lewin Report concluded:

Competition has clearly led to increases and improvements in the services offered in these communities. Both for-profit and non-profit hospitals expanded their service offerings over the competitive periods we studied. This expansion of offerings is one of the major competitive techniques available to hospitals. Service additions both make the hospital a more desirable place for physicians to practice, and attract new patient populations.

(CX 1030 at 1.27-1.28; *see also* CX 1030 at 1.32) AMI Group Vice President Ronald Porter, arguing before a panel of the Western Arizona Health Systems Agency in support of AMI's application for approv-

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al of a new hospital in Yuma, Arizona, summarized the impact of competition in AMI's view: "Competition is good. Competition is healthy for the Yuma community." (CX 1072T) [12] AMI's view of nonprice competition is consistent with the testimony of Complaint Counsel witness Lave:

There are always adverse effects of competition.

* * * * *

... [But] I think that on balance this kind of nonprice competition is extremely productive both in terms of the quality of patient care that one would see as defined by health professionals and the quality of patient care as patients would view it, which is probably just as important as the quality of care as defined by health professionals.

(Tr. Lave 839-40) Because the health care industry is disciplined by an effective price mechanism (although a price mechanism that may be less "effective" than in other industries) and the nonprice competition that does exist in the industry responds to consumers' expressions of their wants by providing services valued by physicians and patients, such as expanding the range of choices available to them, stimulating innovation, and developing expertise by hospitals, we conclude that "rivalry" among hospitals along nonprice dimensions constitutes competition in the economic sense that warrants protection by the antitrust laws.

III. IMPLIED IMMUNITY OF AMI'S ACQUISITION

AMI appeals Judge Barnes' finding that the Planning Act does not confer implied immunity from the antitrust laws on its acquisition of French Hospital. Specifically, Judge Barnes concluded that since nothing in the Planning Act required or authorized AMI to acquire French Hospital, there is no "clear repugnancy" between the Planning Act and the antitrust laws with respect to the acquisition and implied immunity is not necessary to make the Planning Act work. (ID 182)

On appeal, AMI contends that the Planning Act conflicts with the antitrust laws to the extent that it relies for its effectiveness on voluntary cooperation among providers which, though in fulfillment of Planning Act objectives, may be contrary to antitrust standards. (RAB 22) AMI argues that although Congress addressed the perceived problem of future continued overinvestment in health care resources through a "form of direct regulatory control," the certificate-of-need program, Congress explicitly rejected "a coercive regulatory approach" to address what is viewed as the problem of existing duplica-

tive and excess services, instead adopting a program for "voluntary remedial action" by providers in response to agency recommendations. (RAB 22-23) AMI cites to various Congressional findings that stress [13] the importance of voluntary cooperation in the Planning Act scheme. See H.R. Rep. No. 1382, 93d Cong., 2d Sess. 60-61 (1974); H.R. Conf. Rep. No. 1640, 93d Cong., 2d Sess. 77, reprinted in 1974 U.S. Code Cong. & Ad. News 7971 at 7986; 124 Cong. Rec. 29,864 (1978) (statement of Rep. Rogers). AMI argues that since many of the voluntary activities traditionally undertaken in the health planning process would raise antitrust concerns if the antitrust laws were applied to them, there is substantial reason to conclude that Congress did not intend the antitrust laws to apply to activities undertaken by providers in response to advice from health systems agencies. (RAB 25) In support of this argument AMI points to the Supreme Court's conclusion in *National Gerimedical Hospital and Gerontology Center v. Blue Cross*, 452 U.S. 378, 392 (1981), that "the fundamental assumption of Congress, particularly in 1974 when it passed the [Planning] Act, was that competition was not a relevant consideration in the health care field." Because of this conflict, AMI contends that some sort of implied repeal is necessary in order to effectively implement the Planning Act, and that AMI's acquisition of French Hospital is precisely the type of voluntary provider action that Congress and the Supreme Court in *National Gerimedical* envisioned should be immune from antitrust attack. (RAB 27)

We must begin by noting that because implied repeal of the antitrust laws is disfavored, Congressional intent to repeal the antitrust laws "must be clear," see, e.g., *National Gerimedical Hospital and Gerontology Center v. Blue Cross*, 452 U.S. 378, 388 (1981) [hereinafter cited as "*National Gerimedical*"]. Implied immunity will be found only upon a demonstration "of clear repugnancy between the antitrust laws and the regulatory system," *United States v. National Association of Securities Dealers*, 422 U.S. 694, 719-20 (1975), and that it is "necessary to make the [conflicting statutory scheme] work," *Silver v. New York Stock Exchange*, 373 U.S. 341, 357 (1963). We find here that AMI has failed to make that demonstration.

The Supreme Court's reading of the Planning Act in *National Gerimedical* clearly demonstrates that the Planning Act does not rely for its effectiveness on voluntary cooperation among providers of the type asserted by AMI. In that case, National Gerimedical Hospital, a private acute-care community hospital in the Kansas City area, sought to enter into a participating hospital agreement with Blue Cross, a nonprofit provider of individual and group health-care reimbursement plans. Blue Cross refused on the basis of its policy barring participation by any new hospital that could not show that it was

meeting a clearly evident need for health-care services in service area, relying on National Gerimedical's failure to obtain approval for its construction from the local health systems agency [hereinafter referred to as "HSA"] (because of the HSA's announced policy that it would not approve any additional acute-care beds due to existing excess capacity). Alleging a wrongful refusal to deal and a conspiracy between Blue Cross and the HSA, National [14] Gerimedical filed suit against Blue Cross under Sections 1 and 2 of the Sherman Act. Blue Cross contended that the Planning Act of 1974 impliedly repealed the antitrust laws as applied to the conduct in question. The Supreme Court reversed the trial court's decision to grant Blue Cross summary judgment, finding that although the purpose of the Planning Act was to prevent overinvestment in and maldistribution of health care facilities,

The action challenged here was neither compelled nor approved by any governmental, regulatory body. Instead, it was a spontaneous response to the finding of an advisory planning body, the local HSA, that there was a surplus of acute-care hospital beds in the Kansas City area. . . .

. . . It cannot be argued that application of the antitrust laws to the conduct of Blue Cross would frustrate a particular provision of the [Planning Act] or create a conflict with the orders of any regulatory body. The record discloses no formal request from [the local HSA] to Blue Cross to refrain from accepting [National Gerimedical] as a new participating hospital.

452 U.S. at 389-90. As does AMI in this case, Blue Cross relied on the fact that a major function of an HSA was to eliminate unnecessary duplication of hospital services, pointing to statutory language in the Planning Act requiring each HSA to "seek, to the extent practicable, to implement its [health plans] with the assistance of individuals and public and private entities in its health service area." The Supreme Court rejected this:

. . . Here, [Blue Cross] argue[s], the HSA found that [National Gerimedical] was duplicating hospital facilities unnecessarily, and Blue Cross merely sought to aid in the "implementation" of that finding.

We are unpersuaded, however, that the provisions cited by Blue Cross are sufficient to create a "clear repugnancy" between the [Planning Act] and the antitrust laws, at least on the facts of this case. . . . Nothing in the [Planning Act] requires Blue Cross to [15] take an action that, in essence, sought to enforce the advisory decision of [the local HSA]. . . .

Id. at 391.

Admittedly, the Planning Act does rely to some degree upon voluntary cooperation of health care providers. Thus, AMI's contention that the Congressional solution to the maldistribution of existing

costly health services depends for its effectiveness on the willingness of providers to voluntarily conform their activities to HSA plans and goals is not incorrect. Nor is AMI's conclusion that Congress rejected a coercive regulatory system to battle this problem. The fact that Congress did not give HSA's any formal power to enforce their recommendations, as the Supreme Court implied in *National Gerimedical*, 452 U.S. at 385, is consistent with this. However, it is clear from the Supreme Court's reading of the Planning Act in *National Gerimedical* that Congress' reliance on voluntary cooperation by providers to implement that Act envisions something more than a provider's unilateral response to a general statement of policy announced by the local HSA, as was the case in AMI's acquisition of French Hospital. In *National Gerimedical*, the local HSA announced its policy not to approve any additional acute-care beds due to existing excess capacity. The Court noted the absence of a "formal request from [the local HSA] to Blue Cross to refrain from accepting [National Gerimedical] as a new participating hospital," 452 U.S. 390, and presumably this "request" would be a prerequisite to a finding of implied immunity in that case. The fact that the Court would require that the local HSA "request" that the health care provider act in some specific manner is consistent with the voluntary framework that Congress envisioned, as is the requirement that "[t]he action challenged here . . . [be] approved . . ." by the local HSA, *National Gerimedical*, 452 U.S. at 389, "approval" in terms of "state agency review, comment and recommendation to providers." We need not address whether the type of voluntary cooperation by providers that the Planning Act envisions is in conflict with the antitrust laws, necessitating an implied repeal of antitrust liability. Instead, we find that AMI's acquisition of French Hospital is not the type of voluntary conduct that is envisioned by the Planning Act.

The Planning Act envisions voluntary actions by health care providers in response to specific recommendations contained in the Annual Implementation Plan [hereinafter referred to as "AIP"] that is adopted by the local HSA. Specifically, the Planning Act requires HSA's to "develop and publish specific plans and projects for achieving the objectives established in the AIP." 42 U.S.C. 3001-1(b) (4) (1976). To the extent that an HSA recommends an action with this specificity, or as the Supreme Court stated in *National Gerimedical*, "[w]here, for example, an HSA has expressly advocated a form of cost-saving cooperation among providers, . . .," 452 U.S. at 393 n.18 (emphasis added), . . . implied immunity maybe deemed appropriate. The requisite [16] specificity is absent in this case. The Mid-Coast HSA [hereinafter referred to as "MCHSA"] did not expressly direct AMI to acquire French Hospital. AMI's only "official" directive for

the acquisition is general statements favoring consolidation that appeared in the Health Systems Plan [hereinafter referred to as "HSP"] and AIP. As Judge Barnes correctly found, the MCHSA predicted in the 1979–1984 and 1978–1983 HSP's that excess beds would exist in the future. The 1978–1983 HSP recommended the establishment of a task force to prepare a report with specific recommendations for "consolidation of services and/or delicensure of beds." (RX 5466Z181–Z182, Z265–Z266) The report was to serve as the basis for a "preliminary strategy for reallocation, consolidation or delicensure" of hospital beds in the HSA's area, with the feasibility of consolidation to be examined "in specified service[s]." (RX 5466 Z183–Z184, Z266–Z268; RX 5461Z1–Z2) Although this task force was organized, the record is unclear as to whether any such report was, in fact, prepared. (Tr. Bernhardt 1296) Also, although the 1979–1980 AIP noted that low occupancy at area hospitals would improve "through the [MCHSA's] stated policy to encourage conversion of excess beds to services with shortages, *as well as mergers*" (RX 5461Z63 (emphasis added)), a member of the MCHSA was unable to recall any specific discussions as to what was meant by the term "merger" (Tr. Bernhardt 1293–94) and the MCHSA did not contemplate consolidation of particular facilities in writing its plans (Tr. Bernhardt 1273–74). In short, the record amply supports the conclusion that nothing in the MCHSA's HSP, AIP, or any policy statement promulgated pursuant to the Planning Act contemplated AMI's acquisition of French Hospital. Thus, absent specific prompting by the operation of the Planning Act mechanism, AMI's acquisition of French Hospital cannot be considered to be even eligible for implied immunity from the antitrust laws.

AMI's claim that Judge Barnes misread both the Planning Act and *National Gerimedical* is misdirected. First, AMI argues that Congress' rejection of a system of mandatory regulation in favor of voluntary provider cooperation is contrary to what AMI characterizes as Judge Barnes' assumption that an exemption can be found only if the industry is subject to a "traditional, coercive regulatory system." (RAB 30) The Initial Decision makes no reference to "coercive" regulation, in the sense of being subject to the full enforcement power of the law; rather, it is couched in terms of "approval" or "review." This is consistent with the Supreme Court's finding in *National Gerimedical* that "Congress expected HSA planning to be implemented mainly through persuasion and cooperation," 452 U.S. at 391. Second, AMI argues that the Court in *National Gerimedical* does not require specific authorization by a regulatory body or advance review of provider plans by local HSA's. To the contrary, the Planning Act does imply the need to secure HSA approval to the extent that it permits individual providers to identify specific conduct that the HSA, through

community input, deems to be in furtherance of Planning Act goals, not some unilateral conduct that is untested by community [17] interest. The Court's decision in *National Gerimedical* rested on a finding that Blue Cross' refusal to deal "was neither compelled nor approved by any governmental, regulatory body," 452 U.S. at 389. This certainly suggests that approval by a regulatory body (*i.e.*, in the sense that the private conduct is weighed against a public interest standard) is a prerequisite to eligibility for implied immunity.

IV. EFFECT OF THE ACQUISITION ON COMPETITION

A. Relevant Product and Geographic Markets

Having found that AMI's acquisition of French Hospital is subject to antitrust scrutiny under Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, we now turn to a consideration of the competitive effects of the acquisition. Section 7 of the Clayton Act (as amended by the Antitrust Procedural Improvements Act of 1980, Pub. L. 96-349, Section 6(a), 94 Stat. 1157) provides, in pertinent part:

No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, *where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.*

15 U.S.C. 18 (emphasis added). *See Atlantic Richfield Refining Co. v. FTC*, 344 F.2d 599 (6th Cir.), *cert. denied*, 382 U.S. 939 (1965), (Federal Trade Commission Act construed *in pari materia* with Clayton Act). Section 7 specifies two separate statutory standards under which AMI's acquisition of French Hospital may be held unlawful—if its effect: (1) "may be substantially to lessen competition," or (2) "to tend to create a monopoly." *See, e.g., United States v. Pennzoil Co.*, 252 F.Supp. 962 (W.D. Pa. 1965). Both the legislative history surrounding the passage of Section 7 and the case law demonstrate that Section 7 applies to "incipient" violations and that there is no need to prove that the merger would have any actual or definite anticompetitive effects. *See, e.g., FTC v. Proctor & Gamble Co.*, 386 U.S. 568, 577 (1967); *A. G. Spalding & Bros., Inc. v. FTC*, 301 F.2d 585 (3d Cir. 1962). Consequently, if it is *reasonably probable* that the merger would substantially lessen competition or tend to create a monopoly, the merger will be held to be unlawful under Section [18] 7. *See, e.g., United States v. Ingersoll-Rand Co.*, 320 F.2d 509 (3d Cir. 1963). Before determining whether any probable anticompetitive effect is likely to result from

the proposed merger, the "line of commerce" and "section of the country," i.e., the relevant product and geographic markets, must first be determined. Only after delineating these markets can the anticompetitive impact of the merger be measured.

A "line of commerce" is a product, service, or market in which one or both of the merging companies compete. See *United States v. Pennzoil Co.*, 252 F.Supp. 962 (W.D. Pa. 1965). Prior to 1962, three different tests had been used in determining the relevant market in Section 7 cases—"reasonable interchangeability of use," "cross-elasticity of demand," and "particular characteristics and uses," *United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 586 (1957). Accord, *Reynolds Metals Co. v. FTC*, 309 F.2d 223, 226 (D.C. Cir. 1962). But in *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1974) the Supreme Court summarized the controlling test as follows: "[t]he outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." 370 U.S. 294, 325 (1962) (footnotes omitted).⁸ See *Grand Union Co.*, Dkt. No. 9121, slip op. at 15 (July 18, 1983) [102 F.T.C. at 1041]. See also *United States v. Continental Can Co.*, 378 U.S. 441 (1964). The relevant market is determined by examining several factors, not all of which need exist in a Section 7 case: "industry or public recognition of the [market] as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." 370 U.S. at 325. Accord, *Elco Corp. v. Microdot, Inc.*, 360 F.Supp. 741 (D.Del.1973) (metal plate connectors as a relevant submarket of the backpanel connector assemblies market). The Commission Merger Statement and Justice Guidelines employ related criteria in defining the relevant product market. See Statement of Federal Trade Commission Concerning Horizontal Mergers, reprinted in CCH Trade Reg. Rep. (No. 546, June 16, 1982) [hereinafter referred to as "Commission Statement"]; U.S. Department of Justice Merger Guidelines, reprinted in CCH Trade Reg. Rep. ¶4500 (No. 655 (Part [19] 2), June 18, 1984) [hereinafter referred to as "Justice Guidelines"]. According to the Commission Statement:

The purpose of product market analysis is to ascertain what grouping of products or services should be included in a single relevant market. Where the cross-elasticity of demand for separate products or services is high, they normally will be within the same product market. Similarly, a high cross-elasticity of supply tends to suggest the existence of a common product market. Therefore, the issue of whether related products

⁸ If two products are "reasonably interchangeable" (in that they can be used for the same purposes), permitting consumers to switch from one to another, they are within the same product market. Accord, *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377 (1956) (Sherman Act Section 2 context). Products demonstrating positive demand cross-elasticity, i.e., a decrease in the price of one product causes consumers of a similar second product to switch to the first product, likewise compete in the same product market. *Id.*

or services place a significant constraint on the ability of merging firms to raise prices, limit supply or lower quality, is central to evaluating the competitive effects of a horizontal merger.

Commission Statement at 84.

