IN THE MATTER OF

AMERICAN MEDICAL INTERNATIONAL, INC., ET AL.

MODIFYING ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT AND SEC. 7 OF THE CLAYTON ACT

Docket 9158. Final Order, July 2, 1984—Modified Order, Nov. 9, 1984

This Modified Order revises the Commission's Final Order issued on July 2, 1984, 104 F.T.C. 1, which requires a Beverly Hills operator of a chain of proprietary hospitals to divest French Hospital, located in San Luis Obispo, California, and provide the Commission, for a period of ten years, with advance notification of its intention to acquire any hospital costing $1 million or more in the 13-state area specified in the order. As revised, the Modified Order retains the advance notification requirement of the original order, but sets forth in detail the manner in which the firm must prepare and submit the notification to the Commission, and the supplemental information that should be included.

ORDER AND OPINION OF THE COMMISSION GRANTING IN PART AND DENYING IN PART COMPLAINT COUNSEL'S PETITION FOR RECONSIDERATION

BY CALVANI, *Commissioner*:

I. Introduction

On July 2, 1984, the Commission issued its Final Order and Opinion in *American Medical International, Inc.* [hereinafter "order"] [104 F.T.C. 1]. The Commission held that respondents' acquisition of French Hospital in San Luis Obispo, California, 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). The Commission rejected Complaint Counsel's request that respondents be prohibited, for a period of ten years, without prior approval of the Federal Trade Commission, from acquiring general acute care hospitals in areas where they already own or operate such a hospital. In so doing, the Commission stated:

> 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 [2] 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.

Slip op. at 60 [104 F.T.C. at 226]. Complaint Counsel has petitioned for reconsideration of certain portions of the Commission's Order in *American Medical International, Inc.* pursuant to Rule 3.55 of the Commission's Rules of Practice. Respondent American Medical International, Inc. ("AMI") replied in opposition to the Petition by memorandum dated August 6, 1984. AMI's Opposition to Petition for Reconsideration of Final Order [hereinafter "AMI Memorandum"].

After reviewing these filings, as well as the relevant briefs, decisions, orders, and transcripts in this matter, we have concluded that Complaint Counsel's Petition is an appropriate Rule 3.55 petition as to the arguments and modifications it presents concerning prior notification, but that it is inappropriate as to the arguments and modifications it presents concerning prior approval. We have determined that the Order should be modified so as to accomplish the purposes intended by the Commission's Opinion and Order of July 2, 1984. The Order as revised is designed to set forth the details of the prior notification requirement imposed under the Order so as to permit Commission staff to make a meaningful review of AMI's [3] proposed acquisition while, at the same time, guarding against imposing undue burden on AMI as a participant in the acquisition market for general acute care hospitals.

II. Complaint Counsel's Petition for Reconsideration is Appropriate

AMI challenges Complaint Counsel's Petition for Reconsideration on two grounds. First, AMI contends that the Petition does not satisfy the requirements of Rule 3.55 of the Commission's Rules of Practice because it fails to raise any "new questions . . . upon which petitioner had no opportunity to argue before the Commission."[1] Second, AMI argues that the Petition should be denied because the modifications requested would harm AMI's ability to compete for new acquisitions and would "undermine the balance struck in the Commission's order between regulatory review and competitive vitality." AMI Memorandum at 2.

[1] Rule 3.55 of the Commission's Rules of Practice, 16 C.F.R. 3.55 provides, in pertinent part: "any petition filed under this subsection must be confined to new questions raised by the decision or final order and upon which the petitioner had no opportunity to argue before the Commission."

In support of its contention that the Petition fails to satisfy the criteria of Rule 3.55, AMI cites to portions of the briefs that it submitted to Administrative Law Judge Barnes and to the Commission in this matter, and to the transcript of the oral argument before the Commission. There, AMI claims that it raised the issue of prior notification and that Complaint Counsel had an opportunity to present its views on this issue. [4]

In briefs submitted by AMI (both to Administrative Law Judge Barnes and to the Commission), the prior approval remedy was the focus on the "fencing-in" discussion. In AMI's trial brief to Judge Barnes, AMI made only passing reference to a prior notification remedy; the overwhelming part of the "fencing-in" discussion addressed the unfairness of a prior approval requirement. Although AMI had cited to a consent decree involving a hospital merger that had employed a prior notification remedy, *United States v. Hospital Affiliates International, Inc.*, 1982–1 Trade Cas. (CCH) ¶64,696 (E.D. La. 1982), AMI included no discussion in its trial brief of the relative benefits, disadvantages, or problems associated with using this remedy or the mechanics of its use. *See* Trial Brief of Respondent American Medical International, Inc. at 99 & 100.

Similarly, the prior approval remedy was the focus of the "fencing-in" discussion in the two briefs submitted to the Commission by AMI. In its brief on appeal, AMI criticized the prior approval remedy as unfair, unwarranted, and anticompetitive. The only reference in AMI's brief to an alternative to a prior approval "fencing-in" appeared in a footnote that contained citations to two Justice Department merger cases in which prior notification remedies were employed. *See United States v. Stroh Brewery Co.*, 1982–83 Trade Cas. (CCH) ¶65,037 (D.D.C. 1982); *United States v. Hospital Affiliates International, Inc.*, 1982–1 Trade Cas. (CCH) ¶64,696 (E.D. La. 1982). Although AMI cited these two consent decrees, it failed to include any discussion of the advantages, [5] disadvantages, or justifications for use of this remedy. Respondent's Brief on Appeal From Initial Decision at 70 n.87. AMI's Reply Brief again stressed the unfairness of a prior approval remedy and suggested that a prior notification remedy would be much more "reasonable" in the circumstances of this case. AMI's Reply Brief contained no discussion of the mechanics of a prior notification requirement.

Although Complaint Counsel made reference to prior notification as a "fencing-in" remedy in its briefs in this matter, it did not do so in any meaningful way. Complaint Counsel referred in a footnote to premerger notification as a "fencing-in" remedy. *See* Complaint Counsel's Answering Brief at 65 n.92. In this reference, Complaint Counsel simply points out that a process involving premerger notifica-

tion was available to the Commission as an alternative to a prior approval "fencing-in" provision. Complaint Counsel's brief contains no further discussion of this point, or of the prior notification remedy generally. There was no discussion of, or reference to, prior notification "fencing-in" in Complaint Counsel's brief to Administrative Law Judge Barnes.

Thus, it appears that Complaint Counsel in its briefs argued for prior approval "fencing-in." Administrative Law Judge Barnes ordered this remedy in the initial order in this case. *See* Initial Decision at 183–89. AMI argued that "fencing-in" was unnecessary and that, even if the acquisition were found to be violative of Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, prior approval "fencing-in" was not [6] warranted. Both parties focused their discussions on the justification, or lack thereof, for a prior approval remedy, and it appears that the issue of how to devise a prior notification remedy that could be employed effectively by the Commission to monitor future AMI acquisitions simply was never discussed.

As AMI correctly notes, Chairman Miller, in oral argument, did raise the issue of whether a prior notification remedy would adequately "fence-in" respondents, assuming the finding of an unlawful acquisition. Complaint Counsel responded to Chairman Miller's question by pointing out three deficiencies with a prior notification "fencing-in" requirement: (1) the Commission would not have credible information with which to assess a proposed acquisition; (2) the Commission might not have the time it needed to assess the competitive impact of the proposed acquisition; and (3) the Commission would not have any indication as to how quickly the proposed acquisition could be consummated. *See* Transcript of Oral Argument at 53. However, although Complaint Counsel's arguments at oral argument in this matter are similar to the arguments raised in Complaint Counsel's Petition, it does not appear that Complaint Counsel had a meaningful opportunity to argue them before the Commission at that time. Chairman Miller merely posed the possibility of a prior notification requirement, and Complaint Counsel responded in general terms without proposing any specific suggestions to deal with these potential problems. Complaint Counsel's discussion of the problems associated with a prior notification remedy at oral argument occupies only three-quarters of a page in a sixty-eight page [7] transcript. It is not reasonable to conclude that Complaint Counsel had an opportunity to discuss the practical problems associated with this remedy or the mechanics for putting it into use.

After reviewing AMI's briefs and the oral argument transcript, as well as the briefs submitted by Complaint Counsel in this matter, we

conclude that there was no opportunity for Complaint Counsel to address the prior notification issue in a meaningful way earlier in this case. This is due principally to the fact that the *operation* of a prior notification requirement was not at issue earlier in the case, an issue quite different from the *propriety* of imposing a prior approval requirement for future AMI acquisitions. Although Complaint Counsel's Petition for Reconsideration raises some of the issues that were articulated during the oral argument, the Petition discusses, analyzes, and develops these items so that AMI and the Commission can focus for the first time on the difficulties and the practical problems associated with the use of a prior notification remedy. It presents information and specific suggestions that could not have been presented earlier in the case because prior notification "fencing-in" was not at issue until the Commission opted to make it one by rejecting the prior approval provision. When the Commission chose to impose a prior notification requirement on AMI in the order, the practical problems associated with this requirement suddenly became significant for consideration by Complaint Counsel and AMI. Since neither Complaint Counsel nor AMI was in a position to [8] discuss this hypothetical remedy with any degree of precision prior to the Commission's Decision and Order, Complaint Counsel's Petition for Reconsideration is the only means available to Complaint Counsel to present to the Commission suggestions as to how to make the prior notification remedy effective. Thus, we find that those portions of Complaint Counsel's Petition that seek to modify the prior notification provision contained in Section III of the Commission's Final Order present appropriate areas for reconsideration under Rule 3.55 of the Commission's Rules of Practice, which we examine below.

AMI claims that the fact that the petitioning party had an "opportunity to argue" bars a motion for reconsideration under Rule 3.55, citing *Holiday Magic, Inc.*, 85 F.T.C. 19, 20 (1975), *Ash Grove Cement Co.*, 86 F.T.C. 606, 607 (1975), and *National Association of Women's and Children's Apparel Salesmen, Inc.*, 78 F.T.C. 1584, 1585–86 (1970), in support of this proposition. However, we find that these decisions are inapposite to the case at bar. In *Holiday Magic, Inc,*, the Commission apparently had "fully considered in reaching its final decision the arguments raised by counsel in the motion to reconsider." 85 F.T.C. at 20. Here, we gave no such consideration to these matters.[2] In *Ash Grove Cement Co.*, the Commission found that respondent "had [9] an opportunity, which it exercised, to argue before the Commission" the very issues that it addressed in its petition for reconsidera-

[2] AMI's "opportunity to argue" contention in *Holiday Magic* presumably refers to the portion of respondent's motion for reconsideration relating to substitution of counsel in that case. The facts are totally different in this case, and we cannot seriously entertain AMI's reliance on this facet of that case for the proposition that it asserts in the case at bar.

tion. 86 F.T.C. at 607. Similarly, in *National Association of Women's and Children's Apparel Salesmen, Inc,,* the Commission found that "respondents have had opportunities and have made use of such opportunities" to argue the same points raised in their petition for reconsideration. 78 F.T.C. at 1587, There, the matters were discussed extensively in briefs and oral argument. Here, not only was the opportunity never exercised but, in fact, it never existed since the operation of the prior notification requirement was not put in issue before the Commission issued its Final Order on July 2, 1984. None of the three dozen or so reported decisions examining Rule 3.55 that we have uncovered through independent legal research suggests a contrary conclusion.

However, a portion of Complaint Counsel's Petition for Reconsideration reasserts an argument already presented to, and rejected by, the Commission. These modifications would require AMI to obtain Commission approval for a ten year period for any hospital it seeks to acquire in San Luis Obispo County, California. Both parties briefed the prior approval remedy fully before Administrative Law Judge Barnes and the Commission, and it appears that Complaint Counsel's request for reconsideration of this remedy for any geographic market, including San Luis Obispo County, does not present "a new question . . . upon which petitioner had no opportunity to argue before the Commission." Accordingly, we find that the specific modifications presented [10] with regard to Section IV of the Order (and the arguments marshalled in support of these modifications at pages 11 and 12 of Complaint Counsel's Petition) are not appropriate areas for reconsideration under Rule 3.55, and thus this portion of Complaint Counsel's Petition will be denied.

III. The Mechanics of Prior Notification

The Commission's Order requires AMI to notify the Commission when it seeks to acquire a hospital in any of thirteen states, if the acquisition would cost in excess of $1 million and the acquisition would provide AMI with a 20% or more share of the acute care hospital beds in a specifically designated area. Under the Order, AMI is directed to notify the Commission of its intent to acquire a covered hospital either when it issues a letter of intent or enters into a purchase agreement, whichever is earlier,

Complaint Counsel's Petition for Reconsideration focuses on the "fencing-in" provision that the Order imposes. Complaint Counsel requests reconsideration and modification of this provisions and proffers specific language to accomplish the suggested modifications.

Complaint Counsel seeks to modify the prior notification requirement in five specific ways, discussed below.

First, Complaint Counsel requests that the Order provide a specific notification period so that AMI will be required to give the Commission notice of any covered acquisition at least thirty days prior to completion of the acquisition (or fifteen days in [11] the case of a cash tender offer). Petition at 9. Complaint Counsel argues that without a specified notification period in the Order, AMI would be permitted wide discretion in notifying the Commission of covered acquisitions, and that the Commission could be left without sufficient time to obtain the evidence necessary to seek an injunction to block an illegal acquisition. *Id.* at 3. Complaint Counsel contends that a thirty day notification period would provide the Commission with sufficient time with which to assess the acquisition, obtain evidence, and move to enjoin the acquisition if necessary. *See id.* at 3 & 5–6.

Second, Complaint Counsel recommends that the Order require written prior notification of a covered acquisition. *Id.* at 3 & 9. Complaint Counsel suggests that since AMI's notification may trigger significant action by the Commission (such as obtaining evidence sufficient to support an injunction), the notice triggering such efforts by the Commission should be written notice, not oral. *See id.* at 5.

Third, Complaint Counsel requests that language requiring the submission of specific information be provided in the Order so that the Commission will have the opportunity to make an informed decision as to whether the proposed acquisition is lawful. *Id.* at 6. Complaint Counsel points to the difficulties in obtaining information from companies under investigation, particularly if compulsory process and enforcement procedures are required. *Id.* at 4–5. Complaint Counsel, therefore, recommends that the Order provide the Commission with an efficient, orderly, [12] and equitable way of obtaining specific information needed to assess the competitive impact of a covered acquisition. *See id.* at 9–11.

Fourth, Complaint counsel requests that the Order provide Commission staff with a reliable way of obtaining additional information in a timely fashion in the event that the initial information provided is not sufficient to fully assess the impact of the covered acquisition. *Id.* at 8. Complaint Counsel suggests that in some acquisitions, additional time and information may be required to assess the competitive impact. *Id.* at 10. Complaint Counsel argues, therefore, that the Order should provide a way for obtaining more information and additional time in which to assess that information without forcing the Commission to rely on purely voluntary production.

Fifth, Complaint Counsel requests that a prior approval "fencing-in" provision be added to the Commission's Order to cover AMI hospi-

tal acquisitions in San Luis Obispo County. *Id.*, at 11–12. However, since we have determined that this issue is not appropriate for a Rule 3.55 Petition, this issue will not be addressed herein.

AMI's memorandum in opposition to Complaint Counsel's Petition argues that a modified prior notification provision similar to the one contained in Complaint Counsel's Petition would harm AMI competitively. AMI Memorandum at 6. AMI contends that the Order, as originally crafted, struck a balance between the Commission's desire to monitor certain acquisitions by AMI that are not subject to Hart-Scott-Rodino reporting requirements **[13]** and the need to " 'preserve the procompetitive benefits attributable to AMI's presence in the acquisition market.' " *Id.*, citing slip op. at 60 [104 F.T.C. at 226 (1984)]. Under the proposed modification, AMI contends that in every case it would be required to wait for thirty days plus any extensions allowable under Hart-Scott-Rodino, *id.* at 1 & 7 and, since the proposed Order would apply only where Hart-Scott-Rodino was not otherwise applicable, AMI's competitors in the hospital acquisition market would not have to condition their bids on compliance with these regulatory strictures. *See id.* AMI argues that "the proposed order would eliminate AMI's procompetitive presence in circumstances such as the sale of county-owned hospitals to which HSR does not apply," *id.* at 9, and "eliminate AMI's procompetitive presence in covered transactions [and] deprive the public of the benefits that the order was intended to preserve." *Id.* at 12.

AMI does not make a convincing showing that a reasonable notice requirement would harm it competitively or place it at a competitive disadvantage vis-a-vis its competitors in the hospital acquisition market. By arguing that "the proposed modification would uniquely handicap AMI and therefore effectively remove it from the market for acquisitions covered by the order," *id.* at 5, it is apparent that AMI misconstrues the concerns that the Commission expressed when it rejected the prior approval requirement. Under the prior approval requirement ordered by Administrative Law Judge Barnes, AMI would be at a competitive disadvantage due principally to an additional regulatory hurdle that it must jump in order to consummate the **[14]** acquistion of a hospital. This additional hurdle, which for all intents and purposes (subject to further appellate review) constitutes a veto over AMI acquisitions, would likely make a prospective seller of a hospital reluctant to deal with AMI. In practical terms, this would reduce AMI's leverage in negotiating an acquisition and might necessitate AMI paying a premium in price for a potential acquisition over what "unfettered" acquirers, AMI's competitors, would be willing to pay. In the highly competitive market for hospital acquisitions, this would likely eliminate AMI as a viable competitor.