Turning to the specific facts presented in this case, Judge Barnes found general acute care hospital services to be the appropriate product market in which to evaluate the competitive effects of AMI's acquisition of French Hospital. AMI advances several related arguments in its appeal of this finding. AMI argues that the process of defining relevant markets in the health care industry is an artificial exercise because it is necessarily based on the effects of price changes, and buyers and sellers in this industry are not price-sensitive. Instead, AMI urges that the product market be defined in terms of reasonable substitutability. AMI contends that Judge Barnes violated this standard by excluding non-hospital providers of the individual services that comprised the "cluster of services" provided by general acute care hospitals that Judge Barnes found to constitute the relevant product market. AMI points to numerous outpatient substitutes for hospital care in San Luis Obispo, such as clinics, physicians' offices, and medical laboratories, which AMI argues are "completely interchangeable with the outpatient services provided in hospitals" and therefore should be included in the product market definition. (RAB 39)

We begin by noting that the courts and this Commission have found it appropriate to adopt a "cluster of services" as the relevant product market on several earlier occasions. *See generally Grand Union Co.*, Dkt. No. 9121, slip op. at 19 (July 18, 1983) [102 F.T.C. at 1044]. For instance, the district court in *United States v. Philadelphia National Bank*, 201 F.Supp. 348 (E.D. Pa. 1962) [hereinafter cited as "*Philadelphia National Bank*"], faced a similar situation where defendants urged the inclusion of all suppliers of the individual products and services that comprised the "cluster of services" known as commercial banking. The court [20] concluded that that cluster of services "viewed collectively, has efficient peculiar characteristics which negate reasonable interchangeability," 201 F.Supp. at 363, which the Supreme Court affirmed on appeal, 374 U.S. 321, 355-57 (1963). *See also United States v. Connecticut National Bank*, 418 U.S. 656, 664-66 (1974); *United States v. Phillipsburg National Bank & Trust Co.*, 399 U.S. 350, 359-62 (1970). In other instances, the courts have examined a variety of factors to determine the proper content of the "cluster" market definition, such as "the functional complementarity and integration linking the products," the "degree of commonality in the technology and manufacturing processes involving the components

of the market,” whether “all products are marketed through similar channels and to the same group of buyers” and whether “this market has recognition in the industry,” *United States v. Hughes Tool Co.*, 415 F.Supp. 637 (C.D. Cal. 1976) (oil pipe handling products), “whether there are competitive relationships between the lines of commerce warranting them to be aggregated as a group for the purpose of measuring the impact of the merger on competition,” *A. G. Spalding & Bros. v. FTC*, 301 F.2d 585, 603–04 (3d Cir. 1962), *aff’d* 56 F.T.C. 1125, 1160 (1960) (gymnastic equipment), or “where, for technological or other reasons, there is commonality in production and distribution resulting in a distinct and recognized ‘industry’ of firms who sell a broad line of such products,” *British Oxygen Co.*, 86 F.T.C. 1241, 1345 (1975), *rev’d on other grounds sub nom. BOC Int’l Ltd. v. FTC*, 557 F.2d 24 (2d Cir. 1977) (industrial gases). *See also* cases cited in 16B Business Organizations, Von Kalinowski, *Antitrust Laws and Trade Regulation* ¶18.02[3] at 18–83 *et seq.* (1983). Thus, it appears that product market definitions consisting of a “cluster” of products or services is well-established in the case law.

Judge Barnes recited a long list of factors that he felt mandated a finding that the cluster of general acute care hospital services constituted the relevant product market in this case. (*See* ID 129–31) These factors included the uniqueness of the cluster services made available by general acute care hospitals (for instance, California law requires that medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services be offered on a 24-hours basis); unique services or equipment provided by general acute care hospitals (for instance, there are no free standing surgical or emergency room facilities in the area); and the complementarity of the individual services that are provided by general acute care hospitals. Judge Barnes also noted that the cross-elasticity of supply for hospital services is low (due to existing legal requirements imposed on market entry) and that general acute care hospitals are recognized by government agencies, state law, and industry participants as a distinct class of health care provider (to the exclusion of outpatient facilities).

Based on our review of the record, we conclude that AMI’s attack on Judge Barnes’ product market definition is [21] misdirected. In *Philadelphia National Bank*, 201 F.Supp. 348 (E.D. Pa. 1962), the district court noted that

With the possible exception of [one individual service], there is an identical or effective substitute for each one of the services which a commercial bank offers. From this the Court is to conclude that because the services offered by other financial institutions are reasonably interchangeable with those offered by commercial banks, the separate lines of commerce suggested by the plaintiff cannot be limited merely to commercial banks,

but must include in each and every case the services of other financial institutions as well.

201 F.Supp. at 361-62. AMI argues the same position here. In *Philadelphia National Bank*, the court concluded that it was the complementarity of these individual services, taken together, that made them a unique product or service cluster:

It is the conglomeration of all the various services and functions that sets the commercial bank off from other financial institutions. Each item is an integral part of the whole, almost every one of which is dependent upon and would not exist but for the other . . . Nevertheless, the Court feels quite confident in holding that commercial banking, viewed collectively, has sufficient peculiar characteristics which negate reasonable interchangeability.

Id. at 363. A similar result must obtain in this case. Although each individual service that comprises the cluster of general acute care hospital services may well have outpatient substitutes, the benefit that accrues to patient and physician is derived from their complementarity. There is no readily available substitute supplier of the benefit that this complementarity confers on patient and physician. This is consistent with record evidence that shows that those in the market only recognized other hospitals, not suppliers of individual hospital services, as their competitors. (*See* ID 131)

"Section of the country," as that language appears in Section 7, refers to the geographic area of effective competition between the two companies in which the relevant product is traded. *Accord, United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 620-22 (1974). Despite some doubt cast by the Supreme Court's opinion in *United States v. Pabst Brewing Co.*, 384 U.S. 546 (1966), proof of the relevant geographic market—[22] the "section of the country"—is an essential element in a Section 7 case, "a necessary predicate" to deciding whether a merger contravenes the Clayton Act," *United States v. Marine Bancorporation*, 418 U.S. at 618.

The Supreme Court in *Brown Shoe* summarized the controlling criteria for determining the relevant geographic market:

Congress prescribed a pragmatic factual approach to the definition of the relevant market and not a formal, legalistic one. The geographic market selected must, therefore, both "correspond to the commercial realities" of the industry and be economically significant. Thus, although the geographic market in some instances may encompass the entire nation, under other circumstances it may be as small as a single metropolitan area.

370 U.S. at 336-37. *Cf. United States v. Kimberly-Clark Corp.*, 264 F.Supp. 439 (N.D. Cal. 1967) (same criteria used in vertical and hori-

zontal merger cases to determine relevant geographic market). In practice, the courts have read *Brown Shoe* by giving particular emphasis to several somewhat overlapping economic factors in determining relevant geographic markets: (1) competitive price disadvantages resulting from high transportation costs, *see, e.g., Luria Bros. & Co. v. FTC*, 389 F.2d 847 (3d Cir. 1968); (2) availability of alternative suppliers, *see, e.g., United States v. Pennzoil Co.*, 252 F.Supp. 962 (W.D. Pa. 1965); and (3) industry recognition of the market as a separate and distinct market, *see, e.g., United States v. Federal Co.*, 1975-2 Trade Cas. (CCH) ¶60,397 (W.D. Tn. 1975).

Both the Commission Statement and Justice Guidelines focus on the impact of a price change within different geographic areas in defining the relevant geographic market. *See Grand Union Co.*, Dkt. No. 9121, slip op. at 23 (July 18, 1983) [102 F.T.C. at 1047]. Under the Commission Statement, "an area is a separate geographic market if a change in the price of the product in that area does not, within a relevant period of time, induce substantial changes in the quantity of the product sold in other areas." Commission Statement at 13. The geographic market is defined under the Justice Guidelines in a similar fashion.

Judge Barnes concluded that the geographic markets within which to evaluate the competitive effects of AMI's acquisition are San Luis Obispo County and the City of San Luis Obispo. AMI disputes these, arguing that a large number of San Luis Obispo County residents travel outside county boundaries for hospital care and that the three hospitals located within the city of San Luis Obispo rely heavily upon out-of-city residents to occupy their hospital beds. However, AMI does concede that "the [23] relevant considerations [for purposes of geographic market definition] are where patients actually go for care and where they may practicably turn for it." (RAB 40) *See generally Tampa Electric Company v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961).

In defining the geographic markets as he did, Judge Barnes relied in large part on patient flow statistics provided by Complaint Counsel. These patient flow statistics consist of two parts: patient "in flow" into county hospitals, and patient "outmigration" to hospitals located outside the county. The "in flow" statistics showed that over 90% of persons hospitalized in the five county hospitals were residents of San Luis Obispo County. (ID 134) Although the outmigration statistics were less certain, evidence showed that the incidence of outmigration ranged from as low as 5% (estimated by MCHSA) to as much as 14.5% of county residents (estimated for Medicare purposes). (ID 134-35) Assuming that county residents utilize hospitals at the same rate as residents of California in general (instead of employing the MCHSA

utilization rate), AMI estimated patient outmigration to be as high as 30% of the county residents. (ID 135) In support of his narrower geographic market definition, the City of San Luis Obispo, Judge Barnes concluded from an examination of patient flow statistics that residents of the city and environs go almost exclusively to hospitals located within the city. (ID 137)

AMI does not set forth any plausible basis on which we can even consider reversing Judge Barnes' geographic market definitions. AMI does not attack Judge Barnes' reliance on patient flow statistics for purposes of defining the relevant geographic markets ("the relevant considerations are where patients actually go for care and where they may practicably turn for it" (RAB 40)), but instead challenges his patient in flow and outmigration findings. Specifically, AMI alleges that the correct county outmigration figure is "a minimum of about fifteen percent" and that "the true figure may be close to thirty percent;" and that excluding out-of-city residents as patients, "French would have an occupancy rate of approximately 19.7 percent, [San Luis Obispo General Hospital] about 18.7 percent, and Sierra Vista about 34.8 percent." (RAB 40) AMI apparently does *not* dispute Judge Barnes' other very detailed conclusions supporting the county and city market definitions, such as geographic barriers (patient convenience and limited mobility, location of admitting physician) and industry recognition of these markets (as evidenced by AMI planning documents and testimony of hospital administrators).

With regard to AMI's patient outmigration estimates, the study prepared by AMI witness Mittelstaedt specifically for purposes of this litigation is clearly outweighed by other more probative evidence, including Medicare and Medi-Cal estimates, OSHPD estimates, and estimates prepared by AMI's own Friesen prior to this litigation. Correcting the patient utilization rates used by Mittelstaedt to reflect San Luis Obispo residents' [24] lower-than-average utilization, Mittelstaedt's study appears to be in line with Friesen's earlier estimate and the 5% to 14% range found by Judge Barnes. With regard to AMI's patient in flow statistics, although it does appear that the three hospitals in the city do draw a substantial number of patients from sections of the county outside of the city boundaries, AMI's argument ignores practical "commercial realities" that affect competition in the market for inpatient hospital services. First, French and Sierra Vista hospitals appear to be superior (in terms of facilities, size, and equipment) to hospitals outside the city limits and, consequently, it is not surprising that patients from outlying areas travel to the city for services not available locally. Thus, with regard to a number of service offerings (e.g., CAT scan, cardiac catheterization, open heart surgery, obstetrics), out-of-city hospitals simply do not compete with

hospitals located inside the city limits. Second, as we concluded earlier, hospitals engage in very vigorous competition for physicians on nonprice dimensions because, as a general matter, it is the physician who is responsible for admitting patients to hospitals, and hospitals compete for physicians in order to increase admissions. On the basis of our review of the record, it appears that physicians generally admit patients where it is most convenient for the admitting physician (Tr. Bernhardt 1237); that distance and travel time make it difficult for physicians to use hospitals that are not located near their offices (Tr. Boyd 340, Harvey 1682); and that the overwhelming number of patient admissions to French, Sierra Vista, and San Luis Obispo General (approximately 98%) are by physicians located within the city or its immediate vicinity (*see* CX 622-24). Thus, whatever the reason for the high density of hospitals and physicians within the city limits,⁹ competition for patient admissions by French and Sierra Vista appears to focus inside the city limits. Third, participants in the hospital services market in which French and Sierra Vista operate view the city and its immediate environs as a separate geographic market. The former administrator of French Hospital (now administrator at Twin Cities) testified that, as administrator at French, he did not view Twin Cities or Arroyo Grande as competition because they were too far away and had "a distinct medical staff and community" (Tr. Anderson 227); that he "regarded principally Sierra Vista Hospital as our competition" for physicians and patients (Tr. Anderson 228); and that as administrator at Twin Cities he does not attempt to attract patients from the city of San Luis Obispo because "[i]t is unreasonable to expect patients to commute 25 miles to come to Twin Cities Hospital" (Tr. Anderson 239). Internal AMI documents corroborate a finding that the City of San Luis Obispo comprises a separate geographic [25] market. In conjunction with AMI's request to approve the addition of 39 beds for Arroyo Grande Hospital in the early 1970's, AMI's administrator urged health planning authorities to segregate the county into three distinct service areas, "one being the north part of the county, one the central part of the county, encompassing [the City of] San Luis Obispo[,] and the third area is the south portion of the county . . ." (CX 188), with which recommendation the health planning authorities concurred (CX 217Z11-Z12). Similarly, a long-range planning study prepared by the staff of AMI Vice President Loftin supports the division of San Luis Obispo County into competitively-separate markets:

It is important to reiterate that our findings clearly pointed to the fact there is no definable competition for Arroyo Grande Community Hospital. The hospitals south of

⁹ AMI's claim that "[t]he ALJ was confused by the fact that both hospitals and doctors congregate in easily accessible population centers" (RAB 40) is without record support and simply makes no sense whatsoever.

Arroyo Grande are geographically located too far away to be competition and the facilities, Sierra Vista and French and County, in the north likewise are geographically too far away to be considered direct competition

(CX 197N) AMI's claim in its Appeal Brief that "[t]his peculiar analysis leads to the conclusion that every hospital with medical office buildings nearby, such as French Hospital before the acquisition, is a monopolist" (RAB 40) is a meaningless overstatement of Judge Barnes' findings. Before AMI's acquisition, French Hospital engaged in price and nonprice competition with Sierra Vista Hospital and, to a lesser extent, San Luis Obispo General Hospital, for physicians and patient admissions. We conclude that the geographic dimension of this competition is a relevant market for purposes of analysis under the antitrust laws.

B. Market Power in the Health Care Industry

Before proceeding with a consideration of the effects of AMI's acquisition of French Hospital on the general acute care health services markets in San Luis Obispo County and the City of San Luis Obispo, we are compelled to address AMI's contention that Judge Barnes erred in relying on indices based on market shares in determining the competitive effects of the acquisition. AMI argues that the traditional presumption that a substantial increase in market concentration or in a firm's market share results in a lessening of competition, as enunciated by the Supreme Court in *United States v. Philadelphia National Bank*, 374 U.S. 321, 363 (1963), is not applicable in the health care industry because the economic assumptions on which this presumption is based (which AMI argues are present in "manufacturing and related industries") are not present in this industry. (RAB 41) Specifically, AMI contends that since the [26] economic basis for the market share presumption is the notion of market power, and the concept of market power is premised on the existence of a competitive price and price-sensitive buyers and sellers, increased market shares do not necessarily enhance market power in the health care industry where price-sensitivity on behalf of buyers and sellers is absent. For instance, AMI argues that due to the third-party payment mechanism, which is governed by regulatory and contractual payment provisions, a "sole provider" hospital cannot exercise the market power that it ostensibly possesses to exact charges in excess of what it could get in a more competitive market. (RAB 43)

AMI's argument is nothing more than a resynthesis of its earlier argument that price and nonprice competition does not take place in the hospital industry. AMI's basic assumption is that price constraints are not present in this market. To the contrary, as we con-

cluded earlier,¹⁰ the record clearly demonstrates that price constraints influence the decisions made by both buyers and sellers in the health care industry, creating price and nonprice competition among hospitals that occupy overlapping service territories for increased patient admissions. Second, AMI's argument that market share evidence is valuable only in cases involving "manufacturing and related industries in which normal market forces can reasonably be assumed to operate" (RAB 41) is contrary to both common sense and case law precedent. For example, the courts have employed traditional market share criteria in numerous "non-manufacturing" contexts, such as commercial banking services, *see, e.g., United States v. Philadelphia National Bank*, 374 U.S. 321, 363 (1963), in-patient psychiatric care by private psychiatric hospitals, *see, e.g., United States v. Hospital Affiliates Int'l, Inc.*, 1980-81 Trade Cas. (CCH) ¶63,721, at 77,853 (E.D. La. 1980), and acute care community hospital services, *see American Mediacorp, Inc. v. Humana, Inc.*, 445 F.Supp. 589 (E.D. Pa. 1977), to name only a few.

*C. Competitive Effects of the Acquisition:
Price and Nonprice Dimensions*

We now turn to the ultimate question concerning the merits of Complaint Counsel's Section 7 case, whether the effect of the acquisition will be to substantially lessen competition or tend to create a monopoly in the relevant markets. However, before doing so, we note that Section 7 does not prescribe any particular methodology for determining this. In *Brown Shoe*, the Supreme Court refused to extend application of the "quantitative substantiality" doctrine (which developed in the context of Section 3 of the Clayton Act) to Section 7 cases, instead requiring that each case be "functionally viewed" in the context of its particular industry, 370 U.S. at 321-22. The Court [27] concluded that an acquisition should not be judged solely on the basis of market share statistics, but by considering both qualitative factors—the market's "structure, history, and probable future"—and quantitative factors. *Id.* at 322 n.38. *See Grand Union Co.*, Dkt. No. 9121, slip op. (July 18, 1983) [102 F.T.C. at 1032]. Despite the reemergence of a mechanistic quantitative approach in several subsequent Supreme Court cases, *see, e.g., United States v. Pabst Brewing Co.*, 384 U.S. 546 (1966); *United States v. Von's Grocery Co.*, 384 U.S. 270 (1966), in which the Court gave almost conclusive weight to the relative market shares of the merger partners, two recent cases signal the Court's retreat back to the *Brown Shoe* qualitative market structure analysis, *see United States v. Marine Bancorporation, Inc.*, 418 U.S. 602 (1974); *United States v. General Dynamics Corp.*, 415 U.S. 486

¹⁰ See discussion at pages 4-9 *supra*.

(1974). Consequently, although market share evidence is an important starting point in merger analysis, it alone is not conclusive in determining the legality of a merger under Section 7.

Both the Justice Guidelines and Commission Statement reflect the importance of considering both quantitative and qualitative elements of the acquisition. Although the Commission has expressed an intent to give "considerable weight" to the Justice Guidelines, it has not endorsed either the analytical approach or the numerical thresholds and tests for analyzing mergers contained in the Justice Guidelines. See Announcement of Policy: Federal Trade Commission Announces Horizontal Merger - Enforcement Policy, *reprinted in CCH Trade Reg. Rep.* (No. 546), June 16, 1982, at pp. 86-87. More importantly, the Commission emphasizes certain "qualitative" factors over strict "quantitative" industry concentration measures. "Market wide" conditions that may merit consideration include entry barriers and shifts in product demand:

The issue of entry barriers is perhaps the most important qualitative factor, for if entry barriers are very low it is unlikely that market power, whether individually or collectively exercised, will persist for long. Conversely, if entry barriers are quite high, the effect may be to exacerbate any market power conferred by the merger

Market power also may be harder to exercise or less likely to endure in the face of rapid technological change or significant upward shifts in demand. Moreover, this kind of evidence may shed light on questions of market definition and the market's propensity for collusive interdependence Market share fluctuations may represent overt [28] manifestations of underlying market forces and, as such, provide a very useful picture of market dynamics. Of course, like other evidence, the value of such data depends upon the magnitude and likely duration of the shifts that are occurring. Small deviations in market shares, even if they recur on a frequent basis, may be of little significance.

Commission Statement at 77 (footnote omitted). The Commission Statement also requires a consideration of factors thought to facilitate collusive conduct:

The most relevant factors appear to be: the homogeneity (or fungibility) of products in the market; the number of buyers (as well as sellers); the similarity of producers' costs, the history of interfirm behavior, including any evidence of previous price fixing by the firms at issue; and the stability of market shares over time.

Id. at 80. Accord, G. Hay & D. Kelly, "An Empirical Survey of Price Fixing Conspiracies," 17 *J. of Law & Econ.* 13 (1974), *reprinted in* T. Calvani & J. Siegfried, *Economic Analysis and Antitrust Law* 135 (1979).

We now turn to a consideration of the effects of the acquisition on competition. Judge Barnes found that AMI's acquisition of French

Hospital produced an extremely high concentration in both the city and county hospital markets. (ID 155) As a result of the acquisition, he concluded that AMI increased its market share from 55.6% to 75.5% in the county market and from 57.8% to 87% in the city market, measured on the basis of inpatient days.¹¹ The Herfindahl-Hirschman Index increased from 3818 to 6025 in the county market and from 4370 to 7775 in the city market, also measured on the basis of inpatient days.¹² AMI apparently does not dispute any of these statistics on appeal.¹³ Judge Barnes also examined a number of the [29] "qualitative" factors that the Commission Statement (and Justice Guidelines, as well) would require. As a result of the acquisition of French Hospital, AMI faces little or no competition in either market. AMI's only competitor in the city market is San Luis General Hospital, a smaller and older facility that lacks modern equipment and high quality nursing services. (IDF 132, 135) Within the county market, the only other competitor is Twin Cities Community Hospital, also smaller and unable to offer a full range of hospital services. AMI is the top firm in both markets; and there is a considerable size disparity between AMI and its competitors. (ID 156) There has been little volatility in the market shares of hospitals in San Luis Obispo County. (RX 5804; IDF 177) Barriers to entry, in the form of the Planning Act's certificate-of-need requirements, are very high, and in light of excess capacity in the market, new entry is extremely unlikely. (ID 156) AMI does not dispute Judge Barnes' assessment of these "qualitative" factors. Taken together, these are strong indicia of the likely anticompetitive effects of the acquisition.

AMI counters this strong evidence by arguing that the acquisition did not lessen competition or enhance AMI's market power because French and Sierra Vista hospitals did not engage in price competition. Specifically, AMI disputes Judge Barnes' findings that Sierra Vista's pricing was restrained by French prior to the acquisition and that AMI had the ability to charge noncompetitive prices after the acquisition. (RAB 43) AMI makes several separate arguments in support of this. First, AMI maintains that under the third-party payment system (which, AMI alleges, accounts for in excess of 90% of hospital payments in San Luis Obispo County) hospital bills are paid on the basis of costs (Medicare, Medicaid, and Blue Cross) or charges based on costs (private hospital insurance), which are set by statute, rule, or contract and are not affected by the existence of or pricing by

¹¹ Measured on the basis of gross hospital revenues, the comparable figures are 52.2% to 71.3% and 53.3% to 82.4%, respectively, for the county and city markets.

¹² Based on gross hospital revenues, the increase was from 3518 to 5507 in the county market and from 3996 to 7097 in the city market.

¹³ These figures are, of course, well in excess of the threshold that applies under the Justice Guidelines where the post-merger index is in excess of the 1800 point level, and tell a revealing story of the competitive conditions within those markets.

competing facilities. Thus, AMI asserts that as a practical matter the acquisition could not increase AMI's ability to raise its prices. Second, AMI contends that price competition can be said to exist only if a material number of consumers would respond to a price increase by doing business elsewhere, and that Judge Barnes conceded that patients seldom chose among hospitals on the basis of price. (RAB 44) Third, AMI maintains that data depicting gross charges per adjusted hospital admission and movements in annual charge levels strongly suggest that competitive conditions are not present in these markets. (RAB 45) Fourth, AMI contends that Judge Barnes' finding that some patients are sensitive to price is contrary to record evidence. Specifically, AMI maintains that there is no evidence that Sierra Vista reduced its charges in response to patients' "concern" about prices or that reports on comparative hospital charges in [30] any way induced price competition. Although AMI concedes that officials at French and Sierra Vista were "mindful" of each others "visible" charges, AMI contends that this did not translate into price competition because there was no evidence that a material number of patients chose a hospital on the basis of these visible charges and that any reduction in these visible charges could be (and, in the case of French Hospital in 1978, were in fact) offset by increases in "invisible" charges. With regard to evidence that French waived its usual fee for the use of its emergency rooms on weekends, AMI asserts that that did not result in any additional use of French's emergency rooms and had no effect on physicians' admitting patterns. And finally, AMI attacks Judge Barnes' conclusion that, following AMI's acquisition of French, the "lack of restraint on AMI's pricing conduct" enabled it to raise charges to compensate for a low census at French, as having no basis in the record because before the acquisition neither hospital reduced prices in order to increase census and in fact both hospitals increased charges despite low patient census. (RAB 47)

We do not endeavor to recapitulate the basis for our conclusion that price competition exists in this market, albeit "attenuated," "reduced," or "diminished." Regrettably, a large part of AMI's argument above focuses on this precise issue, not on the more narrow issue of whether the acquisition has lessened or is likely to lessen competition in these markets. But we do find that on the basis of the evidence in the record, AMI's acquisition of French Hospital has already lessened price competition and is likely to continue to lessen price competition, to the extent that any price competition remains. Two points need to be made. First, price competition clearly existed between French and Sierra Vista with regard to "visible" items that the market could expect might affect patients in deciding (or in conferring with physicians in the decision as to) which hospital to patronize (to the extent

that the patient's illness permitted such an election to be made). Price competition took place regarding room rates, operating room rates, and emergency room rates. Hospital administrators were aware of this competition and were sensitive to the need to remain competitive on these items. The record amply demonstrates that this price competition resulted in reductions for some of these charges at French. Although any reductions in these "visible" charges could conceivably be offset by increases in "invisible" charges, we cannot conclude that this competition did not have any salutary effects. For instance, in the case where French's "other charges" were increased in 1978 (so that total charges paid by a surgical patient were higher) while the operating room fee was lowered, AMI cites to no record evidence establishing a causal link between the two and ignores the fact that these reductions may have helped to limit the size of the increase in overall charges that was in fact implemented. (see RAB 46 n.56) Furthermore, as Complaint Counsel notes in its Answering Brief (CAB 30), hospitals are limited in their ability to increase charges for some "invisible" services to offset a [31] reduction in "visible" charges. Below average profits earned by AMI's Santa Cruz Hospital on both room charges and charges for ancillary services demonstrate this point. (CAB 30; see CX 1054N) Second, after the acquisition of French, AMI took unequivocal steps to reduce or altogether eliminate the competition that previously had existed between French and Sierra Vista. In 1980, AMI attempted to make charges uniform at all of its hospitals in the San Luis Obispo area. For instance, a memorandum to French's administrator, Mr. Bowytz, recommended that charges for certain items be changed, noting that "these price changes will establish uniformity for the San Luis Obispo area." (CX 301A; see also 302A) The Friesen report recommended as an "action item" to "standardize fee structure for AMI hospitals." (RX 5435Z69) Sierra Vista's competition with French ended after AMI's acquisition of French: in an interview conducted by a Friesen representative, administrator Bowytz noted that he "fe[lt] tied" and couldn't "compete along traditional lines" because the "competition is AMI." (CX 295W) The AMI Quality Assurance Report for Sierra Vista also concluded that competition would be reduced:

For many years Mr. Carlson and his forces [at Sierra Vista] have challenged the French Hospital and won the battle, now *that* activity has to be curbed and a balance of cooperation mixed with healthy competitiveness has to be reached whilst retaining hard earned standards of care.

(CX 425F (emphasis in original)) Thus, the adverse impact of AMI's acquisition of French Hospital is readily apparent.

AMI appears to be arguing that given the very little price competi-

tion that exists in these markets, that competition does not benefit consumer welfare because of pervasive price regulation in the industry and, accordingly, the antitrust laws should be neutral because price competition does not function to augment consumer welfare. This is contrary to a number of cases that have applied the Clayton Act to acquisitions in industries with attenuated price competition. As Judge Barnes noted, the Supreme Court rejected a similar argument in *United States v. Philadelphia National Bank*, 374 U.S. 321 (1963), involving the banking industry, where governmental regulation was pervasive:

[W]e reject the position that commercial banking, because it is subject to a high degree of governmental regulation, or because it deals in the intangibles of credit and services rather than in the manufacture or sale of tangible commodities, is somewhat immune from the anticompetitive effects of undue concentration. Competition among banks exists at every level—price, variety [32] of credit arrangements, convenience of location, attractiveness of physical surroundings, credit information, investment advice, service charges, personal accommodations, advertising, miscellaneous special and extra services—and it is keen; on this appellees' own witnesses were emphatic. There is no reason to think that concentration is less inimical to the free play of competition in banking than in other service industries. On the contrary, it is in all probability more inimical.

374 U.S. at 368–69 (footnote deleted).¹⁴ And in *Stanley Works v. FTC*, 469 F.2d 498 (2d Cir. 1972), the Court of Appeals concluded that Section 7 was particularly applicable to an acquisition in the cabinet hardware industry, which was “a concentrated market manifesting limited signs of price competition,” 469 F.2d at 505.¹⁵ These cases clearly suggest that even assuming that the [33] limited price competition that does exist in these markets may produce only marginal benefits in terms of overall consumer welfare, the antitrust laws will

¹⁴ In *Philadelphia National Bank*, as in this case, there was substantial evidence that although price competition was reduced, there was considerable nonprice competition. The Court quoted with approval the following testimony from the record:

Q. What form does the competition take? Is it competition in price?

A. No, I wouldn't say that it is competition as to price. After all, interest rates are regulated at the top level by the laws of the 50 states.

* * * * *

I do not believe that competition is really affected by the price area. I think it is affected largely by the quality and the caliber of service that banks give and whether or not they feel they are being received in the right way, whether they are welcome in the bank. Personalities enter into it very heavily, but I do not think price as such is a major factor in banking competition. It is there, it is a factor, but not major.

374 U.S. at 368 n.45.

¹⁵ The court's condemnation of that acquisition is particularly apposite to this case:

Finally, we note that though a market may be concentrated, forces may operate so as to maintain some level of competition and thus preserve the possibility of eventual deconcentration. That is why the continued independence of companies with relatively small market shares is so crucial to the health and vitality of a market threatening to become oligopolistic.

469 F.2d at 505 (footnote deleted)

endeavor to protect this price competition, if, for nothing else, the hope that price competition will be enhanced.

AMI also contends that nonprice competition in these markets was not lessened as a result of AMI's acquisition of French because non-price competition did not exist to any appreciable degree. AMI disputes Judge Barnes' finding that hospitals in San Luis Obispo "competed to attract doctors to admit to their facility . . . [and] to satisfy the needs of the doctors who were already admitting there" (IDF 134), arguing that due to polarization in the physician community in San Luis Obispo, physicians there rarely used their control over admissions to force hospitals to purchase equipment or improve services. Although AMI concedes that this may happen in other communities, AMI knew of only "one ten-year old instance . . . , which uncontradicted testimony establishes was unique," (RAB 48) AMI alleges that the practical impact of this polarization was that "doctors in San Luis Obispo were not at all likely to shift their admissions from French to Sierra Vista or vice versa" and, consequently, "neither hospital had a practical opportunity to induce the physicians associated with the other to switch their allegiance." (RAB 49) AMI also criticizes Judge Barnes' Initial Decision for failing to recognize that hospitals have strong incentives, other than nonprice competition, to enhance services and maintain quality. For instance, under the third-party payment system, hospitals increase revenues by providing equipment and services that are needed by their staffs, which AMI argues continues to be true even after its acquisition of French Hospital. (RAB 50) Also, hospitals are subject to strong regulatory and other nonmarket pressures to maintain a high quality standard of care, such as licensure and accreditation requirements as well as the fear of medical malpractice suits. (RAB 50 n.63) Most importantly, AMI contends that Complaint Counsel has not introduced any evidence showing that the quality of care at either French or Sierra Vista declined after the acquisition.

The record does not support AMI's position. We have already concluded that substantial nonprice competition exists in these markets,¹⁶ and we need not repeat the basis for our conclusions here. The record is replete with instances in which hospitals in San Luis Obispo endeavored to attract physicians by upgrading [34] equipment or services. French attempted to attract physicians in this manner, according to the testimony of Dr. Boyd:

The hospital, the partners, tried to improve the services to attract more physicians to admit their patients to French Hospital. I think that the most notable example would be with the ophthalmologists.

¹⁶ See pages 9-12 *supra*.

They obtained additional equipment that the ophthalmologists wanted and, as a result, now most of the ophthalmology is being done at French Hospital as opposed to the fact that it used to be done at Sierra Vista Hospital.

(Tr. Boyd 368; *see also* Tr. Bernhardt 1250) When the new French Hospital was built in 1972, the administration "tried to furnish the necessary instruments and the equipment that would encourage physicians to use French Hospital," such as special equipment for a particular neurosurgeon in the city. (Tr. Anderson 232-33) In the early 1970's Drs. Boyd and Cletsoway began switching admissions from Sierra Vista to French after their suggestions for urology equipment for the new French Hospital were followed. This apparently led to Sierra Vista purchasing similar equipment in an effort to recapture this business, as Dr. Boyd testified:

Sierra Vista Hospital decided to upgrade their equipment in order to move us back, and they acquired some new equipment but it wasn't as good equipment as French had.

So we told them we wouldn't come back until they had as good equipment as French. I think it took about two weeks and they had the other equipment, so that they had exactly the same equipment as French had.

(Tr. Boyd 356) Apparently, San Luis Obispo General Hospital also ordered the same equipment so as to attract Dr. Boyd, although Dr. Boyd apparently did not begin using that hospital for urological surgery until San Luis Obispo General actually received that equipment approximately eighteen months later. (Tr. Boyd 356) The record contains numerous other examples. (*See, e.g.*, Tr. Harvey 1685-86, Schwam 585-86, 593) Hospitals also competed for physicians by maintaining high quality nursing staffs (Tr. Boyd 361; Bernhardt 1297-98) and qualified medical staffs (Tr. Lave 826-27, Carlson 1323). The hospitals understood the importance of satisfying physician needs to retain business, as Mr. Anderson, the former administrator at French, explained: [35]

Obviously I didn't want my patients going to Sierra Vista or any other hospital for that matter. So we did try to create an environment which would encourage [physicians] to continue bringing their patients to French Hospital.

(Tr. Anderson 231) AMI recognized that this nonprice competition existed. (CX 197G) The record also demonstrates that despite AMI's argument to the contrary, physicians in San Luis Obispo would and in fact did switch admissions because of this nonprice competition. (*See, e.g.*, Tr. Boyd 368, 356, Bernhardt 1250) AMI acknowledged in internal documents that physicians were switching patronage between hospitals (CX 56F), notwithstanding the polarization in the

community that AMI asserts existed. Also, a number of physicians admitted patients to both Sierra Vista and French (*see* Tr. Boyd 364–66, 409), again notwithstanding this asserted polarization, and members of the French Clinic also used hospitals other than French (Tr. Harvey 1697, Anderson 248–49). AMI expressed concern about the prospect of losing physicians as a result of one form of this nonprice competition. Mr. Carlson, administrator of AMI's Sierra Vista Hospital, noted in his May 1978 "Monthly Operations Report":

An unknown factor in physician utilization of the hospital is the increasing number of physicians who have been invited to buy into the French Hospital. As of this date, I have not been able to obtain any useful information, except that three men have joined the hospital as owners.