However, the situation with regard to prior notification is quite different from that of prior approval. AMI does not set forth any evidence demonstrating that a notification provision requiring submission of detailed market information would in any way burden an acquisition program. Such an advance notification requirement would not impose any undue burden on AMI because it does not inject any uncertainty into the acquisition process; instead, all it does is afford the Commission a meaningful opportunity to review the competitive impact of the acquisition.

AMI's arguments confuse prior approval and prior notification. Prior approval would preclude AMI from making a definitive purchase commitment; prior notification does not, as even AMI admits. AMI suggests that Complaint Counsel's proposed modifications would make an AMI bid "a conditional offer," *id.* at 7, a "conditioned transaction[ ]," *id.* at 8. But, at the same time, AMI admits that prior notification requirements, such as [**15**] those imposed under Hart-Scott-Rodino, do not make such a transaction "conditional." According to AMI witness Weisman:

> [Sellers of hospitals] do not want conditional transactions. They don't view Hart-Scott-Rodino generally as a condition anymore than they view, for example, a preparation of a definitive agreement as a condition.

Id., quoting Hearing Transcript page at 1727 (Weisman) [hereinafter "Tr."]. Similarly, AMI witness Reilly stated:

> Each of these transactions are, from the seller's perspective, time critical. And as it would be for you as an owner of a substantial piece of real estate, *once you have decided to sell it, you want to get it committed and know it is locked in.* It may take some time for escrow to close, but you want to know you have a deal.

Id., quoting Tr. 1848 (Reilly) (emphasis added). AMI's arguments that prior notification will make its acquisition bid conditional are disingenuous. Under prior notification, the Commission cannot stop a proposed acquisition except by successfully bringing suit, either in federal court or through an administrative complaint. Thus, the notification requirement does not in any way impose a prior approval constraint over the acquisition, as AMI seems to imply. Except for the compliance costs (principally, administrative and legal costs associated with preparation of the notification itself), such a requirement does not diminish AMI's leverage in negotiating an acquisition nor would it necessitate AMI paying a premium price for the acquisition in order to out-bid competitors in the acquisition market. If anything, it injects increased certainty into the acquisition because it subjects the acquisition to an early (albeit, non-binding) antitrust review and, as a

practical [16] matter, lessens the likelihood that the Commission might seek divestiture of the acquisition at some later date on antitrust grounds.

On the other hand, in adopting the advance notification provision contained in the original Order, we never intended to deny staff the time and resources needed "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.' " *See* Petition at 2, quoting slip op, at 60 [104 F.T.C. at 226 (1984)]. A simple statement by respondents of their intent to enter into an acquisition, without more, does not provide Commission staff with a meaningful opportunity to evaluate the competitive effects of the acquisition. Imposing a reasonable prior notification procedure does not simply "make the [Commission] staff's job *easier,"* as AMI contends, Petition at 6 (emphasis added)—rather, it makes it possible for staff to do the job that we anticipated would be done under the Order—assess the competitive effects of the acquisition. Because of the demands of time, it would be highly unlikely that, through normal channels of investigation, staff would be able to learn of the acquisition, assess its competitive impact, and prepare the legal papers needed to pursue a preliminary injunction in the event that the acquisition posed competitive concerns. AMI's offer in its memorandum to "be responsive to reasonable requests for information," AMI Memorandum at 11, does not by any means constitute a legally enforceable obligation that guarantees an [17] opportunity for meaningful review of a covered acquisition.

However, we are not convinced that there is a need to impose a waiting period on AMI in its covered acquisitions. Although AMI may have wide discretion in the *timing of its making a purchase commitment* to a prospective seller, AMI does not have discretion over the *timing of notification of the commitment* to the Commission. The final order requires AMI to notify the Commission once AMI becomes legally bound to make the purchase, which may be as early as issuance of a letter of intent and is certainly no later than entering into the purchase agreement itself. Market incentives encourage AMI to make this commitment as soon as possible so as to take the assets off the market. Consummation of the acquisition, especially consolidation of the acquired entity's operations with those of AMI, often will be delayed well past the purchase date because of externalities beyond AMI's control, such as state certificate-of-need requirements. As a practical matter, the Commission staff will have enough time, even more than the statutory waiting periods prescribed under Hart-Scott-Rodino, to review the notification filing by AMI and assess the likely competitive effects of the acquisition. Imposing an inflexible waiting

period on AMI would subject covered acquisitions to a time constraint that would accomplish little other than disabling AMI vis-a-vis its competitors. We conclude that the Commission staff will have adequate resources, under the present framework, to assess the competitive impact of covered acquisitions and prevent consummation of anticompetitive acquisitions, and that imposition [18] of a waiting period is not necessary.

Complaint Counsel is correct in asserting that "[t]he Commission's expressed intent is similar to the purposes of HSR to provide the government with a meaningful opportunity to challenge unlawful transactions *before* consummation, thus avoiding the problem of constructing post-acquisition relief and preventing injury to the public that would otherwise occur before divestiture." Petition 2 (emphasis in original). A detailed prior notification and reporting requirement would satisfy this concern. Such a requirement is well within the wide discretion accorded the Commission to remedy unlawful practices. *See Jacob Siegel Co. v. FTC,* 327 U.S. 608, 611 (1946). Since the Commission has found prior approval to be appropriate in certain instances, it is fair to conclude that a detailed prior notification requirement (a less drastic remedy than prior approval "fencing-in") is a legally valid remedy that the Commission could order in this case.

Accordingly, we will modify the Final Order in this matter by requiring written notification of AMI's intent to make a covered acquisition.[3] This notification is to be provided when AMI's Board of Directors or Executive Committee, or any entity [19] that is authorized to act on AMI's behalf in such acquisitions,[4] authorizes issuance of a letter of intent or enters into a purchase agreement to make such an acquisition, whichever is earlier. The Modified Order provides for filing information comparable to Hart-Scott-Rodino reporting requirements by AMI in order to permit staff a meaningful opportunity to assess the competitive effects of the proposed acquisition.[5] We will also require that the notification be supplemented with additional information, either in AMI's possession or reasonably available to

[3] As we did in the Final Opinion and Order, we again caution respondents that this Modified Order does not replace Hart-Scott-Rodino filing and waiting period requirements that may apply to any of AMI's future acquisitions. Where both Hart-Scott-Rodino and this Order apply to a particular acquisition, the Hart-Scott-Rodino reporting and waiting period requirements would supercede operation of this Order. However, where AMI's acquisition is otherwise exempt from Hart-Scott-Rodino, the terms of this Order will govern AMI's filing obligations.

[4] We do this *sua sponte* so as to prevent technical inapplicability of the Order if AMI were to assign acquisition responsiblities to a different AMI committee or entity.

[5] Complaint Counsel has also requested a mechanism for obtaining more information and additional time in which to assess that information without forcing the Commission to rely upon purely voluntary compliance. We deny Complaint Counsel's request for additional time for the same reasons that we have denied the request for a waiting period for the acquisition. However, we can envision some circumstances under which additional information may be necessary to fully assess the competitive effects of an acquisition. Therefore, we will require AMI to comply with reasonable requests by staff for additional information within fifteen days of service of such requests.

AMI, relating to the hospital to be acquired, the AMI hospital in the area, and identification and assessment of the area hospital market.[6] We require this supplemental information because, absent such, it would be difficult to determine the [20] existence and extent of market overlaps resulting from the acquisition.

It is hereby ordered, That, for the foregoing reasons, Complaint Counsel's Petition for Reconsideration is granted in part and denied in part. An appropriate order is appended.

MODIFIED ORDER

I

Complaint Counsel has filed a Petition for Reconsideration of the Commission's Order in this matter issued on July 2, 1984 [104 F.T.C. 1]. Respondents have replied in opposition thereto. The Commission has determined upon review of the matter that its Order of July 2, 1984 should be modified, for the reasons set forth in the accompanying opinion. Therefore,

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

[6] This information should include, where available, patient flow data, annual management and strategic plans, hospital untilization and revenue data, and documents relating to market share, formulation of hospital prices, competitive interaction among area hospitals, planned efficiencies, relations with third-party payers, and physician admitting patterns

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 Corporation and French Medical Clinic, Inc., together with any [3] 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 PSMA 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 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 [4] 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: (1) 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); or (2) if notification of the acquisition is required to be made, and in fact is made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. 18a. Such advance notification shall be provided when AMI's Board of Directors or Executive Committee, or any entity that is authorized to act on AMI's behalf in such acquisitions, authorizes issuance of a letter of intent or enters into a purchase agreement to make such an acquisition, whichever is earlier.