(CX 317B) Mr. Carlson's "Monthly Operations Report" for November 1978 underscored this concern:

A problem of major concern is that of competition from French Hospital. Because of doctor ownership, past increases in the number of physicians and possible future additions to the Clinic makes that hospital an increasingly formidable competitor for the limited number of patients in the area. Although the census has remained at approximately the same level, additions to the Clinic could have significant adverse effects on Sierra Vista Hospital.

(CX 318B) Thus, although this polarization might in theory have had some restraining effect on the physicians' ability to respond to this nonprice competition by shifting admissions, in practice it does not appear to have done so. The record suggests that any [36] polarization that may have existed did not "chill" nonprice competition (or at least the need to engage in nonprice competition that was perceived by hospital administrators) among hospitals in San Luis Obispo. Thus, AMI's focus on the theoretical barriers that physician polarization created for hospitals in San Luis Obispo to engage in nonprice competition is largely off the mark. The most important evidence, and on which we principally rely in affirming Judge Barnes' finding of liability, is the record evidence that AMI's acquisition of French Hospital virtually eliminated the nonprice competition that existed between hospitals in San Luis Obispo. An AMI internal memorandum evidences this:

For many years Mr. Carlson and his forces have challenged the French Hospital and won the battle, now *that* activity has to be curbed and a balance of cooperation mixed with healthy competitiveness has to be reached whilst retaining hard earned standards of care The monopoly of the hospital market can only remain constructive if the above situation is achieved

(CX 425F) As noted previously, Mr. Bowytz, AMI's administrator at French after the acquisition, indicated in an interview conducted by Friesen that he could not compete with Sierra Vista along traditional lines, such as "steal[ing]" physicians away from Sierra Vista, because "competition is AMI." (CX 295W) Two hearing witnesses, Complaint Counsel economist Lester Lave and Dr. Schwam, testified that physicians in San Luis Obispo lost their "leverage" to promote improvements in hospital services or equipment by threatening to shift admissions to French Hospital:

So [I] and other members of the medical staff felt that having French Hospital as an independent entity was valuable in keeping our hospital—I won't call it up to the state of the art, [it is] still really quite behind—but at least keeping it roughly in range. When French Hospital was acquired by AMI that leverage was lost. [37]

(Tr. Schwam 585–86)¹⁷ AMI has not introduced any meaningful evidence to contradict the effect of this nonprice competition or any meaningful evidence to contradict the effect of the elimination of this nonprice competition in San Luis Obispo. We conclude that this nonprice competition merits protection by the antitrust laws, even the more so because of the "attenuated" nature of price competition in the health care industry. See *Northern Pacific Railway Co. v. United States*, 356 U.S. 1, 12 (1958). [38]

D. Competitive Effects of the Acquisition: Potential Competition

AMI disputes Judge Barnes' reliance on "the *potential* for price competition" among hospitals in San Luis Obispo in his conclusion that AMI's acquisition of French violated the antitrust laws. (ID 161 (emphasis added)) Judge Barnes concluded that potential competition exists for the business of group purchasers of hospital services, such as health maintenance organizations, self-insured businesses, and preferred provider plans, which had incentives to negotiate with hospitals for hospital care at the lowest cost and began receiving preferred rates from hospitals as early as 1978 (IDF 113–15), although apparently not in San Luis Obispo to any significant degree (IDF 116). He also found that "[i]n 1982, the California Legislature enacted three bills permitting the Medi-Cal program to contract for inpatient hospital services The objective of Medi-Cal contracting is to stimulate competition among hospitals for Medi-Cal patients, which did not

¹⁷ Dr. Lester Lave explained more fully the effect of the acquisition in terms of physician leverage:

Up until the acquisition, French offered [a] major point of threat, a major one that physicians practicing outside of French, at Arroyo Grande or Sierra Vista, or [San Luis Obispo] General could use on their hospital administrator in order to induce some kind of change, some improvement in behavior. Those effects are very important effects in terms of nonprice competition and they were terribly important in disciplining hospital administrators in other hospitals. And when French was acquired a lot of that went away.

(Tr. Lave 899–900)

exist before.”¹⁸ (IDF 117) AMI attacks Judge Barnes’ reliance on these findings on two grounds. First, AMI contends that there is no evidence that competition for the business of third-party providers has ever occurred in San Luis Obispo or that development of competition of this kind was anything other than a “speculative possibilit[y] at the time of the acquisition.”¹⁹ (RAB 51) Second, AMI maintains [39] that Judge Barnes’ reliance on these changes in state health care law as a source of potential competition contravenes “well-established anti-trust standards” because this legislation “was completely unrelated to the acquisition and was enacted long after that transaction had closed.” (RAB 51) AMI contends that in relying on the Medi-Cal legislation to find a lessening of the potential for competition Judge Barnes “was forced to extend the time-of-suit rule in an unprecedented and fundamentally unfair manner.” (RAB 51) AMI argues that the Supreme Court has never invalidated a merger or acquisition on the basis of post-acquisition developments that were unrelated to the defendant’s conduct (RAB 54) and that no case holds that a merger may be retroactively challenged on the basis of post-acquisition developments that are not an outgrowth of the transaction itself (RAB 55).

A review of the relevant case authorities suggests that Judge Barnes correctly invoked the time-of-suit rule in this case by taking cognizance of the passage of the Medi-Cal legislation. The seminal case examining the time-of-suit rule is *United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 586 (1957), in which the Supreme Court held unlawful du Pont’s acquisition of shares of General Motors stock, notwithstanding the fact that the suit was commenced some thirty years after the time of acquisition. The post-acquisition evidence focused on du Pont’s dominant position as General Motors’ principal supplier of automotive finishes and fabrics that it achieved as a result of its acquisition of General Motors stock. The Court concluded:

Section 7 is designed to arrest in its incipiency not only the substantial lessening of competition from the acquisition by one corporation of the whole or any part of the stock of a competing corporation, but also to arrest in their incipiency restraints or monopolies in a relevant market which, as a reasonable probability, appear at the *time of suit* likely to result from the acquisition by one corporation of all or any part of the stock of any other corporation.

¹⁸ The legislation also permits Blue Cross and other commercial health insurance companies to contract with selected hospitals for services for their subscribers, which will have the effect of increasing price competition between hospitals for this business. (IDF 123)

¹⁹ AMI makes specific reference to three findings in the Initial Decision in support of its argument that the Initial Decision is based only on “possibilities”:

(1) that the effects of the acquisition on the new Medi-Cal program are “illustrative of the injury possible to group purchasers of hospital services,” IDF 184; (2) that “it is possible” an HMO might be formed in San Luis Obispo in the future, IDF 183; and (3) that self-insured employers in San Luis Obispo “might well” seek to negotiate discounts with local hospitals. IDF 158.

(RAB 51)

* * * * *

"Incipency" in this context denotes not the time the stock was acquired, but any time when the acquisition threatens to ripen into a prohibited effect. See [40] *Transamerica Corp. v. Board of Governors*, 206 F.2d 163, 166.

* * * * *

We repeat, that the test of a violation of § 7 is whether, at the *time of suit*, there is a reasonable probability that the acquisition is likely to result in the condemned restraints. The conclusion upon this record is inescapable that such likelihood was proved as to this acquisition. The fire that was kindled in 1917 continues to smolder. It burned briskly to forge the ties that bind the General Motors market to du Pont, and if it has quieted down, it remains hot, and, from past performance, is likely at any time to blaze and make the fusion complete.

353 U.S. at 589, 597, 607, (footnote deleted; emphasis added). See also *United States v. Penn-Olin Chemical Co.*, 378 U.S. 158, 168 ("In any event, Penn-Olin was engaged in commerce at the time of suit and the economic effects of an acquisition are to be measured at that point rather than at the time of acquisition.") But in *United States v. Continental Can Co.*, 378 U.S. 441 (1964), in which defendants at trial introduced post-acquisition evidence of the absence of anticompetitive effects of the challenged acquisition, the Supreme Court held that the trial court "erred in placing heavy reliance" on this evidence in dismissing the action since the evidence principally related to defendants' post-acquisition conduct and "[defendant] Continental was under some pressure because of the pending government antitrust suit." 378 U.S. at 463. In *FTC v. Consolidated Foods Corp.*, 380 U.S. 592 (1965), the Supreme Court deemphasized what could be regarded as exculpatory "objective" post-acquisition evidence of the competitive effects—changes in industry market shares and unsuccessful attempts to engage in reciprocal buying—of Consolidated Foods' acquisition of one of its spice suppliers:

The Court of Appeals, on the other hand, gave post-acquisition evidence almost conclusive weight. It pointed out that, while Gentry's share of the dehydrated onion market increased by some 7%, its share of the dehydrated garlic market decreased 12%. 329 F.2d, p. 626. It also relied on apparently unsuccessful attempts at reciprocal buying. *Ibid.* the Court of Appeals concluded that "Probability can best be gauged by what the past has taught." *Id.*, p. 627. [41]

The Court of Appeals was *not in error in considering the post-acquisition evidence* in this case. See *United States v. du Pont & Co.*, 353 U.S. 586, 597 *et seq.*, 602 *et seq.* But we think it gave *too much weight* to it. Cf. *United States v. Continental Can Co.*, 378 U.S. 441, 463. No group acquiring a company with reciprocal buying opportunities is entitled to a "free trial" period. To give it such would be to distort the scheme of § 7. The "mere possibility" of the prohibited restraint is not enough. (*United States v. du Pont & Co.*, *supra*, p. 598.) Probability of the proscribed evil is required, as we have noted. If the post-acquisition evidence were given conclusive weight or allowed to override all probabilities, then acquisitions would go forward willy-nilly, the parties biding their time until reciprocity was allowed fully to bloom. It is, of course, true that

post-acquisition conduct may amount to a violation of § 7 even though there is no evidence to establish probability *in limine*. See *United States v. du Pont & Co.*, *supra*, pp. 597–598. But the force of § 7 is still in probabilities, not in what later transpired. [42]

380 U.S. at 598 (emphasis added). *Accord*, *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 576 (1967).²⁰ And the Court in *United States v. General Dynamics Corp.*, 415 U.S. 486 (1974), found that evidence of post-acquisition changes in the patterns and structure of an industry—there, the coal industry—might be considered in assessing the probable future anticompetitive effect of an acquisition. The government, in its reliance on market statistics based on past production, did not consider coal reserves needed for negotiating future long-term supply contracts. The future competitive impact of the merger was more accurately gauged by measuring access to such reserves, because long-term contracts constituted the competitive reality in the industry. The Court emphasized that “the essential question remains whether the probability of such *future* impact exists at the time of trial.” 415 U.S. at 505. In this regard, the Court clarified the limited role of post-acquisition evidence in that case by distinguishing genuine changes in industry and market [43] conditions and trends from specific post-acquisition competitive conduct under control of the merger parties:

In *FTC v. Consolidated Foods Corp.*, 380 U.S. 592, 598, this Court stated that post-acquisition evidence tending to diminish the probability or impact of anticompetitive effects might be considered in a § 7 case. See also *United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 586, 597 *et seq.*, 602 *et seq.* But in *Consolidated Foods*, *supra* and in *United States v. Continental Can Co.*, 378 U.S. at 463, the probative value of such evidence was found to be extremely limited, and judgments against the Government were in each instance reversed in part because “too much weight” had been given to post-acquisition events. The need for such a limitation is obvious. If a demonstration that no anticompetitive effects had occurred at the time of trial or of judgment constituted a permissible defense to a § 7 divestiture suit, violators could stave off such

²⁰ But the Commission opinion in that case expressed a reluctance to accept post-acquisition evidence:

Specifically, we think that the admission of post-acquisition data is proper only in the unusual case in which the structure of the market has changed radically since the merger—for example, where the market share of the merged firm has dwindled to insignificance—or in the perhaps still more unusual case in which the adverse effects of the merger on competition have already become manifest in the behavior of the firms in the market.

In re Procter & Gamble Co., 63 F.T.C. 1465, 1559 (1963). However, it is clear that the Commission in that case was concerned with exculpatory “subjective” post-acquisition evidence, *i.e.*, evidence of events or conduct that were within the defendants’ exclusive control. See *id.* (“[A] respondent, so long as the merger is the subject of an investigation or proceeding, may deliberately refrain from anti-competitive conduct—may sheathe, as it were, the market power conferred by the merger—and build, instead, a record of good behavior to be used in rebuttal in the proceeding.”) See also *United States v. Continental Can Co.*, 378 U.S. 441, 463 (1964); *Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255, 276 (7th Cir. 1981), *cert. denied*, 455 U.S. 921 (1982). This, of course, is not the case in the matter at bar since passage of the Medi-Cal legislation and its impact on price competition between hospitals is entirely beyond the control of AMI. *Accord*, *United States v. General Dynamics Corp.*, 415 U.S. 486, 504 (1974).

actions merely by refraining from aggressive or anticompetitive behavior when such a suit was threatened or pending.

* * * * *

In this case, the District Court relied on evidence relating to changes in the patterns and structure of the coal industry and in United Electric's coal reserve situation after the time of acquisition in 1959. Such evidence could not reflect a positive decision on the part of the merged companies to deliberately but temporarily refrain from anticompetitive actions, nor could it reasonably be thought to reflect less active competition than that which might have occurred had there not been an acquisition in 1959 Such evidence went directly to the question of whether future lessening of competition was probable, and the District Court was fully justified in using it.

415 U.S. at 504-06 (footnote deleted). *See also Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255, 276-77 (7th Cir. 1981), *cert. denied*, 455 U.S. 921 (1982); *United States v. International Harvester Co.*, 564 F.2d 769, 777-80 (7th Cir. 1977); *Varney v. [44] Coleman Co.*, 385 F.Supp. 1337, 1345-46 (D.N.H. 1974); *United States v. Falstaff Brewing Corp.*, 383 F.Supp. 1020, 1027 (D.R.I. 1974), *on remand from* 410 U.S. 526 (1973). Here, in the case at bar, it is clear that changes in the competitive structure of the market resulting from adoption of Medi-Cal legislation are relevant to the effects of the acquisition on that market. It is equally clear that any changes that may result from operation of the Medi-Cal scheme would largely be beyond the control of AMI. Thus, consideration of post-acquisition evidence of the adoption and effects of the Medi-Cal legislation is appropriate here.

The probative value that should be ascribed to this evidence is another issue, however. In each of the decisions discussed above, the post-acquisition evidence was of known events that could be corroborated. In the *du Pont* case, du Pont's dominance as General Motors' principal supplier of automotive fabrics and finishes was demonstrable. In *General Dynamics*, the Court was able to point to the changes in the structure of the coal industry with some degree of certainty. We can say with certainty that the California Legislature has adopted the Medi-Cal legislation which, as the Judge Barnes found, is intended to stimulate competition among hospitals for Medi-Cal patients. (IDF 117) We can also say with some degree of certainty that the success of Medi-Cal contracting in achieving costs savings depends in large measure on competition among hospitals for Medi-Cal contracts. But we cannot say with any degree of certainty what the effects of the Medi-Cal legislation would have been in San Luis Obispo, but for AMI's acquisition of French, because we do not know what the demonstrable impact of the Medi-Cal legislation has been anywhere else, and Complaint Counsel has not introduced any evidence establishing that. Complaint Counsel asks us to blindly accept

the argument that the objectives of the Medi-Cal legislation—cost savings generated from increased price competition between hospitals—will be realized, and realized in the way that the Medi-Cal legislation intended. Had Complaint Counsel established this—for instance, through evidence of actual price competition and cost savings generated in other communities through “Medi-Cal type” negotiating—the deleterious impact of AMI’s acquisition on price competition in San Luis Obispo would be more easily ascertainable. But here, there is no evidence that Medi-Cal works. To assume that it will is mere speculation. We find that evidence of the effects of the Medi-Cal legislation, if it can be described as evidence at all, is entitled to very little probative weight. Thus, we cannot conclude on the basis of the record before us that AMI’s acquisition of French Hospital eliminated “the potential for price competition,” and we rule that Judge Barnes erred in so holding.