IV

The notification required by Section III shall be the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations, as amended, and shall be prepared and transmitted in accordance with the requirements of that part. The notification required by Section III of this Order shall apply to AMI and shall not apply to any party that AMI seeks to acquire. However, AMI shall provide at the same time of the filing of the Notifiction and Report Form supplemental information, either in AMI's possession or reasonably available to AMI, relating to the hospital to be [5] acquired, the AMI hospital in that geographic area, and identification and assessment of the area hospital market. Such supplemental information should include, where available, patient flow data, annual management and strategic plans, hospital utilization and revenue data, and documents relating to market share, formulation of hospital prices, competitive interaction among area hospitals, implementation of certificate of need standards in the area, planned efficiencies, relations with third-party payers, and physician admitting patterns.

AMI shall comply with reasonable requests by the Commission staff for additional information within fifteen (15) days of service of such requests.

Any acquisition subject to Section III pf this Order, involving an arrangement to lease, manage, or control a hospital, shall be fully described in the notification regardless of whether the acquisition involves the acquisition of any stock or assets of a hospital.

V

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 [6] 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.

VI

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.

Commissioner Bailey voted in the negative.

IN THE MATTER OF

BATUS INC.

MODIFYING ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT AND SEC. 7 OF THE CLAYTON ACT

Docket C-3099. Consent Order, Dec. 6, 1982—Modifying Order, Nov. 13, 1984

This Order reopens the proceeding and modifies the divestiture order issued against a department store operator, 100 F.T.C. 553 (1982), which required the company to divest department stores sufficient to reduce its floor space by 200,000 square feet and its sales volume by $20 million, as measured by 1981 sales. To date, the operator has received Commission approval for divestitures totalling 492,000 square feet and $17.9 million in 1981 sales, and has petitioned for modification of the Order stating that any further divestiture would "account for substantially more than $20 million in 1981 sales." Following an examination of the record and the company's plan of divestiture, the Commission concluded that the company had made a good faith compliance effort and that divestiture of a much larger store to satisfy the remaining $2.1 million sales volume requirement was not in the public interest. Therefore, Paragraph II of the original Order has been modified by substituting for the phrase in the first sentence reading "in an amount not less than $20 million as measured by fiscal 1981 sales" the phrase "in an amount not less than $17.9 million as measured by fiscal 1981 sales."

ORDER REOPENING PROCEEDING AND MODIFYING ORDER

By petition filed July 17, 1984, respondent BATUS Incorporated ("Batus") requests, pursuant, to Section 5(b) of the Federal Trade Commission Act (15 U.S.C. 45(b)), that Paragraph II of the Commission's Order issued in this matter on December 6, 1982 [100 F.T.C. 553], be modified so that Batus will not be required to make further divestitures to reach the $20 million sales volume stan dard set out in Paragraph II of the Order. Pursuant to Section 2.51 of the Commission's Rules of Practice and Procedure, the petition was placed on the public record for thirty days. No comments were received.

The order required Batus to divest department stores in the Milwaukee, Wisconsin SMSA sufficient to reduce its floor space by 200,000 square feet and its sales volume by $20 million, as measured by 1981 sales. To date Batus has received Commission approval for divestitures totalling 492,000 square feet and $17.9 million in 1981 sales.

The Commission has reviewed Batus' plan of compliance with the divestiture requirements of the Order, including its selection of stores, and the efforts undertaken to fulfill its obligations and believes Batus has made a good faith effort to accomplish full compliance with the Order. The record also demonstrates that sale of an additional store having a 1981 sales volume in the range of $2.1 million to a

viable competitor is unlikely. Given Batus' good faith compliance effort and the degree of divestiture already obtained, we believe that it is not in the public interest to require a divestiture of a much larger store to satisfy the remaining $2.1 million sales volume requirement. Therefore, we find that modification of certain language in Paragraph II of the order is in the public interest.

Accordingly, *it is ordered,* that the proceeding be, and it hereby is, reopened for the purpose of modifying the Order entered therein;

It is further ordered, That Paragraph II is amended by substituting in lieu of the phrase at the end of the first sentence which reads:

in an amount not less than $20 million as measured by fiscal 1981 sales.

the phrase,

"in an amount not less than $17.9 million as measured by fiscal 1981 sales."

IN THE MATTER OF

TEAC CORPORATION OF AMERICA

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket C-2752. Consent Order, Oct. 24, 1975—Modifying Order, Nov. 16, 1984

This Order grants the request of a Montebello, California supplier of high fidelity audio components to reopen the proceedings and delete Paragraph I(11) from the Commission's October 24, 1975 Consent Order, 86 F.T.C. 981, *modified*, November 25, 1983, 102 F.T.C. 1814, so as to permit the firm to prevent transshipment of its products to dealers who did not meet non-discriminatory standards of promotion, service and display. After considering company's arguments and other relevant information, the Commission concluded that the public interest warranted reopening and modifying the Order as requested. The transshipment provision had served its remedial purpose. There was no indication that the firm had engaged in resale price maintenance or breached the transshipment provision. Nor was there anything in the record to suggest a need to retain the provision as a fencing-in mechanism, or as a means of preventing anticompetitive effects from nonprice vertical restraints. Accordingly, the Commission ordered that the matter be reopened and Paragraph I(11) of the Order deleted.

ORDER REOPENING AND MODIFYING ORDER ISSUED ON OCTOBER 24, 1975

On June 6, 1984, respondent TEAC Corporation of America ("TEAC") filed its "Request to Reopen Proceedings and to Modify Consent Order" ("Request"), pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), and Section 2.5 of the Commission's Rules of Practice. The Request asked the Commission to reopen the proceeding in Docket No. C-2752 and modify the order issued by the Commission in this case on October 24, 1975—as modified by an order issued November 25, 1983—to remove a provision that restricts TEAC's ability to limit transshipment of its products. TEAC's Request was placed on the public record for thirty days and no comments were received.

After reviewing TEAC's request and other available information, the Commission has concluded that the public interest warrants reopening and modifying the order in the manner requested by TEAC. The transshipment provision of the order [2] (Paragraph I(11)) was adopted principally as a "fencing in" restraint ancillary to the order's ban on resale price maintenance ("RPM"). TEAC has shown that it does not fix the prices at which its authorized dealers resell TEAC products, that TEAC product prices vary from dealer to dealer, and that the transshipment provision therefore has encouraged the emer-

gence of intrabrand price competition in TEAC products. Consequently, Paragraph I(11) need not be retained for that purpose.

To the extent that Paragraph I(11) was also intended to remedy alleged anticompetitive effects of vertical practices other than RPM, the Supreme Court decision in *Continental T.V., Inc.* v. *GTE Sylvania, Inc.*, 433 U.S. 36 (1977)—issued after the original order in this matter—makes further analysis necessary. As the Court explained, non-price vertical restraints may either enhance or impede economic efficiency and consumer welfare, depending upon whether the fundamental purpose or effect of the restraints is on balance to enhance or exploit market power or instead to promote a more efficient form of distribution. It follows that devices that facilitate the imposition of non-price vertical restraints—such as transshipment restrictions—similarly may be beneficial in some situations and harmful in others. These practices are not inherently suspect or so plainly anticompetitive that they can be condemned without more extensive analysis under the rule of reason. The Commission has relied upon *Sylvania* to conclude that [3] it will only prohibit non-price vertical restraints that have "a probable adverse effect on *inter*brand competition" at either the manufacturer or the dealer level.[1]

The foregoing cases establish the need to evaluate the likely consequences of non-price vertical restraints in the recording equipment industry under the rule of reason in considering TEAC's petition. Vertically imposed transshipment restrictions such as those at issue here are most likely to be used in conjunction with a program of other non-price vertical restraints that effectively limits the entities with whom the manufacturer will deal. TEAC apparently seeks authority to use transshipment restrictions to facilitate a distribution program involving only carefully selected dealers. If TEAC's petition is granted, TEAC could use transshipment restrictions to facilitate the imposition and enforcement of other non-price vertical restraints.

I.

When market power either does not exist or cannot be sustained, anticipated efficiency gains are the only rational basis for a manufacturer to impose a vertical restraint. Only procompetitive practices will survive the market test when the [4] creation or enhancement of market power is unlikely; the market does not reward inefficient distribution practices. Thus, when the exercise of market power in a

[1] *Beltone Electronics Corp.*, 100 F.T.C. 68, 208 (1982). The Commission identified two different adverse effects upon interbrand competition that could satisfy this standard. First, the Commission indicated that non-price vertical restraints might in some circumstances support or increase the likelihood of collusion among competing firms. *Id.* at 206–07. Second, the Commission indicated that non-price vertical restraints might in some circumstances create or enhance the market power of one or more competing firms. *Id.* at 207.

properly defined relevant market is unlikely,[2] we consider non-price vertical restraints to be efficiency enhancing in purpose and effect, and therefore lawful, without further inquiry.

Market power can be exercised either by a dominant firm or through the action of competitors acting in concert. Because no firm can claim dominance in the recording equipment market (*see* pp. 6–8, *infra*), we will focus our attention on the possibility of collusive activities in this market.[3] In this context, our concerns are: (1) whether the firms that use the questioned non-price vertical restraints constitute a significant competitive threat; and (2) whether such a threat is effectively constrained by the remainder of the market.

In general, the likelihood of collusion depends on the expected gains from and costs of forming and enforcing a collusive scheme. Collusion is attractive only to the extent [**5**] that there are potential gains from cooperation, such as when market demand is inelastic at the competitive price. As the elasticity of market demand at the competitive level increases, the potential gains from collusion decline. Collusion becomes less likely as the costs of forming or enforcing a collusive agreement increase. The likelihood of collusion is directly related to, among other things, the overall level of market concentration, the distribution and aggregate value of the market shares of the firms using the challenged practice, and the presence and significance of barriers to entry. The likelihood of collusion is inversely related to, among other things, the number of fringe firms and the diffusion of their market shares.[4]

The factors that affect the feasibility of successful collusion often can be used to conclude that it is probably not a threat to consumer welfare in a given market. For example, collusion is unlikely to be successful in an unconcentrated [**6**] market.[5] Moreover, even in a somewhat concentrated market, if the firms actually using the vertical restraint at issue do not collectively possess and are not likely to secure market power, then the restraint is unlikely to facilitate the creation or maintenance of market power. In particular, non-price

[2] The Commission adheres to the principles of relevant market definition it adopted in 1982. *Statement of Federal Trade Commission Concerning Horizontal Mergers ("FTC Merger Statement")*, Trade Reg. Rep. (CCH) No. 546 (June 16, 1982), at 71, 84–85.

[3] The imposition of vertical restraints as a result of collusive activities in the recording equipment market might arise in one of two forms. First, distributors or retailers might act in concert to coerce manufacturers to impose vertical restraints on their competitors in order to limit competition in distribution or retailing. Second, manufacturers might impose vertical restraints in concert in order to facilitate the monitoring of a collusive agreement or otherwise to enhance the exercise of collusive market power.

[4] *E.g.*, R. Posner, *Antitrust Law: An Economic Perspective* 56–59 (1976). The Commission has recognized that other factors, in addition to those enumerated, also affect the likelihood of successful collusion. *FTC Merger Statement, supra* note 2, at 71, 75–80.

[5] In the context of horizontal mergers, the Justice Department has broadly characterized markets with Herfindahl-Hirschman Indexes ("HHIs") below 1000 as "unconcentrated," and markets with HHIs equal to or above 1000 as "moderately concentrated." *Justice Department Merger Guidelines*, 49 FR 26823, 26830–31 (1984). An HHI of 1000 or less certainly indicates an unconcentrated market; however, for the purpose of analyzing non-price vertical restraints, it may also be appropriate to characterize markets with somewhat higher HHIs as unconcentrated.

vertical restraints implemented by new entrants or small established firms are unlikely to threaten consumer welfare. The absence of barriers to entry is also likely to prevent successful collusion. On the facts in this case, we need go no further than to determine that successful collusion in the recording equipment market is highly unlikely. We do not confront a market in which non-price vertical restraints may create both market power and consumer benefits, and we therefore do not need to balance positive and negative effects upon competition and consumer welfare.

II.

We commence our analysis of the TEAC request by evaluating the threat of the exercise of market power. TEAC competes in the home and professional recording equipment segments of the high fidelity audio components market. The facts pertaining to the recording equipment industry indicate that no firm has a dominant [7] position and that the chance of successful collusion is remote. TEAC's share of the home recording market fell substantially between 1974 and 1983, so that it is now only the sixth largest firm in the industry. Moreover, only one firm has more than eight percent of the home recording market. The structure of the distribution and retailing segments of the home recording equipment market is even more diffuse. Thus, existing levels of concentration in this market at the manufacturer, distributor, and retailer levels are significantly lower than the threshold level that should trigger concern with the possibility of successful collusion.

In addition, since the original order was entered, at least twenty manufacturers have entered and/or increased their participation in the high fidelity audio components market and its tape recording equipment segment, indicating the absence of significant impediments to entry. There is similarly no evidence of barriers to entry into the distribution or retailing of home recording equipment. For example, the typical TEAC dealer carries as many as seven competing lines of tape recording equipment. The professional recording segment is similarly competitive. There are at least twelve manufacturers of professional recording equipment. Moreover, professional equipment is sold to knowledgeable buyers on a bid basis by geographically dispersed dealers, making successful collusion among manufacturers even more difficult and unlikely. [8]

In summary, the low levels of concentration and the absence of barriers to entry into the manufacture, distribution, and retailing of recording equipment make the creation of market power in this industry an extremely remote possibility.

CONCLUSION

The transshipment provision in question has served its remedial purpose. There is no indication that TEAC has engaged in RPM (or has breached the transshipment provision) from October 24, 1975 to date, and nothing in the record suggests that there is a need to retain the transshipment provision as a fencing-in mechanism to ensure that TEAC does not reinstitute RPM.

The transshipment provision does not appear to be needed to prevent anticompetitive effects from non-price vertical restraints either. Because the recording equipment market and its constituent segments are unconcentrated at the manufacturer, distributor and retailer levels, and because there has been substantial entry, we conclude that neither market dominance nor successful collusion is likely. The record presented by TEAC and other information indicate that transshipment restraints imposed by TEAC would pose no threat to interbrand competition. At the same time, Paragraph I(11) imposes unnecessary costs by requiring TEAC to prospectively specify and apply qualification standards for all dealers who seek to secure TEAC products transshipped by TEAC's authorized dealers, including dealers not served directly by TEAC. We therefore conclude that an effort by TEAC to control transshipment is very unlikely to harm competition. [9]

Accordingly, *it is ordered* that this matter be, and it hereby is, reopened and that Paragraph I(11) of the order be, and it hereby is, deleted.

Commissioner Bailey voted in the negative.

IN THE MATTER OF

GROLIER, INCORPORATED, ET AL.

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket 8879. Final Order, March 9, 1982—Modifying Order, Nov. 19, 1984

This Order reopens the proceeding and modifies the 1978 Commission Order, 91 F.T.C. 315, revised December 10, 1981 and made final March 9, 1982, 99 F.T.C. 379, which required a seller of encyclopedias to cease engaging in certain unfair and deceptive trade practices in connection with the sale of its products and the recruitment of door-to-door sales personnel. Pursuant to the company's petition, the Order has been modified to closely conform with the modification granted in *Encyclopaedia Britannica, Inc., et al.*, 100 F.T.C. 500. Among other things, the Order no longer requires the firm to include in employment ads information such as the nature of the employment, the location of the company or the basis of compensation, so long as they provide such information to potential employees during the initial job interview. The company may provide information concerning income and expenses to prospective employees when an actual job offer is made. The Order no longer requires the company to disclose in advertisements and promotional material that a sales representative will contact consumers who return inquiry cards, provided the firm can demonstrate through surveys that most readers of the ads understand this implicitly. The business cards of company's sales representatives may be reduced from three-by-five to two-by three-and-a-half inches, and the respondent may follow relevant Commission guidelines when making "free" offers, and is no longer required to attach lists of prices and free products to encyclopedia contracts.

ORDER REOPENING THE PROCEEDING AND MODIFYING CEASE AND DESIST ORDER

On October 13, 1983, respondents, Grolier, Incorporated, et al., filed a "Request to Reopen Proceedings To Modify Order and Application for Stay of the Order." ("Request") The Order became effective on October 11, 1983. On August 23, and October 4, 1984, Grolier supplemented the "Request" with a revised Appendix B, which sets out the methodology to be used by Grolier to show compliance with Paragraph II.A. of the proposed Order.

Grolier granted the Commission until November 19, 1984 to decide it's "Request". The Commission previously granted Grolier's "Request for Extension of Time" for the Commission to act to allow Grolier more time to complete its surveys bearing on the disclosures required by Paragraphs II.A. and B., which are subject paragraphs of the pending "Request".