E. Efficiencies Resulting From the Acquisition

AMI contends that appreciable cost savings are likely to be achieved as a result of its acquisition of French and the consolidation of French and Sierra Vista hospitals. AMI [45] estimates these savings at \$1.2 million in annual operating expense savings and one-time capital expense savings of \$12.2 million. (See RX-5614) AMI’s estimate of operating expense savings assumes that all medical services (except laboratory facilities) currently being provided by French and Sierra Vista will be consolidated and that the hospital at which a particular medical service is consolidated will provide the service at the lower unit cost presently being achieved by French or Sierra Vista. AMI’s estimate of the \$12.2 projected capital expense savings reflects the difference between the \$8.7 million figure that AMI estimates it would incur in implementing the consolidation plan and the \$20.9 million that would be required to maintain Sierra Vista as a “first-rate hospital” in the event that there was no consolidation and AMI were forced to divest French. AMI’s estimates of these savings were referenced in the Friesen consolidation study (see RX-5435Z61; RX-5436Z66; Tr. Mittelstaedt 1041–42) and subsequently quantified by Robert Mittelstaedt (see RX-5614), who supervised the Friesen study. (See also Tr. Schramm 2402)

Judge Barnes rejected AMI’s efficiencies “defense” because of the difficulties inherent in accurately gauging the alleged efficiencies and in balancing these cost savings against the anticipated increase in market power. (ID 176) He made a number of findings in support of this conclusion. First, he found that it was not clear that consolidation of French and Sierra Vista would occur because consolidation would require the preparation of detailed implementation plans and the

approval of AMI's Executive Committee and the Board of Directors of each of the hospitals. (ID 167-68) He also found that a number of practical barriers could prevent implementation of the consolidation: no consolidation on this scale had ever been accomplished before; physicians who currently practice at one hospital might resist relocation of their specialties to the other hospital; and AMI would need approval from the local HSA and the State of California to make most of the capital expenditures required to consolidate French and Sierra Vista. (ID 168) Second, Judge Barnes concluded that it was questionable whether economies of scale, such as the \$1.2 million of operating expense savings alleged by AMI, actually could be gained through consolidation. He noted that AMI's own economic expert, Dr. Schramm, concluded that there was inconsistent evidence as to the existence of scale economies for hospitals. (ID 168-69) Third, Judge Barnes found that AMI had not taken any significant steps towards consolidation of French and Sierra Vista during the seventeen month period between the acquisition of French and the time that AMI learned of the Commission's investigation of the acquisition. He noted that AMI internal documents concluded that the proposed consolidation would only produce "somewhat, not [46] enormously, potential lower costs."²¹ (RX 5435C; *see* ID 169) Fourth, Judge Barnes concluded that the estimate of operating cost savings contained in the Mittelstaedt study made a number of questionable assumptions and omissions that had the effect of overstating the amount of savings that would result from consolidation of French and Sierra Vista hospitals.²² (ID 170-72) Fifth, Judge Barnes concluded that, assuming that the consolidation was not implemented, it was not certain that AMI [47] would be willing to spend the \$21 million that it contended was necessary to maintain Sierra Vista as a "first-rate hospital." He attributed

²¹ The administrator of Sierra Vista, in a 1981 memorandum, apparently concurred with this assessment:

It was my hope that our long range plans would permit consolidation of some services with the eventual objective of at least a slight decrease in the rate at which expenses are increasing. *Even though such cooperative efforts would not necessarily be of major dollar savings, they would have been at least symbolic of our united efforts to hold down costs.*

(CX 1063A (emphasis added))

²² Judge Barnes criticized the Mittelstaedt study, as follows. The study assumes that a consolidated service could be provided at one location for both hospitals at the lower unit cost of the two hospitals, although in some instances the service would be provided by the higher cost hospital. Attribution of a portion of these savings to more effective purchasing arrangements is incorrect, because joint purchasing involving separate-owned hospitals is fairly common in California and, consequently, consolidation is not necessary to achieve these savings. The study ignores the cost of capital for the \$8.7 million expenditure required to consolidate French and Sierra Vista. The study also ignores the cost of depreciation on facilities and renovations that are built in the course of this consolidation. The study fails to include salary increases that would be required because of additional responsibilities that would have to be taken on by existing personnel after the consolidation. The projected operating cost savings for laboratory tests ignores the need to maintain two laboratories after the consolidation. The study assumes, without explanation, certain savings in consolidation of laundry and food services. The study fails to include the administrative expenses associated with implementation of the consolidation by AMI personnel. The study also fails to take into account the cost of physically transporting personnel, goods, and specimens between French and Sierra Vista after the consolidation, since the hospitals are two miles apart. (ID 170-72)

this to several things. AMI presented no proof that such expenditures would be necessary. Even assuming that the improvements in Sierra Vista are needed, he concluded that AMI may not be willing to spend \$21 million in a market area that, according to AMI internal documents, "does not present an ideal situation in terms of market growth and development" and where "[g]rowth in the community is not expected to be high enough to justify major capital expenditures across the board of AMI hospitals."²³ (RX 5435Z66) AMI would also need certificate-of-need authorization to make the changes envisioned by the Mittelstaedt study, and Judge Barnes concluded that California's health planning authorities will closely scrutinize these expenditures to determine whether the improvements were necessary and whether more modest improvements would suffice.²⁴ And finally, Judge Barnes found there to be inconsistencies between AMI's \$20.9 million estimate and other record evidence, which he attributed to the fact that "[i]t is in AMI's interest to make these capital costs appear as high as possible to accentuate the supposed savings to be realized from consolidating with French." (ID 174)

On first impression, it appears that the case law has adopted a slight bias against accepting efficiency justifications in merger cases. However, a correct reading of Supreme Court precedent in this area demonstrates that lower courts' reliance on statements contained in these Supreme Court opinions for rejection of an efficiencies defense is misplaced. A careful examination of these statements reveals that they are dicta only. In *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962), the Justice Department challenged the merger of G. R. Kinney Company and the Brown Shoe Company, both of which manufactured and retailed shoes. In finding the merger to be illegal, the district court accepted the Justice Department's argument that the merger was anticompetitive because, *inter alia*, it lowered [48] prices to the extent that independent retailers could no longer compete in the low and medium-priced shoe markets. See *United States v. Brown Shoe Co.*, 179 F.Supp. 721, 738 (E.D. Mo. 1959). On appeal to the Supreme Court, Brown Shoe argued that the vertical integration that resulted from the merger did not produce any economic efficiencies; the Justice Department contended that the merger caused lower costs, lower prices, and better quality. In its opinion, the Court set forth what has

²³ Judge Barnes concluded that AMI could actually build a new hospital for considerably less than the \$20.9 million that it estimated would be needed to renovate Sierra Hospital. Using AMI's own estimates, which indicate that AMI can build hospitals at a cost averaging \$50,000 to \$60,000 per bed, AMI could build a new fully equipped hospital, with the 50 bed addition contemplated by the Mittelstaedt study, for approximately \$13 million, some \$7 million less than AMI's estimated cost of renovating Sierra Vista.

²⁴ Specifically, Judge Barnes found that more than \$3.1 million of the proposed capital expenditures, for the addition of 50 beds in the late 1980's, may not be approved because San Luis Obispo County currently has excess capacity, a situation which is likely to continue into the future. (ID 173-74)

been generally regarded to be a condemnation of the efficiency defense:

A third significant aspect of this merger is that it creates a large national chain which is integrated with a manufacturing operation. The retail outlets of integrated companies, by eliminating wholesalers and by increasing the volume of purchases from the manufacturing division of the enterprise, can market their own brands at prices below those of competing independent retailers. Of course, some of the results of large integrated or chain operations are beneficial to consumers. Their expansion is not rendered unlawful by the mere fact that small independent stores may be adversely affected. It is competition, not competitors, which the Act protects. But we cannot fail to recognize Congress' desire to promote competition through the protection of viable, small, locally owned businesses. Congress appreciated that occasional higher costs and prices might result from the maintenance of fragmented industries and markets. It resolved these competing considerations in favor of decentralization. We must give effect to that decision.

370 U.S. at 344 (footnote deleted). However, it is obvious that since Brown Shoe did not argue efficiency as a defense (but the *absence* of efficiency as a defense), the Court was not presented with, and did not address, the issue of efficiency as a justification. See *Muris*, "The Efficiency Defense Under Section 7 of the Clayton Act," 30 *Case W. Res. L. Rev.* 381 (1980). In *United States v. Philadelphia National Bank*, 374 U.S. 321 (1963), it appeared that the Supreme Court was rejecting Philadelphia National Bank's efficiency justification for the acquisition when the Court stated:

This brings us to appellees' final contention, that Philadelphia needs a bank larger than it now has in order to bring business to the area and stimulate its [49] economic development We are clear, however, that a merger the effect of which "may be substantially to lessen competition" is *not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial*. A value choice of such magnitude is beyond the ordinary limits of judicial competence, and in any event has been made for us already, by Congress when it enacted the amended § 7. Congress determined to preserve our traditionally competitive economy. It therefore proscribed anticompetitive mergers, the benign and the malignant alike, fully aware, we must assume, that some price might have to be paid.

374 U.S. at 371 (emphasis added). Philadelphia National Bank was clearly *not* arguing an efficiencies defense, but only that the local community would benefit from a larger bank, a "socio-political" justification. The Court explicitly recognized that it was *not* entertaining (and, presumably, not condemning) an efficiencies defense:

There was evidence that Philadelphia, although it ranks fourth or fifth among the Nation's urban areas in terms of general commercial activity, ranks only ninth in terms of the size of its largest bank, and that some large business firms which have their

head offices in Philadelphia must seek elsewhere to satisfy their banking needs because of the inadequate lending limits of Philadelphia's banks; . . .

Appellees offered testimony that the merger would enable certain *economies of scale*, specifically, that it would enable the formation of a more elaborate foreign department than either bank is presently able to maintain. *But this attempted justification, which was not mentioned by the District Court in its opinion and has not been developed with any fullness before this Court, we consider abandoned.*

374 U.S. at 334 n.10 (emphasis added). *See also United States v. Phillipsburg National Bank*, 399 U.S. 350 (1970) (alleging pro-competitive effects, that "by enhancing their competitive position, it would stimulate other small banks in the area to become more aggressive in meeting the needs of the area," not benefiting consumers by reducing operating costs) And in *FTC v. [50] Procter & Gamble Co.*, 386 U.S. 568 (1967), it again appeared that the Supreme Court was intending to condemn the efficiencies defense when it said:

Possible economies cannot be used as a defense to illegality. Congress was aware that some mergers which lessen competition may also result in economies but it struck the balance in favor of protecting competition. *See Brown Shoe Co. v. United States*, *supra*, at 344.

386 U.S. at 580. However, as in *Brown Shoe*, it does not appear that an economies defense was ever asserted by Procter & Gamble. The Court did refer to the cost savings for advertising and sales promotion that would be available because of Procter & Gamble's large volume purchasing in these areas. But Procter & Gamble did not develop the anticipated savings in sales, distribution, and manufacturing that would result from the acquisition as a factor offsetting any anticompetitive effects. In fact, as in *Brown Shoe*, the Court actually viewed the economies in advertising and sales promotion as an anticompetitive effect of the acquisition since the volume discounts that were made available to Clorox by virtue of the acquisition would have the effect of discouraging new entry into the bleach market. *See* 386 U.S. at 579. Thus, on the basis of *Brown Shoe*, *Philadelphia National Bank*, *Phillipsburg National Bank*, and *Procter & Gamble*, it appears that the Supreme Court has stated, in dicta only, a bias against assertion of the efficiencies justification in Section 7 cases,²⁵ and those statements do not appear in the context of an efficiencies defense.

There is language appearing in several cases that suggests that efficiencies should be considered in antitrust analysis, in general, and under Section 7, in particular. The Supreme Court's opinion in *North-*

²⁵ The Supreme Court's decision in *Ford Motor Co. v. United States*, 405 U.S. 562 (1972), on which Judge Barnes relied in his Initial Decision (ID 175), makes no reference to pro-competitive effects of the acquisition in the form of scale economies.

ern Pacific Railway v. United States, 356 U.S. 1 (1958), identifies economic efficiency as one of the principal goals of antitrust:

The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. It rests on the premise that the unrestrained interaction of competitive forces will [51] yield *the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress*, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions.

356 U.S. at 4 (emphasis added). In *United States v. United States Gypsum Co.*, 438 U.S. 421, 442 n.16 (1978), the Supreme Court characterized economic efficiency as procompetitive ("The exchange of price data and other information among competitors does not invariably have anticompetitive effects; indeed such practices can in certain circumstances increase economic efficiency and render markets more, rather than less, competitive.") The Court relied heavily on economic analysis of competitive effects in *Continental T.V. v. GTE Sylvania, Inc.*, 433 U.S. 36 (1977), stating that the rule of reason analysis requires the fact-finder to "weigh[] *all of the circumstances* of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition," 433 U.S. at 49 (emphasis added; footnote deleted). The Court has also indicated a desire to consider economic evidence in assessing the legality of mergers under Section 7, as demonstrated in *United States v. General Dynamics Corp.*, 415 U.S. 486 (1974) and *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602 (1974). The emphasis on economic analysis displayed by the Court in recent decisions has led several circuit courts of appeal to consider scale economies in assessing mergers under Section 7. For instance, in *Fruehauf Corp. v. FTC*, 603 F.2d 345 (2d Cir. 1979), the Second Circuit Court of Appeals explicitly found scale economies in the manufacture of heavy duty truck wheels to be a procompetitive factor in favor of the acquisition. And in *Marathon Oil Co. v. Mobil Corp.*, 669 F.2d 378 (6th Cir. 1981), *cert. denied*, 455 U.S. 982 (1982), the Sixth Circuit Court of Appeals recognized operating and scale efficiencies that could arise as a result of the merger as one factor to consider in analyzing the competitive impact of the merger. See 669 F.2d at 380, 382. These cases have required that such efficiencies be established by substantial evidence.²⁶ [52] See

²⁶ A number of legal scholars have written in support of the efficiency defense in Section 7 cases. Professor Sullivan writes in his treatise:

(W)here cost saving efficiencies are clear, and arise in a context where market forces will oblige the seller to pass them on to consumers, and where competitive harm is only speculative (as for example where the basis for the challenge to the merger is an increased concentration in some setting near the *prima facie* threshold), the wise course is to risk the possible social harm for the certain benefit. Even if the court is not ready to weigh the social benefit of efficiencies against the social harm of competitive injury when both seem similarly likely or certain to eventuate, it might nevertheless value a significant and likely social benefit higher than a much more doubtful harm.

(footnote cont'd)

Fruehauf Corp. v. FTC, 603 F.2d 345, 358 (2d Cir. 1979). *Accord, Marathon Oil Co. v. Mobil Corp.*, 669 F.2d 378 (6th Cir. 1981), *cert. denied*, 455 U.S. 982 (1982) ("convincing evidence"). This is especially so because of the inherent difficulty in identifying and quantifying the efficiencies bearing on Section 7 liability.

In this case, we find that AMI did not establish, with any certainty, that substantial efficiencies exist. Giving AMI *all* the benefits of the many doubts that exist with regard to the Mittelstaedt study, AMI estimates that the consolidation will produce only a 5.6% reduction in operating costs. (RX 5614 B, K) Assuming that these cost savings can be realized, AMI does not establish that they will necessarily inure to the benefit of consumers; in fact, AMI's own economic expert, has suggested the contrary.²⁷ Certainly if we were to accept AMI's assertion that [53] "reimbursement [under Medicare, Medicaid, and Blue Cross] is limited by customary and reasonable charges determined on a regional or nationwide basis" (RAB 43-44), realization of the cost savings may not directly impact the prices charged at French and Sierra Vista and paid by third-party payers. However, AMI's assertion of the efficiencies defense does not satisfy any of the criteria set forth by any of the authorities. Without going into the item-by-item and line-by-line assertions and counter-assertions by AMI and Complaint Counsel, we agree with Judge Barnes that AMI has failed to establish with substantial evidence the existence of the cost savings from the acquisition. (See ID 166-74) AMI has not demonstrated to any degree that these efficiencies are already enjoyed by one or more firms in the industry. AMI has not demonstrated to any degree that these efficiencies could not be achieved within a comparable period of time through a merger that threatened less competitive harm, such as a combination of San Luis Obispo General Hospital and either French or Sierra Vista.²⁸ See generally Justice Guidelines at p. 63-64. AMI does not show that these efficiencies "clearly outweigh any in-

Sullivan, *Antitrust* 631 (1977). See also Areeda & Turner, *Antitrust Law* ¶939-62 (1980); Bork, *The Antitrust Paradox* (1978); Muris, "The Efficiency Defense Under Section 7 of the Clayton Act," 30 *Case W. Res. L. Rev.* 699 (1977); Leibel, "Market Power and Competitive Superiority in Concentrated Industries," 25 *U.C.L.A. L. Rev.* 1221 (1978).

²⁷ Dr. Schramm has written:

[T]he merger movement [in the hospital industry] must be seen in the light of consumer satisfaction. Clearly, absolute consumer choices suffer as consolidations advance. This is traditionally rationalized by citing reductions in unit prices that follow consolidation. Interestingly, however, prices do not always reflect the savings of consolidation and artificial price settings must be controlled through regulation. The apparent risk in consolidation from the consumer perspective is that prices may not reflect true savings.

(CX 1048T) Dr. Schramm has also concluded that "[e]mpirical research . . . leads one to the uneasy conclusion that economies of scale may or may not exist for hospitals" (CX 1048P (footnote deleted)) and that "[c]urrent research has not demonstrated conclusively that hospital consolidation automatically leads to increased efficiency and reduced levels of real spending per capita for hospital care" (CX 1048T).