Grolier seeks Order modifications virtually identical to those the Commission made to a similar Commission Order against *Encyclo-*

paedia Britannica (Docket No. 8908) [100 F.T.C. 500] on October 5, 1982.

On November 23, 1983 the Commission granted the stay as to Order Paragraphs I C. (2)(3) and (4); I D.; I E.; II A.-E.; II G. (7); II M. (1) and (2); II S.; and Paragraph V, pending resolution of the request for Order modification.

On the basis of the information provided by Grolier and in view of the Order modifications granted to Encyclopaedia Britannica the Commission has determined that pursuant to Section 2.51 of the Commission's Rules of Practice changed conditions of fact and the public interest require that the proceedings be reopened and the Order modified. *It is therefore ordered,* That the proceedings be reopened and the Order modified as follows:

I.

* * * * * * *

B. Misrepresenting, in any manner, the amount of income to be earned by any person or that may be earned by any person, the expenses that may be incurred by any person, the method of payment, or any condition or limitation imposed upon the compensation of any person.

C. Failing to disclose, clearly and conspicuously, in all advertising offering employment in any way involving door-to-door sales that the respondent concerned is recruiting persons for the sole purpose of soliciting or selling.

* * * * * * *

(2) [DELETED]
(3) [DELETED]
(4) [DELETED]

D. Failing to provide clearly and conspicuously, both orally and in writing, to any prospective sales employee at the initial face-to-face interview, and prior to executing any employment agreement with any such person, the following information:

(1) (a) that respondent is recruiting persons for the sole purpose of soliciting or selling;

(b) that the products or services being sold are encyclopedias or services to be used in connection therewith, or in the event that encyclopedias or such related services are not being sold, the products and services being sold; and

(c) the basis for compensating persons so engaged;

(2) that conditions or limitations upon the receipt of compensation, if any, do in fact exist, together with an example of such a material condition or limitation, and that all such conditions and limitations will be stated in detail in an interview in the event an offer of employment is made to such person;

* * * * * * *

(4) that expenses will be incurred by such person in performing required duties, together with an example of such a material expense, and that all such expense items will be stated in detail in an interview in the event an offer of employment is made to such person; and

(5) that such soliciting or selling will be on an "in-home" basis, if such is the fact, or will include soliciting or selling on an "in-home" basis, if such is the fact.

E. Failing clearly and conspicuously to provide, both orally and in writing, to any prospective sales employee at an interview at which an offer of employment is made and prior to executing any employment agreement with any such person, the following information:

(1) A complete and detailed description of each condition and limitation imposed upon the receipt of any compensation;

(2) a complete and detailed description of any expense or expenses any such person may incur in performing the required duties;

(3) (a) the total number of sales employees employed by the office offering the position during the most recent calendar quarter, and (b) the number of sales employees employed by the office who, during the prior calendar quarter, received net earnings equivalent to or greater than the amount represented in the advertisement to which the prospective employee is responding; *provided, however,* that if the office has been in existence for less than three months or has fewer than five sales employees, respondents shall provide the information described above pertaining to the Division in which the office is located; *provided further,* that such information need not be furnished if the prospective sales employee contacts respondents more than ten days following the dissemination of the most recent advertisement that contains representations of earnings. Respondents shall afford any prospective sales employee an adequate opportunity to review and consider the above information prior to requesting execution of any employment agreement.

F. Failing to furnish to persons at an interview when an offer of employment is made and prior to executing any employment agreement with any such person, a copy of Paragraphs I, II and V of this

Order together with a cover letter as set forth in Appendix A attached hereto. Respondents shall afford any prospective sales employee an adequate opportunity to review and consider these provisions of the Order prior to requesting execution of any employment agreement.

G. Making, distributing or using any training tapes, sales manuals, or any other document, method or device which contains any representation or instruction inconsistent with any provision of Paragraph I or Paragraph II of the Order.

II.

* * * * * * *

A. Representing, directly or by implication, in any advertisement or promotional material that solicits participation in any contest, drawing, or sweepstakes, or solicits any response to any offer of merchandise, service, or information, and that employs any return card, coupon, or other device to respond to such solicitation, that a person who replies as requested will not be contacted directly by a salesperson for the purpose of selling respondents' products, unless such is the fact. Such advertisements or promotional material shall comply with this Paragraph only if they meet the criteria set forth in Appendix B.

B. Failing, upon the written request of the Associate Director for Enforcement or his designee, to (1) submit any advertisement or promotional material or (2) test any such advertisement or promotional material, using the procedure set forth in Appendix B, to determine whether it complies with Paragraph II.A.

C. Failing to disclose clearly and conspicuously, during any telephone contact and before commencing any sales presentation to prospective customers, the fact that the individual making the call is either soliciting the sale, rental or lease of publications, merchandise or services for respondents, or is arranging for a sales solicitation to be made, and that if the prospective customer so agrees, the respondent concerned will send a salesperson to visit said prospect for the purpose of soliciting the sale, rental or lease of said publications, merchandise or services.

D. Visiting the home or place of business of any person for the purpose of soliciting the sale, rental or lease of any publications, merchandise or service, unless at the time admission is sought into the home or place of business of such person, a business card of at least 2 inches by 3 1/2 inches containing only the following information, is presented to such person:

(1) the name of the corporation;
(2) the name of the salesperson;
(3) the term "sales representative;"
(4) an address and telephone number at which the corporation or salesperson may be contacted;
(5) the product of the corporation logo or identifying mark.

* * * * * * *

G. Representing, directly or by implication, either orally or in writing that:

(1) Any person telephoning or visiting the home of any prospective purchaser is:

* * * * * * *

(c) telephoning or visiting the home of said prospect for the primary purpose of delivering or disseminating any vacation gift certificate, prizes, gifts, gift certificates, chances in any contest, or any other merchandise or item of chance;

* * * * * * *

(7) any publication, merchandise or service is being offered free, without cost, or is given as a bonus or otherwise to any purchaser of any of respondents' publications, merchandise or services, pursuant to any agreement to purchase, rent or lease any other publication, merchandise, or service, or combination thereof, from such respondent, unless respondent complies with all of the terms of the Federal Trade Commission's "Guide Concerning Use of the Word 'Free' and Similar Representations," 16 C.F.R. 251, which is hereby incorporated into this Order, and with any modifications or changes that are made to this Guide. All of the provisions of the aforesaid Guide shall be construed as mandatory and binding upon the respondents.

* * * * * * *

M. Representing to any person, directly or by implication, either orally or in writing that:

(1) any price is the retail, regular, usual or words of similar import or effect, price for any publication in any binding, merchandise or service, unless such price is an actual, bona fide price for which each such publication has been openly and actively offered for sale in the

recent and regular course of business for a reasonably substantial period of time;

(2) any price is the retail, regular, usual, or words of similar import or effect, price for any set of publications in any binding and in combination with any other publication, merchandise or service, unless such price is an actual, bona fide price for which each such publication has been openly and actively offered for sale in the recent and regular course of business for a reasonably substantial period of time.

* * * * * * *

S. [DELETED]
T. [DELETED]

* * * * * * *

APPENDIX A

NOTICE

Attached hereto are the *pertinent provisions* of a cease and desist order entered against Grolier, Incorporated and certain of its subsidiaries, including Grolier Interstate, Inc. by the Federal Trade Commission, an agency of the Federal Government. Violation of any provision of this Order can result in severe monetary penalties to Grolier, Incorporated and Grolier Interstate, Inc. If you are employed by Grolier, Incorporated or any of its subsidiaries, you will be *required* to observe the provisions of this Order. Violation of any provision of this Order by an employee constitutes a violation of a federal law.

You should carefully read this Order before agreeing to any employment arrangement with Grolier, Incorporated or any of its subsidiary companies.

_____

(President)
Grolier, Incorporated

APPENDIX B

This Appendix sets forth the methodology respondents shall employ to determine whether advertisements or promotional materials represent that a person who replies as requested may be contacted directly by a salesperson for the purpose of selling respondents' products, and the criteria for determining whether such advertisements or promotional materials comply with Paragraph II.A.

1. *Format*—Respondents shall test the comprehension level of advertisements or promotional material by conducting a mall-intercept test or an in-home survey using the questionnaires attached hereto as Exhibit 1.
2. *Sample Size*—The sample shall consist of at least 150 subjects.
3. *Demographics*—Test subjects must:

(a) be between 25 and 49 years of age;
(b) have at least one child fifteen years of age or younger living at home;

(c) have household incomes of at least $15,000 per year for 85% of the subjects tested and the remaining 15% must have household incomes of less than $15,000 per year; *provided,* that, upon respondents' request, the Division of Enforcement shall increase this figure by increments of $5,000 whenever the percentage of households earning at least the requested amount equals or exceeds the percentage of households that, according to the 1980 United States Census, have household incomes of at least $15,000 per year. The data for future changes shall be based on the most recently published edition of the *Statistical Abstract of the United States.*

4. *Location of Markets*—The interviewing will be conducted in four geographically dispersed markets. In the case of mall-intercept tests, the same central location facilities will be used wherever possible. If it is necessary to change any interviewing facility, the new facility shall have demographic characteristics similar to those of the facility it is replacing.