²⁸ Contrary to AMI's assertions in its Reply Brief, it is clear that a merger between San Luis Obispo General Hospital and either French or Sierra Vista would have less anticompetitive impact, at least in terms of diminution of nonprice competition, than the merger under consideration, given that French served as Sierra Vista's primary competition in terms of quality of service.

crease in market power" that we have concluded results from AMI's acquisition of French, an increase in market power that we find is "both severe and clearly evident." See Muris, "The Efficiency Defense Under Section 7 of the Clayton Act," 30 *Case W. Res. L. Rev.* 381, 426 (1980); RRB 18 n.27. And, given AMI's complete dominance of the general acute care health services market in these two geographic markets, as a result of the acquisition, it is unlikely that AMI can show that "market forces will oblige [AMI] to pass [cost saving efficiencies] on to consumers." See Sullivan, *Antitrust* 631 (1977). Accordingly, we find that AMI has not made a sufficient showing that such efficiencies exist to warrant their consideration as a procompetitive effect and to be balanced against the anticompetitive impact of this acquisition. [54]

F. Conclusion

We conclude on the basis of the foregoing that AMI's acquisition of French Hospital has and will substantially lessen competition or tend to create a monopoly of general acute care health services in the San Luis Obispo County and the City of San Luis Obispo in violation of Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act.

V. ATTEMPT TO MONOPOLIZE

Judge Barnes held that AMI attempted to monopolize the relevant product and geographic markets, which constitutes an unfair method of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act. AMI appeals this holding, contending that Judge Barnes' ruling ignores AMI documents contemporaneous to the acquisition that establish that AMI's intent in acquiring French "was to make a profitable investment that would promote health planning goals." AMI also maintains that the ruling ignores case law precedent holding that an acquisition, standing alone, does not satisfy the "specific intent" or "unlawful conduct" elements of the attempted monopolization course of action. (RAB 59)

Judge Barnes concluded in his Initial Decision that each of the three elements of the attempted monopolization offense was satisfied in this case. See *Swift & Co. v. United States*, 196 U.S. 375, 396 (1905). Specifically, he concluded that AMI's acquisition of French constituted anticompetitive conduct designed to further its attempt to monopolize, and that because the acquisition had the effect of eliminating AMI's principal competitor and produced a large increase in market share, the acquisition itself provided a sufficient basis for a finding of attempted monopolization. (ID 162-63) Judge Barnes found that, as evidenced by contemporaneous documents authored by AMI Vice

Presidents Loftin and Danko (CX 38B; CX 41C-D), AMI officials involved in the decision to acquire French clearly anticipated the exclusionary effect of the acquisition, demonstrating AMI's specific intent to monopolize. (ID 163-64) Judge Barnes also concluded that there was a dangerous probability that AMI would be successful in its attempt to monopolize the hospital services markets in the City of San Luis Obispo and San Luis Obispo County, and that success was actually achieved, given that AMI controlled over 80% of the city market and over 70% of the county market. (ID 165; *see* CX 425F)

Although AMI's appeal of Judge Barnes' finding of liability for attempted monopolization presents several novel issues that could be examined by this Commission, we decline to do so here. We have already found that AMI's acquisition of French violated Section 7 of the Clayton Act and, with it, Section 5 of the Federal Trade Commission Act. We have ordered an appropriate remedy to correct this violation. We do not believe that it is necessary to consider whether AMI engaged in attempted [55] monopolization in further violation of Section 5 for purposes of the remedy ordered here. Accordingly, we will not do so.

VI. REMEDY

Having decided that AMI's acquisition of French Hospital violates Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, we now turn to a consideration of the appropriate remedy to be ordered in this case. Judge Barnes ordered that AMI divest all assets, rights, and privileges that it obtained in conjunction with the French acquisition, and prohibited AMI for a period of ten years from acquiring, without the prior approval of the Commission, any hospital located within a thirteen state area.²⁹ (*See* ID 192-94 (¶¶II & III)) [56]

²⁹ More specifically, the Order proscribes acquisitions of any hospital located in Oregon, California, Texas, Oklahoma, Missouri, Arkansas, Louisiana, Mississippi, Alabama, Georgia, Florida, South Carolina, or North Carolina, if:

A. The hospital to be acquired is within a Standard Metropolitan Statistical Area ("SMSA") in which AMI already operates a hospital and in which AMI, immediately after the acquisition, would operate hospitals that combined have a twenty (20) percent or more share of the licensed general acute care hospital beds within that SMSA; or

B. The hospital to be acquired is not within an SMSA but is within a county in which AMI already operates a hospital and in which AMI, immediately after the acquisition, would operate hospitals that combined have a twenty (20) percent or more share of the licensed hospital beds within that county; or

C. The hospital to be acquired is (1) not within an SMSA or a county in which AMI already operates a hospital, but is within thirty (30) miles of a hospital which AMI already operates in another SMSA or county, and (2) the hospital to be acquired and any hospital(s) that AMI operates combined have a twenty (20) percent or more share of the licensed hospital beds in the area within thirty (30) miles of the midpoint between the hospital to be acquired and any hospital operated by AMI.

Provided, however, That no acquisition shall be subject to this Section III if the consideration to be paid for the hospital, including assumption by AMI of liabilities of its present owners, does not exceed one million dollars (\$1,000,000).

AMI appeals Judge Barnes' prior approval order on two principal grounds.³⁰ First, AMI argues that the prior approval requirement is not reasonably related to AMI's conduct in this case because the order extends beyond the relevant geographic markets involved here. (RAB 66) AMI contends that a broad order that is to apply beyond the relevant geographic markets can be justified under the case law only when a "knowing and deliberate violation" or a "likelihood of repeated unlawful conduct" has been shown, which Complaint Counsel has failed to do. AMI criticizes Judge Barnes' reliance on *Ekco Products Co.*, 65 F.T.C. 1163 (1964), *Beatrice Foods Co.*, 68 F.T.C. 1003 (1965), and *Liggett & Myers, Inc.*, 87 F.T.C. 1074 (1976), all of which did not involve fencing-in provisions applicable outside the relevant markets, but instead focused on the appropriateness of such provisions in cases involving a nationwide market found to be highly concentrated, which AMI argues is not the case here. Second, AMI argues that the prior approval requirement would be contrary to public interest because it would reduce existing competition for the purchase of hospitals that are put up for sale. (RAB 69-70) AMI contends that because of delays and uncertainty attendant to Commission review of proposed acquisitions, the prior approval requirement "would foreclose AMI from effective participation in the typical bidding contest held by hospitals looking for a buyer" and would "disable AMI since neither it nor a prospective seller could confidently predict the outcome." (RAB 73)

Judge Barnes concluded that the prior approval requirement was warranted because of the merger trend in the hospital industry and AMI's history of growth through acquisition. He noted that the Commission has consistently utilized prior approval as a tool in merger law enforcement: since January 1983 all nine consents that have either been ordered or provisionally accepted contained prior approval requirements, and three of the four that involved local or regional geographic markets required prior approval for all acquisitions anywhere in the country. He also rejected AMI's contention that the prior approval requirement will handicap it in bidding for hospitals, concluding [57] that because of possible certificate-of-need and Hart-Scott-Rodino requirements, time is not as significant in the acquisition process as AMI posits.

We begin by noting that "[t]he Commission has wide discretion in its choice of a remedy deemed adequate to cope with . . . unlawful practices" and "the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to

³⁰ AMI relegates its appeal of the divestiture order to a footnote. (See RAB 66 n.84) Divestiture would clearly work to restore both price and nonprice competition that we have found existed between French and Sierra Vista prior to the acquisition, and consequently we categorically reject AMI's assertion that divestiture would be punitive in this instance.

exist.” *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611, 613 (1946). See also *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952). Although it is well-settled that once a violation of law is established by the Government “all doubts as to the remedy are to be resolved in its favor,” the courts, in civil proceedings, “are not authorized . . . to punish antitrust violators, and relief must not be punitive.” *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 326, 334 (1961). Although divestiture is the usual remedy in the case of Section 7 violations, see, e.g., *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 328–31 (1961), the Commission “acts within the limits of its authority when it bars repetitions of similar conduct with other parties,” *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952), and the Commission has the authority to impose prior approval requirements, see, e.g., *Abex Corp. v. FTC*, 420 F.2d 928 (6th Cir.), cert. denied, 400 U.S. 865 (1970).

The Commission and the courts have employed numerous standards in determining whether a broad remedial order, such as a prior approval requirement, is appropriate. In *United States v. W. T. Grant Co.*, 345 U.S. 629 (1953), in which the United States sought to enjoin defendants from violating Section 8 of the Clayton Act, the Supreme Court identified the appropriate standard to be whether “there exists some *cognizable danger of recurrent violation*, something more than the mere possibility which serves to keep the case alive.” 345 U.S. at 633 (emphasis added). In *Litton Industries, Inc. v. FTC*, 676 F.2d 364 (9th Cir. 1982), the Ninth Circuit Court of Appeals considered “whether the respondents acted in blatant disregard and utter disregard of the law, and whether they had a history of engaging in unfair trade practices” in determining whether a nationwide multi-products advertising ban bore a reasonable relation to deceptive advertising of a single product. 676 F.2d at 371. In *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982), also involving a nationwide multi-products advertising ban, the Ninth Circuit characterized this test to be whether the “advertiser’s conduct shows a ready willingness to flout the law” 676 F.2d at 392. However, as is readily apparent, none of these cases involves the standards to be employed in a Section 7 case, and because the policy considerations at play in these cases may be different from those in a Section 7 case, we will not apply these to the case at bar.

Instead, we will look for guidance to Section 7 cases in which the Commission has adopted a prior approval requirement. In *Jim Walter Corp.*, 90 F.T.C. 671, 764 (1977), the Commission cited [58] respondent’s history of growth in the roofing products industry, a series of more than twenty acquisitions during the ten-year period preceding issuance of the complaint, as the principal justification for ordering a ten-year prior approval requirement. In *Marquette Cement Manu-*

facturing Co., 75 F.T.C. 32, 104 (1969), the Commission found that respondent's acquisition of a ready-mixed concrete company contributed to the anticompetitive trend towards vertical integration in the cement industry, and imposed a ten-year prior approval requirement on future acquisitions by respondents. The Commission justified imposing a ten-year approval requirement in *Liggett & Myers, Inc.*, 87 F.T.C. 1074, 1140 (1976), on the basis of the oligopolistic conditions that the Commission found to exist in the dog food industry, and that it would "prevent[] [respondent] from eliminating through acquisition any of the few remaining independent companies which represent significant competition." In *Beatrice Foods Co.*, 68 F.T.C. 1003, 1006 (1956), the Commission stated that "[p]rophylactic relief, not merely the after-the-fact remedy of divestiture, is essential if the Congressional policy expressed in Section 7 of the Clayton Act is to be effectively carried out" The Commission held that a ten-year prior approval requirement was necessary because

respondent and several other large national dairy companies have embarked on extensive and far-reaching programs of acquisitions whose effect has been the substantial increase of concentration in the industry, and the elimination of a middle tier of local or regional companies capable of furnishing effective competition. The mergers also eliminated respondent and other leading dairy firms as sources of potential competition in these concentrated local markets. If competition in this industry is to be restored and maintained, it is essential that this continuing elimination of viable local or regional competitors through acquisition be halted now and that respondent be restored as a potential competitor by precluding it from entering local markets by acquisition.

68 F.T.C. at 1005-06. As further justification, the Commission cited imposition of similar prohibitions on respondent's leading competitors. And in *Ekco Products Co.*, 65 F.T.C. 1163, 1222 (1964), although the Commission expressed concern about respondent's repeated efforts to restrict competition by acquiring new entrants to the commercial meat-handling equipment market, the Commission's principal rationale for the prior approval requirement was that these acquisitions permitted respondent to retain its monopoly position against new competition. Thus, from these cases we conclude that it is industry market structure and market conditions, not whether a "knowing and deliberate violation" or a "likelihood of repeated [59] unlawful conduct" has been shown, as AMI asserts, that determines the appropriateness of imposing a prior approval requirement in a particular case. Consequently, we must look at the record evidence of market conditions present in the general acute health care services industry to determine whether the ten year prior approval remedy ordered by Judge Barnes is appropriate here.

Complaint Counsel argues that market conditions necessitate im-

sition of a prior approval requirement. The record shows that in 1972, 6.5% of the beds in community hospitals were controlled by for-profit entities; by 1980, that had grown to 8.8%. (RX 5719; ID 185) In the years 1975-1981, the five largest proprietary hospital chains have acquired a total of 192 general acute care hospitals, (CX 608; Tr. Silvia 794-95; ID 186), three of which were acquired in 1975 and 80 of which were acquired in 1981. (ID 186) AMI has acquired nineteen general acute care hospitals since 1980, and intends to acquire hospitals in the future at a rate of between four and six hospitals a year. (CX 430A, C, L, W; ID 186) AMI currently owns, operates, or has under construction 75 hospitals in the United States, nearly all of which were apparently obtained through acquisition. (ID 186) In addition to this, AMI argues that more than a dozen other hospital chains are also actively engaged in acquiring hospitals and that some large hospitals are acquiring other hospitals in their local areas; most of the acquisitions have been made in the "Sunbelt" because of that region's rapid population growth and relatively unrestrictive regulation of hospitals; with this emphasis on acquisitions in the "Sunbelt," there is a greater chance that AMI will acquire hospitals near those it already owns and that concentration in local markets where AMI acquires hospitals will be higher because of acquisitions by other firms; and that AMI's efforts, at least in the case of its acquisition of French, have focused on elimination of its most significant competitor in the local market. (CAB 66-67)

We cannot agree with Complaint Counsel. Although the record evidence clearly indicates that the hospital industry is undergoing a move towards increased consolidation, on the basis of this evidence we are unable to assess the effects of those changes on competitive conditions within the multitude of local and regional geographic markets that may exist for hospital services. Our reading of the record does not indicate any basis for defining the parameters of these markets, determining concentration levels or changes in concentration levels in these markets as a result of the acquisitions that are taking place in this industry, or assessing whether the acquisitions have had either the effect of entrenching monopolists or increasing competition between market participants. Complaint Counsel asks us in essence to assume that acquisitions in this industry, *per se*, are anticompetitive. Although we have concluded that this acquisition is violative of Section 7, we cannot assume on the basis of this record that market conditions and market structure [60] in this industry are such that all such acquisitions, even under the conditions adopted by the prior approval remedy, are necessarily anticompetitive.

In reaching this conclusion, we find that AMI's presence in the hospital market as a potential purchaser of local hospitals that are

put up for sale has a substantial potential procompetitive impact, and that the proposed prior approval requirement will uniquely debilitate or perhaps entirely eliminate AMI as a competitor in this market. Notwithstanding Complaint Counsel's arguments and Judge Barnes' findings to the contrary, we believe that time is of the essence in negotiations for the purchase of local hospitals, and that the ability to make a purchase commitment with some degree of certainty of obtaining the necessary regulatory approvals is an important element in this negotiating process. The prior approval requirement would uniquely disable AMI in these negotiations. On at least one earlier occasion, in its decision in *Beatrice Foods Co.*, 68 F.T.C. 1003, 1006 (1965), the Commission justified the prior approval remedy on the ground that it would put respondent on an equal footing with its leading competitors. Here, such a requirement would clearly put AMI on an unequal footing with its principal competitors. And there is no evidence in the record that indicates that AMI retains monopoly or dominant status in other local markets, as was the case in *Ekco Products Co.*, 65 F.T.C. 1163, 1223 (1964), so as to encourage the erosion of that monopoly position by hampering AMI's acquisition efforts.

Instead of requiring AMI to obtain prior approval from the Commission for acquiring other hospitals under the conditions set forth by Judge Barnes, we believe that many of Complaint Counsel's more legitimate objections to such acquisitions can be satisfied by requiring AMI simply to notify the Commission of its intention to make an acquisition of the variety contemplated by Judge Barnes' order. This would enable the Commission to investigate an acquisition that appears to involve significant antitrust problems, and take enforcement action against the acquisition before the acquisition has progressed beyond the "point of no return," while at the same time preserve the procompetitive benefits attributable to AMI's presence in the acquisition market. This is not intended to replace Hart-Scott-Rodino filing requirements that may apply to any of AMI's future acquisitions, but is to apply to AMI's hospital acquisitions which, for one reason or another, may be exempt from those filing requirements. We contemplate that notification by AMI of such acquisitions is to be provided when AMI's Board of Directors or Executive Committee authorizes issuance of a letter of intent or enters into a purchase agreement to make such an acquisition, whichever is earlier. [61]

An appropriate order³¹ requiring the divestiture by AMI of French

³¹ Complaint Counsel requests that several technical modifications be made to Judge Barnes' Order, relating to the description of the geographic markets, stock divestiture, and limitations on the applicability of the Order. (CAB 73-74) AMI does not appear to object to these modifications, and they will be ordered to the extent that they are not inconsistent with our modifications to the remedy ordered by Judge Barnes.

Hospital and prior notification of acquisitions by AMI of the variety contemplated by Judge Barnes' Order is appended.

OPINION OF COMMISSIONER PERTSCHUK
CONCURRING IN PART AND DISSENTING IN PART

I concur in the majority's decision to require AMI to divest the acquired assets that are the subject of this case. However, I dissent from the majority's unwillingness to require AMI, for a period of ten years, to obtain Commission approval prior to making further acquisitions under the limited circumstances ordered by the ALJ. Instead of the customary prior approval order the majority simply requires AMI to notify the FTC before it makes certain future acquisitions.

The FTC has consistently ordered a ten year prior approval requirement as a standard remedy in cases under Section 7 of the Clayton Act.¹ As a "fencing in" provision, a prior approval order is prophylactic in nature and may be ordered to "simply [2] insure that any future market acquisition is not anticompetitive. This supervisory provision puts a tolerable burden on [a company's] future conduct and is clearly within bounds of reasonableness."² In *Beatrice Foods Co.*, 68 F.T.C. 1003, 1006 (1956), the Commission found a violation of Section 7, ordered divestiture and included a prior approval clause in the order:

If competition in this industry is to be restored and maintained, it is essential that this continuing elimination of viable local or regional competitors through acquisition be halted now and that respondent be restored as a potential competitor by precluding it from entering local markets by acquisition [without the Commission's approval]. . . . Prophylactic relief, not merely the after-the-fact remedy of divestiture, is essential if the congressional policy expressed in Section 7 of the Clayton Act is to be effectively carried out.

A prior approval provision also serves to deter other firms from violating the Clayton Act as well as to prevent the firm under order from repeatedly violating the law in the future.³

The majority articulates no reason for departing from the usual rule in this case. Instead, the majority states that "we cannot assume

¹ As a matter of course the Commission has required a prior approval clause in recent Section 7 consent orders. *Great Lakes Chemical Corp.*, D. 9155 (May 23, 1984) [103 F.T.C. 467]; *Flowers Industries, Inc.*, D. 9148 (Nov. 3, 1983) [102 F.T.C. 1700]; *Dairymen Inc.*, D. 9143 (Sept. 20, 1983) [102 F.T.C. 1151]; *Coca-Cola Co.*, C-3113 (Aug. 3, 1983) [102 F.T.C. 1102]; *Grand Union Co.*, D. 1921 (July 18, 1983) [102 F.T.C. 812]; *Xidex Corp.*, D. 9146 (May 1, 1983) [102 F.T.C. 1]; *Allied Foods Co.*, 101 F.T.C. 721 (1983); *Gulf & Western Industries, Inc.*, 101 F.T.C. 707 (1983); *Con Agra Inc.*, 101 F.T.C. 50 (1983); *Canada Cement Lafarge Ltd.*, 100 F.T.C. 563 (1982); *Batus Inc.*, 100 F.T.C. 553 (1982); *General Electric Co.*, 99 F.T.C. 422 (1982); *Gifford-Hill-American Inc.*, 99 F.T.C. 372 (1982); *Leigh Portland Cement Co.*, 98 F.T.C. 856 (1981); *Godfrey Co.*, 97 F.T.C. 456 (1981); *National Tea Co.*, 96 F.T.C. 42 (1980). See also *Ekco Products Co.*, 65 F.T.C. 1163 (1969); *Jim Walter Corp.*, 90 F.T.C. 671 (1977); *Marquette Cement Manufacturing Co.*, 75 F.T.C. 32 (1969); *Beatrice Foods*, 68 F.T.C. 1003 (1956); *Warner Communications, Inc.*, D. 9174 (March 19, 1984) (complaint).

² *Yamaha Motor Co. v. FTC*, 657 F.2d 971 (8th Cir. 1981), cert. denied, 456 U.S. 915 (1982).

³ See my dissenting statement in *Damon Corp.*, 101 F.T.C. 689, 693 (1983).

on the basis of this record that market conditions and market structure in this industry are such that all such acquisitions, even under the conditions adopted by the prior [3] approval remedy, are necessarily anticompetitive." (Maj. Op. at 60)

This statement misconstrues the purpose of a prior approval order. A prior approval remedy does not operate as a ban on future acquisitions. If the Commission could now determine that subsequent acquisitions would be anticompetitive, it could presumably ban those acquisitions now. By contrast, a prior approval order merely requires a company that has been found to violate the law to seek Commission permission before making certain future acquisitions.

The majority also argues that a prior approval remedy will "uniquely disable" AMI, in that "time is of the essence" in negotiations for hospital acquisitions, and that prior approval is time consuming and would cause significant delays preventing AMI from effectively participating in this negotiation process. (Maj. Op. at 60) The majority's argument, which was rejected by the ALJ, (Maj. Op. at 57) is unsupported by any record evidence, and the opinion cites none. There is no explanation of how a prior approval requirement would adversely affect AMI's lawful, subsequent hospital acquisition activity. Contrary to AMI's assertions that bidding and negotiations for hospitals proceed at a rapid pace, Judge Barnes found that hospital negotiations are typically "lengthy", and concluded "that because of possible certificate-of-need and Hart-Scott-Rodino requirements, time is not as significant in the acquisition process as AMI posits." (ID 188-89) The majority simply disagrees with this conclusion without citation, presumably basing its decision on its own [4] unspecified general expertise. Even though an order for prior approval may involve time delays, there is no reason why the FTC could not in a proper case expedite AMI's request for approval.

Finally, the Commission majority states that in order to determine if a ten year prior approval remedy is appropriate "we must look at the record evidence of market conditions present in the general acute health care services industry." (Maj. Op. at 59) An examination of that record reveals that AMI has acquired 19 general acute care hospitals since 1980 and in the future intends to acquire 4 - 6 hospitals per year. (*Id.*) AMI also currently owns, operates or has under construction 75 hospitals in the U.S., nearly all of which were obtained through acquisition. (*Id.*) Judge Barnes concluded from this evidence that the "prior approval requirement was warranted because of the merger trend in the hospital industry and AMI's history of growth through acquisition." (Maj. Op. at 57) Specifically with respect to the latter reason, Judge Barnes found that "because of health planning laws which limit opportunities for the development of new hospitals,

AMI will continue to seek to grow through acquisitions in the future. Thus, a prior approval clause is a necessary remedial provision.” (ID 187)

The ten year prior approval remedy ordered by Judge Barnes is limited in scope to 13 states where AMI currently owns hospitals and applies only if AMI would have at least a twenty percent share of the market after the acquisition. Furthermore, AMI will not be subject to the order unless an acquisition by AMI [5] exceeds \$1,000,000. Judge Barnes’ ten year prior approval order is, in his own words, more narrow than “past Commission precedent” (ID 189).

A prior notification requirement is an inadequate substitute for a prior approval clause. After a law violation has been found by the Commission it is perfectly appropriate, for a limited period, to shift the presumption of legality of respondent’s future acquisitions from the Commission to the respondent.

It is not clear what kind of evidence the majority would require in future cases before it ordered the kind of carefully limited prior approval requirement that Judge Barnes ordered in this case or that the Commission ordered regularly in past cases and consents. Respondents will doubtless resist prior approval clauses, both in litigated orders and consents, on the ground that some as yet unspecified standard was not met. While I concede there might be some exceptional case when a prior approval requirement is unwarranted, this is not such a case. Only by ignoring the record and the ALJ’s findings and conclusions in this case can the majority reach a different result.

STATEMENT OF COMMISSIONER BAILEY
CONCURRING IN PART AND DISSENTING IN PART

I agree completely with the opinion of the Commission that American Medical International’s (AMI) acquisition of French Hospital in San Luis Obispo, California, violated Section 7 of the Clayton Act, and that the hospital should be ordered divested. I dissent only because the Commission has declined to require respondent to obtain FTC approval for a limited class of future acquisitions of acute care hospitals likely to raise antitrust concerns. Prior approval relief was a primary purpose of this litigation; failure to order such relief here means the Commission has won a lawsuit but lost a cause.¹

My dissent on the prior approval issue is grounded on three points. First, this case originated out of concern with respondent AMI’s rapid growth by repeated horizontal acquisitions of hospital facilities, part of a merger trend among proprietary hospital chains. The French

¹ *U.S. v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 323, 324 (1961) (quoting *International Salt Co., v. United States* 332 U.S. 392, 401 (1947)).

Hospital acquisition is merely illustrative of the larger antitrust concern. Second, contrary to the implication of the Commission that prior approval clauses should be imposed only upon completion of some form of detailed market-by-market analysis, use of such fencing-in clauses has been virtually universal in FTC Section 7 cases over at least the past twenty years. Third, there are substantial practical and [2] policy reasons supporting such relief, which serves as a prophylactic guarantee against future anticompetitive acquisitions by respondent AMI. Such prospective acquisitions will now have to be dealt with by costly and time consuming case-by-case litigation.

I.

The evidence in this record shows that the nation's five largest proprietary hospital chains, including Respondent, have acquired 192 hospitals in the period 1975-1981. In 1981 alone, these firms acquired 80 hospitals. CX 608 The Commission observes in its opinion that in 1972, the five largest proprietary hospital chains had 6.5% of community hospital beds, and that this market share had risen to 8.8% by 1980. A recent study of the Federation of American Hospitals, shows that in 1982, about 10% of U.S. acute care hospital facilities were owned by for-profit chains², and that the number of such hospitals had doubled between 1976 and 1982. Other analysts have predicted that for-profit chains will have up to 20% of the market by 1990.³ [3]

AMI's President has predicted that in the next five years, acquisitions by the five largest companies will range between a combined total of 50 and 100 hospitals a year.⁴ Another observer, testifying in this proceeding, said: "Within the next ten years, hospitals will be merging all over the place. It will be like a waterfall." CX 1048C, W; Schramm, 2365-66. This rapidly increasing pace of hospital acquisitions is of special significance in the "Sunbelt," the region of the U.S. where the large proprietary hospital chains have made most of their acquisitions because of that region's rapid population growth and relatively unrestrictive regulation of hospitals. Derzon, 2184-86; CX 430J-K; CX 613A-D.

AMI's holdings are concentrated in the Sunbelt states, and AMI tends to acquire hospitals near those it already owns. CX 613A-B. Almost all of AMI's hospitals have been obtained through acquisition, nineteen of them since 1980. IDF 236. By the end of 1983, AMI had grown to 77 owned or leased acute care hospitals, up from 70 in 1982. AMI plans to acquire four to six hospitals per year, and has estimated

² Gray, ed., *The New Health Care for Profit: Doctors and Hospitals in a Competitive Environment*, 2, 15 (1983).

³ Perspectives: *McGraw-Hill Washington Report on Medicine and Health*, June 6, 1983, 2.

⁴ "Multi-Units Are Ready to Boost their Market Share," *Modern Healthcare*, May, 1983, 89.

conservatively that 1000 hospitals meet its acquisition criteria. CX 430L-W. AMI's Executive Vice-President has stated:

We emphatically reject the contention that the acquisition market is nearing saturation or that prices have reached levels where there is a substantial degree of risk in most situations. In our view, there are more than enough properties available at attractive prices to keep the whole industry gainfully employed for years to come. CX 4300 [4]

By the end of the decade of the 1980s, AMI estimates that the investor owned sector of this industry has the potential to double its share of the community hospital market. CX 430L. AMI's President declared in 1981:

I can assure you that the opportunities (for acquisitions) are plentiful and that they range over the entire spectrum of acute care hospitals regardless of size or pattern of ownership. There is no doubt that AMI will continue to experience significant growth in the external area for some time to come. CX 430X.

On October 23, 1983, for example, AMI announced the acquisition of Lifemark Corporation for approximately one billion dollars.⁵ Lifemark is a 25-hospital, 4629 bed chain, itself the sixth largest proprietary hospital chain in the United States. It is obvious, and the record of this proceeding clearly shows, that the Commission correctly observed that "the hospital industry is undergoing a move towards increased consolidation. . . ." (Slip Op. at 60).

I disagree with the Commission's interpretation of the evidence, because I do not believe that complaint counsel must prove the existence of actual additional antitrust violations (beyond those being litigated) in order to obtain ancillary prior approval relief. I agree with Justice Brennan when he wrote "the amended §7 was intended to arrest anticompetitive tendencies in their 'incipiency'." *United States v. Philadelphia National [5] Bank*, 374 U.S. 321, 362 (1963). I believe that such a reading of the statute is consistent with its legislative history. The Senate Report on the 1950 amendments to the Clayton Act stated, "The intent here . . . is to cope with monopolistic tendencies in their incipiency and well before they have attained such effects as would justify a Sherman Act proceeding"⁶ The conclusion of the Commission, however, is that neither AMI's policy of expansion by acquisitions, nor the levels and rates of rising national hospital concentration, justify the imposition of the narrowly focused

⁵ "AMI, Lifemark Agree to Merge," *Hospitals*, November 16, 1983, 17. I have no knowledge or opinion as to whether any AMI acquisitions, present or future, raise antitrust concerns on their specific merits, beyond the acquisition litigated in this case. I am referencing the Lifemark acquisition only to illustrate that AMI is continuing to fulfill its announced policy of expansion through acquisition.

⁶ S. Rep. No. 1775, 81st Cong., 2d Sess., 4-5 (1950).

prior approval relief proposed by the ALJ and supported by complaint counsel.

II.

The whole context of the opinion's discussion of the standards applicable to prior approval relief implies that complaint counsel bears a considerable burden establishing the need for such an order provision.

Yet the simple fact is that 143 of the 157 litigated or settled Section 7 orders issued by the Commission in the past 20 years contain prior approval relief.⁷ The almost routine entry [6] of this relief (91% of the orders entered, 1964-84) has occurred because an antitrust case both aims to restore competition where it already has been lost *and* seeks to insure against its loss through similar means in the future. Such ancillary "fencing-in" relief, prospective in nature, is typically broader in coverage than the specific violation and relief involved in a particular case. Further, "it is well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *United States v. E.I. du Pont de Nemours & Co.*, *supra*, at 334.

I have pointed out already that prior approval relief was a primary rather than a secondary focus of relief in this case—even respondent limits its appeal of the divestiture portion of this order to a single footnote in one of its briefs; its arguments against prior approval relief go on for eight pages. Both parties' unusual emphasis on a routine issue may have prompted the Commission to place an extra burden on complaint counsel—but that burden cannot be justified, either by precedent or the situation before us.

The majority concedes the Commission's power to order prior approval relief in appropriate cases. The Commission also acknowledges both that a trend is occurring towards consolidation of hospitals through merger, and that respondent AMI has participated actively in this merger wave and intends to continue to do so. Nevertheless, the Commission rejects prior approval relief here. First, it distinguishes a line of cases where the [7] main impetus to prospective relief was evidence of respondents' repeated willfull or knowing violation of the law, or a history of past conduct that created a "cognizable danger of recurrence" of illegal activity.⁸ The Commission foreswears this line of cases, because, it claims, they do not grow out of Section 7

⁷ These numbers actually *understate* the degree to which prior approval relief is routine in Section 7 cases. Six of the 14 orders without such relief were vertical acquisitions in the cement industry. Because acquisitions in this industry were subject to a special FTC premerger reporting program from 1967 on, there was no necessity to order prior approval relief in specific cases.

⁸ *United States v. W.T. Grant Co.*, 345 U.S. 629 (1953); *Litton Industries, Inc. v. FTC*, 676 F.2d 364 (9th Cir. 1982); and *Sears Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982).

caselaw, and therefore are not directly applicable. The result, of course, is to trivialize strong record evidence of respondent's past and intended future course of acquisitions. On the contrary, there is Section 7 authority acknowledging "respondent's demonstrated proclivity to expansion through acquisition" as an important consideration in formulating prior approval relief. *Beatrice Foods Co.*, 68 F.T.C. 1003, 1006 (1965); *Marquette Cement Manufacturing Co.*, 76 F.T.C. 361, 371 (1969).

The second line of authority relied on by the Commission is a series of Section 7 proceedings where prior approval relief was asserted to have been warranted on the basis of the competitive threat to specific antitrust markets by respondent's past or likely future merger conduct.⁹ According to the Commission's reading of these few cases, prior approval relief must only be ordered when complaint counsel can prove such vulnerable "industry market structure and market conditions" in specific [8] "local and regional geographic markets." (Slip Op. at 60) Of particular concern here, for instance, would be markets where AMI or its competitors are likely to become entrenched as monopolists, or where effects on competition can be actually assessed. Unfortunately, all the Commission has in the record before it in regard to markets other than San Luis Obispo, California, is the fact that the *national* percentage of hospital beds controlled by proprietary hospitals rose from 6.5% in 1972 to 8.8% in 1980. Such national concentration data is not numerically impressive, and is even perhaps irrelevant in an industry characterized by local and or regional markets, such as this one.¹⁰ I do not envy the role of government staff in future cases who must heed the Commission's analysis in this regard. The Commission provides no guidance on what kind and how much evidence is necessary to obtain prior approval relief.¹¹ As a [9] generic matter, the prior approval provision personifies the prophylactic character of Section 7 of the Clayton Act¹² in curbing potentially anticompetitive increases in concentration in their incipency. The implication of the Commission's analysis is that staff should identify

⁹ *Jim Walter Corp.*, 90 F.T.C. 671, 764 (1977); *Marquette Cement Manufacturing Co.*, 75 F.T.C. 32, 104 (1969); *Liggett & Myers, Inc.*, 87 F.T.C. 1074, 1140 (1976); *Beatrice Foods Co.*, 68 F.T.C. 1003, 1006 (1965); and *Ekco Products Co.*, 65 F.T.C. 1163, 1223 (1964).

¹⁰ Oddly, the Commission does not cite to the strongest case for its own proposition, *ITT Continental Banking Company*, 84 F.T.C. 1349 (1974). There, complaint counsel failed to achieve a five year extension of a prior approval clause because its evidence of increasing industry wide concentration through acquisitions in the bread industry was found irrelevant to the question of whether concentration was threatening in appropriate and relevant local markets. And, in his dissent in *National Tea Co.*, 69 F.T.C. 226, 278 (1966), Commission Elman leveled criticism at a prior approval order, specifically because it was based on national concentration statistics for food retailing, rather than on an assessment of local market conditions.

¹¹ In *ITT*, *supra*, however, there is a suggestion of how to proceed: "[W]hile we agree that it can be difficult to establish the facts as to what has been happening in even a sample of three or four relevant local bread markets, we know of no principle of law that permits difficulties of proof to justify the inferring of a fact to be proved from another fact that has no *necessary* causal relation to it. Economic facts do not have to be proven with engineering precision." 84 F.T.C. at 1399.