5. *Criteria for Acceptability of New Coupon Copy*—New promotional material copy shall comply with Paragraph II.A if at least seventy-five percent of the test subjects in both the group surveyed with household incomes in excess of $15,000 and the group with household incomes of less than $15,000 answer "yes" to question 2 of the questionnaires (Exhibit 1).

Modifications to this Appendix, including the questionnaire, may be made upon a request by respondents and the approval of the Associate Director for Enforcement.

EXHIBIT 1

MALL SCREENER

1–4
S–1

COMPREHENSION STUDY-CARD

Hello, I'm _____ from _____, a national marketing research firm. We're conducting a survey and would like to ask you a few brief questions.

A. Are you the (male/female) head of your household?

Male head of household 1
Female head of household 2
} (APPLY TO APPROPRIATE QUOTA)

NEITHER...../1/2/3/4/5/6/7/8/9/0/ ("X" FIRST UNUSED BOX, TERMINATE AND RE-USE.)

B. Which of the following groups best describes your age? Are you ..... (READ LIST)?

Under 25...../1/2/3/4/5/6/7/8/9/0/
("X" FIRST UNUSED BOX, TERMINATE AND RE-USE.)
25–29.....1
30–34.....2
35–39.....3
40–44.....4
45–49.....5
} (CONTINUE)

50 or over...../1/2/3/4/5/6/7/8/9/0/ ("X" FIRST UNUSED BOX, TERMINATE AND RE-USE.)

(DO NOT READ) Refused...../1/2/3/4/5/6/7/8/9/0/ ("X" FIRST UNUSED BOX, TERMINATE AND RE-USE.)

C. And, which of the following groups best describes your annual household income before taxes for 1983? Is it.....(READ LIST)?

Under $15,000 1
$15,000 - $24,999 .....2 } (APPLY TO APPROPRIATE QUOTA)
$25,000 or more 3

(DO NOT READ) Refused...../1/2/3/4/5/6/7/8/9/0/ ("X" FIRST UNUSED BOX, TERMINATE AND RE-USE)

IF OVER QUOTA - $15,000 OR MORE, "X" FIRST UNUSED BOX, TERMINATE AND RE-USE.

/1/2/3/4/5/6/7/8/9/0/

D. How many school age children, 15 years of age or younger, live in your household?

#_____

None...../1/2/3/4/5/6/7/8/9/0/ ("X" FIRST UNUSED BOX, TERMINATE AND RE-USE.)

MALL

COMPREHENSION STUDY - CARD

MAIN QUESTIONNAIRE

(HAND RESPONDENT DRAWING CARD)

1. Now I'd like to ask you a few questions about this free drawing card.

Based on what you just read, what would you expect to happen if you filled out the card? (PROBE) What else would you expect to happen?

_____

_____

_____

_____

2. For the purpose of this research, let's suppose that you filled out the card. That is, you are interested in receiving information about the educational materials described. Would you expect to be contacted by a sales representative?

Yes.....1
No 2

(TAKE BACK DRAWING CARD)

THANK RESPONDENT AND TERMINATE.

RESPONDENT'S NAME:_____TELEPHONE #:( ) _____

ADDRESS: _____

CITY:_____ STATE:_____ ZIP: _____

INTERVIEWER'S NAME:_____ DATE: _____

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.

EXHIBIT A

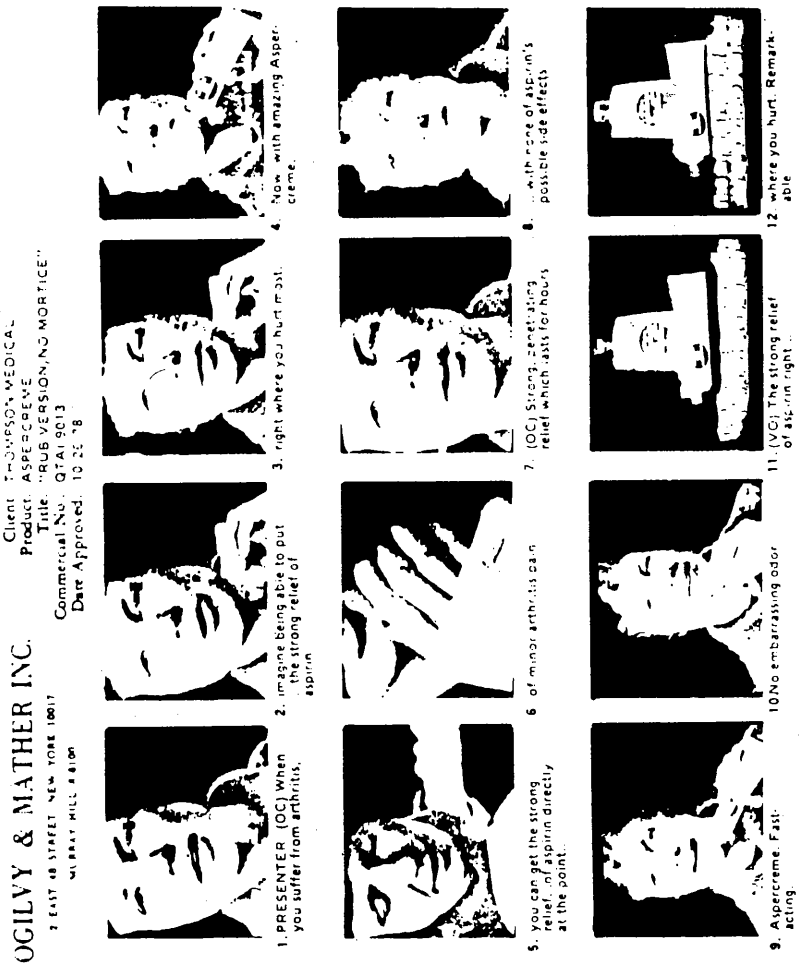

OGILVY & MATHER INC.
Client: THOMPSON MEDICAL
Product: ASPERCREME
Title: "RUB VERSION, NO MORTICE"
Commercial No. QTAI 9013
Date Approved: 10 25 78
1. PRESENTER (OC) When you suffer from arthritis,
2. imagine being able to put the strong relief of aspirin
3. right where you hurt most.
4. Now with amazing Asper-creme.
5. you can get the strong relief of aspirin directly at the point.
6. of minor arthritis pain
7. (OC) Strong, penetrating relief which lasts for hours
8. ... with none of aspirin's possible side effects
9. Aspercreme. Fast-acting.
10 No embarrassing odor
11. (VO) The strong relief of aspirin right
12. where you hurt. Remark-able

EXHIBIT B

OGILVY & MATHER INC.
2 EAST 48 STREET, NEW YORK 10017
MURRAY HILL 8-4100
Client: THOMPSON MEDICAL
Product: ASPERCREME
Title: "VISIBLE MEN"
Commercial No.: QTAJ 9033
Date Approved: 3/30/79
1. PRESENTER: (OC) When you suffer from arthritis,
2. imagine putting the strong relief of aspirin right where you hurt.
3. Aspercreme 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. Aspercreme starts concentrating all the temporary relief of two aspirin
9. directly at the point of minor arthritis pain.
10. Strong, concentrated relief.
11. VO: Aspercreme.
12. The strong relief of aspirin right where you hurt

EXHIBIT C

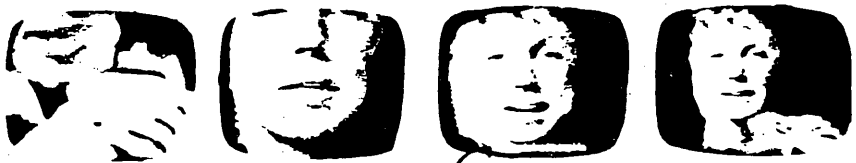
Radio TV Reports

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

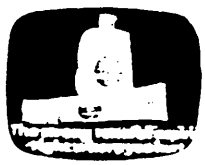
PRODUCT ASPERCREME 80-01116
PROGRAM NEWS 1/23/80 30 SEC.
WNBC-TV (NEW YORK) 7:24PM

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.



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

ALSO AVAILABLE IN COLOR VIDEO-TAPE CASSETTE

EXHIBIT D

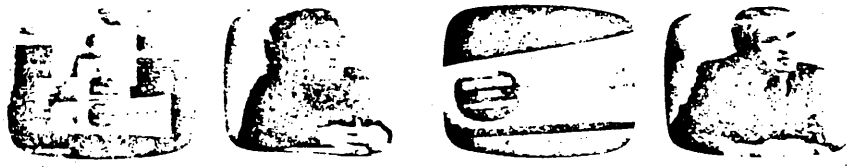
OGILVY & MATHER INC.
2 EAST 48 STREET, NEW YORK 10017
MURRAY HILL 8-4100
Client: THOMPSON MEDICAL
Product: ASPERCREME
Title: "VISIBLE MEN"
Commercial No.: QTAI 9033
Date Approved: 3/30/79
1. PRESENTER: (OC) When you suffer from arthritis,
2. imagine putting the strong relief of aspirin right where you hurt.
3. Aspercreme 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. Aspercreme starts concentrating all the temporary relief of two aspirin
9. directly at the point of minor arthritis pain.
10. Strong, concentrated relief.
11. VO: Aspercreme.
12. The strong relief of aspirin right where you hurt.

EXHIBIT E

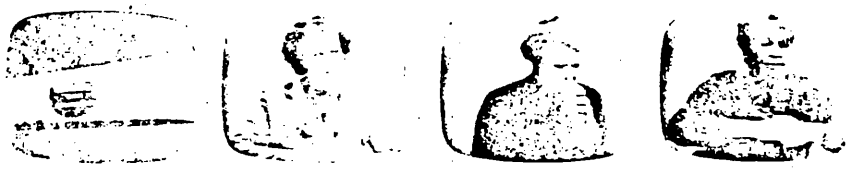
Radio TV Reports

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

PRODUCT ASPERCREME CREME RUB OH80-08742
PROGRAM 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. [illegible] 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. [illegible] 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

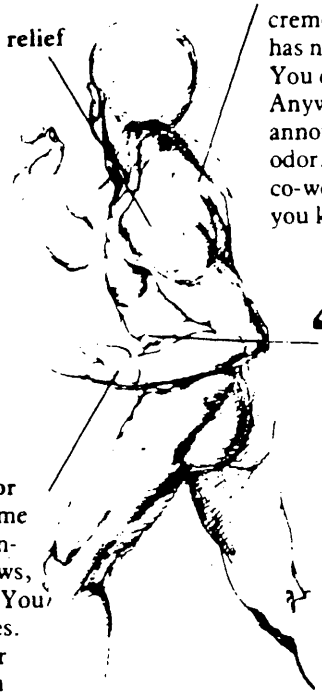
EXHIBIT F

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.

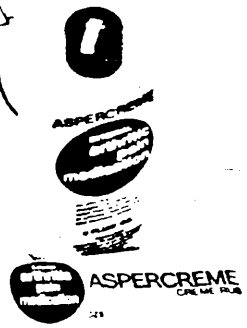
1 Strong concentrated relief Aspercreme™ pinpoints relief where you hurt. Aspirin tablets go throughout your body. But Aspercreme concentrates the relief of an effective aspirin-like analgesic directly at the point of arthritis pain — where you need it the most.

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

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.

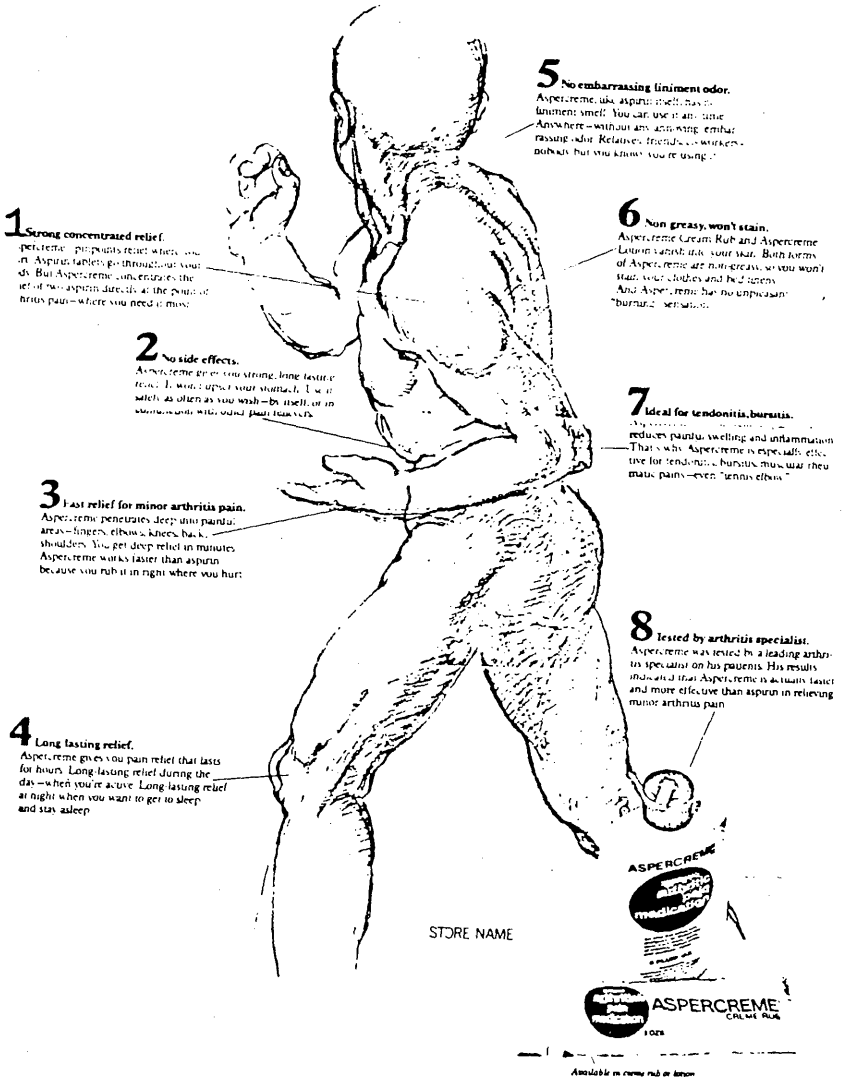
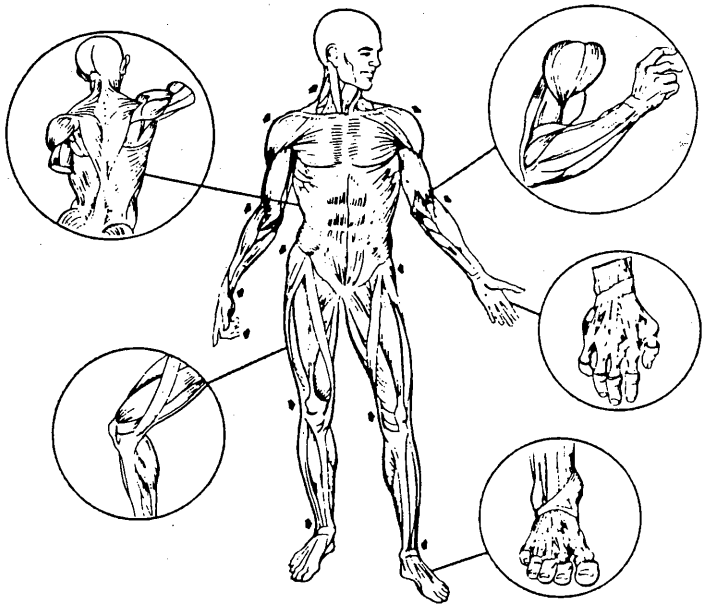


EXHIBIT H

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.R.—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.

Thrifty
DRUG AND DISCOUNT STORES

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

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 insuffficient 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 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 Malinckradt (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 ad 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-arthritic, 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 clincial 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, Cognative 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 or 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 and 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 Elmhurt 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 qualifed 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 compaigns (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:

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 (N=120)	Mobisyl (N=66)	Ben Gay (N=73)	Total Sample (N=259)
Aspirin	78%	8%	3%	39%
Creme	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":

Ingredient Type Mentions (in percentage)	Aspercreme (N=120)	Mobisyl (N=66)	Ben Gay (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 Liberman 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 questinnaire 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 respresentative 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 "respresentativeness" 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 50I). 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 Aspirincreme, or Jay's Aspirincreme (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 Aspirincreme 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-Z-056). The report also contains

the comments of several consumers who felt that, since Aspercreme had aspirin it 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, 59O).

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). Arthritics 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 discomfirmed 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 methodolo-

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-

denthal, 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 ojbectively 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;

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 (Frudenthal, 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