¹² *Beatrice Foods Co.*, 68 F.T.C. 1003, 1006 (1965); *The Seeburg Corp.*, 75 F.T.C. 661, 675 (1969).

markets where already there are dangerous problems of monopoly power.¹³ Complaint counsel has no crystal ball, however, to aid them in predicting with any certainty the specific markets where, over the next ten years, competitive concerns *might* arise on account of possible future acquisitions by AMI.

I do not read the Commission majority as stating that prior approval relief is necessarily limited to the markets pled and proved in a specific Section 7 case—in this case, one county in one state. If this were what the Commission were saying, it would go against scores of cases where prior relief provisions sweep geographically broader than those markets where divestiture relief was proved to be justified.¹⁴ [10]

The Commission *seems* to be saying that there must be some reasonable relationship between the competitive concerns identified in a specific case, and the ancillary relief ordered in that case. Such an interpretation would be consistent with the view taken both in cases and in the legal literature.¹⁵ The Commission and I, perhaps, then disagree only on whether complaint counsel's proof and the ALJ's order together meet a standard of reasonableness.

The prior approval relief proposed by the ALJ and rejected by the Commission majority was expressly tailored to AMI's all-to-obvious acquisition strategy. It imposed the prior approval relief only with regard to the 13 states where AMI is now present in force, based on the record evidence that AMI generally acquires hospitals near those it already owns. The prior approval relief only applied to hospital acquisitions in local geographic areas, near where AMI already owned a facility, *and* where any proposed acquisition would result in an AMI market share of 20% or more of the market, *and* the acquisition proposed exceeded one million dollars. To my mind, this is reasonably specific and narrow relief. [11]

If complaint counsel had put into the record of this proceeding figures on ownership and concentration of hospital beds for a selection of major cities and regions throughout the Sunbelt, would it had

¹³ In her concurring statement in *National Tea*, *supra*, at 299, 309, Commissioner Jones observed the legal futility in permitting the continuation of a series of unsupervised acquisitions in "localized markets totalling hundreds of thousands" to the point where local "direct evidence of anticompetitive impact" can be measured.

¹⁴ It is clear that prior approval merger relief may extend to conduct beyond the scope of a complaint and record confined to specific allegedly illegal acquisitions. *Marquette Cement Manufacturing Co.*, 76 F.T.C. 361, 370, 371 (1969). The Commission has often entered relief in merger cases, extending beyond the geographic parameters of a specific complaint. ID at 188, CAB at 69, 71, 72.

¹⁵ "Future relief (beyond divestiture), however, must be molded in light of the particular facts; the criteria of 'necessary and appropriate' and 'reasonably related' to the Section 7 offense may well be the most precise guidelines feasible in the circumstances." Duke, *Scope of Relief Under Section 7 of the Clayton Act*, 63 Colum. L. Rev., 1192, 1208 (1963). (citations to decision on remand in *U.S. v. E.I. du Pont de Nemours*, 1962 Trade Cas. (CCH) ¶70,245 at 75, 942).

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Statement

won from this Commission the prior approval relief that it sought?¹⁶ The Commission gives no answer to this question, and the arguments that it embraces later about how respondent's unfettered role as a prospective hospital purchaser "has a substantial potential procompetitive impact," leave me somewhat puzzled about the true motives of the Commission in declining to order modest prophylactic relief.

III.

The practical and policy reasons for prior approval relief are simple. As a practical matter, once the Commission has gone through the prolonged and costly process of proving an antitrust violation, it should exercise, as it usually has in the past, some prospective authority over respondent's related conduct for a period of time to prevent likely or possible recurrences. As a [12] policy matter, preventing violations of the antitrust laws is preferable to unraveling them after the fact. It avoids the cost and expenses of litigation, and, in the broader sense, upholds the Clayton Act's policy of preventing, in their incipency, the anticompetitive effects that might flow from certain acquisitions. The best example of this concern is the Hart-Scott-Rodino premerger notification process, which requires advance reporting of all corporate mergers above a certain dollar size, with waiting periods to allow antitrust analysis of such reports, and thus possible injunctive action against suspect mergers prior to consummation. Although some of the future AMI acquisitions of hospitals may be subject to Hart-Scott-Rodino reporting, many would fall below the dollar reporting levels set in that program. CX 1034; RX 5825 at 7, 27; RX 5850. Moreover, prior approval relief flowing specifically from a litigated case record such as here, amounts to a veto leverage potential which is more efficient than the injunctive litigation route associated with premerger notification.

The Commission takes the view that the prior approval provision urged by complaint counsel and recommended by the ALJ "asks us in essence to assume that acquisitions in this industry, *per se* are anticompetitive."¹⁷ The majority misperceives the issue. The relief in question is not a ban on all future [13] acquisitions of acute care hospitals. On the contrary, the remedy in question simply requires respondent to petition for approval of an acquisition that qualifies for

¹⁶ Presumably if complaint counsel had presented some facts as to the present competitive picture in various areas in the Sunbelt, the Commission could not have so likely dismissed their request for relief on the grounds that specific market facts implying antitrust concerns had not been shown. It is always possible, however, that had staff proved the conditions existing in a dozen markets, the Commission would have limited prior approval relief to those areas. However, one commentator has observed of the cases on this point that, "Future merger bans are usually limited to the particular industry involved, but only in exceptional circumstances are they limited to specified geographical areas." Rockefeller, "What Remedies are available to restore competition if a merger is declared unlawful?", *Antitrust Questions and Answers*, 248, 249 (1974).

¹⁷ "... [W]e cannot assume on the basis of this record that market conditions and market structure are such that all such acquisitions, even under the conditions adopted by the prior approval remedy, are necessarily

reporting under the narrow order entered by the ALJ. Past experience has simply been that most such petitions have been granted. Such petitions for acquisitions have been judged by the competitive standards applicable to any merger situation. The Commission is not free to deny prior approval where it has no reason to believe that the acquisition in question would be illegal. *Beatrice Foods Co.*, 67 F.T.C. 473, 731 n. 48 (1965). "Since these orders do not contain outright bans on future acquisitions, the approval requirement must of necessity contemplate some circumstances under which some . . . acquisitions would be approved by the Commission." *Broadway-Hale Stores Inc.*, 75 F.T.C. 374, 377 (1969) (Statement of the Commission approving acquisition subject to prior approval).

Respondent's practical arguments against our imposition of this relief are that hospital merger negotiations are alleged to occur within tight time frames, and delays and uncertainty occasioned by FTC approval review procedures might unfairly hamper AMI in the "competition" to "beat" hospital chains not under FTC order in the ongoing game of making hospital acquisitions. The Commission explicitly embraces these arguments in concluding that AMI's presence in the market as a potential purchaser of local hospitals has a substantial potential procompetitive impact. This is a conclusion for which the Commission offers no record evidence. I might be more sympathetic with those arguments, but for our principle decision [14] today that AMI violated the law by one of its typical acquisitions, and our various findings regarding AMI's pattern of acquisitions and intentions for the future. The Commission, however, gives weight to the concern over impairment of AMI's private interests in making hospital acquisitions, stating that "The prior approval requirement would uniquely disable AMI in these negotiations." (Slip Op. at 60).¹⁸ The practical validity of this statement turns, it seems to me, on the assumption that the Commission is unable to conduct its review of prior approval requests expeditiously. However, actual experience again shows that when expedited treatment is requested in petitions for prior approval, the staff and the Commission usually accommodate such requests. See, e.g., *Foremost Dairies, Inc.*, Docket No. C-1161 (approval granted one day after close of public comment period) [104 F.T.C. 548 (1984)]. The only inevitable delay in regard to such petitions is the requisite 30 day public comment period set out in the Commission's rules. Given regulatory considerations possibly requiring the issuance of Certificates of Need in regard to hospital acquisitions, the "competi-

¹⁸ It is an old and familiar refrain in antitrust cases that an order against just one firm in an industry hampers its competitive struggle against other firms in the same industry that are not under order. This argument has been rejected both as a defense to wrongdoing, and to the entry of specific relief. *FTC v. Universal Rundle Corp.*, 387 U.S. 244 (1967) (citing *Moog Industries, Inc. v. FTC*, 388 U.S. 411 (1958)). See also *Ger-Ro-Mar v. FTC*, 518 F.2d 33 (1975).

tive" need for FTC action prior to 30 days or so is not at all clear. Moreover, the limited notice relief ordered here by the Commission in lieu of prior approval does not give AMI absolute confidence that its [15] negotiations can proceed apace, uninterrupted. The limited notice filing also has some potential to leave AMI uncertain about the FTC's intentions, particularly if such notices are withheld from the public record, and therefore are beyond respondent's ability to monitor the staff's handling of any anti-approval arguments filed by various public and private parties troubled by AMI's acquisition appetite.

Moreover, a certain amount of delay is always necessary in effective premerger notification. The great majority of reported mergers prove to be of no concern to the antitrust laws, yet firms must report nonetheless, and at some cost in time and money. Particularly burdened are those firms that fall subject to premerger "second requests", where additional cost, delay and uncertainty are injected into a reported transaction, even though in most such cases no enforcement action results. Still, Congress has listened to these "danger of delay" arguments¹⁹ and [16] nevertheless determined that such burdens must be borne, in order that the government get timely information on the other mergers which may be anticompetitive.

Prior approval, in a case of this nature, is precisely the sort of relief that is needed to accomplish the prophylactic aims of Section 7 of the Clayton Act. Neither the Department of Justice nor the Federal Trade Commission has resources or time enough to proceed case-by-case in dealing with a merger wave, unless one fruit of such litigation is some legally established curb over potentially anticompetitive future merger activity.²⁰ The Commission's failure to enter prior approval relief here lends unnecessary strength to those who criticize existing law and existing law enforcers for insufficient efforts to deal with anticompetitive merger-related increases in market power. It strains credulity, when, in the past 20 years prior approval relief has been directed in over 90% of final Section 7 orders, to believe that this case falls somewhere short of the mark.

¹⁹ Several of AMI's arguments against government supervision of merger activity are virtually identical to those made in the 1950s and 1960s by witnesses testifying against the earliest forms of legislation that eventually resulted in the present Hart-Scott-Rodino premerger reporting program. In particular, an officer of the American Bar Association predicted that delays in complying with premerger notification requirements would "kill" procompetitive and lawful acquisitions. See, testimony of James A. Sprunk, Hearings on H.R. 2882, H.R. 3563, H.R. 6058 and H.R. 6698 before the Antitrust Subcomm. of the House Comm. on the Judiciary, 87th Cong., 1st Sess., 219,230-237 (1961).

²⁰ "The proper disposition of antitrust cases is obviously of great public importance, and their remedial phase, more often than not, is crucial. For the suit has been a futile exercise if the Government proves a violation but fails to secure a remedy adequate to redress it." *U.S. v. E.I. du Pont de Nemours*, 366 U.S. 316, 323 (1961).

Final Order

104 F.T.C.

FINAL ORDER

I

This matter has been heard by the Commission upon the appeal of Respondents from the Initial Decision, and upon briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying opinion, the Commission has determined to affirm in part and reverse in part the Initial Decision. Accordingly, the Commission enters the following Order.

Definitions

It is ordered, That for purposes of this Order the following definitions shall apply:

A. *Acquire any hospital* means to directly or indirectly acquire all or any part of the stock or assets of any hospital, or enter into any arrangement by which AMI obtains ownership, management, or control of any hospital, including the right to lease or manage any hospital. [2]

B. *AMI* means American Medical International, Inc., a corporation organized under the laws of Delaware with its principal executive offices at 414 North Camden Drive, Beverly Hills, California, and its directors, officers, agents, and employees, and its subsidiaries, divisions, affiliates, successors, and assigns.

C. *AMISUB (French Hospital)* means the wholly-owned subsidiary corporation of AMI that was established for the purpose of acquiring and operating French Hospital located in San Luis Obispo, California.

D. *County* also means a county equivalent such as a parish in Louisiana.

E. *General acute care hospital*, herein referred to as *hospital(s)*, means a health facility, other than a federally-owned facility, having a duly organized governing body with overall administrative and professional responsibility and an organized professional staff that provides 24-hour inpatient care, and whose primary function is to provide inpatient services for medical diagnosis, treatment, and care of physically injured or sick persons with short-term or episodic health problems or infirmities.

F. *Operate a hospital* also means to own, manage or lease a general acute care hospital.

G. *MSA* and *PMSA* mean, respectively, a Metropolitan Statistical Area and a Primary Metropolitan Statistical Area, as defined as of July 1, 1983 by the Office of Management and Budget, Office of Information and Regulatory Affairs.

II

It is ordered, That within twelve (12) months from the date this Order becomes final, AMI shall divest, absolutely and in good faith, all stock, assets, properties, licenses, leases, and other rights and privileges, tangible and intangible, that AMI acquired from Central Coast Hospital Company, French Hospital [3] Corporation and French Medical Clinic, Inc., together with any subsequent improvements. The purpose of the divestiture is to reestablish French Hospital as a viable competitor in San Luis Obispo County. The divestiture shall be subject to the prior approval of the Federal Trade Commission.

Pending divestiture, AMI shall take all measures necessary to maintain French Hospital in its present condition and to prevent any deterioration, except for normal wear and tear, of any of the assets to be divested so as not to impair French Hospital's present operating abilities or market value.

III

It is further ordered, That for a period of ten (10) years from the date this Order becomes final, AMI shall not, without providing advance notification to the Federal Trade Commission, directly or indirectly acquire any hospital located in the states of Oregon, California, Texas, Oklahoma, Missouri, Arkansas, Louisiana, Mississippi, Alabama, Georgia, Florida, South Carolina, or North Carolina, if:

A. The hospital to be acquired is within an MSA or a PMSA in which AMI already operates a hospital and in which AMI, immediately after the acquisition, would operate hospitals that combined have a twenty (20) percent or more share of the licensed general acute care hospital beds within that MSA or PMSA; or

B. The hospital to be acquired is not within an MSA or a PMSA but is within a county in which AMI already operates a hospital and in which AMI, immediately after the acquisition, would operate hospitals that combined have a [4] twenty (20) percent or more share of the licensed hospital beds within that county; or

C. The hospital to be acquired is (1) not within an MSA or a PMSA or a county in which AMI already operates a hospital, but is within thirty (30) miles of a hospital which AMI already operates in another MSA or PMSA or county, and (2) the hospital to be acquired and any hospital(s) that AMI operates combined have a twenty (20) percent or more share of the licensed hospital beds in the area within thirty (30)

miles of the midpoint between the hospital to be acquired and any hospital operated by AMI.

Provided, however, That no acquisition shall be subject to this Section III if the consideration to be paid for the purchase of the hospital, including assumption by AMI of liabilities of its present owners, does not exceed one million dollars (\$1,000,000).

Such advance notification shall be provided when AMI's Board of Directors or Executive Committee authorizes issuance of a letter of intent or enters into a purchase agreement to make such an acquisition, whichever is earlier.

IV

It is further ordered, That AMI shall, within sixty (60) days after the date this Order becomes final and every sixty (60) days thereafter until it has fully complied with the provisions of Section II of this Order, submit a report in writing to the Federal Trade Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with these provisions.

Such compliance reports shall include a summary of all contacts and negotiations with potential purchasers of the stock [5] and assets to be divested under this Order, the identity and address of all such potential purchasers, and copies of all written communications to and from such potential purchasers.

AMI also shall submit such further written reports as the staff of the Federal Trade Commission may from time to time request in writing to assure compliance with this Order.

V

It is further ordered, That AMI shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed corporate change, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation that may affect compliance with the obligations arising out of this Order.

Commissioners Pertschuk and Bailey concurred in part and dissented in part.

IN THE MATTER OF
INTERNATIONAL TELEPHONE & TELEGRAPH
CORPORATION, ET AL.

FINAL ORDER, OPINION, ETC. IN REGARD TO VIOLATION OF SEC. 5 OF
THE FEDERAL TRADE COMMISSION ACT AND SEC. 2(a) OF THE CLAYTON
ACT, AS AMENDED

Docket 9000. Complaint November 26, 1974—Final Order July 25, 1984

For reasons set forth in the Commission's Opinion, this final order reverses the ALJ's initial decision, denies complaint counsel's appeal, grants appeal of respondents and dismisses the complaint charging a New York City conglomerate and its wholly-owned baking company subsidiary with alleged violations of federal law. The complaint had alleged that the baking company had attempted to monopolize the white bread product sales market in five geographic areas and caused competitive injury in those markets by, among other things, engaging in predatory or discriminatory pricing practices for significant periods of time.

Appearances

For the Commission: *Jerry A. Philpott, Renee S. Henning, Stephen E. Nagin, Richard Malatt, Gilda E. Rodriguez, Marimichael O. Skubel and Allen M. Hickey*

For the respondents: *John H. Schafer, S. William Livingston, Jr., David J. Cynamon, Bruce D. Sokler and Jane H. Chalmers, Covington & Burling, Washington, D.C. and Craig D. Walley and Gordon Thomas, New York City.*

COMPLAINT

The Federal Trade Commission, having reason to believe that the above-named respondents have violated and are now violating Section 5 of the Federal Trade Commission Act, as amended (15 U.S.C. 45), and subsection (a) of Section 2 of the Clayton Act, as amended by the Robinson-Patman Act (15 U.S.C. 13), and believing that a proceeding by it in respect thereof is in the public interest, hereby issues this complaint charging as follows:

Definitions

1. For the purpose of this complaint, the following definitions shall apply: