577. It is generally agreed that advertising, experience based on usage and word-of-mouth communications are the three major sources of images (Ross, Tr. 2239; Smith, Tr. 7732; Jacoby, Tr. 5487–88). However, experts recognize that word-of-mouth communications are essentially a derivative factor, dependent upon both advertising and prior product usage (Ross, Tr. 2238; Jacoby, Tr. 5490; Sen, Tr. 7327–28; Smith, Tr. 7732). Thus, advertising and product usage are the two most important sources of consumers' images of products (Ross, Tr. 2239).

578. Advertising also plays an important role in creating and helping to foster awareness of a brand, in creating expectations about how the product will perform and in generating initial trial of the product (Jacoby, Tr. 5292, 5406, 5489).

579. A consumer's initial trial of a product is often explained by the consumer's perception of how the product will perform; these expectations are often generated by advertising (Sen, Tr. 7330–31; Smith, Tr. 7735–36). Consequently, every time a consumer uses a product, that usage experience interacts with the expectations that were created by advertising (Ross, Tr. 2269–70, 2701–02; Jacoby, Tr. 5407; Smith, Tr. 7745). **[153]**

580. Over a period of time, specific claims contained in an advertisement tend to merge with a consumer's beliefs about the product. This proposition remains true even though the consumer may subsequently forget the specific content of those advertising claims (Ross, Tr. 2045, 2689–91; Smith, Tr. 7437). Thus, if a general theme of an advertising campaign is reiterated over time, the product image relating to that theme will endure despite the likelihood that consumers will have forgotten the specific content of previous advertisements directed to that product claim (Smith, Tr. 6108–09; Kuehn, Tr. 6681–82).

581. The importance of usage experience as a source of comparative product image becomes significantly lessened with respect to a product class such as OTC analgesics, where consumers are unable to make an objective evaluation of how the products perform. In this instance, the relative importance of advertising as a primary source of comparative product image is enhanced accordingly (Ross, Tr. 2246–49, 2255–57, 2613–17, 2703–05; Sen, Tr. 7330–31; Smith, Tr. 7745).

582. In the case of OTC analgesic products, a consumer's ability to objectively evaluate the products' pharmacological performance is greatly reduced by the consumer's expectations of performance resulting from exposure to advertising, the placebo effect, the subjective nature of pain in general and minor pain in particular,

and by the fact that each pain experience is different for the consumer at a given time and place. The consumer is, thus, unable to effectively evaluate the comparative pharmacological performance of OTC analgesic products when he or she knows the products being taken (*i.e.,* on an unblinded basis) (F. 210, 211, 218–20, 223 and 225).

583. The essential inability of consumers to evaluate the comparative pharmacological performance of analgesics must be distinguished from the fact that consumers continually form subjective judgments or perceptions concerning product performance. Consumers' subjective perceptions of superior performance, however, are unreliable due to the fact that consumers know the product that they are taking. Consequently, all their expectations about the performance of that product are called into play as they form their subjective perceptions of how the product is working for them. These expectations are continually fueled by advertising (Ross, Tr. 2239–41, 2271, 2276, 2278).

584. Usage experience with OTC analgesic products does not serve, in a true sense, to disconfirm consumers' expectations of how the products will perform. Therefore, **[154]**in the case of OTC analgesic products, usage, more often than not, tends to reinforce the initial product image induced by advertising (Ross, Tr. 2250, 2269–77; Jacoby, Tr. 5449, 5453–55; Blattberg, Tr. 7055–56; Smith, Tr. 7782).

585. The record shows that American Home spent approximately $210 million between 1960 and 1970, advertising Anacin to consumers as a product superior to aspirin in relieving pain and as a tension reliever. During the period 1968 to 1970, Anacin's advertising-to-sales ratio was approximately 37% (CX 611Z157).

586. American Home's presentation of Anacin in advertising as a more effective pain reliever has consistently emphasized speed, extra ingredients, more pain reliever and similar indicia of superior pain relieving performance. For example, respondents' witness, George DeMott, the President of Whitehall Laboratories, testified that American Home has been making an extra strength claim for Anacin since 1967 (DeMott, Tr. 4748; CX 306B; CX 314A).

587. Advertisements disseminated between 1963 and 1973 had consistently portrayed Anacin as effective for tension relief and for helping people cope with the ordinary stresses of everyday life (CX 611).

588. The record also shows that the public has perceived and understood American Home's superiority and tension relief claims in the advertisements for Anacin (F. 66–170, *supra*). The ASI copy tests in evidence confirm that a significant number of consumers

perceived superior efficacy claims and tension relief claims in the advertisements they viewed (F. 67, 86, 101, 110, 117, 133 and 157, *supra*). The advertising penetration studies show that superior efficacy and tension relief claims were being recalled by consumers off the top of their heads (F. 500, *supra*). The consumer image studies consistently show across time, method and sample that a significant number of consumers believe Anacin to be a more effective pain reliever than aspirin (F. 568–70, *supra*).

589. The consumer research comparing Anacin and aspirin has remained generally stable over the years (F. 502, 503, 569 and 570, *supra*). The record indicates that product usage, as a source of product image, is substantially influenced by advertising (F. 578–79 and 584, *supra*).

590. The record also indicates that the role of usage experience, as a source of product image, is significantly diminished in the case of OTC analgesic products (F. 581–82, *supra*). **[155]**

591. In light of these circumstances, it is concluded that advertising has played a substantial, and perhaps the most important, role in the creation and maintenance of consumers' beliefs and images of Anacin as a pain reliever superior to aspirin and as an effective tension reliever.

D. *The Duration Of Advertising Effects*

592. Experts for both parties testified that consumers' recall of specific copy points for advertising themes made in Anacin advertising (*i.e.,* penetration of advertising) will endure for a period of from three to nine months after those claims have been made (Ross, Tr. 2261–62; Smith, Tr. 6086–88; Blattberg, Tr. 7116–20; Sen, Tr. 7181). However, beliefs and images concerning attributes stressed in advertising for Anacin can endure long after the specific information that led to their formation has been forgotten (Ross, Tr. 2261–63; Jacoby, Tr. 5482; Kuehn, Tr. 6681–82; Smith, Tr. 7755; F. 580, *supra*).

593. The durability of consumers' beliefs and images of Anacin as a superior pain reliever and as an effective tension reliever depends upon various factors such as the types of beliefs and images, their importance or salience to consumers, whether they relate to a general favorable opinion of Anacin or to a narrow aspect of its performance and whether the consumers who hold these beliefs are users of Anacin (Ross, Tr. 2258–59, 2264–67; Jacoby, Tr. 5449–55, 5479–80; Smith, Tr. 6094–96, 7768, 7777–81).

594. The record contains evidence that, even if respondents were to cease disseminating advertising claims that Anacin is a more effective pain reliever than aspirin and that it is effective for the

relief of tension, images of Anacin on those attributes would persist in the minds of consumers who did not use the product for approximately one year after those claims ceased (Ross, Tr. 2258–59, 2266; Smith, Tr. 6088, 7774–75). The one year estimate of duration among non-users is based upon professional experience. Dr. Ross's opinion was based, in part, upon his review of literature showing that a substantial number of consumers still have images of some products 20 years after those products have gone off the market (Ross, Tr. 2260, 2265).

595. On the other hand, images of Anacin's superior efficacy and tension relieving efficacy will persist among Anacin users for a period longer than one year because such usage will continually reinforce their images (Ross, Tr. **[156]**2266–67; Jacoby, Tr. 5449–55; Smith, Tr. 6094–96, 7768, 7782, 7821; F. 584, *supra*).

596. Once a consumer has begun to perceive that Anacin is more effective than aspirin and that it relieves tension, and once these beliefs have become a part of the consumer's image of Anacin, these beliefs lose their functional connection with the information that originally generated them (Ross, Tr. 2267).

597. The record, as a whole, shows that until and unless new information is provided to consumers about Anacin that corrects or modifies these beliefs, the beliefs and images will endure for a long period of time because consumers' usage experience with Anacin will not serve to disconfirm the beliefs (Ross, Tr. 2267–71; F. 584, *supra*). On the contrary, each time consumers use Anacin, that usage tends to reinforce the expectations of consumers that advertising induced in the first place (Ross, Tr. 2269–70; Jacoby, Tr. 5453–55).

598. Respondents' expert witnesses, Drs. Blattberg and Sen, contended that a high degree of brand loyalty to Anacin among Anacin users (*i.e.*, a significant number of repeat purchases of the brand) was a prerequisite to a finding that usage reinforces consumers' images of the product, with those images having been substantially influenced by advertising (Blattberg, Tr. 6877, 6887–88; Sen, Tr. 7181–88). To shed light on this question, Drs. Blattberg and Sen prepared an analysis of the purchasing patterns in the analgesics market and the amount of brand switching that occurs (RX 176 through RX 185).

599. Their analysis of how consumers behave in the marketplace was based upon panel data, collected by means of consumer purchase diaries, which were supplied by NPD Research, Inc. ("NPD") (Johnson, Tr. 6136–40; Blattberg, Tr. 6823, 6830). One frequent use of such panel data is to examine brand switching behavior in given product categories (Johnson, Tr. 6151).

600. American Home purchased panels of data for two periods of time from NPD in 1977. One panel covered the period December 1970 to January 1973, with the exception of one missing month, May 1972. For the latter period, there were two panels which were not coterminous in length: one panel covered the period from July 1975 to May 1976, and the other panel covered the period from July 1975 to December 1976 (Johnson, Tr. 6149; Blattberg, Tr. 6831). [157]

601. Tod Johnson, president of NPD, testified that NPD collects data from two nationally representative panels which are demographically and geographically balanced through use of a stratified quota sample, and which consist of a minimum of 6500 reporting households per month (Johnson, Tr. 6140, 6143–45).

602. However, the sample selected by NPD is neither representative of the entire United States population nor a probability sample (Johnson, Tr. 6158–66). NPD contacts potential participants based upon lists compiled from telephone books or automobile registrations. Samples based on telephone books do not include unlisted numbers or people without telephones, while samples based on auto registrations do not include people without cars. Moreover, NPD's invitation to join a panel, which is mailed out to consumers, is rejected by 90% of those contacted. Of the 10% of the families contacted that do accept and respond, less than one-half actually become participants (Johnson, Tr. 6175–77).

603. RX 176 through RX 185 contain the results of Drs. Blattberg and Sen's analysis of two sets of NPD Panel Data on analgesics purchases by families. Neither these exhibits nor, therefore, the NPD data on which they are based include any information on the individuals who actually used the products purchased (Johnson, Tr. 6153–55; Blattberg, Tr. 6930).

604. RX 176 through RX 185 do not take into account several factors which can affect the conclusions which can be drawn about the purchase behavior of families participating in NPD's panels. Such factors, appropriate for analysis, include the size and composition of the participating families, the length of time that they participated, the sequence and mix of the brands purchased and the size of the purchase (Johnson, Tr. 6220; Sen, Tr. 7262, 7263–66; Blattberg, Tr. 6930–31).

605. In this proceeding, Drs. Blattberg and Sen adopted a stringent, narrow definition of brand loyalty: the exclusive, or virtually exclusive, usage of one brand over time (Blattberg, Tr. 6976; Sen, Tr. 7192, 7196). However, Dr. Blattberg also testified that there is much disagreement about the concept of loyalty to one brand versus multiple brand loyalty (Blattberg, Tr. 6978–79).

606. If the criterion for brand loyalty to a product were lowered from Drs. Blattberg and Sen's figure of 90% of consumer purchases being devoted to Anacin to 65%, for [158]instance, then 20% or more of the families who were heavy users of analgesics and who purchased Anacin would be deemed "loyal" to the product (RX 178 and RX 183. See also Sen, Tr. 7303–04, 7309–10; Blattberg, Tr. 6975, 7020, 7028–29).

607. Moreover, there is a category of consumers who may conveniently be called "national brand switchers." While these consumers are not loyal, in the conventional sense, to one brand, their purchase behavior is limited to switching among two or three national brands (Blattberg, Tr. 6959, 6978; Sen, Tr. 7266–70).

608. Dr. Blattberg testified that approximately one-third of those households on the panel who made more than one transaction during the panel period made two or three transactions (RX 180; Blattberg, Tr. 7024–25). Of those households with two or more transactions, and with Anacin representing at least one of those transactions, 67.5% purchased three or fewer brands during the 1970 to 1973 panel period (RX 180B) and 74.44% purchased three or fewer brands during the 1975 to 1976 panel period (RX 185B) (Blattberg, Tr. 7020–22). Of this same group of households, 10.17% were totally loyal to Anacin (*i.e.*, 100% of their purchases were of Anacin) during the 1970 to 1973 period (RX 180B), and 14.64% were totally loyal to Anacin during the 1975 to 1976 period (RX 185B) (Blattberg, Tr. 7028–29).

609. Given the tenuous worth of NPD data as well as the significant degree of brand loyalty either to Anacin or to a small, select group of national brands that would include Anacin, Drs. Blattberg and Sen's analysis of the panel data, presented in RX 176 through RX 185, does not materially weaken the conclusion that usage reinforces consumers' images of Anacin with those images having been substantially influenced by advertising (F. 584, 589 and 591, *supra*).

610. The evidence in the record shows that a pain reliever's attributes of efficacy, speed and strength are of central importance to users of OTC analgesic products. In CX 455, *A Study of Vanquish's Market Opportunities - 1970* , each of over one thousand consumers surveyed was asked to rate the desirability of 37 qualities in pain relievers (CX 455ZC25,Z123). The six qualities picked most often by the total sample of respondents as "extremely desirable" or "very desirable" were, in descending order, "Stops a headache," "Relieves pain," "Completely safe to take," "Provides quick relief," "Doesn't upset the stomach," and "Provides long [159]lasting relief" (CX

456Z058–Z060). A ranking of this kind is a method advocated by one of respondents' witnesses, Dr. Jacoby, to assess the importance or salience of beliefs (Jacoby, Tr. 5240–41, 5243–44). Four of the top six qualities relate to the pain relieving efficacy of analgesic products. Respondents' expert, Dr. Smith, agreed with this conclusion based on his analysis of responses to another question in CX 455 which asked respondents to list the reasons why they used their own brands most often. Those unaided responses confirm that the reasons associated with pain relieving efficacy, speed and strength are paramount in consumers' minds (Smith, Tr. 6026–28; CX 456Z344, Z345). For one OTC analgesic product to be regarded as superior to another along these important, yet general, dimensions strongly suggests that the belief will endure.

611. The record evidence also clearly shows that OTC analgesic users believe that tension relief is an important attribute of these products as a class. Over 50% of the group of regular analgesic users surveyed in CX 455 believed that "Relieves nervous tension" is an "extremely desirable" or "very desirable" attribute of an OTC analgesic product (CX 456Z059; Ross, Tr. 2223). Furthermore, an analysis of the heavy Anacin users surveyed in CX 451 and CX 452 discloses that substantial numbers of Anacin users felt that Anacin is useful for the treatment of nervousness, tension, depression and other mood related problems (Table XX, *infra.* See also RX 136, 137 and 138; Rossi, Tr. 1621).

TABLE XX

Percentage Of Anacin Users Who Feel Anacin Is Particularly Good For A Symptom

	1967*	1970**
Nervousness	58%	46%
Tension	72%	71%
Depression	33%	29%
Sleep Problems	39%	29%
A Heavy Dragging Feeling	30%	21%

* CX 1058Z470, Z473; Ross, Tr. 2229–30.
** CX 1059Z189, Z192; Ross, Tr. 2228–29. [160]

612. The record shows that Anacin's product image as an effective tension reliever is likely to endure for a long period of time

unless that image is corrected or modified by new advertising information (F. 596 and 597, *supra*).

E. *Conclusion*

613. "Corrective" information in advertising has been shown in experimental situations to be an effective means of altering or modifying consumer beliefs in performance attributes and images of products (Smith, Tr. 7770).

614. A general criticism of corrective advertising is that information disseminated in a corrective message will frequently have carryover, or spillover, effects. In other words, the corrective advertisement will invariably have an impact on images and beliefs other than those that are to be corrected and, perhaps, spread to other products of the manufacturer or to the general reputation of the manufacturer (Jacoby, Tr. 5310–13, 5458–62; Smith, Tr. 6102, 7773–74).

615. Respondents' expert witness, Dr. Jacoby, conceded that studies are divided on whether corrective advertising only affects the targeted belief or spreads beyond that belief to other, perhaps valid, beliefs (Jacoby, Tr. 5458–60, 5467).

616. In the setting of this proceeding, it is apparent that most consumers are not familiar with the name, American Home Products Corporation, and, thus, do not associate Anacin with American Home. However, the carryover effects of corrective advertising directed towards Anacin and APF may spread to other products that consumers perceive as associated with them (Smith, Tr. 6104–05).

617. The record as a whole supports the inference that a significant number of consumers believe APF to be a product which causes gastric discomfort less frequently than any other non-prescription internal analgesic (F. 572, *supra*), and that the existence of a substantial question regarding the scientific validity of this claim is a material fact to consumers.

618. Complaint counsel have established by a preponderance of credible evidence that Anacin has an image among a significant number of consumers as a product that is a more effective pain reliever than any other non-prescription internal analgesic and that this image will endure for a **[161]**long period of time (F. 568–70 and 597, *supra*). Complaint counsel, however, have not offered any evidence to show that consumers believe Anacin's superior efficacy is established by medical and scientific substantiation. In the absence of any direct evidence, complaint counsel's proposed corrective advertising provision directed towards Anacin's comparative efficacy claims must necessarily be based on the inference that the record

demonstrates the existence of an establishment image among consumers regarding Anacin's superior efficacy (F. 485, *supra*).

619. It is of course arguable that, since Anacin's comparative efficacy claims also carry implied establishment claims, the existence of Anacin's superior efficacy image among consumers is *ipso facto* a sufficient basis for the inference that there exists an establishment image among consumers and, further, that the establishment image is likely to endure unless altered or modified by corrective advertising. However, such a finding, in the absence of any direct evidence, is an inference based upon an inference (F. 574 and 575, *supra*).

620. The complaint in this proceeding does not allege that advertising claims of Anacin's superior efficacy and APF's superior safety lack a reasonable basis or are false (F. 15, *supra*). Rather, complaint counsel's proposed corrective advertising provision directed to Anacin's and APF's establishment images is based solely on the "substantial question" doctrine, a novel theory of Section 5 liability.

621. To require disclosure of the existence of a substantial question, a material fact, in future advertisements claiming the superior efficacy of Anacin or the superior safety of APF is one thing. To require corrective advertising grounded only upon the substantial question theory is another matter. It is the determination of the administrative law judge that, coupled with the considerations discussed in F. 619, *supra,* to impose such a radical form of relief as a corrective advertising requirement in this case would be fundamentally inequitable and inconsistent with administrative due process.

622. A corrective advertisement, for the purposes of this case, is a statement in an advertisement that will be understood by consumers to say that Anacin is not effective as a tension reliever. Consumers should be able to perceive the source of this new information to be at least as credible as the source of the original claims sought to be corrected (Ross, Tr. 2280–82). **[162]**

DISCUSSION

The Meaning Of Advertisements—General Considerations

It is well established that the Commission, and an administrative law judge, may determine the meaning of an advertisement solely from an examination of what is contained therein, without consumer testimony or survey data as to how an advertisement is perceived by the consumer. The test is whether, after reviewing an advertisement in its entirety, an interpretation is reasonable in light of the claims

made in the advertisement. An advertisement may convey more than one claim, and the same claim may be susceptible of more than one interpretation by the consumer. If an advertisement is capable of conveying more than one impression to the consumer and any one of them is false, the advertisement may be found to be misleading. From its own review of an advertisement, the Commission may find impressions which the advertisement is likely to convey to the public, and determine whether such impressions have a tendency or capacity to deceive the public, even in cases where a number of consumers may testify that they were not actually deceived.[11] In determining the tendency and capacity of an advertisement to mislead, the Commission looks to the impression an advertisement may make on the gullible and unthinking rather than on the trained and sophisticated.[12] Indeed, the central purpose of Section 5 is "to abolish the rule of *caveat emptor* which traditionally defined rights and responsibilities in the world of commerce." *FTC* v. *Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963).

In this connection, the unique impact of television commercials upon the audience deserves further discussion.

The revolutionary insight Marshall McLuhan has provided into contemporary mass communication is that "medium is the [163] message."[13] This epigram invites an understanding of the unique dimensions of today's mass-media communication. Today's printed and electronic mass communication does not aim to communicate classified data and fragments of information in the conventional sense as much as it stresses pattern recognition, in which visual and aural configurations serve as symbols. The "message" is not to be understood through the technical meaning of printed or spoken words or sounds as much as it is through recognition of the aural-visual pattern of the "medium" itself. At the risk of oversimplification, the message is recognized and understood through patterns of aural-visual symbols which are intended to evoke a desired imagery. A casual viewer of today's television commercials is struck by the element of essential truth in McLuhan's epigram. In my view, it is fair to say that, with respect to many television commercials that one encounters today, their evaluation is not complete when one stops at the meaning of their technical "content"—what the spoken words say. One needs to proceed to the "pattern" of symbols—what

[11] *E.g., Ford Motor Company*, 87 F.T.C. 756, 794–795 (1976), and the cases cited therein.

[12] *E.g., Charles of the Ritz Dist. Corp.* v. *FTC*, 143 F.2d 676 (2d Cir. 1944); *FTC* v. *Standard Education Society*, 302 U.S. 112, 116 (1937); *Exposition Press, Inc.* v. *FTC*, 295 F.2d 869, 872 (2d Cir. 1961), *cert. denied*, 370 U.S. 917 (1962); *National Bakers Services* v. *FTC*, 329 F.2d 365, 367 (7th Cir. 1964); *Rodale Press, Inc.*, 71 F.T.C. 1184, 1237 (1971).

[13] See Marshall McLuhan, *Understanding Media* (1964); *The Medium Is The Message* (1967).

the commercial (medium) in its totality symbolizes to the psychic and social consciousness of the audience-viewer. The key to true understanding is not classification and differentiation of the spoken words or sounds, but the imagery evoked by the patterned aural-visual symbols.[14]

This observation appears to have particular application to a television commercial which projects a distinct pattern of compressed, fluid pictorial and aural images, submerging its technical "content" and appealing directly to the viewer's psychic and social consciousness. In a very real sense, the viewer's critical faculties of classification and differentiation are drowned in patterns of imagery and symbols. Thus it is possible that, in skilled and practiced hands, the spoken words of a television commercial may appear to say one thing, while its pictorial and aural imagery conveys to the psyche of the viewer-audience something quite different. This observation is of some importance in evaluating many of the television commercials reviewed in this proceeding. In my view, in evaluating many of the advertisements challenged in this proceeding, the conventional **[164]** wisdom of the psychology of learning is inadequate and needs to be complemented by the McLuhanian perspective. For example, this approach is especially suited to the evaluation of the television commercials involving the "tension relief" claim, which clearly depict situational tensions of various kinds that are distinguished from pain-associated tension.

In evaluating 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 likely to convey to a consumer. When my initial determination is confirmed by the expert testimony of complaint counsel or respondents, 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 such record evidence as the ASI copy tests[15] and verbatim responses[16] before reaching a final determination. In this connection, my determinations agreed in most instances with those of Dr. Ross, complaint counsel's expert, and

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[14] Dr. Smith, respondents' consumer psychology expert, also noted the importance of the "symbolic" or "covert" message that is carried within an advertisement through color, environment and other devices (Smith, Tr. 7493–94).

[15] The ASI copy tests were conducted for and relied upon by American Home. (*E.g.*, CX 611Z155–Z156, CX 306, CX 327, CX 329; DeMott, Tr. 4755). In my view, although the test environment is somewhat artificial and does not purport to simulate the typical home-viewing environment, the ASI tests provide a valuable insight regarding the probable consumer perception of the copy points contained in test ads. See *American Home Products Corp.* v. *Johnson & Johnson*, 436 F. Supp. 785, 794 (S.D.N.Y. 1977), *aff'd* Nos. 77–7503, 7527 (2d Cir. May 1, 1978).

[16] The use of verbatim responses found in copy tests as an aid in determining the meaning of an advertisement is well established. *E.g.*, *Ford Motor Co.*, 87 F.T.C. 756, 779, 794 (1976); *Bristol-Myers Co.*, 85 F.T.C. 688, 706–12, 744–45 (1975).

disagreed with those of Dr. Smith in most instances. This is not surprising for a number of reasons.

First, Dr. Smith's focus was on what an advertisement claimed explicitly in its audio portion. Furthermore, Dr. Smith completely ignored what he calls a "symbolic" or "covert" message that may be carried within an advertisement through the depiction of an environment, the use of color and other non-verbal devices (Smith, Tr. 7493–94). **[165]**

Second, Dr. Smith's focus was further blurred by his seeming preoccupation with an advertiser's promotional campaign theme instead of evaluating each advertisement as a whole and individually (Smith, Tr. 7517–18). This is contrary to the law.[17]

Third, Dr. Smith's analysis was further flawed in that he attempted to gauge the message an advertisement may have carried to consumers in terms of the advertisements of American Home's competitors. (*E.g.*, Smith, Tr. 5649–51, 5703–06, 5775–78). This is contrary to the law.[18]

Fourth, before concluding that an advertisement contained an alleged claim, Dr. Smith appeared to require not only that the claim be perceived by consumers but also that it be retained by them for some definite period of time (Smith, Tr. 7437–39). However, "delayed recall measures consumer interest and advertising persuasiveness as well as message content."[19]

Fifth, Dr. Smith relied heavily on consumer research which did not focus on the question of whether a particular claim was perceived by consumers upon exposure (Smith, Tr. 5785, 7442–48, 7558). Indeed, Dr. Smith conceded that, if the issue was whether a particular advertisement made an alleged claim, he would have relied on his own judgment and on the ASI tests, in that order (Smith, Tr. 7518, 7562). This was what Dr. Ross, complaint counsel's expert, did and differs radically from what Dr. Smith did on his direct examination. (*E.g.*, Smith, Tr. 5785, 7517).

In any event, in determining the meaning of advertisements, in addition to relying on my own judgment as to what an advertisement as a whole can reasonably be interpreted to mean to a consumer, I have carefully considered all relevant record evidence on this issue. Now I shall turn to an examination of the challenged advertising claims. **[166]**

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[17] *E.g., Chrysler Corp.*, 87 F.T.C. 719, 751–52 (1976), *modified on other grounds*, 561 F.2d 357 (1977); *Ford Motor Co., supra*, 87 F.T.C. at 794–95.

[18] *E.g., Chrysler Corp., supra*, 87 F.T.C. at 751–52; Ford *Motor Co., supra*, 87 F.T.C. at 794–95.

[19] *American Home Products Corp.* v. *Johnson & Johnson*, Nos. 77–7503, 7527, Slip Opinion at 2887 n. 15 (2d Cir. May 1, 1978).

The Challenged Advertising Claims For Anacin

With respect to advertising claims for Anacin, all of the challenged claims can be viewed as representing a central claim, the claim of superior efficacy (Comp. ¶ 12(a)), with the exception of two groups. The two exceptions are those related to the so-called "tension relief" claim (Comp. ¶ 15) and the "22 seconds" claim (Comp. ¶ 8(A)(4)). Most of the other claims are related in some way to the central claim of superior efficacy and would be understood by consumers as variations of that central theme.[20] The so-called "establishment" claim (Comp. ¶ 10(A)) is implied as a matter of law from the superior efficacy claim.[21]

As Dr. Smith, respondents' expert, stressed, efficacy is the raison d'etre for OTC analgesic products. Such claims of specific product attributes as speed, strength or quantity of pain reliever will be associated with, and perceived as suggesting, efficacy by consumers (Ross, Tr. 1902–03; Smith, Tr. 5772–74, 5779, 7558–59). Thus, it is reasonable to view claims for such underlying product attributes in terms of superior efficacy.

1. *Representations That Anacin Has More Pain Reliever (Comp. ¶¶ 8(A)(1) and (3))*

It is my determination that a number of American Home's advertisements contained the claim that:

(1) Anacin has more pain relieving ingredients than any other OTC analgesic product (Comp. ¶ 8(A)(1)); and
(2) Anacin has more than twice as much of its pain relieving ingredient as any other OTC analgesic product (Comp. ¶ 8(A)(3)).

The claim that Anacin has more pain reliever is expressly made in many Anacin advertisements. For example, it is expressly claimed that Anacin provides "extra pain reliever" **[167]**(CX 50A through CX 53A) or that "Anacin tablets go further and add an extra slice 'by providing' all this extra pain reliever" (CX 30A). Some Anacin advertisements attempt to limit the comparison to more of a specific pain relieving ingredient. (*E.g.,* CX 13A, CX 14A, CX 23A, CX 164). For example, several advertisements state that:

> Of all the drugs to choose from, doctors most often recommend one pain relieving ingredient. And Anacin has more of it than any other leading headache tablet. (CX 13A, CX 14A).

[20] More pain reliever claim (Comp. ¶¶ 8(A)(1), (3)); better or different pain reliever claim (Comp. ¶ 8(A)(2)); doctors' preference claim (Comp. ¶ 20); and as effective as the leading prescription drug claim (Comp. ¶ 17).

[21] See p. 175, *infra.*

However, the impression that consumers will get is simply that Anacin has more pain reliever and, therefore, will provide significantly more pain relief than any other OTC analgesic product. Consumers will not make the subtle and refined distinction between "more pain reliever" and "more of a pain reliever" for the simple reason that the distinction is not meaningful to them. Indeed, why talk about more pain reliever or more of a pain reliever unless it is to mean significantly greater pain relief? (Ross, Tr. 1851–53, 1855, 1857–58, 1862–64, 1902–03; Smith, Tr. 5772–74, 5779, 7502–03, 7558–59).

Furthermore, the "more pain relief" message is often driven home by a simple, dramatic visual presentation. For example, some of the Anacin advertisements visually equate two Anacin tablets with four of the other extra-strength tablets (*e.g.,* CX 9A, CX 21A, CX 22A), or graphically illustrate Anacin's extra amount of pain reliever (*e.g.,* CX 15A, CX 30A, CX 33A, CX 41A, CX 60A).

It is true that the advertisements in question expressly compare Anacin to the "other extra-strength tablets" (*e.g.,* CX 9A, CX 21A, CX 23A, CX 89, CX115), to the "other leading" tablets (*e.g.,* CX 13A, CX 20A, CX 25A, CX 153), or to a group of other products (plain aspirin, buffered aspirin and the other extra strength tablets) (*e.g.,* CX 1, CX 30, CX 50, CX 105). However, they convey to consumers the message that Anacin provides more pain relief than any other product. For, if Anacin contains more pain reliever than the "leading products" and "extra strength" product, as well as plain aspirin and buffered aspirin, then Anacin has more pain reliever than anything else on the market, and "more pain reliever" means "more pain relief." **[168]**

2. *Representation That Anacin's Pain Relieving Ingredient Is Unusual, Special And Stronger Than Aspirin (Comp. ¶ 8(A)(2))*

It is my determination that a number of Anacin advertisements contained the claim that Anacin is different from ordinary aspirin and that it is stronger than aspirin.

For example, CX 173 states that:

> Anacin isn't just like an ordinary aspirin tablet. It has more of the drug doctors themselves most often choose to relieve pain.

Clearly the message is that Anacin is not like aspirin and that the "drug" in Anacin is something different from, and superior to, aspirin. Another advertisement, CX 41, states:

Anacin starts with as much pain reliever as the leading aspirin tablet. Then adds a core of this specific fast acting ingredient against pain.[22]

Similarly, the message is that Anacin starts with aspirin and adds some fast acting pain reliever to it. This impression is further reinforced by the fact that these advertisements do not say anywhere that Anacin's pain relieving ingredient is aspirin (Ans. of American Home, ¶ 22). In fact, American Home deliberately avoided such a disclosure for fear that "aspirin" will be confused with "Bayer Aspirin" by consumers (DeMott, Tr. 4659).

Furthermore, some of the advertisements emphasized Anacin's special or unique "formula." (See, *e.g.*, CX 26A, CX 89, CX 115). A special formula of Anacin means a special pain relieving formula and more pain relief to consumers. Otherwise, why talk about it in advertisements of an analgesic product?

3. *Representation That A Recommended Dose Of Anacin Is More Effective Than A Recommended Dose Of Any Other OTC Analgesic Product (Comp. ¶ 12(A))*

It is my determination that a number of Anacin advertisements contained the message that a recommended dose of Anacin is more effective than a recommended dose of any other OTC **[169]**analgesic product. This is the "more is better" message, the central theme running through many Anacin advertisements.

From my discussion in the preceding subsections 1 and 2, it follows that the advertisements which claim that Anacin has more pain reliever than any other product or that Anacin's pain reliever is special and stronger than aspirin also impliedly claim that a recommended dose of Anacin (2 tablets) is more effective for the relief of pain than a recommended dose of aspirin, buffered aspirin, the other leading headache tablets, the other extra strength tablets and anything else on the market.

Furthermore, some Anacin advertisements explicitly claimed greater efficacy for Anacin. For example, some claimed that Anacin will "work better" (*e.g.*, CX 153; CX 156), provide "extraordinary relief" (CX 172), or provide "extra pain relief power" (CX 115). Finally, the Anacin advertisements which claimed that Anacin is "as effective as" or provides "the same complete relief as" the leading prescription product (*e.g.*, CX 126 through CX 128, CX 132) clearly mean that Anacin is superior to all other non-prescription products.

[22] Also see CX 42A through CX 45A, CX 59, CX 63.

4. *Representation That Within 22 Seconds After Taking Anacin One May Expect Relief From Headache Pain (Comp. ¶ 8(A)(4))*

Although this alleged claim presents a close question, I have determined that this claim was made in a number of Anacin advertisements.

For example, CX 1A (a television commercial) states in part:

> While you won't feel it for minutes, right now relief is racing to your headache. So quickly that in the short time it takes you to kiss a baby, in just 22 seconds after Anacin is in your blood stream, it's already starting to work on your headache . . . .

In the video portion, a woman with a headache is taking Anacin while the clock begins to tick away. She then goes into her child's room and kisses her baby. Her facial expression changes to smiles. At the same time, the title "twenty-two seconds" appears on the screen. Although the audio message starts with a qualifier that "you won't feel it for minutes," it goes on to talk about how "right now relief is racing to your headache," and "in just 22 seconds after Anacin is in **[170]**your blood stream, it's already starting to work on your headache." In these circumstances, it is of course arguable that the message is qualified, and that consumers know better than to believe that any tablet can relieve a headache in just 22 seconds. However, in my view, a viewer of this television commercial will relate "22 seconds" to "headache relief" or at least understand the commercial to mean that in 22 seconds something will happen that will start the relief action. Thus, in terms of the imagery or environment depicted by the audiovisual presentation as a whole, the commercial can be reasonably interpreted to mean that within 22 seconds one may expect some relief from a headache.

Likewise, CX 151, a print advertisement,[23] states in prominent part:

> In 22 seconds after entering the bloodstream, Anacin is speeding relief to your pain—bringing you remarkable "all-over" relief . . . .

Unlike the television commercial reviewed above (CX 1A), this print commercial does not contain any qualifier. In my view, consumers will understand that "22 seconds" is meant to refer to the time period between the taking of Anacin and the beginning of relief. Otherwise, why would a commercial talk about 22 seconds?

5. *Representation That Anacin Relieves Nervousness, Tension*

[23] Also see, *e.g.*, CX 142 through CX 144, CX 153.

And Depression And Will Enable A Person To Cope With The Ordinary Stresses Of Every Day Life (Comp. ¶ 15)

It is my determination that a number of Anacin advertisements made the so-called tension relief claim alleged in Paragraph 15 of the Complaint.

A number of Anacin advertisements not only contained a generous sprinkling of such words as "tension," "nerves," "stress," "fatigue" and "depression"[24] but also depicted a variety of situational tensions.[25] Indeed, in some [171]television commercials the dominant image is situational tension and pain relief is clearly a secondary message.[26]

In some of the advertisements, stress and tension are emphasized in terms of the advertising time and space. For example, in CX 5, a television commercial, the major portion of both the audio and visual presentation focuses on tension and stress rather than on pain. Similarly, in CX 155, a print commercial, the prominent headline in bold-faced type says that Anacin "Calms Anxiety and Tension." Although the smaller type below this headline goes on to say, "as it relieves headache pain," consumers are likely to perceive the claim in the headline and understand the message to be relief from tension and anxiety apart from headache pain.

A number of the so-called tension relief advertisements represent in my view a skillful use of the imagery or symbolic technique of communication made possible by the television medium. In these commercials, through effective use of aural-visual techniques (sound effects, music and camera), the verbal content of a commercial (tension associated with pain) is submerged and reduced to a faint background noise while the dominant aural-visual imagery (situational tension) comes through dramatically.[27] (*E.g.*, CX 5, 7A, 26A and 89). The overall impact of these advertisements upon a viewer is clearly that Anacin is not only a pain reliever but is also good for tension, nerves, stress, fatigue and depression and helps one to cope with the ordinary stresses of everyday life, as alleged in the Complaint.

Finally, the record shows that a substantial segment of consumers believe that OTC analgesic products are good for tension relief (F. 571). It is therefore reasonable to conclude that Anacin's tension relief advertisements contributed in a substantial measure to the

[24] *E.g.*, CX 3, 5, 7A, 8A, 15A, 17A, 21A, 25A, 26A, 27A, 39A, 40A, 44A, 46A, 89, 115 and 155.

[25] *E.g.*, CX 3, 5, 7A, 8A, 17A, 26A, 40A, 46A, 170 and 171.

[26] *E.g.*, CX 3, 5, 7A, 8A, 40A and 46A.

[27] See pp. 162–64, *supra*. The record also shows that American Home recognized the effectiveness of this technique. *E.g.*, CX 327, CX 329, CX 402D, CX 404E, CX 420N.

creation of this consumer image. See pp. 220–22, *infra.* In my view, it is also obvious that the tension relief advertisements found a receptive audience who readily recognized and understood the tension relief theme. This is confirmed by the [172]ASI verbatims which indicate that as many as 17 to 25% of the viewers perceived the claim that Anacin is good for tension. See CX 420, CX 404; Smith, Tr. 7633–35.

6. *Representation That Certain Tests Prove That Anacin Is As Effective As The Leading Prescription Analgesic Drug And More Effective Than Any Other OTC Product (Comp. ¶ 17)*

It is determined that the alleged representation was made in a number of Anacin advertisements.

American Home has admitted that it made the representation that the scientific tests referred to in certain advertisements prove that Anacin is as effective as the leading prescription analgesic product (Ans. of American Home, ¶ 17. Also see CX 126 through CX 137, CX 140–41, 173 and 179). From this admission, it follows that American Home also impliedly claimed that Anacin is more effective than any other non-prescription analgesic product since consumers will readily perceive the "leading prescription product" to be more effective than non-prescription products.

7. *Representations Concerning Doctors' Survey (Comp. ¶ 20)*

The complaint charges that American Home made the representations that:

(1) A doctors' survey showed that twice as many specialists in internal medicine prefer Anacin for the treatment of headache pain to any other non-prescription analgesic product;

(2) More doctors recommend Anacin than any other non-prescription analgesic product for the treatment of headache pain; and

(3) Such recommendation constitutes convincing proof that Anacin will relieve headache pain more effectively than any other non-prescription analgesic product.

It is determined that a number of Anacin advertisements contain the alleged claims. CX 81 through CX 84 and CX 176 expressly claim that a survey of specialists in internal [173]medicine showed that "twice as many doctors said they would recommend their patients use the Anacin formula to relieve pain over that of the other leading extra-strength tablet" and further that this is "convincing proof about Anacin."

In my view, these advertisements also contain implied claims that twice as many doctors prefer Anacin over any other OTC analgesic product[28] and that such recommendation constitutes convincing proof that Anacin relieves pain more effectively than any other OTC analgesic product.[29] With respect to CX 146 through CX 148, the comparison is expressly limited to "the two leading extra-strength pain relief formulas." However, consumers will perceive that since Anacin is chosen 2 to 1 over the other extra-strength product by doctors, Anacin is more effective than any other OTC analgesic product.

The Challenged Advertising Claims For Arthritis Pain Formula

1. *Representation That APF's Analgesic Ingredient Is Unusual, Special And Stronger Than Aspirin (Comp. ¶ 8(B)(1))*

It is my determination that a number of APF advertisements contained the alleged claim.

For example, several advertisements explicitly contrasted APF's pain reliever with aspirin. CX 201A, a television commercial, stated that:

> I'm on something different . . . Arthritis Pain Formula . . . 50% more pain reliever than a regular aspirin. So strong that you don't need it as often.[30]

The message is clearly that APF has some special pain reliever that is different from, and stronger than, aspirin. Indeed, the name of the product itself, "Arthritis Pain Formula," [174]suggests that meaning. Other television commercials, such as CX 210A, CX 217A and CX 218A, clearly characterize APF's pain reliever as something special and strong. Moreover, none of the challenged APF advertisements tells the consumer that APF's analgesic ingredient is ordinary aspirin. In these circumstances, an interpretation of these advertisements as conveying the message that APF's analgesic ingredient is something other than aspirin and stronger than aspirin is eminently reasonable.

2. *Representation That APF Will Eliminate All Pain, Stiffness And Discomfort Experienced By Arthritics (Comp. ¶ 8(B)(2)*

I have determined that the challenged APF advertisements cannot be reasonably interpreted to convey the alleged claim to consumers. Although it is arguable that several television commercials (*e.g.*, CX

[28] See CX 424; Ross, Tr. 1930–32.

[29] See Smith, Tr. 5903, 7598.

[30] Also see CX 206A, CX 210A, CX 217A, CX 218A.

201A, 202A and 203A), especially in their video portions, are capable of conveying the alleged claim to the consumer, I am not persuaded that it is a reasonable interpretation. In my view, these advertisements are clearly targeted to arthritis sufferers, a group that knows that no OTC drug can be expected to give complete relief from arthritic pain. Any other conclusion would be contrary to common sense. Furthermore, such expressions as "get going without all that pain or stiffness" cannot reasonably be interpreted to mean complete and total relief. When I viewed the challenged television commercials, the thought of a promise of complete relief from all arthritic pain never occurred to me. Even when I went back to them to look for the alleged claim, I was unable to see them. The message of these commercials is that APF is something special for arthritis sufferers, that it is stronger than aspirin, and that it will relieve some of the pain and stiffness of arthritis and help you get going.

3. *Representation That APF Will Cause Gastric Discomfort Less Often Than Any Other OTC Product (Comp. ¶ 12(B))*

It is my determination that a number of APF advertisements conveyed the alleged claim.

The express claim that APF is gentle to the stomach because of its "double-buffering" or because it is "microfined" clearly convey the message that APF has a larger amount of buffering action than other buffered products and is finer than others and that, therefore, it is the **[175]**gentlest of all OTC analgesic or antirheumatic products on the market. See, *e.g.*, CX 203A, CX 204A, CX 205A, CX 206A, CX 210A.

The Challenged Advertising Claims That Certain Claims Have A Reasonable Basis Or Are Established

1. *Representation That Tension Relief Claim Has A Reasonable Basis (Comp. ¶ 16)*

Under *Pfizer*,[31] the affirmative product claim that Anacin relieves tension implies as a matter of law that American Home has a reasonable basis for that claim and that American Home relied on it for the marketing of Anacin.

2. *Representation That Certain Comparative Efficacy Or Safety Claims Have Been Established (Comp. ¶¶ 7, 10(A) and (B), 11 and 17)*

[31] *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

Based upon the reasons discussed in pp. 210–16, *infra*, I have determined that the comparative efficacy claims for Anacin and APF and the comparative safety claim for APF carry within them, as a matter of law and marketplace fairness, an implied representation that the claimed superior efficacy or safety is scientifically established and that the proposition is accepted as proven or as a medical-scientific fact by the vast majority of scientists who are by training and experience competent to evaluate the validity of such propositions.

Furthermore, a number of Anacin advertisements expressly represented that the claim is "medically proved," or that there is "convincing proof" that the claim is a scientifically established fact. *E.g.*, CX 50A through CX 53A, CX 105 through CX 107, CX 149. Some of the advertisements also conveyed this message through the presentation of technical graphs measuring blood levels (CX 50A through CX 56A), by reference to actual scientific or clinical tests (*e.g.*, CX 81, CX 105 through CX 107, CX 126 through CX 137, CX 140 through CX 141), or by the use of chemical formulas (*e.g.*, CX 15A). **[176]**

Pain And Aspirin Products—Some Preliminary Observations

Pain is said to be the most common symptom for which man seeks relief by medication. It is generally agreed that mild to moderate pain that is self-limited ("minor pain") may be treated symptomatically by self-medication.[32] Pain is a subjective condition of diverse and often obscure etiology and defies a precise definition. Beecher, a recognized authority in the study of pain and analgesia, has observed that:

> Pain is a subjective matter clearly "known to us by experience and described by illustration." [However,] lexicographers, philosophers and scientists have none of them succeeded in defining pain. Having said that it is the opposite of pleasure, or that it is different from other sensations (touch, pressure, heat, cold) or how it is mediated (through separate nerve structures), or what the kinds of it are (bright, dull, aching, pricking, cutting, burning), or what kinds of things will produce it (trauma to nerve endings or to nerves, electric shocks, intense stimulation of the sensations of touch, pressure, heat, cold), or what it comes from (injury, bodily derangements, or disease), or that certain types of mild stimulation can probably be stepped up to a painful level through conditioning or what some reaction patterns to it are (escape or avoidance), none of these individual statements, nor indeed their sum total, provides a definition of pain.[33]

"Minor pain" was defined by the FDA OTC Internal Analgesics

[32] CX 367F.
[33] CX 367F–G.

Panel as "pain that is self-limited and which requires no special treatment or prior diagnosis by a physician." Minor pain is usually described as pain "of mild to moderate intensity as opposed to sharp, severe and/or protracted pain."[34] [177]

It is not surprising that aspirin is by far the most widely used OTC drug in the United States. It is estimated that almost 19 billion dosage units are sold annually. This amounts to about 5 million daily dosage units for every man, woman and child. Since aspirin was introduced into the American market some 75 years ago, it has been discussed extensively in the medical-scientific literature.

Although such important aspects of aspirin's pharmacological profile as the specific mechanism of its action and the localization of the site of its chemical action in humans are yet to be definitively determined, a considerable amount of biopharmacological data has been published with respect to the relationship between the dosage of aspirin and its analgesic action and the mechanism of its metabolism in animals and humans. It is now generally agreed, primarily on the basis of historical data, that aspirin is safe and effective as a mild analgesic, antipyretic and antirheumatic agent for humans.

It is generally believed that aspirin alleviates pain by both a peripheral effect (*i.e.*, the blockade of pain impulse generation) and a central nervous system effect.[35]

Aspirin is also an effective antipyretic or fever reducer, and may be safely used for self-medication when fever is due to the common cold or flu. Aspirin lowers the temperature in patients with fever but has no effect on the body temperature when it is normal. Heat loss is increased by increased peripheral blood flow and sweating, which is caused by a central action of aspirin on the hypothalamus.[36]

Inflammation and many rheumatic diseases often are accompanied by pain and sometimes fever. Since, in many rheumatic conditions, the object of therapy is to stop the disease process which usually requires drug dosages higher than those recommended for OTC use, OTC drugs for the treatment of inflammatory conditions and rheumatic disease should be used only under the advice and supervision of a physician. Aspirin acts as an agent which reduces joint or muscle tenderness or swelling. The precise mechanism or mechanisms of [178]action by which aspirin exerts anti-inflammatory effects is not known.[37]

In recent years, the medical-scientific knowledge and understand-

[34] CX 367G.
[35] CX 367G, Z011.
[36] Lasagna, Tr. 4096–97; CX 367G-H.
[37] CX 367H.

ing of aspirin's other (side) effects have been substantially expanded, promising both new benefits (such as the use of aspirin in anticoagulant therapy) and risks (such as the problem of aspirin intolerance). Based upon an exhaustive review of available data in medical-scientific literature, the FDA OTC Internal Analgesics Panel concluded that the most appropriate label indications for pain for OTC analgesic agents including aspirin should state: "For the temporary relief of occasional minor aches, pains and headache." It is generally agreed that aspirin is effective in mild to moderate pain although of limited value in severe pain. Recurrent or chronic pain even of minor intensity, such as frequent headaches or joint pain which flares up periodically, may indicate pathologic condition and should not be treated with OTC analgesics except under the advice and supervision of a physician.[38]

Since one of the most prevalent uses of aspirin and aspirin-containing products is in the treatment of headache pain, it is important to have a general understanding of this all too common affliction.

Headache, or cephalalgia, is a unique symptom and an ambiguous term for pain having many different etiologies. The most common type of headache is occasional headache, which is transient (usually lasting less than one day) and may be secondary to many factors including fatigue, tension, eyestrain, fever or alcohol ingestion. The chronic or recurrent headache may be caused by more serious underlying diseases such as vascular disturbances, brain tumor or abscess, intracranial lesions or lesions of the eye, nose, ear or throat.[39]

Headaches can be differentiated into three major categories: vascular, psychogenic and traction-inflammatory headaches. Vascular headache is provoked by the tendency for vasodilation that accompanies physiological changes **[179]**in cranial blood vessels. Common types of vascular headaches are hypertensive, migraine and toxic. OTC analgesics are inappropriate for hypertensive or migraine headaches. Psychogenic headache, one of the most common types of headache, accounts for up to 90% of chronic headaches. It is accompanied by persistent contraction of the muscles of the head, neck, and face, and may even be described as a sense of pressure rather than a true pain. Apprehension, anxiety, post-traumatic experiences and depression, as well as the individual's life stresses and habits, can precipitate the symptoms. Psychogenic headaches

[38] Generally see CX 367F, G, Z011–Z013; Stevenson, JTr. 1481–88; Grossman, Tr. 841–43; Farr, JTr. 2566–70; Azarnoff, Tr. 618–20.

[39] CX 367H.

are often described by synonymous terms such as muscle contraction and tension headache. Self-medication utilizing OTC analgesic drugs is generally contraindicated for chronic psychogenic headache. Traction and inflammatory headache, evoked by organic disease, is associated with inflammatory disease of the meninges, and intracranial or extracranial arteries or phlebitis. Although the FDA OTC Internal Analgesics Panel concluded that the occasional headache is self-limited and requires no medication, it recognized OTC analgesics' usefulness for symptomatic treatment.[40]

One of the issues in this case, related to the claimed superior efficacy of Anacin and APF, is whether the aspirin dose-response relationship studies, using moderate to severe pain in terminal cancer patients and patients with post-partum pain or post-operative pain, are applicable to headache pain. There is a conflict in the testimony of experts on this issue. In my view, the record as a whole does not show that all pain is alike. The record does show that the precise shape of a dose-response curve for aspirin is not known, and that the applicability of aspirin dose-response studies using pain other than headache pain (such as post-operative, post-partum and cancer pain), and encompassing the pain intensity spectrum of mild to moderate to severe pain (or only severe pain), to headache pain remains to be demonstrated.

The Therapeutic Superiority Of Anacin Over Aspirin Has Not Been Scientifically Established

I have determined that complaint counsel have established, by a preponderance of probative and reliable evidence, the negative proposition that the therapeutic superiority in terms of efficacy or safety of Anacin or APF over aspirin has not [180]been established. The record as a whole clearly shows that in order for therapeutic superiority to be established there must be two or more well-controlled clinical demonstrations which show statistically and clinically significant superior performance and which will cause the proposition to be accepted as a medical-scientific fact, or as "established," by the vast majority of experts who are by their training and experience qualified to evaluate the validity of such propositions. In my view, the record contains substantial medical-scientific evidence tending to show that two tablets of Anacin may reasonably be expected to provide technically greater analgesia than two tablets of aspirin for some individuals. However, that evidence is insufficient

[40] Rickels, Tr. 1198–99; CX 367H-I.

to overcome complaint counsel's *prima facie* showing that the therapeutic superiority of Anacin over aspirin has not been established as a scientific proposition. More importantly, the record also provides a basis for concluding that the extra amount of analgesia posited for Anacin by some dose-response studies does not have clinical significance as a practical matter.[41]

First, respondents have failed to produce or point to two or more well-controlled clinical studies which demonstrate statistically significant difference in analgesia between the two test drugs. Such eminent experts in the field of comparative analgesics as Drs. Moertel, DeKornfeld, Forrest, and Azarnoff testified that nothing short of that can establish respondents' thesis as a medical-scientific proposition (F. 197 and 200). Respondents' experts, Drs. Lasagna, Kantor, Wallenstein, McMahon and Okun expressed an opinion that Anacin will provide greater analgesia than regular aspirin, but they agreed that the only way to *prove* a statistically significant difference in the analgesic effects of Anacin versus aspirin would be to conduct a well-controlled head-to-head clinical trial. (Lasagna, Tr. 4249, 4271–73; Kantor, Tr. 3647; Wallenstein, Tr. 3513; McMahon, Tr. 3981; Okun, Tr. 4475–76, 4493–94, 4522–23).

The requirements with respect to the parameters of a well-controlled clinical demonstration (F. 201–17) are not the whim of a handful of partisan pharmacologists. On the [181]contrary, they represent a crystallization of slow and deliberate evolution in the development of a scientific methodology in clinical pharmacology that began in the early 1950's (F. 199). By the early 1960's, clinical pharmacologists, including respondents' medical-scientific experts, lived by them. Any learned journal of any consequence would not accept for publication a clinical trial of therapeutic agents which purports to measure their efficacy unless the study satisfies all of the essential elements of those requirements (F. 197, 200–17). Indeed, since the advent of the 1962 Amendment to the Food, Drug and Cosmetic Act, the FDA has incorporated these requirements into its regulations governing new drug applications for both prescription and non-prescription drugs. In my view, *the importance of these requirements increases when the question becomes one of comparative efficacy rather than simple efficacy or lack of it.*

Respondents' experts do not dispute the essential validity of the scientific rationale for these requirements, including the principle of replication. (*E.g.*, Lasagna, Tr. 4119–30, 4142–45, 4897–98). Rather,

[41] Although the focus of our analysis will be on the question whether superior efficacy of Anacin over aspirin is scientifically established, what really matters to consumers is whether the difference, if any, is clinically and therapeutically significant. Otherwise, why pay a higher price for Anacin?

the recent disaffection of some clinical pharmacologists appears to be based on socio-medical policy grounds. For example, Dr. Lasagna, a long-time advocate of the application of the scientific method to pharmacological research (Okun, Tr. 4412), has become convinced in recent years that the FDA's "bureaucratic dogma" requiring pre-marketing tests of all new drugs in animals and humans, including two well-controlled clinical demonstrations in humans, is excessively rigorous, resulting in a diminishing number of significant new drug introductions in this country and exacting excessive social costs.[42] (*E.g.*, Lasagna, Tr. 4185-86). **[182]**

American Home argues that in order to establish the existence of a substantial question, complaint counsel must come forward with a substantial amount of clinical data which tends to refute the alleged claim (RB at 6). Although the existence of a substantial amount of contrary scientific data will clearly preclude a claim from being scientifically established, such a requirement would, in my view, go beyond what is necessary to show that a given medical-scientific proposition is not established and may go a long way towards refuting the existence of a reasonable basis for the proposition. This is clearly contrary to the very rationale of the establishment-substantial question theory as a basis of Section 5 liability and should be rejected.[43] **[183]**

The evidence that American Home relies on in support of superior efficacy claim consists primarily of the allegedly "positive" or "ascending" dose-response curve for aspirin. Upon a closer analysis, however, this argument consists of two related, yet distinct, proposi-

[42] It may well be that the FDA's new drug approval procedures could stand improvement in some respects in light of the regulatory experience since the 1960's. Also, a strong argument can be made against restricting the freedom of a practicing physician to prescribe the treatment best suited in his judgment for his patient's condition at a particular stage in the disease process. In the final analysis, however, none of these arguments addresses or refutes the scientific rational of the well-established research methodology in clinical pharmacology. The most that can be said in these circumstances may be that there are a number of respected clinical pharamacologists who will be satisfied by a single, well-controlled clinical demonstration, conducted by an experienced investigator of established repute, and showing statistically significant differences of a substantial magnitude. Be that as it may, it is entirely another matter to argue that the rigors of established research methodology in clinical pharmacology should be discarded in advertising regulation, especially when the question is, as here, the scientific validity of a claim of therapeutic superiority of a particular OTC formulation (800 mg. aspirin and 65 mg. caffeine) over another product (650 mg. aspirin) for a specific condition (relief of minor pain or headache pain). In any event, respondents in this case have failed to produce a single definitive study, of the kind that will satisfy the "revisionists," in support of its claim.

[43] See pp. 210–16, *infra*. However, the record also contains some "contrary" medical-scientific evidence. For example, one of Dr. Kantor's aspirin dose-response studies showed a reverse curve between 600 mg. and 1200 mg. aspirin (F. 254). Dr. Kantor carefully reviewed the test procedures and data and could not explain away the reverse response (Kantor, Tr. 3622–23). Dr. Kantor also admitted that he did not know at what point between 600 mg. and 1200 mg. aspirin reached a plateau (Kantor, Tr. 3596). One of Dr. Parkhouse's aspirin dose-response studies also showed a reverse curve (Lasagna, Tr. 4922). Furthermore, the record contains a substantial amount of "negative" data in that many aspirin dose-response studies failed to show any statistically significant differences between the graded dosages tested (F. 243–55). Dr. Lasagna, respondents' expert witness, agreed that if enough studies fail to show any statistically significant differences between two drugs, then one may conclude that the two drugs were equally effective and that a claim of superiority could not be made (Lasagna, Tr. 4249). In my view, this is such a case.

tions. First, it is argued that a statistically significant, positive dose-response curve for aspirin has been shown to exist. Second, from the first proposition, so it is argued, it may be inferred that 800 mg. aspirin provides greater analgesia than 650 mg. aspirin. In my view, each of the two propositions is open to serious doubt. First, *the precise shape of a dose-response curve for aspirin is far from being established.* Second, and more importantly, even accepting at face value the studies which purport to show a statistically significant positive dose-response curve for aspirin, *the particular proposition that 800 mg. aspirin provides more and statistically significant analgesia than 650 mg. aspirin is nothing but an inference,*[44] albeit one based on sound pharmacological reasoning, *and remains to be verified by direct clinical tests.*[45] **[i84]**

The concept of dose-response relationship is a pharmacological formulation of the common sense notion that there is a relationship between the amount of a drug and the intensity of the drug's effect. The dose-response studies are attempts to quantitate this relationship scientifically and are usually expressed graphically (by way of the dose-response curve). The dose-response curve is generally accepted as a useful statistical tool in estimating the efficacy of a drug in terms of its anticipated potency and also serves as a basis when gauging the risk-benefit ratio of the drug in terms of its toxicity and side effects (dose-finding function). As such, it is an expression of the drug's intensity of action for specific dosages and must be interpreted in terms of such variables as the weight of test subjects, the ratio of the rate of absorption and distribution to the rate of detoxification or excretion, the physical properties of the drug and other specific characteristics of the test subjects. These variables are capable of fairly precise measurements. On the other hand, because of the peculiarities of individuals, judgment factors are

[44] *E.g.*, Kantor, Tr. 3656; Lasagna, Tr. 4271–73.

[45] American Home asserts that "the inferential process is a fundamental principle of all fields of science." (RRB, at 17 n. 14). It is true that the inferential process of induction and deduction is at the heart of the scientific method. By observation of particular events and from established general principles, new hypothetical propositions are formulated; the hypothesis is empirically tested; as the test results satisfy the conditions of the hypothesis, laws are arrived at by induction; from these laws, future results may be determined by deduction. However, the validity of a deductive inference depends on the truth or universality of the original principle, while the validity of an inductive inference depends on the uniformity of the subject matter and attains at most a high degree of probability. To apply this process to aspirin dose-response studies, a comparison of the results obtained at a sufficient number of graded dosage points may provide a basis for an inductive inference that there is a high probability that more aspirin will provide greater analgesia than less aspirin. The validity of this inference, however, depends on the representativeness of the test population. Even in cases where the test subjects were randomized, they were not representative samples of any group. Even assuming the validity of the inductive inference in this example, the validity of the deductive inference that 800 mg. aspirin will provide greater analgesia than 650 mg. aspirin depends on the accuracy of two underlying assumptions: (1) that the line connecting the mean data points actually tested corresponds to the true aspirin dose-response curve; and (2) that all pain is the same. As discussed hereinbelow, the accuracy of these two assumptions is open to serious doubt. *Cf.*, Lasagna, Tr. 4271–73.

inevitably involved. The subjective pain response model studies are attempts to apply this concept to natural or spontaneous pain states.[46]

There appears to be substantial agreement among clinical pharmacologists that, for the relief of mild to moderate pain for which aspirin is indicated, aspirin's minimum effective dosage is in the neighborhood of 325 mg., the usual single dosage about 650 mg., the usual effective dosage range about 325 to 650 mg., the maximum single dosage about 1000 mg., and the maximum daily dosage about 4000 mg. (*e.g.*, CX 367M-N). Until the late 1960's, it was generally agreed that 10 grain (about 650 mg.) aspirin was the maximum effective dosage for headache pain (Friedman and Merrit, p. 40; Wolf, *Headaches: Their Nature and Treatment* (1955), p. 68; Murray, "Evaluation **[185]**of Acetaminophen-Salcyilamide Combinations In Treatment of Headache," *The Journal of Clinical Pharmacology*, 7:150–155, 1967 (discussed in CX 367Z012).[47]

In the early and middle 1970's, a number of studies of graded aspirin dosages using patients with cancer, post-partum or post-operative pain suggested a dose related increase in pain relief between 600 and 1200 mg. aspirin. However, *none of the studies showed statistically significant differences between 650 mg. and 800 mg. aspirin. Furthermore, no headache pain study showed a statistically significant difference beyond 600 mg. aspirin.* For example, in the second Bloomfield study of post-partum patients, the response curve became flat at about the 600 mg. level (F. 246). The 1965 Kantor study showed that the specific dose-response curves were different for uterine cramp pain and episiotomy pain, and for uterine cramp pain a plateau was observed somewhere between 600 and 1200 mg. aspirin (F. 248–55). In Parkhouse's five studies of post-operative patients at three hospitals in England with 600 mg. and 1200 mg. aspirin, two studies showed about the same level of analgesia for the two doses, and three showed somewhat greater analgesia for 1200 mg. aspirin. Although three studies showed generally positive dose-response relationships, no statistically significant difference was observed between the two doses (F. 247). Although Kantor's 1977 study of post-partum patients showed a

[46] See,*e.g.*, Lasagna, Tr. 4047, 4102, 4144–45, 4156–57, 4271–73, 4953–55; Kantor, Tr. 3571–72, 3582–83; Okun, Tr. 4487–4502; Forrest, Tr. 556–57; Azarnoff, Tr. 606–07, 618–20, 629–30, 640–42, 652–54.

[47] Murray concluded that about 53% of headache patients do not need medication, and that of 47% who do need medication, about one-half will experience relief from a standard dosage (650 mg.) of aspirin. Dr. Lasagna, however, is of the view that, although some headache patients may experience complete relief from 10 gr. aspirin, many would experience greater relief with larger dosages (Lasagna, Tr. 4153–56, 4158–59).

In this connection, American Home's argument that the FDA OTC Internal Analgesics Panel recognized the superior efficacy of dosages greater than 650 mg. when it set the maximum single dosage at 1000 mg. is without merit. The 1000 mg. dosage clearly refers to safety rather than to efficacy when viewed in context.

positive dose-response relationship with 300, 600 and 1200 mg. aspirin, one of his earlier studies showed a reverse curve between 600 and 1200 mg. aspirin (F. 252 and 254). **[186]**

American Home places great reliance upon the McMahon study it commissioned for use in this litigation (RX 31). The purpose of the McMahon study was to clinically demonstrate, in a study of uterine cramp pain and episiotomy pain, the superior analgesic efficacy of two tablets of Anacin over two tablets of plain aspirin. The first McMahon study showed that Anacin does not provide statistically significant superior analgesia for a mixed uterine cramp-episiotomy pain population with moderate to severe pain. The second McMahon study showed Anacin provides a statistically significant superior analgesia *for the subgroup of episiotomy patients with severe pain* and *only for hours two and three in two of the four scales used,* and not including the global scale (Lasagna, Tr. 4879–80). However, the second McMahon study is of very limited value because of its numerous and serious defects (See F. 293–311).

At the hearing, respondents' two most eminent experts, Drs. Kantor and Lasagna, suggested that the recent insights provided by pharmacokinetics that saturation of aspirin's metabolic pathway of excretion in humans occurs at well beyond the 1200 mg. aspirin level, in combination with the aspirin dose-response studies and the presence of caffeine in Anacin, provide sufficient scientific support for the proposition that two tablets of Anacin give significantly greater analgesia than two tablets of plain aspirin for all types of pain, including headache pain (Kantor, Tr. 3582–83; Lasagna, Tr. 4207–08). Several questions may be raised with respect to the Kantor-Lasagna thesis. *First,* the relevance of the pharmacokinetic insight to the relief of headache (mild to moderate) pain is not apparent. It may be that an effective analgesia of *headache pain* is attained well before the saturation point is reached. *Second,* the applicability of the dose-response study findings, as inconclusive as they are, to headache pain or to any mild-to-moderate pain is open to serious doubt. It may well be that an effective analgesia of headache (mild to moderate) pain is reached before or near the point where a plateau is reached and the curve becomes flat.[48] *Third,* the efficacy of caffeine in a combination like Anacin has not been proven (Lasagna, Tr. 4227, 4265). **[187]**

The 1969 Hill and Turner studies[49] are illuminating. In a double-

[48] Dr. Lasagna conceded that the effects of 650 mg. and 800 mg. aspirin for mild to moderate pain, including headache pain, may be virtually the same (Lasagna, Tr. 4866).

[49] Hill, R.C. and P. Turner, "Post-Operative Pain in the Assessment of Analgesics in Man," *Brit. J. of Pharmacology* 35:363–364, 1969; "Importance of Initial Pain in Post-Operative Assessment of Analgesic Drugs," *The Journal of Clinical Pharmacology,* 9:324–327, 1969, discussed in Panel report, CX 367Z013.

blinded study of post-operative pain comparing aspirin with meperidine (a narcotic agent), aspirin was preferred at milder pain levels while meperidine was preferred at the severe pain levels. In another double-blinded study with post-operative (gynecological) pain, they could not differentiate between the two drugs and placebo in the patient population as a whole, but could differentiate between them when the patients were classified according to the initial severity of their pain. In the FDA OTC Internal Analgesics Panel's words, the "latter study could have been insensitive if the pain intensity had not been considered and illustrates one of the inherent difficulties in analgesiometry." In my view, these studies strongly suggest that 650 mg. aspirin probably is as effective as 800 mg. aspirin for mild to moderate pain, but 800 mg. aspirin may be preferred for severe pain.

A more fundamental question may be raised about the scientific validity of applying to headache pain inferences drawn from extrapolations based on the subjective pain response model methodology using cancer, post-partum and post-operative patient populations.

First, American Home vigorously argues that pain is pain and that the aspirin dose-response studies using post-operative, post-partum and cancer pain resolve the question of comparative efficacy in its favor. However, *there is no scientific evidence that headache pain is the same as post-partum pain, or pain in terminal cancer patients.* Indeed, not only is there evidence to the contrary, but common experience also suggests a contrary conclusion.[50] Dr. Lasagna, respondents' expert, agreed that one should show the comparative efficacy of one analgesic drug over another in several different types of pain before generally assuming that the drug would be superior to another in other untested types of pain (Lasagna, Tr. 4968). Drs. Kantor, Lasagna and Okun, [188]all respondents' experts, agreed that uterine cramp pain responses differ from episiotomy pain.[51] Drs. Kantor and Lasagna agreed that pain accompanied by inflammation responds differently from pain unaccompanied by inflammation.[52] Dr. Lasagna also testified that migraine headache pain does not respond to aspirin because of its different etiology.[53] Dr. Kantor also criticized the dose-response studies using cancer pain (such as the studies by Moertel, Houde, Sunshine and Wallenstein).[54]

[50] Anyone who has undergone surgery or experienced toothaches will agree that post-operative pain or dental pain is not like headache pain. Common experience also shows that the threshold of pain might differ substantially among individuals, as might their interpretation of pain. Moreover, pain response has a strong emotional component.

[51] Kantor, Tr. 3559–60; Okun, Tr. 4537–39, 4547–48; Lasagna, Tr. 4883–84.

[52] Lasagna, Tr. 4069–70. Dr. Kantor's study with trauma pain produced a reverse response curve between 600 mg. and 1200 mg. aspirin (Kantor, Tr. 3616).

[53] Lasagna, Tr. 4069–70. See also CX 367H-I.

[54] Kantor, Tr. 3645–46.

Dr. Okun agreed that the relative efficacy of two drugs may differ depending upon the type of pain involved.[55]

Second, complaint counsel's experts testified almost without exception[56] that the appropriate pain model for the purpose of determining the comparative efficacy of two dosages of a drug or two drugs is one using patients suffering from the particular type of pain in question. Dr. DeKornfeld insisted that at least one of the two well-controlled clinical demonstrations must use the particular pain in question before the findings can be applied to that pain.[57]

Third, complaint counsel's expert witnesses, with impressive experience and reputation in the field of comparative study of analgesics, testified that owing to the **[189]**subjective nature of pain the aspirin dose-response studies require that the test data be conservatively interpreted. For example, Dr. DeKornfeld observed that, because the analgesic testing is generally more fuzzy and imprecise in the sense of reliable results, more rigorous methodological requirements are indicated for comparative efficacy studies of analgesic agents than for some other pharmacological agents.[58] Dr. Forrest testified that in dose-response studies, a 10% difference may mean something when a subjective element (such as pain) is not involved, but that in subjective pain response model studies, a 10% difference may not mean anything.[59]

Fourth, both complaint counsel's and respondents' experts generally agreed that, with specific reference to mild to moderate pain, or headache pain, the 150 mg. difference in the amount of aspirin between two tablets of Anacin and two tablets of regular aspirin may not be sufficient to produce a therapeutically significant difference in analgesia.[60]

It is true that American Home's experts expressed an opinion upon direct examination that pain is pain and suggested that the findings of the aspirin dose-response studies using post-partum, post-operative and cancer pain are equally applicable to all types of pain, including headache pain. However, the experts were addressing the applicability of these findings to totally undifferentiated pain without regard to its intensity. Dr. Lasagna conceded that, for the relief of minor pain (including headache pain), the relief obtained

[55] Okun, Tr. 4422.

[56] Dr. Moertel, who conducted a comparative analgesic study using cancer pain, is of the view that the perception of pain may be different between headache and cancer, because the underlying causes are different, even though the responses are comparable (Moertel, Tr. 937–40). However, Dr. Moertel indicated that superior efficacy of Anacin over aspirin can be established only by two or more well-controlled clinical demonstrations, one of which should use headache pain (Moertel, Tr. 959–60).

[57] DeKornfeld, Tr. 2778–80, 2785–86, 2802–03, 2832. See also Lasagna, Tr. 4968.

[58] DeKornfeld, Tr. 2831.

[59] Forrest, Tr. 567–69. See also Azarnoff, Tr. 653.

[60] *E.g.*, DeKornfeld, Tr. 2790–91; Lasagna, Tr. 4168, 4070, 4866.

from the two doses (650 mg. and 800 mg.) may be virtually the same (*e.g.,* Lasagna, Tr. 4866).[61]

The NAS/NRC Analgesic Review Committee recommendation on which American Home relies is not of much aid to respondents. That Committee simply felt that if an OTC drug is shown to work for one type of pain, it should be presumed to work for other types of pain as well and therefore should **[190]**be certified as a general-purpose analgesic product in the absence of contrary evidence. This was undoubtedly a sound, common sense expedience in the massive drug screening project, for which the Committee labored long and hard, *where the sole concern was efficacy, or lack of it, and not comparative efficacy.* Certainly that expedience cannot be transformed into a universal scientific proposition that study findings based on cancer pain, post-partum pain and post-operative pain apply to headache pain or other minor pain.[62] **[191]**

American Home's second proposition, that from a positive aspirin dose-response curve based on studies using various graded dosages (600, 900 and 1200 mg.) of aspirin it can be inferred that 800 mg. aspirin provides significantly superior analgesia than 650 mg. aspirin, is patently an inference and no more than an inference.[63] Although it may be based on rational and sound pharmacological reasoning and thus provide a reasonable basis for the claim, it certainly is not established as a scientific proposition. *This conclusion follows from the very function of dose-response curves and the way in which they are plotted.*

As discussed hereinabove, the function of any dose-response curve is to provide a convenient statistical basis for *guessing* the relative efficacy of dosages not actually studied. *Respondents' experts agree*

[61] See also Lasagna, Tr. 4249.

[62] Furthermore, to a layman at any rate, the subjective pain response model methodology suggests important inherent limitations. In view of the known difficulties attending the experimental pain study methodology (for example, using electric schocks on volunteer subjects), popularity of the subjective pain response model using such captive patient populations as terminal cancer, post-partum and post-operative patients is understandable from the standpoint of frequency and accessibility. However, it is useful to keep in mind that the patients studied are not representative samples of any group. Nor are the studies epidemiological studies. Moreover, pain relief does not lend itself to an objective and precise measurement by the use of uniform, standard units (as do blood pressure, pulse rate, blood count, etc.). Patients' subjective responses to any given pain impulse are bound to vary from one individual to the next. In addition, the eliciting and recording of patients' subjective responses require the intervention of nurses as observer-recorders, a human element of unknown reliability. The endemic problem of the high rate of placebo responders observed in those studies must be added to all this. They are generally in the 30% to 40% range, and can be as high as 57% (Lasagna, Tr. 4132). Despite the substantial scientific trappings in which it is clothed, it is fair to conclude that the subjective pain response model study is not an exact science. Granting its obvious utility for the purpose of setting a range for indicated dosage levels of an analgesic agent, it certainly falls far short of an objective, exact, scientific tool for the purpose of determining the *comparative* efficacy of drugs not tested. Indeed, several of respondents' experts suggested that a headache pain model study may not be sensitive enough to differentiate analgesia obtained by 650 mg. and 800 mg. aspirin (*e.g.,* McMahon, Tr. 3761; Lasagna, Tr. 4058–59). However, it is equally plausible to say that, for the relief of minor pain, there may not be any significant difference to be measured in the first place between 650 mg. and 800 mg. aspirin. See Lasagna, Tr. 4866.

[63] See p. 183 n. 45, *supra.*

that a dose-response curve is not designed to, and cannot, answer the question (1) whether the two dosages not tested will in fact perform differently or (2) whether, if they do, the differences will be statistically significant.[64]

The dose-response curve connecting the data points for graded dosages actually tested is simply a matter of connecting the two points representing statistically valid mean values at each data point tested. At each data point, the test data regarding individual test subjects ideally form a cluster. The degree of the spread of this cluster varies from one test to the next. It may be "sloppy" or "compact." Clinical pharmacologists then pick a mean point, based on a statistical analysis of the cluster, and connect it with another data point similarly arrived at (See F. 227 and 228). Thus, *if only two dosages are tested, the dose-response curve will be linear. However, if more than two are tested, the curve may not be linear* (Azarnoff, Tr. 665–66). In fact, the classical dose-response curve common to most active drugs is one that shows an increasing effect as the dosage is increased until a plateau is reached beyond which any increase in dosage does not produce an increase in effect (Lasagna, Tr. 4102). Furthermore, in many drugs, the "log dose" relationship is such that the dose effect is proportional to the logarithm of the dosage. In other words, a small **[192]**increase in dosage is not anticipated to produce any significant incremental increase in effect. This is believed to be the case with aspirin (Kantor, Tr. 3572–73, 3613–14; CX 367T). Therefore, *the precise shape of the aspirin dose-response curve must first be determined. Even then, it does not provide a scientific basis for claiming that the difference between any two dosage points not tested will be statistically significant. Only head-to-head clinical trials of the two points can provide that answer.* There is agreement on this point among both complaint counsel's and respondents' experts who testified in this proceeding.[65] The McMahon study, the only study which purports to provide an answer to that question, fell far short of its goal.

Thus, in a nutshell, even assuming the existence of a positive dose-response curve for aspirin, its precise shape is not known, and American Home has failed to overcome complaint counsel's *prima facie* showing that the superior efficacy of Anacin (800 mg. aspirin in two tablets) over regular aspirin (650 mg. in two tablets) is not established and that there exists a substantial question about that proposition.

[64] *E.g.,* Wallenstein, Tr. 3513; Kantor, Tr. 3647–49, 3565; Lasagna, Tr. 4271–73; Okun, Tr. 4475–76, 4493–94, 4522–23.

[65] *E.g.,* Forrest, Tr. 559–64; Azarnoff, Tr. 605–06; Wallenstein, Tr. 3513; McMahon, Tr. 3981; Lasagna, Tr. 4271–73; Okun, Tr. 4475–76, 4493–94, 4522–23.

367-444 O - 82 - 21 : QL 3

I am aware of the testimony of several practicing physicians suggesting that the findings of the aspirin dose-response studies, including the McMahon study, provide a sufficient basis for preferring 800 mg. aspirin over 650 mg. aspirin for the treatment of headache pain.[66] However, Dr. Lasagna, for example, admitted that the practice of medicine is not an exact science but an art, and that, as a clinician, he would form a professional judgment regarding the comparative efficacy of 650 and 800 mg. aspirin, based on the existing data, and would be willing to try 800 mg. instead of 650 mg. aspirin on his patients (Lasagna, Tr. 4172–76). This is as it should be in the practice of medicine. The application of clinical pharmacology to clinical medicine inevitably involves the professional judgment of the clinician and is a matter of trial and error based on long experience, insight and wisdom. However, this is not to say that the superior efficacy of 800 mg. aspirin over 650 mg. aspirin has been scientifically established.[67] **[193]**

In the final analysis, the record as a whole shows that, for the relief of mild to moderate pain, including headache pain, for which aspirin is indicated, 650 mg. and 800 mg. aspirin are about equally effective. The best that can be said for American Home is that the record evidence may provide a reasonable basis for a claim that 800 mg. aspirin may sometimes be expected to provide somewhat greater analgesia to some people than 650 mg. aspirin. However, that claim has not been scientifically established. This conclusion is in accord with the FDA OTC Internal Analgesics Panel's findings.[68] **[194]**

Finally, as a practical matter, the superior efficacy claim that consumers perceive from the challenged advertising representations

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[66] *E.g.*, Lasagna, Tr. 4893–95.

[67] Clinical pharmacologists generally demand that statistically significant differences be established first by well-controlled clinical demonstrations; they then determine according to their professional judgment, whether there is any clinical significance, taking into account such factors as the magnitude and duration of the observed difference, side effects, ease of administration and price (Forrest, Tr. 557–59, 568–69; Azarnoff, Tr. 650; DeKornfeld, Tr. 2825–27).

[68] The Panel answered the question as follows (CX 367T):

> . . . Dosages above 650 mg. [aspirin] do not result in a significantly greater incidence or degree of pain relief in most studies. In some studies, however, dosages of 975 mg. (four 325 [*sic*] mg. tablets) appeared to have a greater analgesic effect based on dose-response curves which appeared to be increasing above 650 mg. The difference between the larger dosages compared with 650 mg. generally could not be shown to be statistically significant but the apparent increase in the dose-response curve above 650 mg. dosages suggests that greater pain relief may be obtained in some individuals with some types of pain with single dosages of 975 mg. to 1300 mg.
>
> Although the dose-response curves in a few studies suggest that larger dosages may produce a slightly greater incidence of analgesia than 650 mg. dosages, there are important limitations in this assumption.
>
> First, the relationship of increased analgesia to increased dosage is not linear but, like many drugs, the effect is proportional to the logarithm of the dosage. Second, the increase is generally relatively small because the dose-response curve is relatively flat requiring large increases in the dosage to obtain a relatively small increase in analgesic response.
>
> A third consideration is that most studies of analgesic effects have involved only single dosages. There is relatively little information on the dose-response curves after multiple dosages.

See also *The Medical Letter*, CX 363; *The AMA Drug Evaluation*, CX 362.

is not that Anacin or APF provides a larger amount of pain relief than aspirin *in an absolute or technical sense,* but that the difference is *therapeutically significant* —that it makes a real difference which consumers can feel. Otherwise, why choose Anacin or APF and not aspirin, or pay a higher price for them? In this sense, the record evidence is convincing that the proposition that there is a *therapeutically* significant difference in pain relief between Anacin or APF on the one hand and aspirin on the other hand is far from being established. Indeed, on the basis of this record, one may arguably dispute the existence of any reasonable basis for that proposition.

More Aspirin Is Not Better But May Be Worse

The focus of analysis in this case has been upon whether or not the proposition "more is better"—specifically, the therapeutic superiority of 800 mg. aspirin over 650 mg. aspirin—is scientifically established. On the basis of the record evidence, I have reached a negative determination. The analysis in this respect compared the evidence of analgesic effects of graded, single aspirin dosages, totally ignoring the effect of multiple dosages or chronic use of aspirin. However, it should be pointed out that, in terms of chronic use, the record evidence strongly suggest that more aspirin may be worse than less aspirin. For example, aspirin-induced gastrointestinal lesions and mucosal erosions **[195]**have been endoscopically observed.[69] Aspirin's adverse effects on renal and hepatic functions, including salicylate hepatitis, are also well established.[70] So is aspirin's systemic effect on the blood, including its anticoagulant effect.[71] Some of these adverse effects can be serious indeed, especially for persons with certain predisposing conditions (F. 403, 411, 412 and 432). Indeed, the cumulative evidence related to the various adverse effects of aspirin (F. 403, 404, 406–20 and 426–52) compels the conclusion that aspirin is a potent drug and should not be taken in quantities larger than is effective for the condition for which it is indicated. Considered in conjunction with the remarkable popularity of OTC analgesic products among American consumers and their long-held faith in the products' efficacy and safety for the relief of ills,[72] not to mention

[69] *E.g.,* Grossman, Tr. 839–40; Shapiro, Tr. 2951–52. See also CX 367Z017–Z018.

[70] F. 450. It should also be noted that the side effects of aspirin on renal and hepatic functions are more closely tied with aspects of the disease activity rather than aspirin dosage and can result from small or normal doses (Plotz, Tr. 1083).

[71] F. 451 and 452.

[72] See, *e.g.,* CX 463 and CX 468. See also Rickels, Tr. 1196–97.

the substantial number of chronic users of aspirin including rheumatic persons,[73] the importance of the record evidence tending to show that "more may be worse" cannot be overemphasized.[74] **[196]**

Caffeine As An Active Agent Or An Adjuvant In OTC Analgesic Products

American Home contends that the presence of about 32.5 mg. caffeine in Anacin is another factor in support of its claim of Anacin's superior efficacy. However, the record evidence is persuasive that (1) there is no reliable medical-scientific evidence showing caffeine to be an effective analgesic agent in humans and (2) the medical-scientific evidence to show that an aspirin-caffeine combination is more effective than aspirin alone for analgesic purposes is insufficient.

It is generally agreed that caffeine, commonly ingested in the form of coffee or tea beverages, is a mild central nervous system stimulant as well as a cardiac stimulant.[75] As such, it is useful in fighting fatigue or sleepiness. There is evidence that caffeine acts on the kidney to produce diuresis and relaxes stomach muscles. It has also been reported to cause increased gastric secretion in the stomach and possibly contribute to gastric bleeding.[76] Caffeine also inhibits platelet aggregation in vitro.[77] When used alone in an adult oral dosage of 65 mg. not to exceed 600 mg. in 24 hours, caffeine is safe but ineffective as an OTC analgesic, antipyretic and/or antirheumatic ingredient.[78]

OTC analgesic products which combine aspirin and caffeine have been widely available for many decades. Anacin and the so-called APC tablets are common examples.[79] In spite of the popularity of APC and other aspirin-caffeine combinations, the pharmacological rationale for their use as analgesics is not clearly understood. It is claimed that caffeine is an effective analgesic agent in animals and is useful for the treatment of certain headaches **[197]**due to the

[73] F. 403.

[74] In this connection, the FDA OTC Internal Analgesics Panel recommended that the standard dosage unit of aspirin be determined to be 325 mg., that products containing 325 mg. aspirin per dosage unit be clearly labeled "Contains the standard strength of 325 mg. (5 gr.) aspirin per dosage unit," and that products containing an amount of aspirin other than 325 mg. aspirin per dosage unit be clearly labeled "Contains non-standard strength of X mg. (X gr.) aspirin per dosage unit compared to the established standard of 325 mg. (5 gr.) aspirin per dosage unit." CX 367-O.

[75] Okun, Tr. 4354–55.

[76] Grossman, Tr. 855–56; Shapiro, Tr. 2969; Lasagna, Tr. 4194.

[77] CX 367Z114.

[78] CX 367Z112.

[79] APC is a combination of aspirin, phenacetin and caffeine. Until the early 1960's, Anacin was an APC formulation. Anacin has since dropped phenacetin from its formulation and slightly increased its caffeine content to about 32 mg. (Shaul, Tr. 3321).

constriction of blood vessels in humans. Despite some clinical evidence that an aspirin-caffeine combination appears to perform better for some individuals and the historical feeling among many clinicians that caffeine has a legitimate function in an OTC analgesic product formulation,[80] caffeine has not been established as an effective analgesic agent. Also, there is insufficient clinical data to show that caffeine is an effective adjuvant when used in combination with aspirin for analgesic purposes.[81] This is in accord with the FDA OTC Internal Analgesics Panel's conclusion on this subject.[82]

On the other hand, there is evidence to show that an aspirin-caffeine combination may be pharmacologically unsound. For example, it is known that caffeine stimulates secretion of gastric juices and, thus, an aspirin-caffeine combination would exacerbate aspirin's adverse side effects on the gastrointestinal tract. Also, there is a possibility that caffeine could heighten a person's awareness of pain (Lasagna, Tr. 4973). **[198]**

In sum, the record evidence is clear that the efficacy of caffeine, either as an active analgesic agent or an adjuvant in an aspirin-caffeine combination, has not been scientifically established.

Respondent Did Not Have A Reasonable Basis For Making The Tension Relief Claim For Anacin And Respondent's Tension Relief Claim Was Not Only Unfair But Also False

With respect to the tension relief claim for Anacin, American Home's defense is not that it had a reasonable basis for making such a claim but that it did not make such a claim, either directly or by implication. For the reasons discussed heretofore, I have determined that respondent's advertisements contained the alleged claim. See pp. 170–72, *supra.*

The record as a whole clearly shows that Anacin will not relieve tension. Dr. Rickels, an eminent authority in the study of psychopharmacologic drugs, testified that aspirin or Anacin will not relieve

[80] Dr. Okun, respondents' expert, suggested that caffeine liberates catecholamines, a group of hormones which cause analgesia in humans (Okun, Tr. 4358).

[81] In Dr. Moertel's clinical study of certain analgesic combinations using cancer pain, CX 361, an aspirin-caffeine combination was shown less effective than aspirin alone, although the difference was not statistically significant (Moertel, Tr. 968, 982).

Dr. DeKornfeld clinically compared aspirin, aspirin in combination with phenacetin, salicylamide with caffeine, and aspirin/phenacetin with caffeine. Although the combinations produced a mean pain relief score higher than aspirin alone, the difference was not statistically significant. See DeKornfeld, Tr. 2799–2803; CX 367Z113-Z114.

The Houde study using cancer pain, on which American Home relies, is inconclusive. Houde found that a combination of 210 mg. aspirin, 150 mg. acetominophen and 30 mg. caffeine gave somewhat better pain relief than either aspirin or acetaminophen alone. Houde, however, admitted that his data did not permit a conclusive statement that caffeine contributes to the efficacy of aspirin or acetominophen (Wallenstein, Tr. 3460–64, 3501–02, 3504–05, 3511–12; CX 367Z113-Z114).

[82] CX 367Z112-Z114.

tension or emotional anxiety (Rickels, Tr. 1205, 1209, 1236). Drs. Lasagna and Okun, respondents' experts, agreed with Dr. Rickels in this respect (Lasagna, Tr. 4100, 4198–99; Okun, Tr. 4437–38). In a well-controlled, double-blinded clinical trial evaluating the effects of aspirin on tension, aspirin was found not to be significantly superior to placebo in the relief of moderate tension (Rickels, Tr. 1194–98). Moreover, the study showed no difference in the results regardless of whether the study population was combined or broken down into those who also suffered moderate pain and those who did not.[83] (Rickels, Tr. 1197). The medical literature confirms that aspirin cannot be expected to relieve tension (Rickels, Tr. 1198, 1205). The FDA OTC Internal Analgesics Panel concluded that aspirin was "clearly ineffective" for "nervous tension" (CX 367K). Also, the FDA OTC Sedative Panel determined that aspirin was "ineffective" as a "day-time sedative" product, which was defined as one claiming "mood-modifying indications **[199]**such as 'for the relief of occasional simple nervous tension' " (CX 366E, Z002).

With respect to caffeine, Dr. Rickels testified that it would be "contraindicated" for a symptom of tension (Rickels, Tr. 1207, 1209). Although there is evidence that caffeine is a mild stimulant and relieves the feeling of fatigue to some extent, it does not provide any relief for tension.

However, American Home argues that Anacin is effective for pain-associated tension, a claim that it admits making. This claim refers to the so-called "tension-headache-tension" cycle, meaning a situation where headache pain is caused by underlying tension and the headache pain in turn causes further tension. Although aspirin or Anacin will relieve pain and thereby may cause some reduction in the irritability or tenseness resulting from pain, namely "secondary tension," this does not make aspirin or Anacin a tension relieving drug, a claim found to have been made by respondent. In this respect, Dr. Rickels explicitly testified that it "was not true" that "Anacin relieves headache pain and so its tension" or that Anacin "relieves tension as it relieves headache pain" (Rickels, Tr. 1236). Dr. Rickels' testimony stands undisputed. Since the claim is "not true," it follows that there can be no reasonable basis for the claim and that the claim is false.

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[83] Respondents' expert, Mr. Wallenstein, agreed that his study (RX 32) which compared two aspirin combinations, including an aspirin-acetominophen-caffeine combination, found that the caffeine combination data were "equivocal" (Wallenstein, Tr. 3501–02). Respondents' expert, Dr. Lasagna, agreed that RX 32's findings regarding the caffeine combination was inconclusive (Lasagna, Tr. 4217–18).

The Comparative Safety Of Micro-Fine And Buffered Aspirin Has Not Been Established

Also in issue in this case are two claims regarding Arthritis Pain Formula involving questions of drug formulations and comparative safety: the claims that APF will cause gastric discomfort less frequently than other OTC analgesic products (1) because APF is formulated with microfine aspirin particles and/or (2) because APF is formulated with two buffering agents (Paragraph 10(B) of the Complaint and 2(h) of Contested Issues of Fact). The subjective symptoms of gastric discomfort due to aspirin ingestion have been discussed in conjunction with other adverse effects of aspirin on the gastrointestinal tract (F. 363 and 406). The record evidence shows that the data in support of those claims of comparative safety are inconclusive at best and that the claims have not been established as medical-scientific propositions.

First, with respect to the first claim, although it is based on sound biopharmaceutical reasoning, it lacks supportive clinical data. It is of course theoretically plausible to hypothesize that the smaller the size of aspirin particles **[200]**the faster will be the rate of disintegration and absorption from the gastrointestinal tract and that, therefore, APF can reasonably be anticipated to cause less gastric discomfort than regular aspirin.[84] However, the crucial question is whether any statistically significant differences in terms of the incidence or severity of gastric discomfort have been established by well-controlled clinical demonstrations, and there is little scientific data one way or the other on this question.[85] Furthermore, it has been demonstrated that factors other than the size of the aspirin particles (for instance, the choice of excipient and the tablet compression during manufacture) may be important variables. The FDA OTC Internal Analgesics Panel, therefore, recommended a standardized dissolution test which can be used to detect preparations which will be so slowly absorbed as to potentially increase local adverse effects on the gastric mucosa or decrease efficacy due to decreased bioavailability.[86]

Second, with respect to the second claim that buffered aspirin causes less gastric discomfort than unbuffered or plain aspirin, the record shows a general consensus of a large number of studies which

[84] F. 362 and 364. See also Grossman, Tr. 851–52; Plotz, Tr. 1089–90; Sliwinski, Tr. 1136–37, 1165.

[85] F. 366, 368–70 and 378; CX 367Z006.

[86] See the Panel report, CX 367Z003-Z004.

Respondents' reliance on the blood level studies in support of the superior efficacy claims for Anacin and APF is not persuasive in that the record evidence is clear that no direct correlation between blood levels and analgesia has been shown with respect either to aspirin or to aspirin-caffeine combinations (F. 222 and 321–22).

demonstrate that buffered aspirin is more rapidly absorbed from the gastrointestinal tract.[87] The evidence also indicates that some persons who experience subjective symptoms of gastric distress may experience less gastric discomfort with some buffered aspirin than with unbuffered aspirin.[88] However, studies also indicate that simply adding buffers does not always increase the dissolution rate. The type and quantity of buffering [201]agents used, the tablet compression during manufacture, the choice of excipient and other pharmaceutical factors are also important variables. Therefore, actual testing of the dissolution rate is required to determine whether buffers present in APF actually affect the dissolution rate and, if so, to what extent. The totality of formulation and manufacturing variables of unbuffered and buffered aspirin products is crucial in determining their dissolution times.[89] Indeed, it has been shown that an adequately buffered aspirin may not have an advantage over a well-formulated unbuffered aspirin in terms of dissolution rate.[90] The discussions regarding the superior efficacy claim in terms of "establishment" in the preceding sections, apply here with equal force. See pp. 180–82, *supra.* In sum, in the absence of any well-controlled clinical study which demonstrates that APF tablets, with the two buffering agents in the quantities present in APF, cause gastric discomfort less often than unbuffered aspirin and show statistically significant differences between the two, the second comparative safety claim regarding APF has not been scientifically established.[91] This determination is in accord with the conclusion of the FDA OTC Internal Analgesics Panel.[92] [202]

The Studies Referred To In Certain Advertisements Do Not Prove That Anacin Is As Effective As The Leading Prescription Analgesic Product And More Effective Than Any Other OTC Analgesic Product

The two studies referred to in certain of the Anacin advertise-

[87] F. 373 and 374; CX 367Z005.

[88] F. 372–74.

[89] F. 362, 367 and 374; CX 367Z005.

[90] F. 373, 374 and 376; CX 367Z005.

[91] The only clinical study of APF conducted by American Home's Whitehall Laboratories (CX 304) failed to establish that APF causes a significantly less incidence of gastric discomfort than plain aspirin (Plotz, Tr. 1054–60; Sliwinski, Tr. 1138–47, 1162).

[92] CX 367Z099-Z100. See also *The Medical Letter,* CX 363; *AMA Drug Evaluations,* CX 362.

I am aware of the testimony in the record of some practicing physicians that their own clinical experience have convinced them that buffered aspirin causes subjective symptoms of gastric distress less often than unbuffered aspirin in some or many of their patients. This is generally consistent with the substantial amount of data reviewed by the FDA OTC Internal Analgesics Panel. However, I have determined that, with respect to a claim of *comparative* safety, as is involved herein, a greater degree of certainty is required and that nothing less than a well-controlled clinical demonstration satisfies this requirement.

ments (*e.g.,* CX 301 and CX 302) are the studies purporting to compare the analgesic efficacy of Anacin and Darvon Compound 65. Although the record shows that there is a general agreement among clinical pharmacologists that aspirin and aspirin-related products are as effective as Darvon Compound 65 for the relief of minor pain, the question in this case is whether the express or implied advertising representations that the two studies prove that Anacin is as effective as Darvon Compound 65 and more effective than any other OTC analgesic product have a reasonable basis.

The record clearly shows that neither CX 301 nor CX 302 proves the claim, let alone the implied claim that Anacin is more effective than any other OTC analgesic product. In order to prove the claimed parity with Darvon Compound 65, well-controlled clinical demonstrations are required. Neither CX 301 nor CX 302 can be reasonably said to qualify as a well-controlled study (F. 335–40). Similarly, neither study can be said to prove the implied claim of Anacin's superiority over other OTC analgesic products (F. 341–42).

Respondent's Survey Of Doctors Does Not Prove A Reasonable Basis For The Alleged Claims

It is my determination that the survey of doctors ("Doctors' Survey") referred to in some of the Anacin advertisements (*e.g.,* CX 81 through CX 84; CX 146 through CX 148; CX 176) and in Paragraph 21 of the Complaint does not provide a reasonable basis for the claims alleged in Paragraph 20 of the Complaint and found to have been made (F. 392–94).

The record clearly shows that the Doctors' Survey was so deficient in its design and execution that it could not provide any basis for the implied claim that more physicians recommended Anacin or that more specialists in internal medicine preferred it. The survey population was confined to physicians with a primary specialty in internal medicine who were in private practice and who were willing to receive promotional mail. The response rate was only about 10%. Obviously, such a mail survey does not provide any basis for the generalized claims found to have been made by American Home. Such a survey cannot be said to constitute reasonable substantiation for the alleged claims in any meaningful sense. **[203]**

Aspirin Disclosure Statements In Advertisements For Anacin And Arthritis Pain Formula Are Essential

An important issue in this case is whether the incidence and severity of adverse side effects of aspirin, either separately or

collectively, are of such magnitude as to make the presence of aspirin in Anacin and APF a material fact, within the meaning of Sections 5, 12 and 15 of the FTC Act, which should be affirmatively disclosed in future advertisements for the products. Section 15 of the Act provides in effect that a fact may become "material" in light of the "consequences which may result from the use of the commodity to which the advertisement relates" under "customary or usual" conditions. There is a vigorous dispute among the parties as to both the incidence and severity of adverse side effects and the utility of an advertising disclosure requirement, especially in view of the fact that the labels for Anacin and Arthritis Pain Formula list aspirin (or its chemical denomination "acetylsalicylic acid") as an ingredient, in accordance with FDA labeling regulations.

Aspirin is said to be the most popular OTC drug in this country. It is estimated that almost 19 billion dosage units are sold annually: this means over 5 million units a day. Without a doubt, aspirin is a highly effective and relatively safe analgesic agent. Its versatility and usefulness in terms of a risk-benefit ratio have been established over many decades. However, aspirin is also a potent drug and has a number of serious adverse side effects. Numerous expert witnesses in this case discussed the nature and extent of the principal side effects (F. 403, 404, 406–20, and 426–52). The FDA OTC Internal Analgesics Panel's report contains a handy compendium of aspirin side effects in eight major areas of concern (CX 367Z013-Z041). They include: effects on various organ systems such as the gastrointestinal tract, central nervous system, kidney, liver and the blood; specialized effects on hypersensitive persons, persons with certain disease states or during pregnancy; and effects when used with other drugs (See F. 406, 426, 444, 448 and 450–52). Some of these side effects are known to be serious and even life-threatening to many high risk subjects. The record shows that aspirin-induced or related hospital emergencies have reached alarming proportions. For example, in a recent survey, aspirin was found to be the second most frequent drug involved in adverse effects of drugs that were serious enough to require hospitalization. Two out of every 1,000 hospital admissions were attributed to aspirin (CX 367Z022). **[204]**

Consonant with its concern about the varied and substantial adverse effects of aspirin, the FDA OTC Internal Analgesics Panel recommended that appropriate warnings and cautionary statements be included on labels of all aspirin-containing OTC products (CX 367Z123-Z124). A number of these warnings and cautionary statements say that aspirin-containing products should not be taken under certain conditions or by certain persons without a prior

consultation with a physician. For the consumer to whom the warnings and cautions are intended, his knowledge that a given product contains aspirin is crucial. However, the record clearly shows that a large number of consumers are unaware of the fact that many OTC analgesic products, including Anacin, contain aspirin and that a large number of consumers neglect to read labels of such products (F. 402 and 457–64). These facts, involving important questions of public health, make aspirin ingredient disclosure highly desirable in all advertisements for aspirin-containing OTC products. In my view, the frequency and severity of two types of adverse effects, which can be life-threatening, make such advertising disclosure mandatory. They are aspirin-induced massive gastrointestinal bleeding and acute asthmatic attacks in aspirin-intolerant persons [93] (F. 410, 412–14, 426 and 428).

A. *Aspirin-Related Massive Gastrointestinal Bleeding*

Although the mechanism of action of aspirin upon the gastrointestinal tract resulting in sudden, massive bleeding is not definitively understood (F. 411), it is generally agreed that orally administered aspirin, as well as intravenously administered aspirin, can cause sudden, massive and life-threatening bleeding in the gastrointestinal tract, especially in persons with certain predisposed conditions such as dyspepsia, gastrointestinal lesions, peptic ulcers or other bleeding problems in the gastrointestinal tract (F. 413).

A recent survey showed aspirin to be the second most frequent drug involved in all hospitalizations due to the adverse effects of drugs. Two out of every 1,000 such **[205]**hospital admissions were attributed to aspirin. Massive gastrointestinal bleeding was second only to digitalis intoxication as the most frequent cause of drug-related hospitalization and aspirin and aspirin-containing products were involved in 60% of the cases.[94] Moreover, the mortality rate associated with this condition is high. Death occurs in 4 to 10% of all patients with massive gastrointestinal bleeding, including those associated with aspirin ingestion.[95] Even higher mortality rates are shown in those patients who require surgical intervention to stop the massive internal bleeding (CX 367Z022). Furthermore, there is evidence that aspirin can cause gastric ulcers when taken in large

[93] The record shows that a relatively small amount of aspirin (3 mg.) can cause a severe reaction, including anaphylactic shock, in aspirin-intolerant persons (F. 426 and 429).

[94] CX 367Z022. See also Dr. Grossman's discussion of Miller, "Hospital Admissions Due to Adverse Drug Reactions - A Report From The Boston Collaborative Drug Surveillance Program," *Clinical Pharmacology and Therapeutics*, 14:142–143, 1973 (Grossman, Tr. 877–80; CX 367Z022); F. 418.

[95] F. 414.

doses and aspirin may cause a specific kind of ulcer not seen in its absence.[96] Gastric ulcer is a serious disease with significant morbidity, and often requires surgery on the stomach.[97] By conservative estimate, aspirin ingestion results in 10 out of every 100,000 users developing a gastric ulcer, requiring hospitalization.[98] Levy's Boston Collaborative group study also estimated that one-eighth of all gastric ulcers were aspirin-related (CX 367Z020). Although these incidences are relatively small in terms of absolute numbers, they clearly present a serious public health problem. Therefore, the FDA OTC Internal Analgesics Panel recommended that all products containing aspirin should bear a warning: "*Caution*: Do not take this product if you have stomach distress, ulcers or bleeding problems except under the advice and supervision of a physician." (CX 367Z025). The aspirin-related gastrointestinal massive bleeding is compounded by aspirin's recently known anticoagulation effect (CX 367Z015). **[206]**

B. *Aspirin Intolerant Individuals*

Aspirin hypersensitivity reactions (or aspirin-intolerant reactions) are varied. They include: effects on the respiratory tract ranging from shortness of breath to severe asthmatic attacks; effects on the skin such as urticaria, angioedema, edema and rash; and anaphylactic shock involving laryngeal swelling, blockage of air pathways and a sudden drop in blood pressure which can result in death if not treated rapidly (F. 426 and 444). Although the incidence of aspirin intolerance in the general population is relatively small, it clearly presents a serious and substantial problem of public health. Therefore, the FDA OTC Internal Analgesics Panel recommended that labels for all products containing aspirin include the warning: "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician." (CX 367Z029). Dr. Moertel testified that the existence of aspirin in OTC analgesic products should be disclosed in advertising in order to protect persons with gastrointestinal bleeding or bleeding problems and aspirin-intolerant persons (Moertel, Tr. 1012).

In addition, in 1973 the American Academy of Allergy, a professional body composed of some 2,200 allergy specialists in the United States, adopted a resolution recommending that a "formulation containing aspirin and advertisements promoting the formulation

[96] F. 415.
[97] F. 416.
[98] F. 417.

should clearly indicate that the preparation contains aspirin and that aspirin can be harmful to some persons." (CX 367Z028; Farr, JTr. 2608–13). The FDA OTC Internal Analgesics Panel expressed its agreement with this resolution (CX 367Z028–Z029).[99] The 1973 resolution of the American College of Allergists, another professional body composed of allergy specialists, is also in accord with the 1973 resolution of the American Academy of Allergists (F. 446; Farr, Tr. 2613, 3650).

Against the unamimous judgment of two responsible professional organizations of specialists and the FDA OTC Internal Analgesics Panel, American Home argues that such advertising disclosure is totally unnecessary because **[207]**(1) the incidence of aspirin intolerance or massive gastrointestinal bleeding is small and (2) consumers can be counted on to read OTC drug labels. These arguments are unacceptable.

First, with respect to aspirin-intolerance, the incidence figures for asthmatics in the record varies from a low of 0.1% to a high of 28%.[100] Even if we were to take the low range, it represents close to one-quarter of a million persons who will suffer a severe adverse reaction from aspirin ingestion, which can be life-threatening. When we take into account the significant number of people who may suffer serious gastrointestinal side effects, the considerations for mandating advertising disclosure of aspirin content is overwhelming.

Respondents' argument that consumers know that Anacin and APF contain aspirin is unpersuasive. There is evidence that a substantial portion of consumers do not know that OTC analgesic products, such as Anacin, contain aspirin. This is not surprising in view of the long history of Anacin advertisements which carefully avoided any hint that it contains aspirin and suggested by implication that its analgesic ingredient is something special and that it is something other than aspirin.[101] Similarly unpersuasive is respondents' argument that those consumers who should not take aspirin are advised not to take aspirin and instructed to read labels by their physicians. First, many aspirin-intolerant persons are not aware of their condition in this respect until they experience a severe adverse reaction.[102] Second, the number of consumers who do not read labels

[99] The Panel also "strongly urges the Federal Trade Commission to require that cautionary language and warnings developed by the Panel be given emphasis in commercial advertising more so than is currently being done . . . ." (CX 367L).

[100] Stevenson, JTr. 1495. Dr. Stevenson testified that 10% is a conservative figure. The record as a whole supports the conclusion that 10% is probably the best estimate. On this basis, the number of persons who are aspirin intolerant reaches some 2.25 million.

[101] See the discussion of Anacin and APF advertisements, pp. 168, 173–74, *supra*.

[102] F. 455.

before they take an OTC product is as large as, if not larger than, those who read the labels.[103]

Finally, the presence of aspirin in Anacin and APF is a material fact from an economic point of view. The record shows that a substantial number of consumers do not know that [208]the analgesic ingredient in Anacin and APF is aspirin. Obviously, if this fact were known to consumers, that fact would be an important factor in making a choice between higher priced Anacin/APF and lower priced aspirin. In this sense as well, the presence of aspirin in Anacin and APF is a material fact which ought be disclosed in future advertisements.

Thus, the record evidence clearly establishes in my view the necessity of aspirin ingredient disclosure in Anacin and APF advertisements.

Caffeine Safety—Caffeine Disclosure Statements In Advertisements For Anacin Are Not Required

The record shows that caffeine when used as an adjuvant is safe at a single dose of 65 mg. not to exceed 600 mg. in 24 hours. The recommended dosages of Anacin is within this range.[104] Although chronic caffeine toxicity has not been observed in humans, some resistance to caffeine is known to develop. Tolerance to caffeine is likely to develop with daily use. Caffeine is a cardiac stimulant. It is known to cause increased gastric secretion in the stomach and possibly contribute to gastric bleeding. It has been suggested that caffeine can cause peptic ulcers and should be avoided by patients with peptic ulcers.[105] Caffeine inhibits platelet aggregation in vitro and its use in patients with gastric bleeding is not recommended.[106] Caffeine also is associated with an increase in blood pressure and keeping users awake or jittery.[107]

Complaint counsel maintain that the public is seriously concerned with the effects of caffeine and desires to avoid ingestion of caffeine-containing products. They further argue that the public is entitled to a caffeine disclosure statement in all Anacin advertisements. However, the record does not show that the incidence and severity of adverse effects of caffeine are of such magnitude as to require an [209]advertising disclosure of the kind complaint counsel advocate. Although the record contains some evidence that a substantial

[103] F. 464.
[104] F. 424; Lasagna, Tr. 4098–99.
[105] Grossman, Tr. 872–75; Lasagna, Tr. 4194.
[106] Grossman, Tr. 866–67. See also CX 367Z114.
[107] Lasagna, Tr. 4194.

segment of the public may desire to avoid caffeine ingestion for one reason or another, the record as a whole does not support a conclusion that the adverse effects of caffeine are such as to present a serious public health problem.[108] After all, complaint counsel do not dispute that the amount of caffeine in two tablets of Anacin (about 65 mg.) is smaller than that present in a single cup of coffee. In my view, the record as a whole does not support a conclusion that the presence of caffeine in Anacin is a material fact of which the failure to disclose would make Anacin advertisements unfair or deceptive.

Furthermore, there is a practical problem of requiring an advertising disclosure for caffeine on top of a similar disclosure for aspirin. As a practical matter, television and radio commercials are usually of a short duration, lasting for 30 to 60 seconds. In my view, to add the caffeine disclosure requirement may have the undesirable effect of diluting the impact of aspirin disclosure, a much more important message, and blurring its focus. Also, there is a real practical problem in requiring multiple affirmative disclosures in a single, short commercial. Accommodation of the two ingredient disclosures in a short commercial may present difficult, if not insurmountable, technical problems.

Finally, an affirmative disclosure requirement is a form of prior restraint upon commercial speech and should not be lightly imposed in the absence of a clear showing that non-disclosure would make the advertisement unfair to the consumer or deceptive. The record as a whole fails to make out such a showing in my view. Therefore, complaint counsel's arguments for a caffeine disclosure requirement are rejected. **[210]**

The Unfairness Doctrine And The Substantial Question Theory

Complaint counsel argue that a comparative or superlative claim of efficacy or safety of an OTC analgesic product, made expressly or by implication, constitutes, as a matter of law, a representation that the claim is scientifically established. They further argue that, with respect to the comparative efficacy claim for Anacin and the comparative safety claim for APF, the claims are not established because there exists a substantial medical-scientific question about their validity among scientists who by their training and experience

[108] F. 421–25. The General Foods study (CX 471—received *in camera*) is less than persuasive on this point. In my view, there is a real question whether the study's findings can be transferred in a meaningful sense to a drug. While coffee is a beverage of refreshment nature, Anacin is a drug to be taken for specific physical conditions. The record contains scant evidence as to the extent of caffeine concern, if any, among consumers of OTC analgesic products or medical experts.

are competent to judge the validity of such claims. Complaint counsel finally argue that the existence of a substantial question is a material fact and that an advertisement which carries such a comparative claim without disclosing the existence of a substantial question is not only false within the meaning of Sections 12 and 5 of the FTC Act but also an unfair act or practice within the meaning of Section 5. At first blush, this theory of Section 5 liability is a novel one.

Upon reflection, however, I am persuaded that the substantial question theory outlined hereinabove is, in the particular factual context of this case, a reasonable and logical refinement of the "reasonable basis" doctrine, which has been judicially sanctioned. *Pfizer, Inc.*, 81 F.T.C. 23 (1972); *Firestone Tire & Rubber Co.*, 81 F.T.C. 398 (1972), *aff'd*, 481 F.2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 1112 (1973); *National Dynamics Corp.*, 82 F.T.C. 488 (1973), *aff'd*, 492 F.2d 1333 (2d Cir. 1974), *cert. denied*, 419 U.S. 993 (1974).

The basic rationale of *Pfizer* is that an affirmative product claim carries with it an implied representation that the advertiser possessed and relied on a reasonable basis for the claim when the claim was made and that such an advertising claim in the absence of a reasonable basis is an unfair act or practice in violation of Section 5 within the meaning of Section 5. See *FTC* v. *Sperry & Hutchison Co.*, 405 U.S. 233 234 (1972). The reasonable basis requirement applies even if an advertisement claim is in fact true. 81 F.T.C. at 63. Also see *id.* at 67–68.

In *Pfizer*, a case involving a simple efficacy claim for a topical OTC anesthesic preparation, the Commission reasoned that (81 F.T.C. at 62): **[211]**

> Given the imbalance of knowledge and resources between a business enterprise and each of its customers, economically it is more rational, and imposes far less cost on society, to require a manufacturer to confirm his affirmative product claims rather than impose a burden upon each individual consumer to test, investigate, or experiment for himself. The manufacturer has the ability, the knowhow, the equipment, the time and resources to undertake such information by testing or otherwise—the consumer usually does not.
>
> * * * Absent a reasonable basis for a vendor's affirmative product claims, a consumer's ability to make an economically rational product choice, and a competitor's ability to compete on the basis of price, quality, service or convenience, are materially impaired.

The Commission, therefore, concluded that as a matter of marketplace fairness, a consumer is entitled to rely upon the manufacturer to have a reasonable basis for making performance claims. *Id.*

In determining what constitutes "a reasonable basis," the Commis-

sion set forth a number of guidelines in *Pfizer*. First, the Commission made it clear that the requirement is not solely a "reasonable man" test. The reasonable basis requirement questions both the reasonableness of an advertiser's actions and the adequacy of evidence upon which such action is based.[109] The reasonable basis standard is essentially a fact issue to be determined on a case-by-case basis, and depends on such overlapping considerations as: (1) the type and specificity of the claim made (*e.g.*, safety, efficacy, dietary, health, medical); (2) the type of product (*e.g.*, food, drug, potentially hazardous products); (3) the possible consequences of a false claim (*e.g.*, personal injury); (4) the degree of reliance on the claim by consumers; and (5) the type and accessibility of evidence adequate to form a reasonable basis for the particular claim.[110] For some types of claims and for some types of products, the only reasonable basis "in fairness and in the expectation of the consumers" would be an adequate and well-controlled scientific test.[111] **[212]**

This proceeding involves comparative and superlative efficacy and safety claims for aspirin-based OTC internal analgesic products. Such drugs as a class is known to be the most popular OTC drug in this country. American consumers purchase some 19 billion dosage units annually (F. 14). Although they are generally safe and effective for the relief of minor pain and headache pain and for the reduction of inflammation and fever, they are potent drugs and have numerous adverse side effects, some of which are serious and can be life-threatening (F. 404 and 406–52). Anacin is the largest selling and most heavily advertised aspirin-based OTC internal analgesic product. Against this background, what is the reasonable level of substantiation required under the fairness doctrine for a claim that Anacin is more effective than aspirin because of the extra amount of aspirin (150 mg.) and caffeine (65 mg.) contained in two tablets of Anacin over two tablets of 5 gr. aspirin, or for a claim that Anacin is more effective than any other OTC analgesic product?

Consumers obviously have no means of verifying the truth of such a pharmacological-clinical superiority claim for themselves (See F. 210, 211, 218–20, 223, 225, 581 and 582). Moreover, consumers are willing to pay, and do pay, a significantly higher price for the alleged superior efficacy of the product. If the alleged superiority is not established, the consumer's evidently widespread self-medication with such higher-priced, "extra-strength" OTC analgesic products is not only pharmacologically superfluous and economically wasteful

[109] See *id.* at 64.
[110] *Id.* at 64.
[111] *Id.* at 64, 66–67.

but also is accompanied by significant health hazards (increased potential for adverse side effects) (See F. 403–52).

In my view, in the circumstances of this case, such a comparative or superlative claim constitutes, "in fairness and in the expectation of the consumers" and as a matter of law, an implied representation that the manufacturer has a sufficient kind and degree of substantiation for its claim. To state it another way, the consumers of OTC analgesic products are entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a sufficient kind and level of substantiation for the claim. In the circumstances of this case, the only sufficient substantiation for the claim is that the claim is accepted as established by the medical-scientific community. The record is clear that, with respect to OTC internal analgesic products, the medical-scientific community requires two or more well-controlled [213]clinical studies using appropriate pain models, one of which is a headache pain model (F. 197–225).

It is also clear that the absence of that kind and level of substantiation leaves a substantial question regarding a claim of comparative or superlative efficacy or safety, and that the existence of such a question is a material fact, of which the failure to disclose will render an advertisement deceptive (See pp. 216–17, *infra*). What then is a substantial question? A substantial question is a fact issue to be determined on a case-by-case basis. In this case, complaint counsel argue essentially that a substantial question exists because the comparative or superlative efficacy or safety claim is not accepted as true or as a proven scientific fact by the vast majority of medical scientists who are by their training and experience competent to judge the scientific validity of such claims. In this sense, a substantial question does not mean unanimity of medical-scientific opinions. Nor do occasional dissents make out a substantial question. It relates rather to the quality and quantum of medical-scientific evidence in support of a proposition. In the field of clinical pharmacology, it is generally agreed that two or more well-controlled clinical demonstrations showing statistically significant results are sufficient to establish a medical-scientific proposition. The record as a whole shows that in the absence of that level of supporting data, the medical scientists are unwilling to accept a proposition as true or proven. The expert witnesses who testified in this proceeding virtually without exception supported this view.

American Home, on the other hand, contends that the existence of substantial question requires more, that it requires a substantial mount of *negative* data from well-controlled clinical studies (RB at

6). However, this position is contrary to the weight of record evidence in this case[112] (See F. 195, 223, 225, 260–62, 276–78 and 318–20).

Furthermore, the rationale of the substantial question theory as applied to advertising claims for comparative or superlative efficacy or safety of OTC analgesic products is not only consistent with congressional policy of drug regulation embodied in the 1962 Amendment to the Food, Drug and Cosmetic Act and implemented by the FDA, but also is consonant with the findings and recommendations of the FDA OTC Internal Analgesics Panel. **[214]**

In Section 505(d) of the Food, Drug and Cosmetic Act, as amended (21 U.S.C. 355), Congress mandated a "substantial evidence" standard for granting a new drug application (NDA) with respect to all drugs, including new OTC drugs. Congress defined "substantial evidence" of drug efficacy in Section 505(d) as

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have . . . .

Under the HEW regulations promulgated to implement that congressional policy, the FDA has set forth several principles which, in its words,

> have been developed over a period of years and are recognized by the scientific community as essentials of adequate and well-controlled clinical investigations. They provide the basis for the determination whether there is "substantial evidence" to support the claims of effectiveness for "new drugs" . . . . 21 CFR 314.111(a)(5)(ii).

It should be pointed out that many of the FDA's "principles" closely parallel the very criteria testified to by the expert witnesses in this proceeding as important elements of a well-controlled clinical study. *Cf.* 21 CFR 314.111(a)(5)(ii)(a) through (c) and F. 201–17. Furthermore, these FDA requirements have been consistently upheld by courts. See *e.g., Weinberger* v. *Bentex Pharmaceutical, Inc.,* 412 U.S. 645 (1973); *Ciba Corp.* v. *Weinberger,* 412 U.S. 640 (1973); *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973); *United States* v. *Articles of Food and Drug Consisting of Coli-Trol 80, etc.*, 518 F.2d 743 (5th Cir. 1975); *Sterling Drug, Inc.* v. *Weinberger,* 503 F.2d 675 (2d Cir. 1974).

These well-established criteria for establishing the effectiveness of new prescription and non-prescription drugs have been recently reaffirmed by the FDA when it promulgated review procedures for

[112] With respect to aspirin's dose-response curve, the record contains a substantial amount of such negative clinical test data. *E.g.*, F. 243–57.

OTC drugs by various panels of experts, including the Panel on Analgesic, Antipyretic and Antirheumatic Products, and when the FDA initiated rulemaking proceedings [215]known as "monograph" proceedings. See 21 CFR 330.10(a)(4)(ii). Pursuant to this mandate, the FDA OTC Internal Analgesics Panel set forth specific criteria for well-controlled clinical studies required to establish the efficacy and safety of active agents used in OTC analgesic products. The Panel's criteria closely resemble the criteria extensively testified to by various experts, including American Home's, at trial in this proceeding.[113] More specifically, "to establish Category I status for a Category III compound,"[114] the Panel required "at least two studies by independent investigators" (CX 367Z075) which conformed to a number of specific criteria. These criteria are virtually identical to the ones testified to by expert witnesses in this proceeding. *Cf.* CX 367Z074–075 and F. 200–17.

Thus, the FDA, pursuant to congressional policy embodied in the Food, Drug and Cosmetic Act, requires at least two well-controlled clinical demonstrations of efficacy for both new prescription drugs and new OTC drugs. The FDA has reaffirmed the same standard in connection with its OTC drug review with respect to the issue of *simple* efficacy. The FDA OTC Internal Analgesics Panel recommended the same standard for OTC analgesic products for labeling with respect to the issue of *simple* efficacy and safety. It is eminently reasonable, therefore, for the Commission to apply the same standard to advertising claims of *comparative* or *superlative* [216] efficacy or safety for OTC analgesic products involved in this proceeding.[115]

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[113] Although the specific task of the Panel was to determine the effectiveness and safety of active ingredients used in OTC analgesic products for labeling purposes, the Panel dealt with issues of comparative efficacy or safety on several occasions, applying the same criteria. *E.g.*, CX 367Z110–Z111 ("faster to the bloodstream" issue); CX 367Z075 (greater analgesia postulated for aspirin-caffeine combination drugs).

[114] Category I was defined as "generally recognized as safe and effective," Category II as "not generally recognized as safe and effective," and Category III as "conditions for which the available data are inconsistent to permit final classification [either as Category I or II] at this time." (CX 367C-D).

[115] American Home argues that since Anacin and APF are effective and safe for the indicated conditions, it is not equitable to require a standard higher than a reasonable basis for comparative claims for these products (RRB, at 6–10). While this argument has some surface plausibility, it pales before the compelling rationale of the unfairness doctrine discussed hereinabove. On the contrary, in view of this record, it would be unthinkable for the Commission to allow a lesser standard for *comparative* claims in advertisements than what the FDA requires for *simple* (or absolute) claims in labels. To do so may tend to encourage OTC drug manufacturers to make unnecessary and therapeutically insignificant modifications to well known drugs, all having the same general actions or similar efficacy or safety factors, in order to achieve some marketing advantage as a result of advertising designed to emphasize the modifications and thereby imply superior product performance. In my view, this does not seem to be consistent with the basic purposes of Sections 5 and 12 of the FTC Act.

The Establishment Claims Related To Anacin And APF Will Be Deceptive Unless Qualified By An Affirmative Disclosure Of the Existence Of A Substantial Question

It is axiomatic that the Commission's power under Sections 5 and 12 to proscribe deceptive or misleading advertisements includes the power to require affirmative disclosure of a material fact in future advertisements of a product claim. In this sense, a fact is material if non-disclosure of that fact makes a claim patently deceptive and misleading. *E.g., ITT Continental Baking Co.,* 83 F.T.C. 865, 965 (1973), *rev'd in part,* 532 F.2d 207 (2d Cir. 1976); *FTC* v. *Royal Milling Co.*, 288 U.S. 212, 216–17 (1933); *Pep Boys-Manny Moe & Jack Co.* v. *FTC,* 22 F.2d 158, 161 (3rd Cir. 1941). *Cf., National Commission On Egg Nutrition,* 88 F.T.C. 89, 192–94 (1976), *modified,* 570 F.2d 157 (7th Cir. 1977). In this case, an establishment claim, express or implied, would clearly be misleading and deceptive unless qualified by disclosure of the fact that a substantial question exists regarding its scientific validity.

The record shows that the only scientifically established analgesic ingredient in Anacin and APF is aspirin. Respondents impliedly claimed that the propositions that Anacin and [217]APF are more effective or safer than aspirin have been scientifically established. These claims are based on the differences in formulation between Anacin/APF and aspirin. Respondents' unqualified claims in this regard imply that the difference in formulation, or rather the slight modification made to a regular aspirin tablet (150 mg. additional aspirin in Anacin), provides therapeutically superior analgesia. In the circumstances of this case, the fact that the implied claims have not been scientifically established, or that there is a substantial question among scientists who by training and experience are qualified to evaluate the validity of such claims, is a material fact which must be disclosed to consumers. The fact that there is a substantial scientific question is a vital factor for consumers in making their purchasing decisions.

The existence of a substantial question discussed above is even more material, indeed crucial, in this case because consumers cannot be expected to evaluate the validity of these establishment claims. Faced with an unqualified establishment claim, consumers are unable to make the intelligent and informed choice that is a paramount objective of Section 5. See p. 212, *supra.*

American Home's Constitutional Objections To The Substantial Question Theory Are Without Merit

American Home has raised two major objections to the substantial question theory on constitutional grounds. First, it argues that the establishment standard is vague and unpredictable and, thus, violative of due process. Second, it argues that the establishment standard is an invalid prior restraint on constitutionally protected commercial speech (RB 18–23). In my view, these arguments are without merit.

First, it is clear from the discussions in the preceding sections that the substantial question theory in the context of this case requires of American Home for advertising purposes nothing more than the quality and quantum of medical-scientific evidence long required by the FDA with respect to all new drugs (both prescription and non-prescription drugs) for labeling purposes. This standard is both well-established and clearly defined, and has been judicially reviewed and sanctioned. All American Home need do to meet the substantial question test is to have that kind and level of medical-scientific evidence (essentially two or more well-controlled [218]clinical demonstrations) which will establish its comparative or superlative claim when such claim is made.[116] There is nothing vague or unpredictable about this standard.

With respect to the fact that the performance claim challenged in this case is an implied claim rather than an express one, it clearly does not rise to the level of vagueness in the due process sense. Findings of Section 5 liability involving implied advertising claims have been upheld by the Supreme Court in numerous cases throughout the history of Section 5 jurisprudence. Therefore, American Home's vagueness argument is rejected.

Secondly, American Home's free speech argument is not well founded. It is well established that so-called commercial speech is entitled to the full protections of the First Amendment. *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Counsel,* 425 U.S. 748 (1976). However, it is also well established that commercial speech that is false or misleading forfeits that protection. *Id.* at 771 n. 24; *Warner-Lambert Co.* v. *FTC,* 562 F.2d 749 (D.C. Cir. 1977), *reversing in part, Warner-Lambert Co.,* 86 F.T.C. 1398 (1975), *cert. denied,* 46 U.S.L.W. 3616 (April 14, 1978); *National Commission on Egg Nutrition,* 88 F.T.C. 89, 195–99 (1976), *modified,* 570 F.2d 137 (7th Cir. 1977).

[116] During the oral argument, complaint counsel agreed that two or more well-controlled clinical studies supporting such claims when they are made will constitute an absolute defense in a substantial question action under Section 5. See Transcript of Oral Argument, Tr. 7842–46.

In the cases involving commercial speech, the important test is whether the proposed prior restraint will prohibit truthful speech or otherwise unduly tend to inhibit truthful speech. In this proceeding, it was found that respondents' comparative claims of superior efficacy and safety have not been established and that the existence of a substantial question with respect to these advertising claims is a material fact, of which the failure to disclose would render the advertising claim deceptive and misleading. In these circumstances, the requirement for affirmative disclosure of that material fact is well within the long established proscription against deceptive commercial speech.[117] American Home's argument [219]that such a requirement in the context of the substantial question theory would have the effect of chilling truthful speech is, therefore, without merit.

Finally, the constitutional challenge against the reasonable basis requirement is misdirected for the reason that the tension relief claim in this case not only lacked a reasonable basis but also is false.

Anacin's Product Image—Source And Duration And The Corrective Advertising Requirement

Complaint counsel contend that: (1) a substantial number of consumers believe that Anacin is a more effective pain reliever than aspirin and is a tension reliever; (2) these mistaken images are due in substantial part to American Home's misleading advertising claims made over a long period of time; (3) these consumer images will persist in the absence of corrective advertising designed to convey to consumers a corrective message that Anacin's superior efficacy is not established and that Anacin will not relieve tension. Respondent vigorously argues that: (1) the record evidence does not demonstrate consumers' belief that it has been established that Anacin is a more effective drug than aspirin or their belief that Anacin is a tension-relieving drug; (2) the record evidence does not show that the challenged advertising claims were the principal or significant source of such images, if such images were found to exist; and (3) the corrective advertising proposed by complaint counsel would have a punitive effect and is unjustified. It is my determination that: (1) the record as a whole does not support anything more than an inference that consumers have the establishment image alleged by complaint counsel; (2) the corrective advertising directed to the superior

[117] During the oral argument, respondents' counsel agreed that if the record supports a finding that the existence of a substantial question is a material fact, the requirement for affirmative disclosure of that fact would be consistent with the constitutionally sanctioned proscription against deceptive advertising under Section 5 of the FTC Act (Transcript of oral argument, Tr. 7896–97).

efficacy image is, thus, not justified; (3) the record as a whole supports the conclusion that consumers believe Anacin to be a tension reliever; and (4) the corrective advertising directed to the tension relief image is justified. **[220]**

A. *Product Images, Sources And Duration*

In my view, the mere fact that American Home has disseminated the challenged advertising claims for a long period of time (at least since 1963) supports a fair inference that consumers will believe that Anacin is a more effective analgesic drug than aspirin and that Anacin is a tension reliever.[118] This inference is further confirmed by some empirical data in this case, although such empirical evidence is less than overwhelming.

First, the record as a whole clearly supports the conclusion that consumers have for some time believed that Anacin is a more effective analgesic drug than aspirin and is a tension reliever. A number of commercial market research documents in evidence, including CX 451, 452, 454 and 455, support that conclusion. Although these market surveys were conducted at various times during the 1967 to 1970 period, for different clients, by different firms, using different methodologies and drawing upon different samples, they produced fairly consistent results. Although they were neither perfectly designed nor flawlessly executed, they were in general of the kind and quality normally used by business firms to help guide their marketing efforts (Smith, Tr. 5948–50). See also F. 502 and 503. An analysis of the data pertaining to efficacy-related product attributes shows that consumers believed that Anacin was a more effective drug than aspirin (F. 521, 523, 524 and 568–70).

Second, *The Leavitt Study* (CX 457), conducted for complaint counsel in 1975 for use in this litigation, provides further confirmation. Although *The Leavitt Study* suffers from a serious and major defect in that the completion rate was only about 50%, it nevertheless shows that more than one-half of the survey population (between 56 to 60%) had a comparative image of Anacin and aspirin, and that among them a significantly larger segment believed Anacin to be more effective than aspirin (F. 530 and 550–67).

The Leavitt Study is less impressive with respect to the tension relief image, but it produced spontaneous **[221]**responses from a not insignificant number of respondents, indicating that the tension relief image did exist in the fall of 1975 (F. 525). This is noteworthy

[118] *Cf. Warner-Lambert Co.*, 86 F.T.C. 1398, 1501–02, 1503 (1975), *rev'd in part*, 562 F.2d 749, 762 (D.C. Cir. 1977), *cert. denied*, 46 U.S.L.W. 3616 (U.S. April 14, 1978); *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157 (7th Cir. 1977, supp. opinion Jan. 28, 1978).

in view of the fact that tension relief advertisements had ceased about December 1973.

Thus, the penetration/image studies referred to above confirm what common sense and experience suggest, namely, that American Home's dissemination of the challenged advertising claims for a long period of time led to consumer images that Anacin is more effective than aspirin and that it relieves tension.

Next, respondents' sole-source argument is contrary to Commission precedent and should be rejected. The record as a whole clearly supports the inference that respondents' challenged advertising claims, made over a long period of time, played a substantial role in creating or reinforcing the misleading beliefs about Anacin among consumers.[119] Anacin has been advertised as a more effective pain reliever than aspirin and as a tension reliever. A substantial segment of consumers believe that Anacin is a more effective pain reliever than aspirin and is a tension reliever. This correspondence between advertising themes and consumer beliefs is a further indication that Anacin's advertising played a significant role in creating or reinforcing those beliefs.

With respect to the duration issue, the record as a whole supports the conclusion that the consumer beliefs about Anacin that have been found to exist will endure for some time and will tend to be reinforced either by subsequent advertising about Anacin or by subsequent use[120] (F. 579-84, 589–97 and 618). The duration of specific consumer beliefs and images generally depends on such factors as their importance to consumers, their specificity and the frequency with which they are reinforced by subsequent advertising or **[222]**by consumers' experience with Anacin that appear to them to be consistent with those beliefs (F. 584, 593 and 595–97). Clearly, efficacy is the *raison d'etre* of analgesics and is the most important product attribute for an analgesic product (F. 120). Tension relief is also an important attribute of an analgesic for a large segment of consumers of OTC analgesics (F. 495–500, 525–27 and 571). Respondents' expert, Dr. Smith, agreed that if a product is held in high esteem along the product dimensions that are important, it is likely that such beliefs will endure (Smith, Tr. 7776–77). The record evidence thus confirms what common sense and experience suggest, namely that product images about attributes important to consum-

[119] See *Warner-Lambert Co., supra*, 86 F.T.C. at 1501–02, 1503 (1975), 562 F.2d at 762; *Waltham Instrument Co.* 61 F.T.C. 1027, 1049 (1962), *aff'd*, 327 F.2d 427 (7th Cir. 1964), *cert. denied*, 377 U.S. 992 (1964).

[120] *Cf. Warner-Lambert Co., supra*, 86 F.T.C. at 1502–03, 562 F.2d at 762; *National Commission on Egg Nutrition* v. *FTC, supra.*

ers, once created, will endure for a long time and will tend to be reinforced by subsequent advertising or by subsequent use.[121]

B. *The Corrective Advertising Requirement*

The basic rationale of corrective advertising is that a misleading product image, once created, is likely to endure unless that image is unlearned by consumers through exposure to an appropriate corrective message for a sufficient time period. The Commission's Section 5 power to require corrective advertising in appropriate cases is not open to question. *Warner-Lambert Co., supra; National Commission on Egg Nutrition, supra.* Complaint counsel appear to argue that the finding that some of respondents' advertisements contained an implied establishment claim of superior efficacy for Anacin and the finding that some consumers believe that Anacin is more effective than aspirin *ipso facto* requires a corrective advertising requirement. I am of the view that the corrective advertising requirement is a discretionary remedy and that considerations of fundamental fairness and equity are relevant, although in all cases the elimination of mistaken consumer images is the paramount consideration.

In this case, although the finding of an implied establishment claim in certain advertisements is supported by the record and is a fair inference, I am not persuaded that the record supports an inference that consumers have an *establishment* image or that such an inference is fair in the circumstances of this case. In my view, to find an implied establishment claim in certain of respondents' **[223]** advertisements and to require in future advertisements containing such claims an affirmative disclosure of the material fact that a substantial question exists is one thing. To find an implied establishment claim, *which is not alleged to be false*, and to require corrective advertising in every future Anacin advertisement simply on the basis of consumer belief that Anacin is more effective than aspirin is another matter. The unfairness of the latter proposition is also compounded by the fact that complaint counsel's theory of liability, in this respect, is a novel one. Furthermore, if the finding of an establishment image among consumers is to be implied from consumers' image of Anacin's superior efficacy as a logical consequence of the implied establishment claim theory, the basis for doing so in this case is less than substantial since the evidentiary basis for finding a consumer belief that Anacin is superior than aspirin is itself less than overwhelming. Finally, as a practical matter, the aspirin disclosure requirement in the order will also have the further

[121] *Cf. Warner-Lambert Co., supra*, 86 F.T.C. at 1501–02.

effect of alerting consumers to the fact that the analgesic ingredient in Anacin is aspirin and may reasonably be expected to cause some consumers to modify their image of Anacin's superior efficacy to some extent. On balance, it is my determination that, on the basis of this record, corrective advertising directed to the superior efficacy image is not justified.

Corrective advertising directed to the tension relief image, however, stands on a different footing and is clearly required in my view. The tension relief claim was shown to be *false*. The evidentiary basis for the finding that American Home made that claim is solid as is the basis for concluding that consumers believe that Anacin is a tension reliever. Although the tension relief claim ceased by December 1973, it had been made for a long time. In view of the record evidence showing that consumers perceive tension relief as an important attribute of Anacin, it is reasonable to conclude that the tension relief image is likely to persist for some time to come in the absence of a corrective message. Therefore, it is my view that corrective advertising directed to the tension relief image is clearly justified.

The Liability Of Clyne, The Advertising Agency for APF

Complaint counsel and Clyne agree that an advertising agency may be held liable for false advertising if it actually participated in the deception and that it may be found to have participated in such deception if it knew or [224]had reason to know that the advertising was false. *Doherty, Clifford, Steers & Shenfield, Inc.*, v. *FTC*, 392 F.2d 921, 928 (6th Cir. 1968). Clyne was the advertising agency for APF since 1969 and does not deny that it participated generally in the preparation and dissemination of the APF advertisements containing the challenged claims. However, it vigorously contends that it did not know and had no reason to know that any of the challenged claims was false, that in fact it in good faith relied on the substantiation information furnished by American Home, and that under the law it had a right to do so. Complaint counsel agree that an advertising agency does not have the duty to conduct an independent scientific investigation or to retain medical scientists as expert consultants in order to insure that the medical-scientific claims contained in an advertisement are true or have been established. However, they argue that in this case Clyne knew or should have known that the substantiation material was patently inadequate and that, therefore, Clyne is equally liable. It is my determination that the record as a whole shows that: (1) Clyne either

knew or had reason to know that the uniqueness claim for APF was false; and (2) that Clyne's good faith reliance on the substantiation information obtained from American Home with respect to the comparative safety claim for APF was reasonable.

First, with respect to the uniqueness claim for APF (Comp. ¶8(B)(1)), there is no question that Clyne knew that the analgesic ingredient in APF is aspirin and that APF is essentially a buffered aspirin preparation. Therefore, the express and implied claims that APF's analgesic ingredient is unusual or special were patently false, and Clyne knew or should have known that they were false.

Second, with respect to the comparative safety claim for APF (Comp. ¶ 10(B)), the substantiation information furnished by American Home (CX 304) indicated that APF demonstrated less incidence of gastrointestinal irritation than buffered aspirin (CX 304S). Clyne should not be faulted for having equated "gastrointestinal irritation" with "stomach discomfort." Clyne had no reason to doubt the veracity or competency of American Home's medical-scientific research. Thus, it is reasonable to assume that Clyne relied in good faith upon this information. The key question is whether it was reasonable for Clyne to have relied on American Home with respect to the safety claim for APF. In my view, it was not unreasonable for Clyne to have done so. The Complaint does not allege that the claim is false; it merely alleges that the claim is not **[225]**established. This is not a case where the disparity between the advertising representations and the substantiation information is so great as to preclude a conclusion that the advertisements were conceived through reasonable reliance on the assurances of the manufacturer that the claim is true or has a reasonable basis. *Cf. Standard Oil Co. of California*, 84 F.T.C. 1401, 1474–75 (1974). Clyne cannot be reasonably charged with the duty to conduct an independent investigation that the claim is scientifically established in the sense that there existed two or more well-controlled clinical demonstrations in support of the claim. In these circumstances, Clyne's good faith reliance on American Home's assurances, as embodied in CX 304, was reasonable.

Relief

It is axiomatic that in Section 5 cases the Commission has the power and duty to fashion appropriate remedies which are reasonably calculated to prohibit the unlawful practices found to exist. *E.g.*, *Jacob Siegel Co.* v. *FTC*, 327 U.S. 608, 611–13 (1946); *FTC* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952); *FTC* v. *National Lead Co.*, 352 U.S. 419, 428–30 (1957). The remedy must have a reasonable relationship to

the unlawful practice and be no broader than is reasonably necessary to remedy the violation. *Jacob Siegel Co.* v. *FTC*, *supra*, at 613; *Beneficial Corp.* v. *FTC*, 542 F.2d 611, 619–20 (3d Cir. 1976). See also *Warner-Lambert Co.* v. *FTC*, 562 F.2d 749, 757–58 (D.C. Cir. 1977); *National Commission On Egg Nutrition* v. *FTC*, 570 F.2d 157, 164 (7th Cir. 1977).

A. *The Entry Of An Order Covering All Non-Prescription Drug Products Is Justified With Respect To American Home*

About a decade ago, the Commission had occasion to observe, in a case involving American Home, that:

> The law is clear that an order . . . need not be confined to the particular product or even the type of products sold by a respondent, particularly where the respondent has, by past conduct, demonstrated that the misrepresentations with which it has been charged are not isolated examples of its practices.[122] **[226]**
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> * * * * * * *
>
> In the field of drug advertisements it is particularly important that the Commission's orders be sufficiently broad to ensure that the public will be fully protected against any future misrepresentations made by respondents with respect to the entire line of proprietary preparations which it sells and that it not be limited to just one type of preparation.[123]

In that case, the Commission ordered respondents not to "misrepresent . . . the efficacy of [any] drug." Although the reviewing court disagreed that respondents' past conduct justified the broad order in that case,[124] it is my view that now is the time to place American Home under a broad proscription with respect to all OTC drug products marketed by it. Furthermore, the proscription here is narrower and is related to the particular type of unlawful practice found to exist in this case.

B. *The Reasonable Basis Provision Is Justified*

Part II B of the Order would prohibit simple and non-comparative efficacy or safety claims that are not supported by a reasonable basis. This prohibition is based on the finding that respondent for a long period of time claimed that Anacin was a tension reliever without a reasonable basis therefor. Although the tension relief claim ceased about December 1973, the provision is necessary in order to prevent in the future the renewal of that claim as well as any other simple

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[122] *American Home Products Corp.*, 70 F.T.C. 1524, 1625–26.

[123] *Id.* at 1627.

[124] *American Home Products Corp.* v. *FTC*, 402 F.2d 232, 237 (6th Cir. 1968).

and non-comparative efficacy or safety claim concerning any non-prescription drug product not supported by a reasonable basis.

C. *The Requirements For Affirmative Disclosure Are Appropriate*

Part III A and B of the Order would require disclosure of the presence of aspirin in future advertisements for aspirin-containing products. Part III D would prohibit [227]advertising claims of comparative efficacy or safety unless such claims are established. However, Part III E would permit comparative efficacy or safety claims whenever they are qualified by a disclosure statement that there exists a substantial question regarding the claims.

Part III D's requirement for two or more "adequate and well-controlled" clinical investigations are based on the FDA regulation which sets forth similar criteria necessary to provide "substantial evidence" of efficacy for new drugs (21 CFR 331.111(a)(5)(ii) and 330.10(a)(4)(ii)), with certain modifications. The FDA regulation has been modified to reflect the facts that (1) this case involves comparative efficacy and safety, and (2) this case involves only OTC drug products. In this respect, I have adopted complaint counsel's proposed order provisions and hereby subscribe to the reasons explained in complaint counsel's Memorandum (CB, 183–88).

D. *The Corrective Advertising Provision*

The Order requires American Home to include in every Anacin advertisement a statement that "Anacin is not a tension reliever." The duration of the corrective advertisement to be required is a difficult question. However, I am persuaded that it is reasonable to adopt for the purposes of this case the one-year formula used by the Commision in the *Warner-Lambert* case, which met the reviewing court's approval. *Warner-Lambert Co.*, D. 8891, Modified Order To Cease And Desist, July 20, 1978. The average should be based on the period 1968 through 1973, when the tension relief claim ceased.

E. *The Provisions Directed To Clyne*

The provisions directed to Clyne are based on its liability for the false uniqueness claim with respect to APF, and will be confined to advertisements of OTC internal analgesic products. Complaint counsel have not shown that a broader product coverage with respect to Clyne is justified in view of its past Section 5 violations.

CONCLUSIONS OF LAW

1. The Federal Trade Commission has jurisdiction over the advertising of Anacin and Arthritis Pain Formula under Section 5 of the Federal Trade Commission Act. [228]

2. Respondents' use of false and misleading advertising representations as found herein has had and now has the capacity and tendency to mislead consumers into the mistaken belief that the said representations are true and into purchasing substantial quantities of Anacin and Arthritis Pain Formula by reason of said mistaken belief. In the absence of an appropriate order, consumers are likely to continue to purchase substantial quantities of said products in the mistaken belief that respondents' past advertising representations regarding the comparative efficacy of said products were supported by evidence generally accepted by the scientific community as establishing such propositions, and that the tension relieving representations regarding Anacin had adequate substantiation.

3. The acts and practices of respondents as found herein were and are prejudicial and injurious to the public and constitute unfair methods of competition and unfair and deceptive acts in commerce in violation of Section 5 of the Federal Trade Commission Act.

4. The Complaint is hereby dismissed as to all respondents insofar as it relates to the advertising representations that Arthritis Pain Formula will eliminate all pain, stiffness and discomfort usually experienced by arthritis sufferers in the morning (Comp. 8(B)(2)). The complaint is dismissed as to the C.T. Clyne Company, Inc. except as relates to the advertising representations that Arthritis Pain Formula's analgesic ingredient is unusual and special (Comp. 8(B)(1) in part).

5. The accompanying order is necessary and proper for the purpose of prohibiting the continuation of the proscribed acts and remedying the injury and unfairness to the consuming public.

ORDER

I

It is ordered, That respondent American Home Products Corporation, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or [229]other device, in connection with the labeling, advertising, offering for sale, sale or distribution of "Anacin," in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist

from representing, directly or by implication, that Anacin relieves nervousness, tension, anxiety or depression or will enable persons to cope with the ordinary stresses of everyday life.

II

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing, directly or by implication:

1. That such product contains more of any ingredient than any other non-prescription internal analgesic product or products, or otherwise making a quantitative comparison with any other product or products, unless: **[230]**

a. The ingredient is named by its common, or usual, name;
b. The product, or products, used for comparison is, or are, named;
c. The ingredient is present in greater amount in such preparation than in the product, or products, used for comparison;

and unless each advertisement containing such representation also contains a clear and conspicuous disclosure stating that the comparative efficacy or safety claim "has not been scientifically proven." Such disclosure statement shall be further subject to the requirements of IV A 1 and 2 of this Order.

2. That such product contains any ingredient, or combination of ingredients, which is unusual, special or exclusive when such ingredient, or combination of ingredients, is available in other non-prescription internal analgesic products.

3. That such product will relieve headache pain in any period or amount of time; *provided, however,* that it shall be a defense in any enforcement proceeding instituted under this prohibition **[231]**for respondent affirmatively to establish that there is a reasonable probability that a great majority of consumers will obtain relief from headache pain within such period or amount of time.

B. Making any simple and non-comparative representations, directly or by implication, concerning the effectiveness or safety of such product unless, at the time such representation is made, respondent has a reasonable basis for such representation which shall consist of competent and reliable scientific evidence.

III

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula" or any other non-prescription drug product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Referring, directly or by implication, to aspirin, or to any commonly known ingredient, by any word or words without disclosing the common, or usual, name of such ingredient. **[232]**

B. Failing to disclose in the advertising of such product the presence of aspirin when such product contains such ingredient.

C. Misrepresenting, in any manner, any test, study or survey or any or all of the results thereof.

D. Representing, directly or by implication, that a claim concerning the comparative effectiveness or comparative freedom from side effects of such product has been established unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the effectiveness and comparative effectiveness or comparative safety of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness or safety that it is represented to have, and (2) that such comparative effectiveness or safety is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be **[233]**conducted on any disease or condition referred to, directly or by implication; or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. To provide the

basis for the determination whether any clinical investigation is "adequate and well-controlled," the plan or protocol for the investigation and the report of the results shall include the following:

1. A clear statement of the objective of the investigation.
2. A method of selection of the subjects that:

a. Provides adequate assurance that they are suitable for the purposes of the investigation, and diagnostic criteria of the condition to be treated (if any);

b. Assigns the subjects to the test groups in such a way as to minimize bias; and

c. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity, or duration of disease or condition (if any), and use of drugs other than the test drugs.

3. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment [234]of any subject's response and steps taken to minimize bias on the part of the subject and observer.

4. A comparison of the results of treatments or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. The investigation must be conducted double-blind, and methods of double blinding must be documented. In addition, the investigation shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

5. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

E. D. hereinabove shall not be construed to prohibit respondent from making any representation, directly or by implication, concerning the comparative efficacy or safety of such product when such representation or claim is not established by two or more well-controlled clinical investigations as specified in D. hereinabove, [235] provided each advertisement containing such representation also contains a clear and conspicuous disclosure stating that the comparative efficacy or safety claim "has not been proven." Such disclosure statement shall be further subject to the requirements of IV A 1 and 2 of this Order.

IV

A. *It is further ordered,* That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, do forthwith cease and desist from disseminating or causing the dissemination of any advertisements for the product Anacin unless it is clearly and conspicuously stated in each such advertisement that "Anacin is not a tension reliever."

1. In print advertisements, the disclosure shall be displayed in type size which is at least the same size as that in which the principal portion of the text of the advertisement appears and shall be separated from the text so that it can be readily noticed.

2. In television advertisements, the disclosure shall be presented simultaneously in both the audio and video portions. During the audio portion of the disclosure in television and radio advertisements, no other sounds, including music, shall [236]occur. Each such disclosure shall be presented in the language, *e.g.*, English, Spanish, principally employed in the advertisement.

B. The aforesaid duty to disclose as provided in Paragraph IV A shall continue until respondent has expended on Anacin advertising a sum equal to the average annual Anacin advertising budget for the period of April 1968 to April 1973.

V

It is further ordered, That respondent the C.T. Clyne Company, Inc., a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising of "Arthritis Pain Formula" or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that such product contains any ingredient or combination of ingredients which is unusual or special when such ingredient or combination of ingredients is available in other non-prescription analgesic product or products.

VI

It is further ordered, That respondents American Home Products

Corporation and the C.T. Clyne Company, Inc. shall notify the Commission at least thirty (30) days prior to any [237]proposed change in their respective corporate respondent 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 their respective corporation which may affect compliance obligations under this Order.

VII

It is further ordered, That the respondents herein shall within sixty (60) days after service of this Order upon them, file with the Commission a written report setting forth in detail the manner and form in which they have complied or intend to comply with this Order.

Paragraph Eight B 2 of the Complaint is hereby dismissed as against American Home Product Corporation. The Complaint is dismissed as against the C.T. Clyne Company, Inc. except with respect to Paragraph Eight B 1 and related allegations.

APPENDIX I

A Description Of The Methodology Of The Image And Penetration Studies In Evidence

CX 451 – *A Study In-Depth Of Heavy Users Of Analgesics For Headache Relief*

Client: Whitehall Laboratories, division of American Home.

Purpose: To study consumer attitudes toward, and images[1] of analgesics with emphasis placed on the leading brands—Anacin, Bayer, Bufferin and Excedrin; to examine brand switching patterns; to aid in developing marketing strategies for the products involved (Weinberger, Tr. 683–84, 686; CX 451D–E).

Date of Study: Interviewing took place during the month of May 1967 (CX 451Z086).

Background of Researchers: The study was conducted by Oxtoby-

[1] See F. 486, *supra*, for the meaning attributed to the term, "consumer image," in this proceeding.

Smith, a consumer and market research organization, with Mr. Martin Weinberger bearing primary responsibility for the project (Weinberger, Tr. 682–83). Mr. Weinberger has had ample experience in the area of consumer research (Weinberger, Tr. 680–81).

Mr. Weinberger designed the research and the questionnaire, prepared the tabulation plan, analyzed the data and drafted the report (Weinberger, Tr. 684, 686, 702–03). Oxtoby–Smith's field director prepared written instructions for the interview supervisors (Weinberger, Tr. 689; CX 452Z090–Z092). These supervisors, who did not work exclusively for Oxtoby-Smith, often had been utilized in previous field work done for the firm; the supervisors selected the interviewers (Weinberger, Tr. 693).

In-house coding and keypunching allowed for close supervision by Oxtoby-Smith (Weinberger, Tr. 684, 697–98, 699). The tabulation of the data was done by an outside computer firm. CX 1058 contains the tabulations for this study (Weinberger, Tr. 701).

Methodology: The questionnaire was pretested (Weinberger, Tr. 687).

Interviews were conducted in 21 cities selected for geographic dispersion and intended to be representative of the national distribution of city populations (CX 451Z085; CX 452Z088). The study was conducted among 1,509 respondents, divided equally by sex (CX 451Z084). Quotas were set for the following groups: [2]

(1) Heavy users, defined as those who took six or more pain relievers for headache in the two-week period prior to the interview and representing users of each of the four leading brands (Anacin, Bayer, Bufferin and Excedrin) as well as a group to represent users of non-leading brands. Excluded from this heavy user group were those who took pills for problems other than headache; took more pills for arthritis than for headache; or use an effervescent tablet as their regular brand.

(2) Light users, defined as those who took at least one pain reliever for headache in the month preceding the interview.

(CX 451Z084; Weinberger, Tr. 687–89).

Interviews were conducted on a door-to-door basis (CX 451Z086; CX 452Z087) during days, evenings and Saturdays so as to find working persons and persons of both sexes at home (CX 452Z090). Interview supervisors developed routes that were assigned to the interviewers. If the appropriate person in a household were not available, the interviewer was instructed to proceed to the next household. Call-backs (in the event no one was home) were not

made (Weinberger, Tr. 695). Thus, the sample selection was not shown to have been based on principles of accepted statistical sampling that assure representativeness and projectability of the sample.

There is no indication of the interview refusal rate.

Interviewers utilized a written questionnaire, with detailed instructions, on which they recorded the responses of those interviewed (CX 452Z090–Z108).

The interview supervisors validated, by telephone, 15% of the interviews completed in their area. Oxtoby-Smith also validated 15% of the completed interviews, with 5% overlapping the 15% that had been validated by the interview supervisors. If validation revealed that an interview was not conducted, then all of that interviewer's work would be validated and possibly thrown out (Weinberger, Tr. 696–97; CX 451Z086). [3]

CX 452 – *A Follow-Up Study Of Attitudes Toward Headaches And Analgesics Among Heavy Users Of Leading Brands*

CX 452 was designed as a follow-up study to CX 451 and was developed to explore whether there had been significant shifts in public sentiment toward the leading analgesic products (CX 452D–E). The description and statement of methodology provided for CX 451 (Appendix I, pp. 1–2) are applicable to this study as well and are incorporated herein unless otherwise stated.

Date of Study: Interviewing took place during the week starting July 6, 1970 (CX 452Z088).

CX 1059 contains the tabulations for this study (Weinberger, Tr. 701).

Methodology: The study was conducted among 759 respondents, divided equally by sex (CX 452Z087–Z088).

In addition to the four leading brands included in CX 451 (Anacin, Bayer, Bufferin and Excedrin), users of Alka-Seltzer were also included in this study (CX 452Z087–Z088). The results for light users were tabulated for this study as well as for CX 451 (Weinberger, Tr. 691–92).

Approximately three-fourths of the items in each individual question in CX 451 were repeated in CX 452 (Weinberger, Tr. 706).

CX 453 – *Headache Remedy/Pain Reliever Product Usage And Advertising Penetration*

Client: Whitehall Laboratories division of American Home.

Purpose: To ascertain current advertising penetration[2] levels of Anacin, Bayer, Bufferin, Excedrin and Tylenol (CX 453C).

Date of Study: Interviewing was done between March 19 and April 9, 1973 (CX 453D).

Background of Researchers: The study was conducted by Sobel-Chaikin Research Associates, an independent market research organization, in cooperation with American Home [4](CX 453D). Mr. Charles Sobel had primary responsibility for the study (Sobel, JTr. 462). Mr. Sobel has had extensive experience in the design and execution of consumer research, with almost all of his work involving advertising penetration (Sobel, JTr. 448–53, 455).

Sobel-Chaikin selected the interview supervisors based on prior experience; the supervisors selected the actual interviewers. Both supervisors and interviewers were given detailed instructions (Sobel, JTr. 472).

In-house coding (Sobel, JTr. 483–85) and in-house data processing (Sobel, JTr. 485–86) allowed for supervision by Sobel-Chaikin.

Methodology: There was no pretesting of the questionnaire, but the questions had been used before (Sobel, JTr. 464).

The survey covered 10 market cities (Sobel, JTr. 465; CX 453C).

The 500-person sample, evenly divided by sex (Sobel, JTr. 465–66), is not statistically projectable (Sobel, JTr. 557–58). The survey population was randomly selected from listed telephone numbers (Sobel, JTr. 466–69).

Interviewers recorded responses from the phone interviews on call record sheets; no call-backs were made (Sobel, JTr. 469–70). The interview refusal rate was not tabulated.

The survey was limited to users of headache remedies or pain relievers who had taken such medications in the 30 days prior to the interview (Sobel, JTr. 474).

The survey only reports responses that were given by more than eight respondents (Sobel, JTr. 524–27).

Respondents were asked about their recall of brands on an unaided basis first and, then, on an aided basis (Sobel, JTr. 505).

Interview supervisors performed some of the validation and revalidation of the interviews; Sobel-Chaikin contracted with an outside research firm for 10 to 15% of the revalidation (Sobel, JTr. 477–81). This process served to reduce bias since the outside firm had

[2] See F. 488, *supra*, for the meaning attributed to the term, "advertising penetration," in this proceeding.

no interest in whether or not the interviews were properly conducted. [5]

CX 454 – *Assets And Liabilities Study Of Adult Analgesics*

Client: Glenbrook Laboratories, division of Sterling Drug.

Purpose: To provide assets and liabilities profiles for Bayer Aspirin and other leading analgesic products in the context of consumers' images of the products (CX 454C).

Date of Study: Interviewing took place during the first half of July 1967 (CX 454E).

Background of Researchers: The study was conducted by the research department of Dancer-Fitzgerald-Sample, Inc., an advertising and market research organization, with Mr. Lloyd C. Miller in charge (Miller, JTr. 209–10). Mr. Miller was responsible for the design and analysis of the study. The field work was subcontracted out to Crossley Surveys, an organization that designs and conducts surveys on consumer products, with Mr. Franklin B. Leonard in charge (Leonard, JTr. 83, 85–87). Mr. Leonard was responsible for selecting the sample, conducting the interviews and coding the results (Leonard, JTr. 89, 119–20). Both Mr. Leonard and Mr. Miller have extensive experience in consumer market research (Leonard, JTr. 83–86; Miller, JTr. 206–09).

The interview supervisors were carefully chosen by Crossley. They were constantly monitored, trained and provided with detailed instructions. The interviewers, selected by Crossley as well as by the supervisors, were also carefully trained and instructed (Leonard, JTr. 105–13). Crossley did the editing and coding, while the tabulations were farmed out to another organization (Leonard, JTr. 118).

Methodology: The questionnaire was not pretested inasmuch as many of questions, as well as the technique utilized, were taken from a 1963 study (Leonard, JTr. 94–95).

Personal in-home interviews were conducted of 605 analgesic users, geographically and economically dispersed throughout the country. A sex quota of an even distribution of males and females was imposed (CX 454E, Z156–Z157). The selection of the sample, termed a multistage stratified area sample, was done in several steps. It involved going from 35 primary sampling units to minor civil divisions, to blocks, to households and, finally, to one individual within a household. This systematic selection of the sample, intended

to be representative of the U.S. population in terms of 4 geographic regions and in terms of 3 sizes of standard metropolitan statistical areas and one size of all nonmetropolitan areas, resulted in about 15 to 20 interviews per sampling unit (Leonard, JTr. 95–99). The interviewers were instructed to proceed from a random starting point and travel in a specified direction; such instructions [6]were provided by Crossley, and removed as much discretion from the interviewers as possible (Leonard, JTr. 99–100). The sample, however, was not a straight probability sample and the results are not statistically projectable to the entire country (Leonard, JTr. 127–28; Miller, JTr. 261).

Call-backs were not made. The interval refusal rate was not tabulated (Leonard, JTr. 114; Miller, JTr. 260).

After a respondent was qualified as an analgesics user, a questionnaire and booklet technique was utilized to elicit the respondent's image of seven brands of analgesics (Leonard, JTr. 89–90; CX 454F). The respondents were given a notebook of 31 pages, each page containing a positive statement relating to an attribute associated with analgesics at the top and a negative statement at the bottom; they were asked to place a card for each of the seven brands into one of six pockets running from top to bottom and, thereby, to express an attitude about each brand for each attribute (Leonard, JTr. 90, 91; Miller, JTr. 215–16; CX 454D, Z155). There was an absence of a precise differentiation between the middle ranges of the six-point rating scale; whether such a middle rating indicated one or another meaning or no meaning at all could not be ascertained (Leonard, JTr. 139–41). Only the top and the two bottom gradations on the rating scale were used in the analysis with the other three ignored (Miller, JTr. 243–47, CX 454Z155). Persons who gave the same rating to all brands were classified as non-discriminators and were reported separately in the tabulations (CX 454Z155–Z156). Once the notebook part of the survey was completed, several questions relating to usage and awareness of analgesic brands were asked (CX 454D). The interviewers were required to carefully transfer the results of each interview from the notebook to a recording sheet (CX 454Z155; Leonard, JTr. 131–32).

Validation was done by the interview supervisors. Crossley also validated about 15% of the interviews, and Dancer-Fitzgerald-Sample validated an additional 10% on top of that (Leonard, JTr. 109, 115; Miller, JTr. 229–30).

CX 455 and 456 – *A Study of Vanquish's Market Opportunities*

Client: Glenbrook Laboratories, division of Sterling Drug (Pernica, JTr. 1893).

Purpose: To provide a market segmentation study, which divided consumers into groups based upon their motivations and needs with regard to analgesics; to assess the performance of Vanquish and to evaluate how it fitted into the analgesics market from a motivational perspective at the date of the study (Fishman, JTr. 1288; Pernica, JTr. 1891–92; CX 455E). [7]

Date of Study: November 1970 (CX 455B).

Background of Researchers: The study was conducted by Benton and Bowles, an advertising agency, with Mr. Joseph Pernica in charge (Pernica, JTr. 1891). Mr. Pernica was responsible for developing the methodology, study design, questionnaire, overseeing the execution of the study and reporting the results (Pernica, JTr. 1893, 1933–34). The field work was subcontracted to Lieberman Research, West, with Mr. Arnold Fishman, president of the firm, in charge (Fishman, JTr. 1281; Pernica, JTr. 1891). Mr. Fishman was responsible for carrying out the interviewing, coding and tabulations (Pernica, JTr. 1896). Both Mr. Fishman and Mr. Pernica have extensive experience in the area of consumer market research (Fishman, JTr. 1284–85; Pernica, JTr. 1887–90).

Area supervisors were selected by Mr. Fishman on the basis of past performance. The supervisors selected the interviewers. The supervisors and interviewers were provided with written instructions (Fishman, JTr. 1301–03).

Mr. Fishman's firm did the coding (Fishman, JTr. 1320–21), with Mr. Pernica involved in the approval of the codes used (Pernica, JTr. 1929). Mr. Fishman subcontracted out the keypunching and tabulations to Dataprobe (Fishman, JTr. 1321; Pernica, JTr. 1929–30).

Methodology: The questionnaire was pretested (Fishman, JTr. 1296; Pernica, JTr. 1898).

Personal in-home interviews of 827 analgesics users formed the basic sample, with an additional supplementary sample of 186 Vanquish users interviewed (CX 455F). Those respondents selected for the basic sample were from cities in "heavy-up advertising regions" of the Mid-Atlantic and West Coast; these were regions where the greatest amount of advertising dollars for Vanquish had been spent (CX 455F; Pernica, JTr. 1988–89). The basic sample was subject to a quota of 50% males/50% females. The supplementary sample came from high Vanquish share cities and was not subject to

a sex quota (CX 455F). The basic sample came from eight cities, with the intention of obtaining 100 respondents from each of the markets (Fishman, JTr. 1336, 1392; CX 455F). No weighting factors were used despite the fact that the same number of respondents was selected from cities of disparate populations (Fishman, JTr. 1397–99; Pernica, JTr. 1989).

The respondents had to be 18 years old or older (CX 455F). The sample was selected randomly. Telephone directories were used to generate initial street addresses; interviewers were instructed to go to the house next to that address and then around the block in sequence so as to control for unlisted telephone numbers (Fishman, JTr. 1298–1300; Pernica, JTr. 1926). [8]

Call-backs were not made in the event a suitable respondent were not at home (Fishman, JTr. 1392). The interview refusal rate was not tabulated.

The order of the brands was rotated in the questionnaire so as to reduce any bias that might be due to the order of presentation (Pernica, JTr. 1898).

The interviews were about 45 minutes in length (Fishman, JTr. 1294).

A six-point rating scale containing no neutral step was utilized. The sum of the two top ratings was reported so as to compress the data; the other four ratings were ignored (Pernica, JTr. 1915–18).

Validation of about 15% of the interviews was done by an outside validation service (Fishman, JTr. 1316–18, 1326).

The study contains a narrowly drawn sample and is not a national probability sample (Fishman, JTr. 1338; Pernica, JTr. 1926). Therefore, it is not statistically projectable to the entire nation (Fishman, JTr. 1357).

CX 457 – *Public Beliefs About Selected Analgesic Products*

Client: Federal Trade Commission (Leavitt, Tr. 1267; Crespi, JTr. 2267–68).

Purpose: To determine whether Anacin, Bufferin and Excedrin are each rated higher than aspirin on four attributes—effectiveness, speed, strength and gentleness (CX 457B and W; Leavitt, Tr. 1278). The study was conducted with the fore-knowledge that it would be used in litigation (Leavitt, Tr. 1270; Crespi, JTr. 2456).

Date of Study: Interviewing was conducted from December 5–10, 1975 (CX 457Q').

Background of Researchers: Dr. Clark Leavitt developed the

questionnaire and performed the analysis (Crespi, JTr. 2268). Dr. Leavitt also decided on the criteria that would be utilized in the field work (Leavitt, Tr. 1276–77). Dr. Irving Crespi, of the Gallup organization, had responsibility for the field work which consisted of conducting, recording, tabulating and coding the interviews as well as punching the results on computer cards and checking for internal consistency (Leavitt, Tr. 1290; Crespi, JTr. 2268). The sample was drawn by Gallup (Leavitt, Tr. 1288). Both Drs. Leavitt and Crespi have excellent academic [9]credentials and extensive experience in the design and execution of research surveys (Leavitt, Tr. 1245–55; Crespi, JTr. 2261–67; CX 507A–K; CX 508A–B). Dr. Leavitt was responsible for writing the report (Leavitt, Tr. 1315; CX 457).

The interviewers were regularly employed by Gallup and were given in-house training; they were provided with written instructions (Crespi, JTr. 2288–90).

The coding and keypunching were done by Gallup personnel (Crespi, JTr. 2296–2300).

Methodology: The questionnaire went through evaluation and pretesting stages by Gallup (Leavitt, Tr. 1287; Crespi, JTr. 2269–73).

Telephone interviews, approximately 10 minutes in length each, were completed for 786 persons (Crespi, JTr. 2277, 2296). Data from 780 interviews were sent to Dr. Leavitt (Crespi, JTr. 2387–88). Dr. Leavitt eliminated 17 interviews, leaving 763, because those 17 persons had not heard of one or more of the four brands (Leavitt, Tr. 1299; CX 457D).

The sample was drawn in two stages: first, utilizing current Census Bureau information and random mathematical selection procedures, a systematic sample from a random starting point with a probability of selection proportional to size was generated (Crespi, JTr. 2285–88; CX 457R–S); second, from telephone numbers arrived at in the first stage, and used as starting points, randomly selected digits were added onto the last digit of the telephone number in order to insure a representative proportion of residential listings as well as unlisted numbers (Crespi, JTr. 2282–85; CX 457Q').

The population surveyed was intended to be a national probability sample, representative of residential telephone numbers and projectable to persons 18 years of age or over with telephones (Leavitt, Tr. 1289; Crespi, JTr. 2288; CX 457D, Q').

If no one were at home, one call-back was made (Crespi, JTr. 2293). The interview refusal rate was 21.3%. From the initial sample of 2,020 telephone numbers, there were 445 invalid numbers, leaving 1,575. The interview completion rate was 49.9% (Crespi, JTr. 2294–

96; CX 1053). The interviews were conducted on weekday evenings and on the weekend in order to pick up working people (CX 457Q').

The order of the presentation of the four products (Anacin, Bufferin, Excedrin and Aspirin) was rotated so as to reduce position bias (Crespi, JTr. 2274, 2276; CX 457H). **[10]**

A four-point rating scale, with three positive steps ("extremely," "very" and "fairly") and one negative step ("not"), was used (CX 457D–F). Absolute, rather than comparative, questions were asked (CX 457F–G). There was no pretest regarding the validity of the assumption that the four attributes—effectiveness, speed, strength and gentleness—were important to consumers (Leavitt, Tr. 1333–34, 1337–40).

Approximately 8% of the interviews were validated by the interview supervisors (Crespi, JTr. 2293–94).

CX 462 – *The 1969 Excedrin Study*

Client: Bristol-Myers.

Purpose: To study primary and secondary users of Excedrin, brand image, brand switching, occasions for usage, awareness and advertising penetration, all within the context of Excedrin compared to other analgesics (Rosenbluth, JTr. 2863–64; Randall, JTr. 2986; CX 462J–L).

Date of Study: The field work was conducted from June 6, 1969 through July 20, 1969 (CX 462L).

Background of Researchers: The study was conducted by the research department of Young and Rubicam, an advertising agency, with Mr. Leon Rosenbluth in charge (Rosenbluth, JTr. 2856, 2864). Mr. Rosenbluth engaged Mr. Stanley Randall to analyze the data and write the report (Rosenbluth, JTr. 2870–71; Randall, JTr. 2981). Mr. Randall was the principal author (Randall, JTr. 2983). Grudin Appel, a market research firm, was chosen to conduct the interviews, draw the sample, and do the coding and tabulating (Rosenbluth, JTr. 2865, 2868; Nudorf, JTr. 2901); Mr. H. William Nudorf was in charge (Nudorf, JTr. 2900, 2902). Each of these individuals, and their respective companies, has extensive experience in the consumer market research field (Rosenbluth, JTr. 2855–62, 2868, 2871–73; Nudorf, JTr. 2900–01; Randall, JTr. 2978–80).

Mr. Nudorf personally selected the interview supervisors on the basis of experience. The supervisors selected the interviewers (Nudorf, JTr. 2946–47). Detailed written instructions were provided for the interviewers (Nudorf, JTr. 2906–07, 2913, 2922–31).

Grudin Appel did the coding (Nudorf, JTr. 2951). They subcontracted the tabulation to Donovan Data, a well-qualified data processing firm (Rosenbluth, JTr. 2868–69; Nudorf, JTr. 2952). [11]

Methodology: The questionnaire was put through limited pretesting to assure its utility for field work (Nudorf, JTr. 2909).

Personal, in-home interviews of 1,045 male and female analgesic users, 18 years of age or older, were conducted (CX 462L). The sample was arrived at through the use of Census Bureau information, telephone directories to generate initial addresses and mathematical and random selection of households to be interviewed (Nudorf, JTr. 2932–44, 2963–65). The study was conducted in Nielsen A and B counties which were where Excedrin had its highest market shares; these are urbanized, major metropolitan areas and make up about 66% of the country (Nudorf, JTr. 2932; Randall, JTr. 2986). Sixty geographically dispersed sampling points were used (CX 462L). In order to obtain a sufficient base of Excedrin primary and secondary users for analysis, other analgesic users were intentionally undersampled. Subsequently, the sample was statistically weighted so as to represent the population of A and B counties, yielding a total weighted sample of 1926 interviews (Randall, JTr. 2987–89; CX 462L). The resultant sample of 1926 respondents is projectable to A and B counties (that is, to urbanized metropolitan areas) (Nudorf, JTr. 2944–45; Randall, JTr. 2988, 3024, 3026–27).

Each interview ran about 50 minutes (Nudorf, JTr. 2931). The responses were recorded by the interviewers on worksheets that allowed for validation as to whether the interviewer was following the prescribed sampling procedure (Nudorf, JTr. 2943). Anyone in a household, 18 years of age or older, qualified as a respondent (Nudorf, JTr. 2966). Interviewers worked evenings and on weekends so as to pick up working people (Nudorf, JTr. 2967). There was provision for call-backs in the event no one was at home (Randall, JTr. 2987). The interview refusal rate was not tabulated.

The four brands—Anacin, Bayer, Bufferin and Excedrin—had their order of presentation rotated so as to reduce position bias (Nudorf, JTr. 2928–29).

The interview supervisors validated a portion of the interviews (Nudorf, JTr. 2948–49). Grudin Appel checked the sampling points against maps. If a discrepancy arose, then 5–20% of that interviewer's work was validated (Nudorf, JTr. 2949–50). Mr. Randall spot-checked some questionnaires, coding and tabulations (Randall, JTr. 2991–93); he excluded any data that he felt was unreliable (Randall, JTr. 2996–97). [12]

CX 467 – *Consumer Use of Headache Remedies And Knowledge Of Their Ingredients*

Client: Bristol-Myers.

Purpose: As stated in title, for Anacin, Bayer and Bufferin (CX 467C).

Date of Study: Interviewing was conducted in May 1964 (CX 467D).

Background of Researchers: The study was conducted by the Gallup Organization, with Dr. Irving Crespi in charge (Crespi, JTr. 2314, 2316–20). Dr. Crespi has excellent academic credentials and extensive experience in the design and execution of research surveys (Crespi, JTr. 2261–67; CX 508A–B).

The interviewers were regularly employed and directly supervised by Gallup; they were provided with written instructions (Crespi, JTr. 2327–29).

The coding and keypunching were done by Gallup; checking and verification were done by Gallup supervisors (Crespi, JTr. 2296–2300, 2330). The tabulation of the data was done by an outside computer service (Crespi, JTr. 2331–32).

Methodology: The questionnaire was pretested (Crespi, JTr. 2324).

Personal interviews of 1607 persons were conducted (Crespi, JTr. 2327; CX 467D). Allowance for persons not at home was made by incorporating a "times-at-home" weighting to all results, rather than by call-backs (CX 467R). The interview refusal rate was not tabulated.

The interviewers recorded respondents' answers in check boxes for closed-ended questions (Crespi, JTr. 2329). Five questions out of nine were open-ended, requiring the interviewers to record verbatim answers (CX 467C–D; Crespi, JTr. 2329–30).

Twenty to thirty percent of the interviews were validated by sending postcards to respondents (Crespi, JTr. 2330–31).

The order of questioning about each of the brands was rotated to control for any bias that might be due to the order of presentation (CX 467C–D).

The sample was intended to be a national probability sample down to the block level in urban areas and down to segments of townships in rural areas. Based upon Census Bureau data and random mathematical selection procedures, 150 different sampling areas were selected—technically, this is known as a systematic sample from a random starting point with probability proportional [13]to size. This sampling procedure should produce a sample representa-

tive of the adult population, 21 years of age or older, living in private households in the United States. The sample is designed to be statistically projectable to that portion of the total population (Crespi, JTr. 2326–27, 2285–88; CX 467S).

CX 468 – *Pain Reliever Telephone Study*

Client: Bristol-Myers.

Purpose: Unstated; presumably, to assess usage of and awareness of ingredients in non-prescription analgesics, focusing on users of Bufferin and Excedrin (*See* questionnaire at CX 468Z019–Z021).

Date of Study: Interviewing was conducted during the week of July 10, 1972 (CX 468C).

Background of Researchers: The study was conducted by Edward Blank Research, Inc., a market research firm (Blank, JTr. 2657–58, 2664). Mr. Edward Blank, president of the firm (Blank, JTr. 2657), has had ample experience in conducting market research surveys (Blank, JTr. 2658–63).

The field work was conducted by local interviewers who were selected by interview supervisors. The supervisors were chosen by Mr. Blank on the basis of past performance or recommendations (Blank, JTr. 2670). Both the supervisors and interviewers were provided with rudimentary written instructions (Blank, JTr. 2671–73. *See* also questionnaire at CX 468Z019–021).

Mr. Blank's firm did the coding (Blank, JTr. 2676–77). The processing and tabulations of the data were subcontracted out to Datatab. Datatab checked the coding for errors (Blank, JTr. 2678–80).

There was no analysis done of the data in CX 468 (Blank, JTr. 2681).

Methodology: The questionnaire was not pretested (Blank, JTr. 2668).

The interviews were conducted by telephone (Blank, JTr. 2666). No call-backs were made if a suitable respondent were not home. The interview completion rate was not tabulated (Blank, JTr. 2673).

The sample size was 500 interviews, 100 in each of five markets (New York, Atlanta, Chicago, Denver and San Francisco), with a quota of 40% males/60% females, regardless of their use of analgesics. 499 interviews were completed (Blank, JTr. 2665; CX 468C). The sample was systematically selected in a random [14] fashion from telephone directories (Blank, JTr. 2668–70); only listed

telephone numbers were called (Blank, JTr. 2689). The respondents had to be 18 years of age or older (Blank, JTr. 2673). The survey population is not statistically projectable to the entire country nor, in the case of the New York market, is it projectable to that entire city (Blank, JTr. 2685–86).

The interviewers and supervisors were responsible for selecting the sample (Blank, JTr. 2671–73).

There was rotation of the order of the brands in the questionnaire so as to reduce position bias (Blank, JTr. 2667).

Validation of approximately 15% of the interviews was done by an independent Watts company. Validation was done by telephone and was limited to verifying that an interview had taken place (Blank, JTr. 2674–76).

CX 477 – *Advertising Penetration Study*

Client: Bristol-Myers.

Purpose: To assess the penetration of two ideas in the "Glass Men" advertising campaign (for Bufferin)—"faster to your headache" and "gentler to your stomach" (Weitz, JTr. 911; CX 477C).

Date of Study: Interviewing was conducted in April 1971 (CX 477C).

Background of Researchers: The study was conducted by the research department of Ted Bates and Co., utilizing the services of Valley Forge Information Services ("Valley Forge"). Both Mr. Kenneth Frato, for Valley Forge, and Ms. Anne Weitz, for Ted Bates, have had extensive experience in working with consumer surveys (Frato, JTr. 717–18; Weitz, JTr. 807, 810).

The interviewers were employees of Valley Forge, thereby assuring a degree of control and supervision over the manner in which the interviews were conducted (Frato, JTr. 723). The coding and tabulation were done by Ted Bates (Weitz, JTr. 823, 826; CX 477C).

Methodology: The questionnaire was pretested (Frato, JTr. 727).

The interviews took place over the telephone (Frato, JTr. 721). As each telephone interview was taking place it could be monitored by a supervisor (Frato, JTr. 742), thereby eliminating the need for validation (Frato, JTr. 746). **[15]**

The interviewers recorded responses on call record sheets (Frato, JTr. 753). There was provision for up to two call-backs to be made (Frato, JTr. 744). The interview refusal rate was not tabulated.

Where respondents gave general answers to a question, the

367-444 O - 82 - 24 : QL 3

interviewer would follow-up with questions of a probing nature which tended to elicit responses (Frato, JTr. 729–31).

The survey population was intended to represent a national probability sample. Telephone numbers were randomly selected on a systematic basis from United States phone books; there were 100 sampling points across the country (Frato, JTr. 736–39, 750, 753–54; CX 477Z004). The sample was 70% female, 30% male, according to the assigned quota (Weitz, JTr. 887–89). The respondents had to be 18 years of age or older (CX 477Z004). The sample consisted of 1,004 individuals, but 125 West Coast residents were excluded (resulting in a sample of 879) because that part of the country was a test area for Bufferin and Excedrin (CX 477C). Thus, the projectability of the survey was limited to persons over 18 years of age, with listed telephone numbers, who did not reside on the West Coast (Frato, JTr. 755; Weitz, JTr. 931–32).

Opinion of the Commission

By Pertschuk, *Commissioner:*

Aspirin: homey, familiar, time-tested aspirin has long been an honored staple in the American family's arsenal against common maladies. So homey is this ingredient that it evokes no aura of mystery or magic, though indeed its therapeutic properties are significant; so familiar that the firm that pioneered its development was stripped of its trademark in private litigation 60 years ago;[1] so commonplace that a maker of one aspirin-based pain reliever seeking to differentiate its product from the rest faces a formidable marketing task. What better way to meet this challenge than to establish a new identity for the product, dissociated from ordinary aspirin, and then to represent it as special and more effective than its competitors? That effort may solve the marketer's marketing problem—but if the representations of specialness and superiority are not adequately supported, they can be, simply put, deceptive. That is the heart of the case before us.

At issue is the lawfulness of advertising claims made for Anacin and Arthritis Pain Formula (APF), two over-the-counter (nonprescription, or "OTC") aspirin-based analgesic (pain relief) products.[2] The Commission's complaint, issued on February 23, 1973 [2]against American Home Products Corporation (AHP) and Clyne Maxon, Inc. (Clyne), AHP's advertising agency for APF, charged that the respondents had violated Sections 5 and 12 of the Federal Trade

[1] *Bayer Co.* v. *United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921).

[2] Anacin's active ingredients are aspirin and caffeine; APF's are aspirin and two antacids. See *infra*, p. 5.

Commission Act (15 U.S.C. 45, 52) in making certain advertising claims as to the efficacy, freedom from side effects, and analgesic content of Anacin and APF. In particular, the complaint alleged that AHP advertised Anacin and APF without disclosing that the analgesic ingredient in these products is ordinary aspirin (Complaint ¶ 22), and that AHP had, directly or by implication, made the following claims, which were alleged to be false, deceptive or unfair:

(1) the analgesic ingredient in Anacin and APF is unusual, special, and stronger than aspirin (Comp. ¶ 8(A)(2) and 8(B)(1));

(2) Anacin contains more pain-relieving ingredients per tablet than any other over-the-counter internal analgesic (Comp. ¶ 8(A)(1)), and more than twice as much of its analgesic ingredient as any other analgesic product (Comp. ¶ 8(A)(3));

(3) a recommended dose of Anacin is more effective for the relief of pain than a recommended dose of any other OTC internal analgesic (Comp. ¶ 12(A));

(4) it has been established, or proved by scientific tests or studies by experts qualified by scientific training, that Anacin is more effective than any other OTC analgesic for the relief of headache pain (Comp. ¶ 10(A)), and as effective for the relief of such pain as the leading prescription analgesic (Comp. ¶ 17);

(5) within approximately 22 seconds after taking Anacin a person may expect relief from headache pain (Comp. ¶ 8(A)(4));

(6) Anacin relieves nervousness, tension, stress, fatigue, and depression and will enable persons to cope with the ordinary stresses of life (Comp. ¶ 15);

(7) doctors prefer and recommend Anacin for the treatment of headache pain over any other OTC internal analgesic (Comp.¶ 20);

(8) APF causes gastric discomfort less frequently than any other OTC internal analgesic (Comp. ¶ 10(B)); and its freedom from such side effects has been established (Comp. ¶ 12(B)); and

(9) APF will eliminate all pain, stiffness, and discomfort usually experienced by arthritis sufferers in the morning (Comp. ¶ 8(B)(2)). **[3]**

AHP's advertising agency, Clyne, was charged with responsibility only for the claims relating to APF.

Hearings were held before Administrative Law Judge (ALJ) Montgomery K. Hyun, who rendered an initial decision finding against respondent AHP on all allegations of the complaint except that concerning the noncomparative efficacy claim for APF (Comp. ¶8(B)(2)). The charges against Clyne were dismissed with the

exception of that relating to APF's unusual ingredient claim (Comp. ¶8(B)(1)).

Judge Hyun's order would require AHP to disclose the presence of aspirin in any OTC drug advertisement, and to disclose the presence of any commonly known ingredient in Anacin, APF or any other OTC drug product when an advertisement refers to common ingredients directly or by implication. It would also prohibit false claims that an ingredient is unusual. The order would set certain standards for comparative efficacy or side effects claims for OTC drug products: claims that the superiority of such a product has been established would be required to be supported by at least two adequate clinical tests, and other comparative ads would be required to disclose that the claims have not been proven. Misrepresentations of test or survey results would be prohibited.

The order would also bar AHP from making tension relief claims for Anacin, unsubstantiated claims that AHP's products will relieve headache pain in any period of time, and any other noncomparative efficacy or safety claim for an OTC analgesic without reliable scientific evidence. The ALJ's order would also require AHP to include in all Anacin advertising the statement "Anacin is not a tension reliever" until a sum equal to the average annual Anacin advertising budget for a certain period of years has been spent. Finally, it would prohibit Clyne from falsely representing that APF, or any other OTC analgesic, contains an unusual ingredient.

The matter is before the Commission on the appeals of respondents and complaint counsel from the initial decision and order. Respondents' principal contentions on appeal are that (1) the ALJ erred in finding that certain of the representations alleged in the complaint were made in AHP's advertising; (2) the clinical testing standard imposed by the ALJ's order for comparative claims is without support in the record; (3) the principal advertising claims are supported by adequate medical and scientific evidence; and (4) the provisions of the order are overbroad, unsupported by the record, or in violation of respondents' First Amendment rights. Complaint counsel take exception to the ALJ's failure to order corrective advertising to remedy asserted lingering effects of AHP's comparative efficacy claims for Anacin, as well as his decision not to impose liability on Clyne for all APF claims. In all other respects, complaint counsel argue in support of the ALJ's findings and conclusions. [4]

As this overview indicates, the allegations in this case primarily charge respondents with conveying the superiority of Anacin and APF over competing analgesics through a variety of allegedly misleading techniques. They are alleged to have used false claims,

deceptive omissions of material fact, and claims which were neither substantiated by the methods of proof required in the relevant scientific community nor adequately qualified to reveal the lack of such proof. In our discussion below, we will review each alleged claim or omission in turn, to determine first whether the alleged representation was made and then whether it is false, deceptive or unfair within the meaning of the FTC Act. The comparative claims will be discussed first, and then the noncomparative claims which were also challenged in the complaint.[3] **[5]**

I. *"Unusual Ingredient" Claims; Failure To Disclose Aspirin*[4]

The ALJ sustained the allegations of the complaint charging respondents with claiming falsely that the analgesic ingredient in Anacin and APF is unusual, special and stronger than aspirin (Comp. ¶ 8(A)(2) and 8(B)(1)), and with failing to disclose that the analgesic ingredient in these products is ordinary aspirin (¶ 22). AHP appeals these findings.

We note first the relevant factual background. The only analgesic ingredient in either Anacin or APF is aspirin. F.F. 387, 391. The active ingredients in Anacin are aspirin (400 mg. per tablet) and caffeine (32.5 mg.). The active ingredients in APF are microfine (micronized) aspirin (486 mg. per tablet) and two antacids (dried aluminum hydroxide gel (20.14 mg.) and magnesium hydroxide (60.42 mg.). F.F. 11, 14. Aspirin is a commonplace substance, available in many products. F. 387. Indeed, with almost 19 billion dosage units sold annually, it is the most widely used analgesic in the United States. F. 14. There can thus be no doubt about the falsity of any advertisements representing the analgesic ingredient in Anacin or APF to be unusual, special, or stronger than aspirin.[5]

[3] The following abbreviations are used in this opinion:

F.	–	Initial Decision, Finding No.
I.D. p.	–	Initial Decision, Page No.
CX	–	Complaint Counsel's Exhibit No.
RX	–	Respondent's Exhibit No.
Tr.	–	Transcript of Testimony, Page No.
TROA	–	Transcript of Oral Argument Before Commission
R.A.B.	–	Respondent's (AHP's) Appeal Brief
C.C.A.B.	–	Complaint Counsel's Appeal Brief

[4] Respondents presented several arguments on appeal concerning the ALJ's methods of determining the meanings conveyed by the challenged advertisements. We have addressed those arguments fully in the Appendix attached to this opinion.

[5] As a federal court has commented, "A claim of superior analgesia for Anacin compared to [aspirin] would be nonsensical since the only analgesic ingredient in Anacin is [aspirin]." *American Home Products Corp.* v. *Johnson & Johnson*, 436 F. Supp. 785, 801 (S.D.N.Y. 1977), *aff'd*, 577 F.2d 160 (2d Cir. 1978).

While respondents do not contest the finding that such claims are false, AHP argues on appeal that its advertising did not represent Anacin's and APF's analgesic ingredient to be unusual, special, and stronger than regular aspirin. We believe the ALJ's finding that these claims were made is amply supported by the advertisements themselves as well as by expert testimony (F.F. 85–98, 171–77).

The advertising campaign for these products consisted of an attempt to differentiate them from ordinary aspirin, as respondents' witness testified (Smith, Tr. 7550–51). Indeed, that was the company's objective, according to Mr. DeMott, the president of AHP's Whitehall Laboratories Division, who had responsibility [6]for advertising and marketing of Anacin (DeMott, Tr. 4659). On the basis of the small actual differences in formulation between the Anacin (and APF) compounds and plain aspirin, respondents' advertisements have created an impression that the products are based on some special, unusually strong pain reliever entirely different from and superior to aspirin. Whenever aspirin is named in the Anacin ads, it is used in such a way to contrast it with Anacin and associate it with Anacin's competitors. None of the challenged Anacin advertisements discloses that the analgesic ingredient in Anacin itself is, in fact, aspirin; instead, the identity of Anacin's ingredient is in every single instance obscured with phrases like "the pain reliever doctors recommend most" and "this specific fast acting ingredient against pain."

For example, in one series of advertisements it is claimed:

> Anacin starts with as much pain reliever as the leading aspirin tablet. Then adds an extra core of this specific fast-acting ingredient against pain (CX 41A-45A).

In this series a scale is shown, with one side labeled "ANACIN TABLET" and the other "ASPIRIN TABLET." Other advertisements claim:

> ● Anacin isn't just like an ordinary aspirin tablet. It has more of the drug doctors themselves most choose to relieve pain (CX 173);
>
> ● anacin rushes to your head more pain reliever than the leading aspirin tablet * * * more than the leading buffered aspirin tablet * * * more of the pain reliever doctors recommend most (CX 46A);
>
> ● Anacin tablets are so effective because they are like a doctor's prescription. That is, a combination of ingredients. Anacin contains the pain reliever most recommended by doctors plus an extra active ingredient not found in leading buffered aspirin * * *. The big difference in Anacin makes a difference in the way you feel (CX 151).

The strained syntax of many of the advertisements (*e.g.*, CX 41–45A)—in which the references to Anacin's analgesic ingredient do

not appear to relate back to the word "aspirin"—fosters the impression that Anacin contains something other than [7]aspirin (Ross, Tr. 1891–92). The clear import of these advertisements is that the analgesic ingredient in Anacin is something other than aspirin (Ross, Tr. 1880, 1882, 1896).[6]

In addition, in many of the advertisements, Anacin is described as an "exceptional" (CX 26A, 28A) or "special fortified" formula (CX 89, 93–94, 115–17, 142–44, 146, 154–56), or as containing "an extra active ingredient not found in leading aspirin or buffered aspirin tablets" (CX 151). The record shows that consumers would reasonably have understood such claims to refer to an analgesic ingredient, and therefore to mean either that Anacin contains no aspirin, or that it contains something in addition to aspirin which significantly contributes to the analgesic function of the product (Ross, Tr. 1892–96; CX 404 at p. 37).

The challenged APF advertisements (CX 201–07, 210, 217–18) make similar claims by the same techniques. Through statements specifically contrasting APF's analgesic ingredient with aspirin (*e.g.*, CX 201, 203–07, 210), and representations about the "specialness" of its formulation, (*e.g.*, CX 210, 217–18,), respondents' advertising suggested that the analgesic ingredient in APF was something other than aspirin (Ross, Tr. 2303–05).

The combination of affirmative misrepresentations and consistent failure to identify the actual analgesic ingredient in Anacin and APF not only implies that something other than aspirin distinguishes AHP's products, but also has a capacity to cause consumers to believe the products do not contain any aspirin. Expert testimony in the record indicates that respondents' ads are likely to mislead consumers in this manner (*e.g.*, Ross, Tr. 1880–83, 1892–3, 1896, 2303–5). Other evidence, including testimony of experts on both sides as well as several consumer surveys, shows that a significant proportion of consumers is in fact unaware that Anacin contains aspirin. (See generally F. 402, 457–464, and CX 451, CX 452, CX 468, Shapiro, Tr. 2989–5; Moertel, Tr. 985; Stevenson Tr. 1509.) [8]

In light of these findings, we conclude that respondents' representations about the analgesic ingredient in Anacin and APF, and, in

[6] Dr. Smith, respondents' expert on advertising interpretation, stated that some consumers would have understood ads such as CX 41 and CX 173 to mean that Anacin's analgesic ingredient is something other than aspirin (Smith, Tr. 7551–53, 7557–58), although in his view the image and penetration data and the ASI studies tend to show that the representation alleged was not conveyed. As we discuss in the Appendix to this opinion, the image and penetration data provide little guidance on the meaning of the specific ads we have before us. Moreover, in our view, ASI copy tests conducted on the "extra core" ads provide confirmatory evidence of the ALJ's findings. See CX 421 at pp. 28, 30–33, 35–36, CX 422 at pp. 27, 29–30, 33, 34.

the context of these representations the failure to disclose the presence of aspirin, had a capacity to mislead consumers.[7] A misleading claim or omission in advertising will violate Section 5 or Section 12, however, only if the omitted information would be a material factor in the consumer's decision to purchase the product. *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965). Section 15 provides that an omission may be material "in the light of representations made or suggested . . . or material with respect to consequences which may result from the use" of the product.

There can be little doubt about the materiality to buyers of Anacin and APF of the fact that the unnamed analgesic ingredient is ordinary aspirin, in light of the representations made and suggested in the ads that the substance is unusual and special, described above. The very fact that AHP sought to distinguish its products from aspirin strongly implies that knowledge of the true ingredients of those products would be material to purchasers. In addition, the actual identity of the ingredient takes on particular significance due to the potentially serious consequences which may result from aspirin consumption, demonstrated by the record here. Aspirin may cause adverse side effects such as dyspepsia for some individuals (Grossman, Tr. 828; Plotz, Tr. 1044). For others, including asthmatics, a dangerous allergic reaction to aspirin is possible. (Falliers, Tr. 3187; Moertel, Tr. 1012; Stevenson, Tr. 1474). The Report for OTC Internal Analgesics (CX 367) of the Food and Drug Administration's (FDA) advisory review panel (a panel of outside experts established by FDA to review the safety and efficacy of OTC drugs)[8] summarizes the possible adverse side effects of aspirin, which range from massive gastrointestinal bleeding (which may be fatal) to hepatic (liver) [9] dysfunctions (CX 367014).[9] For example, aspirin may interfere with

[7] It has long been held that deception can occur by material omission as well as affirmative statement. See, *e.g.*, *Porter & Dietsch, Inc.* v. *FTC*, 605 F.2d 294 (7th Cir. 1979), *cert. denied* 445 U.S. 950 (1980); *Simeon Management Corp.* v. *FTC*, 579 F.2d 1137, 1146 (9th Cir. 1978); *J.B. Williams Co.* v. *FTC*, 381 F.2d 884 (6th Cir. 1967). Section 15 of the FTC Act, 15 U.S.C. 55, specifically provides that a drug advertisement may be false under Section 12 for a misleading failure to reveal material facts.

[8] For a more complete discussion of FDA's regulatory scheme, see *infra* at 20–24.

[9] Respondents' objections to the admission into evidence of the FDA Panel Reports (CX 366 and CX 367), R.A.B. at 25 n.**, are without merit. AHP contends that the reports are inadmissible because they are hearsay and are preliminary documents subject to revision. It has long been acknowledged, however, that "administrative agencies like the Federal Trade Commission have never been restricted by the rigid rules of evidence." *FTC* v. *Cement Institute*, 333 U.S. 683, 706 (1948). Under the Commission's Rules of Practice, all relevant and material evidence—whether it is hearsay or not—is admissible, as long as it is reliable. 16 C.F.R. 3.43(b). The information contained in the panel reports is unquestionably material and relevant, and we believe scientific reports prepared by groups of experts for the FDA pursuant to its regulations to be presumptively reliable. Respondent has given us no reason to doubt the trustworthiness of the findings and conclusions of the panels.

Our determination of reliability is bolstered when the exceptions to the hearsay rule are considered. The reports would fall under the well-recognized exception for public records and reports, codified in the Federal Rules of Evidence at Rule 803(8). This exception is premised both on necessity and on the inherent trustworthiness of official records. 4 *Weinstein's Evidence* ¶ 803(8)[01], at 803–189 (1979). Under this exception, and under case law developed prior to the codification of the Federal Rules, records of administrative proceedings have been admitted

(Continued)

normal blood clotting, increase internal bleeding, cause peptic ulcers, increase the incidence of neonatal deaths, depress the central nervous system, and cause anemia. For individuals with aspirin allergies, according to the Report, ingestion of aspirin may result in shortness of breath, laryngeal swelling from anaphylactic shock, blocking of air pathways, and a sudden drop in blood pressure (*id.*). **[10]**

Respondents argue that only a small number of individuals suffer these adverse side effects from aspirin consumption (R.A.B. at 65–67). The ALJ found, however, and we agree, that the number of individuals who may be adversely affected by aspirin is significant. F. 453.[10] We note that the FDA's Internal Analgesics Panel considered the problems associated with aspirin great enough to recommend that the labeling of all products containing aspirin carry an aspirin disclosure.[11] The FDA Panel also stated its agreement with the 1973 resolution of the American Academy of Allergy recommending that advertisements promoting formulations containing aspirin clearly indicate that they contain aspirin. CX 367Z028–29.[12] In addition, the Panel expressed its view that the consumer "needs to be correctly and fully informed" about OTC analgesics, and that advertising of OTC analgesics may not provide adequate warnings about their potential hazards. CX 367L. In this context, the Panel noted that the FDA does not regulate the advertising of OTC drugs, and thus requested that "the proper authority, *i.e.*, the Federal Trade Commission * * * more effectively regulate the commercial advertising of internal analgesic[s] * * * on the basis of the labeling recommendations contained in this document [the Panel's Report]." *Id.*

The ALJ also stated that the presence of aspirin is material "from an economic point of view" (I.D. at pp. 207–08), and complaint counsel argue in support of this proposition on appeal (*e.g.*, Complaint Counsel's Ans. Br. at 65). If the record contained evidence of a significant disparity between the prices of Anacin and plain aspirin, it would form a further basis for a finding of materiality. That is, there is reason to believe consumers are willing to pay a premium for

into evidence by the courts. See Weinstein, *supra* Section 803(8)[03] at 803–202. Moreover, submissions to an administrative agency from an outside person that have become part of the agency's official file have also been admitted. See *Sternberg Dredging Co.* v. *Moran Towing & Transp. Co.*, 196 F.2d 1002, 1004–05 (2d Cir. 1952); Weinstein, *supra*, ¶ 803(8), at 803–197.

[10] For example, two out of every 1,000 hospital admissions were caused by aspirin-related problems (CX 367Z022) and approximately one-eighth of all gastric ulcers are related to aspirin (CX 367Z021).

[11] The recommended disclosure would read, "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have Asthma except under the advice and supervision of a physician." CX 367Z029. See also CX 367(0).

[12] The American College of Allergists passed a similar resolution. Farr, JTr. 2608–12.

a product believed to contain a special analgesic ingredient, but not for a product [11]whose analgesic is ordinary aspirin.[13] The record contains no evidence on comparative prices, however,[14] and our finding of materiality is not based on the suggested economic effects.

Respondents also suggest that the labeling of OTC drugs with their active ingredients provides sufficient notice to the consumer that a product contains aspirin (R.A.B. at 64 n.**). We note first, however, that when the first contact between a seller and buyer occurs through a deceptive advertisement, the law is violated even if the truth is subsequently made known to the purchaser through information on the label. *Carter Products, Inc.* v. *FTC*, 186 F.2d 821 (7th Cir. 1951). The record is replete with evidence, moreover, including the testimony of respondents' own witnesses, that in spite of the fact that aspirin is listed on the label, many consumers are unaware of the aspirin content of Anacin, APF and other OTC drugs (F.464; Shapiro, Tr. 2984–85; Falliers, Tr. 3264; Lasagna, Tr. 4194; Moertel, Tr. 985, 1019). It is for this very reason that the FDA Panel recommended that the FTC regulate advertising of OTC drugs in accordance with the Panel's labeling recommendations (CX 367L). Finally, given that respondents' Anacin and APF advertising implied by omission and affirmative misrepresentations that the products did *not* contain aspirin, it is even less likely that labeling disclosures can be adequate in this context to alert people to the presence of aspirin in the products.

For all of these reasons, we hold that respondents' misrepresentations about the analgesic ingredient in its products, and the related failure to disclose the presence of aspirin, constitute a violation of Sections 5 and 12 of the FTC Act. [12]

II. *Comparative Efficacy and Side Effects Claims*

A. Introduction

The complaint contains two sets of allegations challenging respondents' comparative claims, discussed separately in Parts B and C below. First, Paragraphs 10 and 11 of the complaint charged that

[13] We also suspect, based on common experience in the marketplace, that a sizable price disparity between Anacin or APF and plain aspirin could in fact be shown. A comment by respondent's counsel, on oral argument before the ALJ, lends some support to this suspicion:

> Judge Hyun: You don't deny the fact that Anacin is more expensive than plain aspirin?
>
> Mr. Murphy: Than some aspirin. I have no knowledge, Judge. I know that I can buy A&P aspirin for less than I can buy Bayer aspirin. And I presume I can buy it for less than I can pay for Anacin.

Tr. 7916.

[14] An article in "The Medical Letter" which includes data purporting to show a difference between the price of Anacin and that of other aspirin-based products, including generic aspirin, was admitted into evidence. CX 363C. However, the remarks of Judge Hyun and complaint counsel at the time the article was admitted make clear that it was not received for the purpose of establishing the relative prices of the products. JTr. 2841–43.

respondents represented falsely that Anacin's superior efficacy for pain relief and APF's superior freedom from side effects (gastric discomfort) have been "established." In Part B, we consider the alleged representations of establishment (proof), the scientific view of the meaning of proof in this context, and the existence of the requisite proof.

Paragraphs 12, 13 and 14 of the complaint charged that respondents represented that Anacin is more effective, and that APF will cause less gastric discomfort, than any other OTC analgesic, without disclosing that at the time these claims were made there existed a substantial question recognized by qualified scientific experts concerning the validity of such representations. Under these charges, claims representing the superiority of AHP's products even without the use of direct references to scientific proof, research, tests or the like were alleged to be unfair or deceptive due to the existence of and failure to disclose a "substantial question." Part C below reviews this set of allegations.

Before addressing the "established superiority" and "failure to disclose a substantial question" allegations in turn, however, we must consider two arguments AHP has raised concerning exactly what comparative representations were made, as they relate to both the sets of allegations covered in Part B and Part C. Respondents contend, first, that the advertisements stating that Anacin contains more analgesic ingredient than competing products[15] did not represent that Anacin is more effective (R.A.B. at 38–39). In our view, however, there is little room to doubt the ALJ's conclusion that the references in those ads to the amount of "pain-reliever" or "pain-relieving ingredient" would reasonably have been understood by consumers as meaning that the product is more effective for relief of headache pain. See generally F.F. 71–73, and I.D. at 166–67. [13]

Respondents argue more strenuously that the ALJ erred in concluding (F.F. 66–84, 116–47, 181–89) that any claims were made for the superiority of its products over *all other* OTC analgesic products, and assert that its advertising in fact made only limited comparisons to specific products. R.A.B. at 35–39. In support of its contention, AHP cites chiefly the results of image and penetration studies. Yet as we explain more fully in the Appendix, such studies provide only limited guidance on the meaning consumers take from specific ads, and they cannot in any event establish the negative: that an individual ad did *not* convey a particular meaning.

We find that the ALJ's conclusion was correct. First, some of the

[15] See F. 66.

ads make sweeping comparisons expressly. For example, in CX 9 and CX 164 the audio portion begins as follows: "With all of the pain relievers in the world to choose from . . ."[16] The record shows that consumers could reasonably have understood this language to refer generally to all analgesics on the market. See, *e.g.*, Ross, Tr. 1879.

In other advertisements, Anacin or a characteristic of Anacin is compared favorably with "aspirin, buffered aspirin or the so-called extra-strength tablet."[17] Respondents' own expert conceded that at the time the advertisements were disseminated, all of the major OTC analgesic products fell into one of those three categories. Consequently, consumers could reasonably have interpreted the enumerated categories as an exhaustive listing of all OTC analgesics (Smith, Tr. 7503–04). [14]

In addition, in some ads Anacin's efficacy is compared with "the other leading extra-strength tablets"[18] or "any other leading headache tablet."[19] We believe that consumers could reasonably interpret these claims to mean that Anacin is better than what are otherwise the best products in the category. See Ross, Tr. 1870. While respondents' expert Dr. Smith stated that in his view it was unlikely that a significant number of consumers would understand "the other leading products" to refer to all other OTC analgesics, he nevertheless conceded that "some not insignificant number of consumers" would interpret that language to mean the best products in that product category (Tr. 7505–07). He later testified that products perceived to be "better than the best" are also necessarily perceived to be "better than all the others" (Tr. 7516).

Finally, in still other advertisements respondents claimed that tests have proven that Anacin is as effective as the leading *prescription* analgesic. CX 81–84, 105–07, 126–37, 141, 173–77, and 179. AHP has admitted that certain ads represented that tests and studies show Anacin is as effective for the treatment of headache pain as the leading prescription product. Ans. of AHP ¶ 17; Tr. 406–07. There is testimony in the record indicating that because

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[16] See also CX 13A, 14A.

[17] In CX 152, for example, it is claimed:

> EXTRA POWER * * * Anacin contains the pain reliever doctors recommend most. And Anacin gives you more of this pain reliever than aspirin, buffered aspirin or the so called extra-strength tablet * * *. See if Anacin tablets do not work better for you. CONTAINS WHAT 2 OUT OF 3 DOCTORS CALL THE GREATEST PAIN FIGHTER EVER DISCOVERED.

The same or similar language is used in, *e.g.*, CX 105, 107.

[18] For example, in CX 21A–22A it is claimed as follows:

> Two Anacin tablets have more of the one pain reliever doctors recommend most than 4 of the other leading extra-strength tablets * * *. Anacin contains more of the specific pain reliever than 4 of the others.

Substantially the same language is found in CX 1A, 9, 23A, 163–64, 170–71.

[19] In CX 20A, for example, it is claimed: "Anacin tablets have more of the one strong pain reliever doctors specify most. More than any other leading headache tablet." CX 13A–14A, 25A, 39A–40A, 142A–44A and 153A contain the same or similar language.

prescription drugs are generally perceived to be stronger and more effective than non-prescription products, consumers could reasonably understand these representations to mean that Anacin is more effective than all other OTC analgesics (Ross, Tr. 1933–34, 1937–40, 1941; Smith, Tr. 7576).

For all of these reasons, we affirm the ALJ's conclusion as to the breadth of respondents' comparative claims for Anacin.[20] In addition, the challenged advertising made claims for APF's comparative freedom from side effects (gastric discomfort) [15]using statements to the effect that its "double-buffering" makes APF gentle on the stomach. See, *e.g.*, CX 203A, 204A–206A. Consumers could reasonably have understood "double-buffering" to mean that APF has twice as much buffering as the otherwise most buffered brand in the product category (Ross, Tr. 2306–08). As even Dr. Smith conceded, many consumers (especially those suffering from arthritis) believe that buffered products are more gentle to the stomach than regular, unbuffered aspirin (Smith, Tr. 7645); the "double buffering" representation therefore suggests that APF is less likely to cause discomfort than any other OTC analgesic.

B. Proven ("Established") Superiority (Complaint ¶¶ 10 and 11)

We must determine next whether any of respondents' ads represented that the products' superiority is proven (or "established") as alleged, and, if so, what type and degree of support constitutes such proof and whether the record demonstrates that such proof exists.

1. Claims of Scientific Proof

The ALJ found that respondents represented that Anacin's superior efficacy for pain relief and APF's superior freedom from side effects (gastric discomfort) are proven or established, and that these representations were conveyed through a variety of statements referring to scientific studies and expert opinion in conjunction with references to the superiority of Anacin and APF (F.F. 132–47, 186–89). Respondents deny that any of their advertisements conveyed the alleged representations of proof (R.A.B. at pp. 34–35).

The Commission finds that many of the challenged Anacin

[20] There is no dispute that the claims of more pain relieving ingredients per tablet than any other OTC analgesic, and more than twice as much analgesic ingredient as any other OTC analgesic, are both false as alleged in the Complaint, ¶¶ 8(A)(1) and 8(A)(3). See Noncontested Issues of Fact 11 and 12 (F.F. 194, 193).

advertisements, when viewed in their entirety, did convey the message that the superiority of this product has been proven.[21] It is immaterial that the word "established," which was used in the complaint, generally did not appear in the ads; the important consideration is the net impression conveyed to the public. See *Carter Products Inc.* v. *FTC*, 323 F.2d 523, 528 (5th Cir. 1963). Many of the ads do make explicit reference to underlying medical or scientific proof.[22] For example, CX 154 claims [16]in pertinent part: "*Medical research has definitely established* that the most reliable medication in the treatment of arthritis * * * is the compound in today's Anacin Tablets * * * . Anacin's great pain fighter is the first choice of doctors * * * " (emphasis added). Claims such as "medically-proven Anacin" were used repeatedly.[23] This language could reasonably be understood by consumers to mean that Anacin's superior efficacy has been established as a matter of medical or scientific fact (Ross, Tr. 1926). In addition, many of the challenged advertisements cite the results of "doctors' tests," "medical reports," "scientific research," or "clinical tests," specifically announcing that the studies were performed by physicians and in some instances that the results appeared in medical journals.[24]

Each of the advertisements in this latter group also contains an express claim that the specified study or test "proves" "substantiates," "shows," or even (CX 107) proves "beyond a doubt" that Anacin is as effective as the leading prescription analgesic. As we noted *supra* at 14, consumers may reasonably understand that prescription drugs are stronger and more effective than OTC products, and therefore would reasonably understand such representations to signify that Anacin was also proven by scientific tests to be more effective than any other OTC analgesic.

Finally, the express claims are in some instances coupled with a description of the controls purportedly used in conducting the tests,[25] or references to the results of doctors' surveys,[26] [17]which are asserted to demonstrate a preference for Anacin's pain relieving

[21] The ALJ also found, citing only CX 204 (and 204A), that respondents made similar claims of proof for APF's comparative freedom from side effects (F.F. 186–89). The Commission does not believe that such representation can reasonably be found in these or any other APF ads in the record.

[22] See, *e.g.*, CX 81–84, 105–07, 115–17, 126–37, 141–44, 154, 176–79.

[23] *E.g.*, CX 115–17, 142–44, 149.

[24] See CX 81–84, 105–07, 126–37, 141, 173–77, 179.

[25] CX 128–30, for example, describes how the tests were performed:

> These tests were conducted by physicians who specialize in scientific research. The tests were done in a clinic of one of the nation's largest electronic plants on hundreds of men and women who often get headaches from the exacting precision work they do. Half the patients were given Anacin and the other half given the prescription. Neither the patients nor the doctor knew which tablet was given until the results were reviewed.

See also CX 141 ("clinical evidence in a double blind randomized study").

[26] CX 81–84, 176–77, 179.

ingredient. The net result in each case is an implicit suggestion that the superior efficacy claims for Anacin had been proved to the satisfaction of the medical-scientific community.

In addition to the explicit references to medical or scientific proof, AHP also used depiction of technical graphs and chemical formulas to convey the suggestion that the claimed superior efficacy claims for Anacin are supported by scientific proof.[27] For example, the video portion of CX 15A shows a series of benzene rings representing the chemical structure of aspirin. These are used in the challenged advertisement to contrast the amount of pain-reliever contained in Anacin with that contained in the "other well-known extra-strength tablet."[28] The prominent display of medical reference texts in some ads (CX 14A) reinforced the suggestion that the claims rest on medical evidence or authority. Respondents' own expert testified that consumers believe that medical treatises are based on scientific evidence (Smith, Tr. 7589–90).

Similar advertising techniques have previously been held to imply the existence of scientific proof. For example, in *Porter & Dietsch, supra*, 90 F.T.C. at 865, we found that explicit references to clinical tests were used to convey [18]the suggestion that claims of weight loss for users of the diet tablets at issue in that case were substantiated by "competent scientific proof." On the other hand, in *Pfizer, Inc.*, 81 F.T.C. 23 (1972), complaint counsel argued that certain advertising claims for "Unburn" contained implied representations of scientific proof, but we upheld the ALJ's finding that the implied representations of scientific testing had not been made. In that case, however, we noted specifically the respondents' argument that "the total setting of the ad, the frivolous nature of the dialogue, the use of a bikinied model, and the general 'aura of sexiness' prevent the ad, taken as a whole, from carrying the scientific overtones argued by complaint counsel." *Pfizer, Inc., supra*, 81 F.T.C. at 59. AHP's advertising of Anacin is easily distinguished. As we described above, some of AHP's ads expressly referred to scientific or medical proof, and others used imagery strongly suggesting scientific

[27] Nonverbal images such as pictorial elements and graphics are capable of conveying deceptive advertising messages. *ITT Continental Baking Co.*, 83 F.T.C. 865, 959–60 (1973), *modified on other grounds*, 532 F.2d 207 (2d Cir. 1976).

[28] Other advertisements, aired after the complaint issued (CX 50A–54A, CX 56A–58A, and CX 61), display a form of graph superimposed on a profile of the headache sufferer, which purports to measure levels of aspirin in the blood and to reflect the comparative efficacy, in terms of speed and strength, of Anacin, buffered aspirin, and plain aspirin. The record shows that at least some consumers would understand the claim regarding the differences among pain relievers in the bloodstream to be based on authoritative medical opinion (Ross Tr. 1924–25) or scientific tests (Smith, Tr. 7588–89). In some of these advertisements, a figure dressed as a doctor or pharmacist, or seated in what appears to be a professional office, uses the graph or formulas to explain why Anacin is more effective than its competitors. Verbatim comments recorded in one ASI copy test document the tendency of consumers to perceive the spokesperson in such an ad as a doctor or pharmacist (see CX 425 at p.27).

or medical support. Reading these ads, as we must, for their total or general message to the consuming public, we conclude they contain a claim that Anacin's superior efficacy is proven by competent scientific evidence.

2. Requisites of Scientific Proof

The record reflects no real dispute as to the type of evidence scientists require before they regard it as having been proven (established) that one drug is more effective than another. Complaint counsel and respondent called numerous expert witnesses on the issues related to medical and scientific substantiation of the claims made in the advertisements. From their testimony, it is clear that at least since the early 1950's well-controlled clinical testing (*i.e.*, the observation and analysis of pain and relief in patients suffering actual pain) conforming in design and execution to generally recognized criteria have been required to establish or prove absolute or relative drug efficacy (Azarnoff, Tr. 600–01; Moertel, Tr. 942–43, 956–57, 1021–25, 1028; DeKornfeld, Tr. 2777–78, 2780–81, 2785–86; Lasagna, Tr. 4119, 4142-44, 4177–78; Forrest, Tr. 447, 449–50, 472–73; Rickels, Tr. 1228–29; Wallenstein, Tr. 3490). The use of generally recognized standards serves to reduce the chance of systematic bias entering into clinical studies (Moertel, Tr. 943–44; DeKornfeld, Tr. 2778–79; Lasagna, Tr. 4142).

Experts in the field of clinical testing of analgesics are generally agreed on the requisites of a well-designed clinical study (Azarnoff, Tr. 463). Pre-existing bias toward the tested product on the part of the subjects or those involved in the execution of the study must be eliminated. To this end, the well-designed clinical study should be double-blinded—that is, neither the subjects nor those conducting the study should be able to identify the test drugs until preliminary analysis of the data is complete [19](Forrest, Tr. 444, 457–58; Moertel, Tr. 948; DeKornfeld, Tr. 2778–82; Wallenstein, Tr. 3488; Lasagna, Tr. 4123, 4126, 4128).[29] The record shows that the expectations of both subjects and observers can affect the amount of relief obtained from the tested drug, and that this is a major source of bias in clinical testing (DeKornfeld, Tr. 2782). Pre-existing bias toward the tested product is a particularly significant factor in working with OTC analgesics, which are readily identifiable by color, shape, or other distinctive attributes (DeKornfeld, Tr. 2782). Random distribution of the subject population among treatment groups

[29] In some instances (*e.g.*, a study of acupuncture), a double-blinded study may not be possible. It is critical, however, in comparative studies involving subjective response information (Forrest, Tr. 554–55).

further balances out variables and biases not otherwise controlled for (Forrest, Tr. 444; Azarnoff, Tr. 601; Wallenstein, Tr. 3488; Lasagna, Tr. 4123). The development of a written protocol, which sets out in advance the purposes of the study, the number and types of patients to be studied, the parameters to be evaluated, and the analytic techniques to be used in evaluating the results, protects against biases which might develop during the course of execution or analysis through manipulation of the data (Azarnoff, Tr. 604–05, 605–09, 643; Moertel, Tr. 947–48, 952; DeKornfeld, Tr. 2778–2783; Lasagna, Tr. 4124, 4858–59).

The record also shows that the customary practice in drug comparison studies is to require a pharmacologically inactive treatment (placebo control) as a direct measure of test sensitivity. Placebo control is particularly important in the case of analgesic studies because a subjective response like pain relief is highly susceptible to influence by the subject's expectations (Okun, Tr. 4419). In clinical studies of mild to moderate pain, the rate of positive response to a pharmacologically inactive rate has been as high as 60% (Forrest, Tr. 496; Lasagna, Tr. 431–33). The inert substance serves as a control for perceived pain relief based on expectations alone, or attributable to the self-limiting nature of mild to moderate pain (Forrest, Tr. 444, 446, 459–61; Azarnoff, Tr. 605–06; Moertel, Tr. 950; DeKornfeld, Tr. 2785; Lasagna, Tr. 4128, 4130, 4134).[30]

In addition, if the objective is to determine comparative drug efficacy, the tested products should be evaluated in the same study (together with a placebo). Without such head-to-head studies, the investigator is unable to determine whether products vary from each other to a significant degree (Azarnoff, Tr. 605–06). Finally, scientists have historically required the results of clinical studies showing a difference among drugs to be statistically significant to the 95% level of confidence. This insures that the likelihood of the results being attributable to chance will not be greater than 5% (Forrest, Tr. 456; Azarnoff, Tr. 608; Moertel, Tr. 954–55; DeKornfeld, Tr. 2784; Lasagna, Tr. 4136–37; Okun, Tr. 4420). **[20]**

The record shows that a minimum of two clinical trials conforming in design to the aforementioned criteria and reaching the same conclusions and statistical significance is required to establish comparative drug efficacy. (Forrest, Tr. 449–50; Azarnoff, Tr. 601, 609–10; Moertel, Tr. 942, 956–57; DeKornfeld, Tr. 2778, 2780–81; Lasagna, Tr. 4142–44). The two-test minimum further reduces the

[30] The potential impact of the placebo effect and the self-limiting nature of some ailments have been previously recognized by the Commission. *Warner-Lambert Co.*, 86 F.T.C. 1398, 1495–96 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

chance that any observed therapeutic value is attributable to factors other than the pharmacologic activity of the tested drug. Even in the most meticulously planned study, unknown factors that the investigator simply could not have recognized could be operative (Moertel, Tr. 956–57). Dr. Azarnoff, explained:

> One reason is to reduce the chance that there was any systematic bias in the study. That is, if you do a study in Los Angeles in a certain group of subjects, there may be something inherent in those subjects either because of the region in which they live, genetic background, environmental factors, a variety of other things, which would not be picked up because it is systematically occurring throughout all subjects. [Tr. 610–11.]

Finally, since ultimately the test of analgesic efficacy is established by the subject's response, at least one of the required studies should be conducted on the type of pain for which the superior efficacy claim is being made. Because scientists do not fully understand the mechanism by which trauma evokes pain, they are not comfortable about extrapolating from one pain situation to another, or from experimental pain models, which employ artifically induced pain, to a clinical situation (Forrest, Tr. 443–44, 447–49; Azarnoff, Tr. 610–11; DeKornfeld, Tr. 2778–80; Lasagna, Tr. 4144–45).

The criteria testified to by the expert witnesses in this proceeding are fully consistent with and reflected in regulations adopted by the Food and Drug Administration (FDA) to implement the congressional policy of drug regulation that was mandated in the 1962 amendments to the Food, Drug, and Cosmetic Act of 1938 (52 Stat. 1040).[31] The Drug Amendments of 1962 (Harris-Kefauver Act) **[21]** (Pub. Law No. 87–781, 76 Stat. 780), modified the 1938 Act to prohibit the introduction into commerce of "new drugs" not generally recognized by qualified experts to be effective (as well as safe) for their indicated uses.[32] (See 21 U.S.C. 321 (p)(1).) The Act requires that a new drug application (NDA) be filed with the FDA before a new drug is marketed, and the FDA is now directed to refuse approval of an NDA in the absence of "substantial evidence" that the drug is effective for its indicated uses. (21 U.S.C. 355(d) and (e)). "Substantial evidence" is defined in the Act to mean:

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[31] The FDA and the FTC of course share authority over representations about the efficacy of drugs. Although it is often stated that the FDA has authority to regulate drug labeling and the FTC has authority to regulate drug advertising, the jurisdiction in fact overlaps. The FTC has authority to challenge false or misleading labeling (*Houbigant* v. *FTC*, 139 F.2d 1019 (2d Cir.), *cert. denied*, 323 U.S. 763 (1944)), and under certain circumstances the FDA may challenge representations made in advertising (*Alberty Food Products Co.* v. *United States*, 185 F.2d 321 (D.C. Cir. 1950)). In practice, however, pursuant to a liaison agreement between the two agencies, the FTC has assumed primary responsibility for advertising and the FDA for labeling. 36 FR 18539 (1971).

[32] The Act does not define what constitutes "general recognition" among experts, but it has been held to require "substantial evidence," the meaning of which is discussed in the text. See also n.[59] at p. 35, *infra*.

evidence consisting of *adequate and well-controlled investigations, including clinical investigations*, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling thereof.

Section 505, 21 U.S.C. 355(d)(1976) (emphasis added).[33] [22]

The legislative history of the 1962 Amendments, fully reviewed in *Pharmaceutical Manufacturers Assn.* v. *Richardson*, 318 F. Supp. 301 (D. Del. 1970), demonstrates Congress' judgment that it was imperative to require an objective determination—based on reliable scientific evaluation, not anecdote or uncontrolled study—not only that a drug is "safe" but that it produces the results claimed for it. One concern, for example, was that ineffectual treatment can lead to delays in receiving proper medical care.[34] As summarized by the Supreme Court, "The hearings underlying the 1962 Act show a marked concern that impressions or beliefs of physicians [about the efficacy of a drug], no matter how fervently held, are treacherous." *Weinberger* v. *Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 619 (1973).

To implement the congressional policy, the FDA has promulgated regulations which embody the essential principles of "adequate and well-controlled clinical investigations," and provide the basis for the statutory determination whether there is "substantial evidence" to support drug efficacy claims. In the FDA's own words, the criteria established by the regulations "have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations." 21 C.F.R. 314.111(a)(5)(ii). They include: (1) a clear statement of the objectives of the study; (2) a method of subject selection which minimizes bias, assures suitability of subjects, and assures comparability of pertinent variables; (3) an explanation of observation and

[33] The Act contains grandfather clauses that exempt certain drugs which were subject to the Food and Drug Act of June 30, 1906, and certain drugs which were in use prior to the 1962 Amendments, from the premarket clearance requirement. (21 U.S.C. 321 (p)(1)(1976); 21 U.S.C. 321 note (1976)). As AHP points out (R.A.B. at 22), the principal ingredient in Anacin and APF (aspirin) is an "old drug" which is not subject to the efficacy requirements of the Food and Drug Act. However, to fall under the first grandfather clause AHP would have to show that as to the drug marketed earlier the "labeling contained the same representations concerning the conditions of its use" as Anacin's, 21 U.S.C. 321 (p)(1), and to fall under the second grandfather clause Anacin would have to be "intended solely for use under conditions prescribed, recommended or suggested in [the] labeling" of the earlier drug, 21 U.S.C. 321 note. Moreover, aspirin combination drugs such as Anacin and APF have been subject to the OTC drug review procedures under FDA regulations. See *infra* at p. 28.

In any event, our use of the Food and Drug Act standards here as a benchmark against which to measure the adequacy of AHP's proof of efficacy does not require a determination that Anacin and APF are subject to the efficacy requirements of that Act.

[34] See, *e.g.*, comments of Sen. Kefauver (chief sponsor of the 1962 Amendments) regarding the dangers of using a drug that does not produce its purported therapeutic effects. 107 Cong. Rec. 5640 (1961). See also *United States* v. *Rutherford*, 441 U.S. 903 (1979).

recording methods, including steps taken to minimize bias on the part of the subject or observer; (4) a comparison of results with a control, in such a way as to permit quantitative evaluation; and (5) a summary of methods of analysis and an evaluation of data, including any appropriate statistical methods. (21 C.F.R. 314.111(a)(5)(ii)(a).)[35]

The requirement that at least two adequate tests be conducted is also consistent with FDA standards. Ordinarily, reports from more than one independent investigator are required to establish "substantial evidence" of drug efficacy. The applicable regulation provides in pertinent part: **[23]**

> b. An application may be refused unless it includes substantial evidence consisting of adequate and well-controlled investigations including *clinical investigations*, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved * * *.
>
> * * * * * * *
>
> c. Ordinarily, the reports of clinical studies will not be regarded as adequate unless they include reports *from more than one independent, competent investigator* who maintains adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated and comparable records on any individuals employed as controls.

21 C.F.R. 314.1(b)(1980) (emphasis added).

The criteria for establishing efficacy were reaffirmed in the FDA procedures adopted in 1972 for reviewing the safety and efficacy of OTC drugs already on the market (21 C.F.R. 330 (1979)). The FDA established a drug review program, utilizing advisory review panels of outside experts to evaluate the safety and efficacy of OTC drugs, to review OTC drug labeling and to propose monographs establishing conditions under which OTC drugs are generally recognized as safe and effective (21 C.F.R. 330.10(a)(I)). The FDA issued general safety, efficacy, and labeling standards to be used by the panels in evaluating the data. The FDA-mandated standard of efficacy for panel review of OTC drugs provides:

> *Proof of effectiveness shall consist of controlled clinical investigations as defined in ¶314.111(a)(5)(ii) of this chapter*, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. **[24]**

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[35] A petition for waiver of any or all of these criteria may be filed under 21 C.F.R. 314.111(a). See discussion *infra* at p. 52.

Effective December 26, 1979, the same standards—requiring substantial evidence of drug efficacy and safety based on adequate and well-controlled studies as defined in Section 314.111 (a)(5)(ii)(a)—were made applicable to indication-for-use claims in labeling for prescription drugs and also to comparative safety and efficacy claims made in prescription drug advertising (44 FR 37434, 37466–67 (June 26, 1979)).

21 C.F.R. 330.10(a)(4)(1980) (emphasis added).[36]

The advisory panel on OTC internal analgesics has specifically commented on the design of clinical studies used to evaluate analgesic drugs, and the criteria are substantially the same as those recognized by the expert witnesses in this proceeding. CX 367Z074-75. Significantly, establishment of "Category I" status (generally recognized as safe and effective) for a "Category III" compound (drugs for which the available data are insufficient to permit final classification), requires at least two studies by independent investigators conforming in design to the standards previously described. CX 367Z075.[37] **[25]**

3. Existence of Scientific Proof

To summarize, we have found that AHP made claims in its advertisements that Anacin's superiority over other OTC analgesics for pain relief has been proven or established by evidence considered adequate in the relevant medical and scientific community. We have also found that the scientific community requires at least two adequate, well-controlled clinical studies, meeting certain specific criteria, for proof of OTC drug claims, and that these standards are reflected in the statute and regulations under which the FDA reviews OTC drug claims. We must next determine whether Anacin's purported proven superiority has in fact been established by the requisite clinical tests.

Respondents first contend that the two studies performed by Dr. Gilbert McMahon (RX 31) "satisfy even the 'establishment' theory of substantiation," because they are two "adequate and well-controlled [clinical studies] demonstrating Anacin's superior efficacy to regular aspirin tablets" (R.A.B. at 48). We disagree, and affirm the ALJ's conclusion that the studies were so seriously flawed that they did not establish Anacin's superiority.

The McMahon studies purported to be head-on comparisons of the

[36] The FDA's statutory and regulatory requirements outlined here have been judicially upheld, as constituting an expression of well-established principles of scientific investigation." *Weinberger* v. *Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 617–19 (1973). There is no basis, moreover, for AHP's assertion that FDA's substantiation requirements for OTC drugs are in any respect lower than its requirements for prescription drugs (R.A.B. at 23). (The statements of former FDA Commissioner Edwards cited by respondent appear to reflect mainly his views that evaluation of prescription drugs should have a higher priority within FDA, and that a drug-by-drug approach to OTC drugs—as opposed to the type of review undertaken by the panels—appeared impractical. If Commissioner Edwards did believe the substantiation standards for the two classes of drugs should differ, that view is not reflected in any statute or regulation.)

[37] The portion of the FDA regulations that permits Category III drugs to be marketed (21 C.F.R. 330.10(a)(13)) was declared to be unlawful in 1979 because it was in conflict with the provisions of the Food and Drug Act. *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The FDA has published a proposed revision to its regulations in response to this decision, which would delete Category III from the regulatory scheme (45 FR 31422 (1980)). The revision, which is not yet final, would not affect the standards for proof of efficacy. *Id.*

efficacy of Anacin and generic aspirin (RX 31A). The first study compared the effects of an aspirin-caffeine preparation similar to Anacin with those of generic aspirin on two types of moderate to severe post-partum pain: uterine and episiotomy pain (RX 31B). The second made the same comparison for severe uterine or episiotomy pain (*id.*). The ALJ did not credit the testimony of Dr. McMahon (McMahon, Tr. 3771) and other experts (Lasagna, Tr. 4938; Okun, Tr. 4352), that the studies demonstrated Anacin's superiority to aspirin (F. 318–20).

Several defects in the McMahon studies prevent them from providing adequate substantiation for claims of Anacin's established superiority.[38] First, neither study reached statistical significance for the entire group tested (F. 318–19). The first test did not produce statistically significant results for patients suffering from *either* type of pain, and the second did not do so for those afflicted with uterine cramping pain (*id*; McMahon, [26]Tr. 3752, 3887; Okun, Tr. 4525).[39] Second, the aspirin-caffeine combination tested against aspirin was not shown to be equivalent to Anacin in its commercial form (McMahon, Tr. 3838–39; F. 296). It is thus not clear that a test of Anacin itself would achieve similar results, since a different compound could behave differently.

Third, the effects of a particular analgesic on one type of pain are not necessarily the same as its effects on another kind of pain (F. 314). The record establishes that the particular pain for which an analgesic is intended should be used as a model in at least one of the studies conducted to establish the analgesic's efficacy (*e.g.*, Forrest, Tr. 44344; Azarnoff, Tr. 610–11; F. 204),[40] and respondents' witnesses admitted that headache pain is different from other kinds of pain (*e.g.*, Lasagna, Tr. 4148). For example, because headache pain is ordinarily self-limiting (McMahon, Tr. 3823), relief of headache pain may or may not be due to consumption of an analgesic. In addition, it is not known whether headache pain is a cramping pain (similar to

[38] In addition, we note that these tests could not show that respondents possessed and relied upon a "reasonable basis" for their claims, as respondent has asserted (*e.g.*, R.A.B. at 42), because they were conducted well after the claims had begun to be disseminated (indeed, after the commencement of this litigation). See *infra* at 40, n.[63].

[39] Even the statistically significant results for severe episiotomy pain of the second test are questionable. The study was terminated as soon as statistical significance was reached; if the study had been permitted to continue for the full length of time specified in its protocol, the results might have been different. Although Dr. McMahon testified that terminating a study when statistical significance is achieved is a commonly accepted practice (McMahon, Tr. 3843), Dr. Lasagna (one of respondent's own experts) did not agree (Lasagna, Tr. 4863).

[40] Respondents' witness, Dr. Lasagna, testified that post-partum pain is a valid model for the study of oral analgesics (Lasagna, Tr. 4055), but later stated that certain kinds of drugs may be better for certain kinds of pain than for others (Lasagna, Tr. 4068). Even assuming that results from tests involving post-partum pain can be extrapolated to headache pain (*id.*), such extrapolation remains an inference, and not established scientific fact. (See F. 317.)

uterine cramping pain) or a constant pain (like epistiotomy pain) (Lasagna, Tr. 4883).

For all these reasons, the studies did not establish Anacin's superiority over aspirin for relief of headache pain. Nor is there any basis in the record for finding Anacin to be more effective than other OTC analgesics, as the ads represented, as no clinical studies were conducted to support such a claim.

Respondents also assert, however, that "the aspirin dose response curve" proves that Anacin is more effective than regular aspirin tablets (R.A.B. at 43). A dose response curve is established by plotting points on a graph representing the average degree of pain relief (according to data from clinical studies) corresponding to different dosages of a drug, and drawing a line through the points. F.F. 226–27. Respondents argue that because the ascending shape of the dose response curve for aspirin indicates that more aspirin produces greater pain relief at some dosages, and because Anacin (with 800 mg. of aspirin) contains [27]150 mg. more aspirin per dose than common five-grain aspirin, Anacin is shown to produce more pain relief than aspirin. We believe, however, that while the dose response curve is recognized by most clinicians as useful for predicting the efficacy of a particular dosage (F. 229), for several reasons it cannot be said to establish scientifically Anacin's superiority over aspirin.

First, every point on the curve has not been scientifically established; rather, the curve is created by a series of inferences. Most of the points on the curve are in fact estimates, which are extrapolated from the few points that have been established by clinical studies (Kantor, Tr. 3572; Lasagna, Tr. 4273; DeKornfeld, Tr. 2816–17). Thus, a given dosage may or may not relieve pain to the extent indicated by the curve.[41] Even respondents' experts testified that points on the curve that have not been placed by actual studies cannot be said to have been established in a manner that is statistically significant (McMahon, Tr. 3933; Okun, Tr. 4475–76).

But more significant for our purposes is the fact that even assuming that the curve as a whole has been established, the evidence indicates that above 600 mg. the curve is either very shallow or levels off to a plateau (Kantor, Tr. 3573; Lasagna, Tr. 4881).[42] In other words, a substantial increase in dosage is necessary to produce even a small increase in pain relief (Kantor, Tr. 3573; Azarnoff, Tr. 642; F. 257), yet Anacin contains only 150 mg. more aspirin than common aspirin. Indeed, several dose-response studies

[41] F. 228–342.

[42] See F. 244–256.

showed *no* statistically significant differences in pain relief for dosages greater than 600 mg. (F. 246–55). Thus, the aspirin dose response curve cannot establish the superiority of 800 mg. of aspirin over 650 mg.,[43] or, consequently, the superiority of Anacin over aspirin (or other analgesic products).[44] **[28]**

Finally, we have determined (*supra* at p. 14) that respondents' claim of established superiority was also made implicitly through a claim that Anacin is as effective as the leading prescription pain reliever, which was Darvon Compound 65. Respondents offer as substantiation the results of two studies conducted by Dr. Lay (CX 301) and Dr. Teschner (CX 302). Neither of these studies, however, is adequate to establish that Anacin is as effective as Darvon Compound 65. The Lay study was flawed because it was not properly double-blinded (CX 301G; see Forrest, Tr. 508). The Teschner study was not double blinded (CX 302C), and did not include a placebo (Lasagna, Tr. 4200–01; DeKornfeld, Tr. 2792). Expert witnesses for both complaint counsel (Moertel, Tr. 970, 972; DeKornfeld, Tr. 2792–92; Forrest Tr. 508) and respondents (Lasagna, Tr. 4200–01; Okun, Tr. 4431) concluded that both studies had significant drawbacks.[45]

In sum, in view of the absence of adequate testing, Anacin's superiority has not been established. Where advertising representations reasonably lead consumers to understand that the claims are supported by adequate scientific testing, the claims must be documented by scientific tests. *Porter & Dietsch* v. *FTC*, 90 F.T.C. 770, 865–72 (1977), *aff'd*, 605 F. 2d 294 (7th Cir. 1979), *cert. denied* 445 U.S. 950 (1980); *National Dynamics Corp.*, 82 F.T.C. 488, 560–61 (1973), *aff'd in part, remanded on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974). AHP's advertisements conveying an unmistakable claim of proven or established superiority for Anacin are therefore false and deceptive, and constitute a violation of Sections 5 and 12 of the FTC Act. **[29]**

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[43] It is of course possible that for some individuals, an 800 mg. dosage of aspirin may provide greater relief than 650 mg. (see F. 258), but this proposition has not been established for the population as a whole, or even the average individual.

[44] As the ALJ pointed out, the fact that Anacin also contains caffeine could conceivably affect Anacin's dose response curve as compared to that of aspirin (F. 261), but there is no reason to expect the caffeine to improve pain relief since caffeine is not an analgesic (CX 367Z112).

[45] Moreover, even if Anacin were proven to be as effective as Darvon Compound 65, that would not necessarily establish Anacin's superior efficacy over other OTC drugs (Lasagna, Tr. 4202; Okun, Tr. 4436; DeKornfeld, Tr. 2794; Moertel, Tr. 978). There is some evidence indicating that regular aspirin is actually as effective as Darvon Compound 65 (*e.g.*, CX 360A (Moertel study published in *New England Journal of Medicine*); DeKornfeld, Tr. 2820). The American Medical Association's *Drug Evaluations* (a reference book for doctors with current information on drug uses and effects, CX 362N; see also Moertel, Tr. 990) states that Darvon is probably no more effective than aspirin (CX 362P). Thus, it is not clear that Anacin, even if it worked as well as this Darvon compound, would necessarily perform better than its aspirin-based competitors.

C. Failure To Disclose Existence of a Substantial Question (Complaint ¶¶ 12, 13, 14)

As we noted earlier, a second category of allegations is contained in Paragraphs 12, 13 and 14 of the complaint. The complaint alleges that in some advertisements respondents made affirmative and unqualified representations of Anacin's superior efficacy or APF's freedom from side effects[46] which, unlike the advertisements discussed in Part B above, are unembellished with specific references to underlying scientific proof or tests, or other clear indicia of scientific or medical evidence (graphs, charts, treatises, etc). See, *e.g.*, CX 1A, 9A, 20A–25A, 38A, 39A, 89A, 90A, 92A–97A, 99A, 100A, 121–24A, 160A–64A.[47] It is alleged that such advertisements are deceptive or unfair because of their failure to disclose that the claims are open to substantial question (Comp. ¶ 25). The ALJ sustained these allegations. For the reasons given below, we find that such advertisements have a capacity to deceive.

When an analgesic advertiser claims its product to be superior in performance, even without the additional explicit claim that it has been so proven, it is reasonable for consumers to construe that claim to be the assertion of a fact that is generally accepted, within the scientific community, as established. By their nature, therapeutic drug products raise special public health concerns, in light of the [30] risks associated with their use.[48] Harmful side effects present the most obvious danger. Other risks attending inappropriate consumption of drugs include the possibility that the consumer will forego other, necessary treatment for a medical condition, or will consume in unsafe doses an otherwise harmless product.[49] It is these latter concerns that underlay the passage in 1962 of the amendments to

[46] We explained above in Part A why we concluded that respondents' claims about the quantity of analgesic ingredient in Anacin and APF did constitute comparative efficacy claims, and that respondents' claims did compare its products to all other OTC analgesic products.

[47] Many of the ads in this category do mention briefly that "doctors recommend" or "doctors specify" Anacin's pain reliever, without any other references to or symbols of medicine, science or proof. While we believe that these indications of medical approbation can contribute somewhat to an aura of scientific authority, they do not, standing alone, constitute quite the same sort of direct, forceful representation of scientific proof as is conveyed by the techniques described *supra* at pp. 15–18. See Smith, Tr. 7587–88.

[48] See Sections 12, 13(a) and 15 of the FTC Act, under which the Commission has specific authority to seek to enjoin the dissemination of false drug advertising, and the legislative history attending passage of those provisions. Senator Wheeler commented, for example, "We are more strict with the advertising of foods, drugs, devices and cosmetics because their effect is direct and their use might endanger life." 83 Cong. Rec. 4435–36 (1938). The enactment and legislative history of the Federal Food, Drug, and Cosmetic Act, as amended, 52 stat. 1040, and the regulatory scheme that Act imposes on the marketing of OTC as well as prescription drugs, also establishes unequivocally the Congressional concern in this area. See, *e.g.*, Hearings on S. 1552 before Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong. We note, further, that in a recent judicial decision involving AHP and its representations of the superiority of Maximum Strength Anacin, the court took into account the fact that the claims had a bearing on matters of public health. *McNeilab, Inc.* v. *American Home Products Corp.*, 79 Civ. 3973, slip op. at 30 (S.D.N.Y., filed July 21, 1980).

[49] See discussion of the evidence adduced in this proceeding concerning the risks associated with aspirin, *supra* at pp. 8–10.

the Federal Food, Drug and Cosmetic Act requiring "substantial evidence" to demonstrate drug effectiveness claims, as we have described *supra* at 22. When the nature of a product is such that it gives rise to a serious safety concern, advertisers are held to a high standard of care, in order to assure to the greatest extent possible that their claims will not be misunderstood by the public. See *Firestone Tire and Rubber Co.*, 81 F.T.C. 398, 456 (1972), *aff'd* 481 F. 2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 112 (1974).[50]

In addition, the effects of many drugs, including analgesics, are such that while it is possible to verify objectively the consequences of their use, the ability to do so lies peculiarly within the power of the manufacturer; that is, the producer is uniquely equipped with the facilities and expertise necessary to ascertain reliably the drug's effects, or the comparative effects of two drugs, by controlling for the placebo effect and other spurious factors. (See discussion *supra* at pp. 18–24 concerning the requisites of meaningful scientific substantiation of claims that one analgesic is superior to another.) [31]

Under these circumstances, we find that when an advertiser has made unequivocal, unqualified claims about a drug product's effects, particularly in an intensive, long-running campaign,[51] consumers may be led to expect, quite reasonably, that the claims are supported by meaningful evidence, of the sort that would be likely to satisfy the relevant scientific community.[52] While some consumers may be skeptical, and treat all objectively verifiable representations in advertisements as mere expressions of the advertiser's opinion rather than as generally accepted facts upon which a rational purchasing decision may confidently be based, we doubt that advertising could long remain the powerful method of communication that it is were such an attitude common to the large majority of consumers.[53] In short, advertisements are an important source of decision-guiding information because many consumers assume that when advertisements make unqualified assertions of fact, those

[50] We note that in *Firestone* some of the claims directly involved the safety of the respondent's tires while others did not, and the Commission's order required cessation of any "safety or performance" claims unless "fully and completely substantiated by competent scientific tests." 81 F.T.C. at 475.

[51] See discussion *infra* at 58–60 concerning the evidence indicating that the extensive promotion of Anacin as a stronger, faster and otherwise better pain reliever has created a widespread belief in the product's superiority over other brands. See also *infra* at 48 for reference to the ALJ's findings on the extent of dissemination of the claims.

[52] In addition, consumers may reasonably believe that the marketing of therapeutic drugs is closely regulated by the government, and that scientific standards of substantiation are thereby imposed. See *Simeon Management Corp.*, 87 F.T.C. 1184, 1230 (1976), *aff'd*, 579 F.2d 1137 (9th Cir. 1978). We note that the same scheme of regulation to which both the Commission and the court referred in *Simeon* applies to the over-the-counter drugs at issue in the present case. See *supra* at 24, n.[36].

[53] Respondent conceded in its brief on appeal that consumers may infer from a "straight and unembellished comparative performance claim" that the advertiser's evidence "would be acceptable to responsible medical experts." R.A.B. at 35. Moreover, respondent's expert witness testified that consumers are likely to expect a higher level of support for claims about drug products than for claims about other products. Smith, Tr. 7586.

assertions are, indeed, not open to substantial question. *National Comm'n on Egg Nutrition*, 88 F.T.C. 89, 197–98 (1976), *aff'd and ordered enforced as modified*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Sears, Roebuck & Co.*, Docket No. 9104 (April, 1980), slip op. p. 16, *appeal pending*, No. 80–7368 (9th Cir.).

Thus, AHP's advertising representations have a capacity to lead consumers to believe that the superiority of Anacin and APF has been established in the manner customarily [32]required by the scientific community.[54] And it follows that if such an unequivocal assertion is in fact open to substantial question—a matter to which we will turn in a moment—then the failure to disclose as much constitutes the misleading omission of a material fact.[55]

That the fact omitted is material, and its omission misleading, is evident from consideration of the difference in persuasive impact between the following two claims:

1. Anacin is more effective than aspirin in the relief of pain.
2. Although the matter is still open to question, we believe that Anacin is more effective than aspirin in the relief of pain. [33]

The first claim, like claims made in the advertising challenged here, assures the consumer that there is simply no question: Anacin is better than aspirin, and the consumer can thus rely, in purchasing Anacin, upon the fact he or she will be doing more thereby to relieve pain symptoms than were he or she to purchase plain aspirin. The second claim leaves the matter in some doubt: the advertiser certainly believes its product is better than aspirin, perhaps based on some evidence, but a prudent consumer could decide that inasmuch as the matter remains open to substantial question, he or she is better off buying aspirin, or buying neither product in the event the

[54] Advertisements having the capacity to deceive are deceptive within the meaning of the FTC Act; actual deception need not be shown. See, *e.g.*, *Murray Space Shoe Corp.* v. *FTC*, 304 F.2d 270, 272 (2d Cir. 1962); *U.S. Retail Credit Ass'n* v. *FTC*, 300 F.2d 212, 221 (4th Cir. 1962); *Rhodes Pharmacal Co. Inc.* v. *FTC*, 208 F.2d 382, 387 (7th Cir. 1953), *aff'd*, 348 U.S. 940 (1955). It is well settled that the Commission has the expertise to determine whether advertisements have the capacity to mislead the public. Consumer testimony or survey data, although sometimes helpful, is not essential. *Resort Car Rental System, Inc.* v. *FTC*, 518 F.2d 962, 964 (9th Cir. 1965); see *FTC* v. *Colgate Palmolive*, 380 U.S. 374, 391–2 (1965).

[55] The conclusions set forth herein are merely an elaboration, in the specific context of drug products, upon well-established principles of advertising law requiring that advertisers possess and rely upon a reasonable basis for affirmative product claims. *Pfizer, Inc.*, 81 F.T.C. 23, 60–65 (1972). It has repeatedly been held that failure to possess a reasonable basis for advertising claims is a deceptive practice, *e.g.*, *Porter & Dietsch*, 90 F.T.C. 751, 866 (1978), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980); *Jay Norris, Inc.*, 91 F.T.C. 751, 854 (1978), *aff'd*, 598 F.2d 1244 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979); *National Dynamics Corp.*, 82 F.T.C. 488, 550 n. 10 (1973), *aff'd in part and remanded in part on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974). Deception derives from the failure to disclose to consumers the material fact that an affirmative product claim lacks the support that would be presumed absent some qualification of it. The appropriate measure for such support is, of course, to be determined in light of the particular claims made and the products for which they are made. For reasons noted in the text, we believe that such support in the case of drugs consists of the two or more well-controlled clinical studies deemed necessary by a broad spectrum of relevant experts to justify assertions as to drug performance.

consumer has already decided that aspirin is not a suitable palliative. The first claim may make better copy, but the second claim comes much closer to the truth.

There is a substantial question, recognized by the qualified experts, about the superiority of Anacin and APF over aspirin and other OTC analgesics. The record demonstrates the relevant scientific community to be unanimous in its view that the superiority of one analgesic product over another (or a class of others) cannot be established unless more than one adequate, well-controlled clinical test has been conducted. See discussion *supra* at pp. 18–24. Thus, in the absence of such tests, there necessarily exists scientific doubt, characterized in the complaint as a "substantial question," about the validity of the claims.[56] **[34]**

We have already concluded that Anacin's superior efficacy for headache relief has not been demonstrated by the requisite tests. Moreover, additional evidence of doubt within the relevant scientific community is supplied by the unanimous testimony of complaint counsel's witnesses, who stated that Anacin's superior efficacy has *not* been established (Forrest, Tr. 465; Azarnoff, Tr. 611–12; DeKornfeld, Tr. 2788; Moertel, Tr. 959). Indeed, some of these witnesses testified to their belief that Anacin is in fact no better than aspirin (Forrest, Tr. 520; Moertel, Tr. 959). While some of respondent's witnesses said that they believe that Anacin *is* better than aspirin (*e.g.*, Lasagna, Tr. 4938; Okun, Tr. 4352), it is clear from the record that there are, overall, significant doubts in the scientific community.

Nor has APF been proven to the satisfaction of the scientific and medical community to cause less gastric discomfort than other analgesics.[57] Respondents base their claim on inferences drawn from the product's composition, arguing that the formulation of APF—486 mg. of micronized aspirin (aspirin with a smaller particle size) combined with "two recognized buffering agents" (both of which are

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[56] This reasoning, we note, parallels the approach of the Food and Drug Administration. When the FDA reviews OTC drug claims, it presumes a lack of general expert recognition of the validity of the claims if adequate controlled clinical tests have not been performed, and this approach has been upheld by the Supreme Court. In *Weinberger* v. *Hynson, Wescott & Dunning, Inc.* 412 U.S. 609, 629–32, (1973), the Court noted that the Federal Food, Drug and Cosmetic Act defines a new drug as one "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective ***" 21 U.S.C. 321(p), but that the Act nowhere defines "general recognition among experts." The Court reasoned that "general recognition" of effectiveness must require at least "substantial evidence," which is required under Section 505(d) of the Act for approval of a new drug application (21 U.S.C. 355(d)). "Substantial evidence," as we discussed *supra* at pp. 20–24, must consist of adequate controlled clinical tests. (The Court also commented, in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652 (1973), that whether a drug is a "new drug" depends on "the expert knowledge and expertise of scientists based on controlled clinical experimentation and backed by substantial support in scientific literature.")

[57] We have determined that AHP did not make a direct "establishment" claim with regard to APF (see *supra* at 15, n.[21]), but it did claim that APF causes less gastric discomfort than other analgesics. This claim is open to substantial question, as explained in the text.

antacids (RX 96B))—reduces the amount of gastric discomfort caused by its consumption (R.A.B. at 59).[58] **[35]**

While there is some testimony in the record that buffered aspirin may cause less gastric discomfort than regular aspirin (*e.g.*, Shapiro, Tr. 3041; CX 367Z100; see RX 96B),[59] even respondents' experts were not convinced that the use of buffers necessarily reduced gastric discomfort (*e.g.*, Lasagna, Tr. 4192–93). Complaint counsel's experts testified that substantial evidence that the addition of buffers results in less gastric discomfort does not exist (Sliwinski, Tr. 1149; Plotz, Tr. 1063; Grossman, Tr. 862; F. 383).[60] In fact, the American Medical Association's *Drug Evaluations* [61] states that the available evidence does not indicate that buffered aspirin is any better than ordinary aspirin (CX 362W). **[36]**

It is also open to question whether the substitution of microfine (micronized) aspirin for regular aspirin reduces the incidence of gastric discomfort. There is some evidence that micronized particles may be absorbed more quickly and thus cause less irritation (*e.g.*, RX 96B). Complaint counsel's experts testified, however, that it has not been established that microfine aspirin causes less gastric discomfort (Sliwinski, Tr. 1149; Plotz, Tr. 1061; F. 369). Indeed, Dr. Grossman stated that it is unlikely that microfine aspirin makes any difference at all (Grossman, Tr. 850–51). The fact that these medical experts did not agree that micronized aspirin reduced gastric discomfort demonstrates the existence of doubt in the medical community.

Thus, APF's claimed superiority in terms of gastric discomfort, like Anacin's purported superior efficacy for pain relief, has not been established, and is open to substantial question in the scientific community. Respondent has, then, advertised the superiority of its analgesic products without either demonstrating that superiority adequately or qualifying the claims by disclosure of the existence of a

[58] The only study of APF in the record is one that compared its efficacy to that of buffered aspirin (CX 304). Since the only data from that study concerning gastric discomfort was generated incidentally, in the course of the efficacy comparisons (CX 304Z023; see Plotz, Tr. 1054), it is not sufficient to show APF's superior freedom from side effects. (See discussion *infra* at 43–44.) Respondent quite properly does not rely on CX 304 for substantiation of the freedom from gastric discomfort claim.

[59] RX 96 is a letter written by Dr. Arthur Grollman, a professor of experimental medicine at the University of Texas Medical School, reciting his views on the safety and efficacy of a drug formulated in the same manner as APF. The letter states Dr. Grollman's opinion that micronized particles are "less apt to cause gastric irritation" and that the antacids "give additional protection against gastric irritation" (RX 96A). This letter is evidence of only one physician's opinion as to the freedom from side effects of a drug like APF and it is refuted by complaint counsel's showing that APF's comparative freedom from gastric discomfort is open to substantial question in the scientific and medical community.

[60] Respondents quote the FDA panel report which concludes that buffered products "can be expected" to reduce gastric discomfort (R.A.B. at 60, quoting CX 367Z100). The panel report, however, speaks of only *some* of the persons who suffer gastric discomfort from consumption of regular aspirin, and goes on to conclude that "the evidence is insufficient to substantiate the claims that buffered * * * aspirin * * * is safe for use in patients who should not take regular * * * aspirin" (CX 367Z101).

[61] See *supra* at 28, n.[45].

substantial question. The advertisements in question are therefore deceptive within the meaning of Section 5 of the FTC Act.[62]

There remains for our consideration, however, respondents' contention that they were denied notice and a fair opportunity to be heard on the "substantial question theory" of liability. R.A.B. at 7–10. Respondent's argument appears to consist of three separate assertions. First, AHP contends that the "substantial question theory" pleaded in the complaint is a "novel theory," in that it challenges neither the truthfulness nor the lack of a "reasonable basis" for the claims made. R.A.B. at 8. But the fact that the "substantial question" phrasing used in this complaint may not have appeared in Commission cases previously would not constitute any violation of AHPs' rights. As we have explained, respondents' liability for their failure to disclose the existence of a substantial question rests on principles of deception in advertising that are established under Section 5. Respondents cite no legal authority for the proposition that a violation of due process may arise from an interpretation of the law which, although not previously articulated, flows directly from existing precedent. **[37]**

Indeed, it is settled that "there is . . . a very definite place for the case-by-case evolution of statutory standards," *SEC* v. *Chenery Corp.*, 332 U.S. 194, 203 (1947). See also *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). The Supreme Court has specifically confirmed the Commission's authority to interpret Section 5 of the FTC Act in a case-by-case manner. See, *e.g.*, *FTC* v. *R.F. Keppel & Bros.*, 291 U.S. 304 (1934). A problem only arises if the retroactive effect of applying a new standard causes a detriment to the respondent which outweighs the need for administrative flexibility. *NLRB* v. *Bell Aerospace Co., supra.* That is not the case here, where respondent will only be required to cease deceptive advertising practices, and will not be subject to fines, damages, or other immediate penalties.

Second, AHP argues that this theory of liability is "vague." R.A.B. at 8. We take this to mean that respondents believe it was denied notice and an opportunity to defend itself on the allegation of failure to disclose the existence of a substantial question. We believe, however, that the issue this allegation raised—*i.e.*, the question of what level of substantiation the scientific community would require to support the validity of respondents' claims such that no substantial question would remain—was hardly one which AHP could not perceive from the complaint and progress of the proceedings. *NLRB*

[62] In light of this conclusion, we do not reach the question whether the advertisements are also unfair under Section 5.

v. *Mackay Radio & Tel. Co.*, 304 U.S. 333, 349–50 (1930); cf. *NLRB* v. *Johnson*, 322 F.2d 216, 219–20 (6th Cir. 1963).

The complaint charged, in Paragraph 13, that at the time respondents made the comparative claims alleged in Paragraph 12, "there existed a substantial question, recognized by experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug products, concerning the validity of such representations," and in Paragraph 14, that respondents failed to disclose the existence of a substantial question. In Paragraph 25, the complaint charged that this failure to disclose constituted an unfair or deceptive act or practice.

The pretrial proceedings made clear that to establish liability under this standard, complaint counsel would have to demonstrate the existence of a substantial question about the validity of the claims on the basis of the entire state of medical knowledge and opinion. Statement of Complaint Counsel on Certain Issues in Response to the Order of the Administrative Law Judge, filed July 27, 1973 ("Statement on Certain Issues") at 1–2; Pre-Trial Conference Transcript of Feb. 20, 1974, at 52, 64 (remarks of Judge Jackson), of Feb. 9, 1976, at 13–14 (remarks of Judge Hyun), and at 49 (remarks of Mr. Donegan). As complaint counsel repeatedly explained before trial, and as the ALJ confirmed, the issue of whether there is in the scientific community a substantial question **[38]**about a given proposition is a factual determination to be made on the basis of expert testimony and other evidence on the record. Statement on Certain Issues at 3; Pre-Trial Conference Transcript of March 4, 1976, at 74–6. Respondents were not deprived of an opportunity to rebut complaint counsel's showing of a substantial scientific question; indeed, the ALJ specifically announced at a Prehearing Conference, "I will allow both sides to put on evidence which conforms to any statement of their version of substantial question." Pre-Trial Conference Transcript of Feb. 20, 1974, at 48, 55–6. As we discussed above, the record ultimately demonstrated that the scientific community retains doubts about the validity of comparative analgesics claims if those claims have not been established by more than one adequate controlled clinical test, and that a substantial question did in fact exist as to Anacin's and APF's superiority.

Finally, respondents contend that the ALJ resolved this aspect of the case under the "reasonable basis" standard notwithstanding respondents' understanding throughout the trial that that was not the relevant legal standard. R.A.B. at 10. The ALJ, in applying the substantial question standard, stated that this standard "is, in the

particular factual context of this case, a reasonable and logical refinement of the 'reasonable basis' doctrine . . . ." I.D. at 210 (emphasis added). In our view, Judge Hyun was correct. The Commission's formulation of the substantial question allegations in this complaint constituted an assertion that a specific type of substantiation is required for the OTC analgesics claims challenged—*i.e.*, that the existence of a substantial question among the qualified scientists concerning these analgesic claims renders them deceptive, unless the existence of a substantial question is disclosed in the ads. Our reasoning in support of this interpretation of Section 5 is provided above. Respondents were on notice that this standard is not precisely the same as "reasonable basis," but is an extension of it, insofar as it requires that we look beyond the reasonableness of the supporting evidence in a respondent's possession when its claims were made, to the universe of relevant scientific knowledge and opinion.

For all the foregoing reasons we find unpersuasive respondents' assertions of a denial of due process arising from the application of the substantial question standard of liability.

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In sum, we have examined two categories of comparative efficacy and side effects claims made by respondents, and found each to be deceptive under the appropriate legal standard. The first category of claims, covered by Paragraphs 10 and 11 of the complaint (and discussed in Part B above), consists of direct representations that the superiority of AHP's drug products has been *proven*. Where those claims are made, they must, based on the testimony in this case (and consistent with FDA's standards), find support in more than one adequate clinical test. We found further that AHP failed to meet this standard here, and that its claims of proof were therefore false and deceptive. **[39]**

Advertising claims in the second category, covered by Paragraphs 12, 13 and 14 of the complaint (and discussed in Part C above), represent that AHP's products are better than its competitors', but do not rely on affirmative indicia of "proof." We have held that in the context of drug products, consumers may reasonably expect such claims to be supported by evidence sufficient to satisfy the scientific community, which this record shows to be more than one adequate clinical test. Because respondents' claims were neither supported by the requisite evidence nor accompanied by a disclosure of the absence of proof or existence of doubt, we found them to be deceptive.

III. *Other Alleged Claims*

A. Tension relief

Respondents are alleged to have claimed in numerous advertisements "that a recommended dose of Anacin relieves nervousness, tension, stress, fatigue and depression and will enable persons to cope with the ordinary stresses of everyday life" (Comp. ¶ 15). AHP argues that the advertisements at issue promised relief from tension and related mood effects only when those effects are caused by headache pain (R.A.B. at 40–41).

We agree with the ALJ that many of respondents' advertisements convey the message that Anacin is not only a pain reliever, but is also independently effective for relief of tension, nervousness, and stress. F.F. 156–170; I.D. at 170–72. These advertisements emphasize the "mood" effects that could be achieved by taking Anacin, and give far less attention to the secondary message that Anacin relieves headache pain.

One scene repeatedly depicted, for example, is a household situation in which one family member, feeling tense or pressured by some minor irritation, takes Anacin, with the result that the irritation is removed and harmony in the home restored. See, *e.g.*, CX 39–46. See also the "Housewife Headache" series of print ads, CX 92–95, stressing the "nervous tension and fatigue" that can result from housework ("a mild form of torture"). Another variation on this theme is CX–160, a radio ad in which the announcer, against a background that includes a baby crying and a dog barking, cites "fatigue" (twice), "stress" (twice), "nerves" (twice), "tension" and "headache pain," concluding, "Yes, there can be more to a headache than just pain."

Other advertisements are based on the tension associated with stressful jobs. For example, CX 31A shows a bank teller handling a long line of customers on payday, the teller's tension headache dissolving into a smile after Anacin is taken. In still other ads we see an individual in a hurry (CX 22A) or pressured by a variety of burdensome tasks (CX 8A), and witness the tension "relaxed" by Anacin (as it relieves pain, we are told). **[40]**

Another technique used to create a sense of tension is to remind viewers of typically stressful situations that they might have encountered in the past. For example, one advertisement shows a man anxiously waiting in an employment office (CX 38); another shows a young couple looking for an apartment (CX 26). In the apartment advertisement, the tension is depicted by outward signs of stress on the part of the young woman: in one frame she is biting her

lip, in another she appears to be biting her nails. After Anacin is taken, the couple finds an apartment, and the tension is relieved.

The ASI copy test for this commercial (CX 418) shows that "tension/nervous tension" was the symptom most often identified by viewers. Twenty-two percent identified tension/nervous tension as a symptom relieved by Anacin, while only three percent named "tension headache" (CX 418J). Dr. Ross pointed out that relief by Anacin of tension *per se* was perceived by more consumers than relief of a tension-caused headache (Ross, Tr. 1997). Indeed, Dr. Ross testified that in viewing these Anacin advertisements, particularly the family scenes, the consumer perceives that "the dominant benefit that is being promised by Anacin is the relief of fatigue, stress and nerves, not dominantly pain or headache" (Ross, Tr. 1953). Referring to CX 26 (apartment commercial), Dr. Ross stated that the primary theme of the advertisement is that nerves and stress (rather than pain) are relieved by Anacin (Ross, Tr. 1995). Dr. Ross also testified that the print advertisements (*e.g.*, CX 89) were devoid of references to pain and that the headache to be relieved by Anacin ("Housewife's Headache") was characterized as being composed of tension and fatigue, not of pain (Tr. 2004–05).

These ads, considered in their totality, convey a strong message that Anacin relieves anxiety, stress and other mood problems entirely apart from its function as a pain reliever.

Having found that respondents' advertisements made the tension relief claims as alleged, we must consider whether respondents had a reasonable basis for making such claims.[63] AHP argues only [41]that it had a reasonable basis for its claim "that Anacin will relieve *tension-associated pain*," (R.A.B. at 59 (emphasis added)). This is essentially a repetition of its argument that the Anacin advertisements made representations only about tension caused by headache pain, an argument which we have already rejected. Respondents do not claim to have had a reasonable basis for the representations that Anacin will relieve tension and stress apart from its pain-relieving properties. The record is clear and uncontradicted that Anacin does not possess such properties (DeMott, Tr. 4765; Rickels, Tr. 1236–37; F.F. 343–57).

[63] As to this noncomparative claim, the complaint charged respondents with lack of a reasonable basis, "in that respondent had no competent and reliable scientific evidence to support such representations" (Comp. ¶ 16), rather than failure to disclose the existence of a substantial question. The Commission is aware that the application of these two different standards (see *supra* at 38 for discussion of the difference) to noncomparative and comparative advertising claims could create an appearance that comparative claims will be burdened hereafter by more stringent substantiation requirements, and that comparisons—which when truthful and nondeceptive may be useful to consumers—will be thereby disadvantaged. The Commission does not intend any such result, nor does it believe such a result necessarily flows from this case. We note that the FDA statute and regulations discussed earlier directly apply the "substantial evidence" standard to noncomparative claims on OTC drug labels (and to noncomparative and comparative claims in prescription drug labeling and advertising).

B. Relief in 22 Seconds

The complaint (¶8(A)(4)) also alleged that AHP's advertising represented "that within approximately 22 seconds after taking Anacin a person may expect relief from headache pain." Unlike the ALJ, we find it improbable that consumers would believe, based on the advertisements in the record, that Anacin can relieve headache pain only 22 seconds after it is taken. The print advertisements (CX 142–44, 151, 153) all stated that Anacin would provide relief 22 seconds "after entering your bloodstream," not after it is taken. Moreover, the one television ad that used this theme (CX 1) specifically qualified the 22-second claim with the comment, "[w]hile you won't feel it for minutes * * *." Therefore, we do not adopt F.F. 148–55.

C. Survey Claims

Paragraph 20 of the complaint alleges, and the ALJ found, that AHP's advertisements also contained claims representing that physicians or specialists prefer and recommend Anacin more than other OTC analgesics, as demonstrated by surveys. See F.F. 109–12. The ALJ found that the mail survey on which these representations were based was inadequate to substantiate them. Respondent has not appealed these findings. We agree with the ALJ that the claims were made and that there was no adequate basis for them, in light of the response rate in the survey of only 10%. See F. 393.

IV. *Liability of C. T. Clyne Company*[64]

The ALJ concluded that respondent Clyne, AHP's advertising agency for APF, was liable for the false claim that APF's analgesic ingredient is unusual or special, but not for the claim that it is established by medical or scientific proof that APF causes less gastric discomfort than other OTC internal analgesics (I.D. at 224). The ALJ's order thus requires that Clyne cease and desist from representing, with respect to any OTC internal analgesics, that such products contain any ingredient or combination of ingredients that is unusual or special, when that ingredient or combination of ingredients is contained in other OTC analgesics. **[42]**

Complaint counsel appeal from the limitation of Clyne's liability to the ingredient content claim and assert that Clyne should be held liable for the gastric discomfort comparative claim as well (C.C.A.B.

[64] The C. T. Clyne Company, Inc. is the corporate successor to Clyne Maxon, Inc., the advertising agency named in the complaint (CX 610B (Stip. 1)).

at 26). They argue that the order should be expanded to apply to Clyne requirements for comparative efficacy claims comparable to those applied to AHP (C.C.A.B. at 40). Respondent Clyne does not appeal directly from the findings of the ALJ, although in its answering brief it contends that it is entitled to a clause in the order precluding liability unless Clyne knew or had reason to know that the representations at issue were false or deceptive (Clyne Ans. Br. at 26–27), and a clause that expressly provides that Clyne is permitted to rely on its client for any substantiation required by the order (Clyne Ans. Br. at 27).

The liability of advertising agencies for violations of Section 5 is governed by two general principles. First, in order for the agency to be held liable, it must have been an active participant in the preparation of the advertisements at issue. *Doherty, Clifford, Steers & Shenfield, Inc.* v. *FTC*, 392 F.2d 921, 927 (6th Cir. 1968); *Carter Products, Inc.* v. *FTC*, 323 F.2d 523, 534 (5th Cir. 1963); *ITT Continental Baking Co., Inc.*, 83 F.T.C. 865, 967 (1973), *aff'd and modified*, 532 F.2d 207 (2d Cir. 1976). Second, it must have known or have had reason to know that the advertisements were false or deceptive. *Doherty, supra*, 392 F.2d at 927; *Standard Oil Co.* 84 F.T.C. 1401, 1475 (1974); *aff'd and modified*, 577 F.2d 653 (9th Cir. 1978).[65]

The record demonstrates that Clyne was a sufficiently active participant in the creation of the Arthritis Pain Formula advertisements at issue[66] to satisfy the first criterion for advertising agency liability (Ans. of Clyne, ¶ 4; CX 610B (Stip. 3, 5, 6); CX 611Z165; F.9, 467 (I.D. at 9, 116)).[67] It is evident, moreover, that Clyne was aware of both the aspirin content of APF (Noncontested Facts ¶ 13) and the fact that aspirin is available in many OTC drug products (Noncontested Facts ¶ 14). Clyne, therefore, not only had reason to know that APF's analgesic ingredient was not unusual, but the ALJ correctly found that Clyne actually knew that the unusualness representations were false (I.D. at 224). We sustain the ALJ's finding of Clyne's liability for these claims. **[43]**

We have found that the claim that it is established that APF causes less gastric discomfort than other internal OTC analgesics was not made by means of the same techniques conveying proof that AHP used for Anacin (*supra* at 15, n.[21]). We have also found,

[65] Although as we discuss *infra* complaint counsel have affirmatively established that Clyne knew or should have known that the ads were deceptive, we note that it has been held that the burden of proof rests in the first instance on the advertising agency: "An agency is clearly liable for the advertising it has created, produced or assisted in producing unless it can be shown that it did not know or could not know that the challenged advertising was false." *ITT Continental, supra*, 83 F.T.C. at 968.

[66] The only allegations in the complaint relating to Clyne are those that deal with the advertising of Arthritis Pain Formula (*e.g.*, Comp. ¶¶ 4, 8B, 9B, 10B, 12B and 22).

[67] Moreover, Clyne's active participation is undisputed on appeal.

however, that AHP and Clyne did make the unqualified claim that APF will cause gastric discomfort less frequently than other internal OTC analgesics, without disclosing that this claim is open to substantial question in the medical community. We must therefore decide whether Clyne knew or had reason to know that this unqualified claim was deceptive.

Clyne argues that an advertising agency has no responsibility to conduct an independent examination of the relevant scientific evidence before participating in the creation of its clients' advertising programs (Clyne Ans. Br. at 4–5). Nevertheless, under the circumstances presented, Clyne should have inquired further than it did into the state of the medical evidence supporting the comparative efficacy claim.

Clyne admits that the only evidence it had before it that the claim was true was CX 304, a study conducted by the research division of AHP (CX 611Z144), and that no experts other than those employed by AHP were consulted (CX 611Z169). CX 304 (entitled "Arthritis Pain Formula Evaluation") consists of a study conducted by AHP to compare the efficacy of APF and buffered aspirin for relief of the symptoms of arthritis. Although the purpose of the study was not to compare the gastric effects of the two formulations, and data on such effects were gathered only incidentally, the study concluded that "[i]t was established that Arthritis Pain Formula demonstrated significantly less evidence of gastrointestinal irritation and bleeding than did the buffered aspirin formula" (CX 304S).[68]

The ALJ found that Clyne's reliance on the AHP study was not unreasonable, and that a contrary finding would impose a duty on the advertising agency, unwarranted by the facts of the case, to conduct an independent investigation of its clients' substantiation for their claims (I.D. 224–25).

An advertising agency may, of course, rely on a *reliable* study provided by its client to substantiate advertising claims. If a study is on its face defective, however, such reliance cannot be considered reasonable. The APF evaluation here at issue is so clearly inadequate to support the claim that APF's freedom from gastric discomfort is superior to that of other analgesics that Clyne cannot be said to have been reasonable in its reliance. **[44]**

It should have been clear, even to the untrained eye, that the data on gastric discomfort generated by the study were collateral to its main purposes. A glance at the study's protocol (which was provided

[68] Complaint counsel point out that "gastrointestinal irritation" is not necessarily the same as "gastric discomfort" (C.C.A.B. at 29 n. 73). That proposition, however, is not self-evident, and Clyne's assumption that the two terms were synonymous is understandable. We agree with the ALJ that "Clyne should not be faulted for having equated 'gastrointestinal irritation' with 'stomach discomfort' " (I.D. 224).

to Clyne along with the study (CX 304A021–27)) demonstrates that only those side effects that happened to be volunteered by the patients were to be recorded (CX 304Z023). The data tables show that very few patients did volunteer that information (CX 304Z019). Such uncorroborated data are patently insufficient to prove scientifically APF's relative freedom from gastric discomfort. Thus, it should have been obvious to Clyne that there was a disparity between the type of substantiation provided and the unqualified representations made for the superiority claim. Under these circumstances, Clyne should have inquired further into AHP's substantiation.

We hold, then, that Clyne could not have reasonably relied on the AHP study as support for the claim that APF's freedom from gastric discomfort is superior to that of other internal OTC analgesics, and that Clyne is therefore liable for the deception caused by the claim.[69] This holding does not, as Clyne suggests, burden advertising agencies with a duty to conduct independent scientific investigations in order to substantiate their clients' claims (Clyne Ans. Br. at 5). Clyne could easily have fulfilled its responsibility here by insisting that its client provide further substantiation or by disclosing the lack of proof or existence of a substantial question. We hold only that when presented with a facially inadequate study as substantiation, an advertising agency may not ignore the study's defects. **[45]**

V. *Relief*

A. Overview

The attached order encompasses the acts and practices of respondents which we have found to violate Sections 5 and 12, as described in the foregoing discussion, and, where we believe it to be necessary, circumscribes potential closely-related violations under the Commission's well-established authority to close off all avenues to prohibited conduct. *FTC* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952). See also *Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 468 (1972), *aff'd* 481 F.2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 1112 (1973); *Carter Products, Inc.* v. *FTC*, 268 F.2d 461, 498 (9th Cir.), *cert. denied*, 361 U.S. 884 (1959).

The order diverges in several important respects from that proposed by the ALJ (described above at p. 3). For example, the ALJ's order would have applied a clinical testing requirement to

[69] For the sake of clarity we have included a "know or reason to know" clause in Part V.A of the order. Although such a clause is not required (*ITT Continental Baking Co.* v. *FTC*, *supra*, 532 F.2d at 224), complaint counsel do not object to its inclusion (C.C.A.B. at 31 n. 78). In part V.B, we have included "know or reason to believe," because we can assume that Clyne does not itself have the expertise to evaluate thoroughly the validity of these studies, and must to a certain extent rely on its client for expert evaluation.

advertising by respondent of any OTC drug, whereas the attached order applies such requirements only to advertisements for OTC internal analgesic drugs, for reasons to be explained below. Under this order, in all such advertisements, AHP must cease any claim of proven superior effectiveness or proven superior freedom from side effects unless the claim is proven by adequate clinical studies, and cease any other claim of superior effectiveness or superior freedom from side effects unless it is either proven by adequate clinical studies or qualified by disclosure of the existence of a substantial question or the absence of scientific proof.

In addition, the attached order requires that along with ceasing false "unusual ingredient" claims for any OTC drug, AHP must disclose the presence of aspirin in any Anacin or APF ad making any performance claim. We have deleted the provision in the ALJ's order requiring disclosure of the presence of aspirin in any advertisement for an OTC drug containing aspirin.

Under our order AHP must also cease misrepresentations of test or survey results, and false representations about the quantity of any active ingredient in comparison to the quantity in competing products. Finally, AHP is ordered to cease tension relief claims for Anacin, and other non-comparative claims for Anacin, APF, or any other OTC drug product for which a reasonable basis, consisting of reliable scientific evidence, is lacking. **[46]**

Respondent C.T. Clyne is ordered to cease unusualness claims for APF and other OTC analgesics which it knows or has reason to know are false, and with respect to claims of comparative freedom from side effects of APF or other OTC analgesics, Clyne must either know or have reason to believe that a product's superiority has been established, or make the necessary disclosure. The latter provision was not imposed under the ALJ's order.

We find it unnecessary to order corrective advertising to remedy previous claims of Anacin's superior efficacy. In addition, we reverse the ALJ and decline to order a corrective remedy for the tension relief claims. Finally, our order, unlike the ALJ's, does not cover labeling, but is limited to advertising claims.

B. Comparative Efficacy and Side Effects Claims

Under Part I.A. of the order, claims by AHP representing that the superior effectiveness or freedom from side effects of any OTC internal analgesic has been proven are prohibited unless they are supported by at least two adequate well-controlled clinical studies. The criteria shown by the record to be necessary to ensure that the clinical studies are adequate and well-controlled are set forth in the

order. Advertisements will trigger this testing requirement if they expressly claim that the product's superiority is proven or established; refer to medical or scientific research, tests or reports; or imply the existence of scientific or medical support through any of the sorts of techniques AHP has used, including references to or visual depiction of scientific graphs, formulas or diagrams, or a scientific or medical setting, conveyed *e.g.*, by the use of medical reference texts. See discussion *supra* at 15–18.

Part I.B. of the order provides that any other comparative claim by AHP for an OTC analgesic must be either supported by the same type of clinical testing set forth in Part I.A., or qualified by a disclosure that the claim has not been proven or that there is a substantial question about its validity.[70] A similar provision applies to analgesic advertising by Clyne, under Part V. As we have said, this record shows that any comparative analgesic claim not supported by adequate clinical tests cannot be considered to have been proven, and is necessarily open to a substantial question. We have also explained why the Commission believes that when such proof is lacking, it is deceptive to make a superiority [47]claim unless the existence of a substantial question or the absence of proof is disclosed.[71]

If respondents' advertising triggers the disclosure provision of Part I.B, the necessary disclosure must be made clearly and conspicuously in the ads. To eliminate uncertainty on respondents' part, the order permits them to use one of the forms of disclosure specified in the order itself.[72] In the alternative, they may design a disclosure of their own choosing. If respondents use language other than that specified in the order, they must maintain records that will be adequate to demonstrate that the required message will be or has been effectively conveyed to the advertisement's intended audience. Such records may consist of the copy tests performed in the routine course of respondents' business.

These provisions of the order apply to advertising of Anacin and

[70] False claims about the comparative quantity of analgesic or other active ingredients in respondent's OTC drug products are specifically prohibited under Part II.B.

[71] Affirmative disclosure requirements have been included in Commission cease and desist orders on numerous occasions where advertisements would otherwise be misleading (*e.g.*, *National Comm'n on Egg Nutrition*, 88 F.T.C. 89 (1976), *aff'd and ordered enforced as modified*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Keele Hair & Scalp Specialists, Inc.*, 55 F.T.C. 1840 (1959), *aff'd*, 275 F.2d 18 (5th Cir. 1960), and the Commission's authority to order such disclosures is no longer open to question. *Warner-Lambert Co.* v. *FTC*, 562 F.2d 749, 759 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

[72] The disclosures specified are that the claim is "open to substantial question" or that the claim "has not been proven." Because this language constitutes precisely that message necessary to remedy what we have found to be otherwise misleading superiority claims, we have included it, rather than language proposed by complaint counsel, in the order. Complaint counsel proposed a disclosure that "it is not known whether . . ." or that "there is a real question whether . . . ." C.C.A.B. at 23. If those or other forms of disclosure can be shown to convey the required message, they would of course be acceptable under Part I.B.2.

APF, and of any other OTC internal analgesic product as well. While the case law makes clear that we are not required to restrict our order to the particular products at issue,[73] we [48]believe that some discussion of this issue is appropriate in light of the judicial modification of an earlier order against AHP. *American Home Products Corp*, v. *FTC*, 402 F.2d 232 (6th Cir. 1968).[74] As summarized recently in *Sears Roebuck & Co.*, Docket No. 9104 (April 28, 1980), slip op. p. 11, *appeal pending* No. 80–7368 (9th Cir.), "The appropriate scope of an order necessarily depends upon a rough evaluation of the extent to which a practice is likely to be repeated", as measured by factors including the transferability of the practice to other contexts, extent of the violation, state of mind of respondent, and past history of respondent.

Respondent could, with no difficulty, make unsubstantiated and unqualified assertions of superiority in advertising for other analgesic products as it has done in its promotion of Anacin and APF.[75] We turn, then, to consideration of those factors indicating whether AHP is likely to do so.

The advertising challenged in this proceeding was widely disseminated, in print and broadcast media, over a period of many years and at a cost of millions of dollars annually. F.F. 4, 5, 585, 586.[76] A reading of those advertisements demonstrates that respondent consistently made the deceptive claims. Moreover, as we stated in a previous opinion, "respondent is hardly a stranger to Commission proceedings." *American Home Products Corp.*, 70 F.T.C. 1524, 1625 (1966). This case represents the fourth time that we have entered a litigated cease and desist order against respondent on the basis of misleading advertising [49]claims for OTC drug products.[77] As we

[73] See, *e.g.*, *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 394–5 (1965); *Jay Norris* v. *FTC*, 598 F.2d 1244, 1250 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979); *ITT Continental Baking Co*, v. *FTC*, 532 F.2d 207 (2d Cir. 1976); *Sears Roebuck Co.*, Docket 9104 (April 28, 1980), appeal docketed No. 80–7368 (9th Cir.). Other court decisions sustaining Commission orders prohibiting specified deceptions as to a category of products, based upon findings of deception in the sale of one product, include *Porter & Dietsch, Inc.* v. *FTC*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (order prohibiting unsubstantiated efficacy claims for any "food, drug, cosmetic, or device" sustained on basis of findings that efficacy of one product was misrepresented); *National Dynamics Corp.* v. *FTC*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974) (order prohibiting certain unsubstantiated performance claims for *all* products sustained on basis of findings of deceptive advertising for one product).

[74] That case involved a hemorrhoid treatment product ("Preparation H") and the original order would have prohibited respondent from misrepresenting the efficacy of any drug. The court limited the order to the specific product at issue.

[75] This situation thus differs from that in *Standard Oil Co. of Calif.* v. *FTC*, 577 F.2d 653 (9th Cir. 1978), where the court found that "the petitioners' violations involved use of a visual image which was misleading because of the specific subject matter of the advertising. The violations were not a technique of deception that easily could be transferred to an advertising campaign for some other product." 577 F.2d at 663.

[76] In *FTC* v. *Colgate-Palmolive Co.*, *supra*, three commercials were found sufficient to support an "all products" order; in *ITT Continental Baking Co., Inc.* v. *FTC*, *supra*, "numerous advertisements comprising two large campaigns over a number of years" were found to support an order relating to growth properties of any food product.

[77] Our previous orders concerned: false representations of the drug "Freezone" to remove corns by respondent's wholly-owned subsidiary, *Wyeth Chemical Co.*, 29 F.T.C. 281 (1939); misrepresentations concerning

(Continued)

have stated, those previous Commission proceedings all concerned "the making of misleading exaggerations and misstatements in advertisements with respect to the efficacy of the drugs which [it] was selling." 70 F.T.C. 1524, 1625. There is simply no room left to doubt that respondent is "a habitual violator of the Federal Trade Commission Act," *American Home Products Corp.* v. *FTC, supra*, 402 F.2d at 237,[78] and that in order to protect the public adequately against future deception of the same sort, these provisions of our order must cover claims for more than the two products misrepresented.

We have, however, extended this section of the order only to OTC internal analgesics rather than all OTC drugs as the ALJ proposed,[79] in recognition of the possibility that comparative claims for other OTC drug products may be adequately substantiated, at least in some instances, by evidence other than two clinical tests meeting the criteria outlined above. Respondent has argued that a single standard of proof is inappropriate for assessing the comparative efficacy of different types of drugs. Resp. Reply Br. at 20–23. **[50]**

The record establishes that the standard requiring at least two tests, with placebo controls, is required for substantiation of analgesics claims, due to the likelihood that a subject's expectations will influence a subjective response like pain relief. But while the requirement for two such studies to support OTC drug claims in general has been widely accepted, we note that the FDA regulation for new drug approvals, which is expressly based on this standard, does provide that the testing criteria may be waived in whole or in part where a waiver petition demonstrates that "some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be, or have been, followed, the results of which will or have yielded [sic] data that can and should be accepted

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"Outgro" for restoring ingrown toenails, *American Home Products Corp.*, 63 F.T.C. 933 (1963); and misrepresentations about its hemorrhoid treatment product "Preparation H." *American Home Products Corp.*, 70 F.T.C. 1524 (1966).

[78] We also take notice of the fact that respondent has elsewhere been found to have made false and misleading representations concerning the properties of Anacin and "Maximum Strength Anacin." *American Home Products Corp.* v. *Johnson and Johnson*, 436 F. Supp. 785, 803 (S.D.N.Y. 1977), *aff'd*, 577 F.2d 160 (2d Cir. 1978) (representations concerning superiority of Anacin to Tylenol generally and for inflammation); *McNeilab, Inc.* v. *American Home Products Corp.*, 79 Civ. 3973 (S.D.N.Y., filed July 21, 1980) (representations that Maximum Strength Anacin is a stronger analgesic than Extra Strength Tylenol, and has the maximum strength allowed without a prescription).

[79] The ALJ subsequently stated in his decision in *Bristol-Myers Co.*, Docket No. 8917 (Sept. 18, 1979), that he has modified his views concerning the scope of this provision (see Initial Decision in that proceeding, at 254–55), and he would presumably agree with the product coverage of our order. In light of our resolution of this issue, we deny AHP's motion of Feb. 13, 1981 for remand and reopening of proceedings, which respondent bases on the ALJ's proposed orders in *Bristol-Myers* and in *Sterling Drug*, Docket 8919.

as substantial evidence of the drug's effectiveness." 21 C.F.R. 314.111 (a)(5)(ii)(a).[80] Therefore, although complaint counsel assert that this waiver has been applied to date by FDA's advisory panels only in "extremely unusual instances," none of which involved comparative drug claims (C.C.A.B. at 71–3), we cannot assume that a similar allowance for exceptions would be unwarranted for comparative OTC drug claims far afield from the scope of this litigation.[81]

AHP argues, however, that the testing standard applied by the ALJ violates its First Amendment rights. Relying on political speech cases, it contends that the requirement of two well-controlled clinical studies for comparative claims is an impermissible prior restraint, and that the alternative offered (disclosing that the representations made have not been proven) is similarly prohibited. R.A.B. at 19. Respondent also claims that the order provision infringes the First Amendment by chilling "truthful" comparative claims because of the expense of substantiating such claims. We find these arguments to be without merit. **[51]**

The order provision challenged by respondent does no more than prohibit advertising that is deceptive, by stating or implying that the superiority of respondent's analgesic products has been established by scientific or medical evidence, without disclosing the absence of scientific proof, or the existence of substantial scientific doubt. As the Supreme Court has only recently reiterated, there is no constitutional protection for deceptive advertising:

> There can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it . . . .

Central Hudson Gas & Electric Corp. v. *Public Service Comm'n*, 100 S. Ct. 2343, 2346 (1980).[82]

Where deceptive advertising occurs, the First Amendment does not prevent the imposition of such relief as is needed to prevent recurrence of the deception, *National Soc. of Professional Engineers* v. *United States*, 435 U.S. 679, 697–98 (1978); and the specific remedial requirement that advertising be substantiated has been judicially sustained in the face of First Amendment challenge, *Jay*

[80] See also 21 C.F.R. 330.10(a)(4)(ii), which incorporates the waiver provision quoted above in establishing procedures for FDA advisory review panels to follow in classifying OTC drugs as safe and effective and in promulgating monographs specifying conditions of use for each category of drugs.

[81] If in the future respondent discovers changed conditions of law or fact which would dictate that even comparative analgesic claims be subject to requirements different from those in this order, it is of course free to file a request for modification of the order under the Commission's Rules of Practice.

[82] Other cases establishing this point include, *e.g.*, *Friedman* v. *Rogers*, 440 U.S. 1, 13, 15–16 (1979); *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 383–4 (1977); *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 771–2, n. 24 (1976).

Norris Corp. v. *FTC*, 598 F.2d 1244, 1252 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979).

In *Jay Norris*, as here, respondent argued that an order (much broader than here) requiring that certain claims be substantiated would chill advertising. As the Commission noted, however, a substantiation requirement fosters rather than impairs First Amendment objectives, because substantiation by an advertiser is the only way to insure that claims are reliable. *Jay Norris Corp.*, 91 F.T.C. 751, 851–855 (1978), *aff'd*, 598 F.2d 1244 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979).[83] Moreover, the dissemination of advertising claims for which the advertiser lacks appropriate [52]support is itself a deceptive practice[84] and prohibition of such claims amounts, therefore, to no more than a constitutionally unobjectionable ban on deceptive advertising.

AHP argues more particularly that even if a requirement of prior substantiation is appropriate, the requirement that AHP possess at least two clinical tests in support of analgesic efficacy claims is overly restrictive. The order, however, does not prevent AHP from suggesting that its analgesic products possess certain properties, even absent two clinical tests, provided that AHP reveals that its claim remains open to question.[85] Given that the record shows that at least two clinical tests are required to establish claims of analgesic efficacy, any attempt to make an unequivocal claim of efficacy without that level of support would clearly be misleading. The testing requirement, therefore, constitutes a necessary and proper restraint on the precise type of misleading advertising that gave rise to this case.

C. Ingredient Claims and Omissions

We have described above, at pp. 5–8, the ways in which respondents conveyed a false representation of the unusualness or specialness of the analgesic ingredient in Anacin and APF. The

[83] The requirement that advertisements be substantiated has been repeatedly sustained. See, *e.g.*, *Porter & Dietsch, Inc.*, 90 F.T.C. 770 (1977), *aff'd* 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980); *Fedders Corp.*, 85 F.T.C. 38, 69 (1975), *aff'd*, 529 F.2d 1398 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976); *Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 475 (1972), *aff'd*, 481 F.2d 246 (6th Cir. 1973), *cert. denied*, 414 U.S. 1112 (1973). We note that in *Central Hudson*, *supra*, the Supreme Court reaffirmed a major premise underlying the requirements of advertising substantiation when it stated that one reason the content of commercial speech may be regulated is that "commerical speakers have extensive knowledge of both the market and their products. Thus, they are well-situated to evaluate the accuracy of their messages . . . ." 100 S. Ct. at 2350, n. 6.

[84] *E.g.*, *National Comm'n on Egg Nutrition*, 88 F.T.C. 84, 191 (1976), *aff'd and ordered enforced as modified*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *National Dynamics Corp.*, 83 F.T.C. 488, 549–550 (1973), *remanded in part on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974).

[85] Requirements that commercial messages include "additional information, warnings and disclaimers" have been recognized as permissible under the First Amendment as a means of preventing deception. *Virginia State Bd. of Pharmacy*, *supra*, at 772, n. 24. See also, *Warner-Lambert Co.* v. *FTC*, 562 F.2d 749, 769–70 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

advertisements emphasized the purported difference between AHP's aspirin-based competitors and its own products, associating the competitors with aspirin but never identifying the analgesic ingredient in AHP's own products as aspirin. Under Part II.A of the order, the misleading affirmative claims may not henceforth be made by AHP in any OTC drug advertising when the ingredient represented as special is in fact commonly used in other products intended for the same purpose.[86] Under Part V, Clyne may not make such claims in any analgesic advertising when it has reason to know of the falsity of the claim. **[53]**

We believe it essential that Part II.A encompass all OTC drug advertising by AHP, and bar misrepresentations of the specialness of common ingredients other than aspirin. The effort to misrepresent the nature of a quite ordinary ingredient—whether it is aspirin, caffeine, or some other substance[87]—is a technique that could easily be applied to advertising of OTC drug products other than Anacin or APF. And as we have described above in detail, this respondent's history of misleading advertising raises a serious concern that the order imposed here be carefully drawn if it is to succeed in preventing future violations.[88]

In addition, Part III of the order requires that in Anacin and APF ads[89] making any performance claims (such as strength, ability to relieve pain, or freedom from side effects), the analgesic ingredient must be clearly and conspicuously disclosed **[54]**as aspirin (when it is aspirin). Part III will ensure that all Anacin and APF ads, save those that merely identify the product without any representation about performance, will reveal the analgesic ingredient to be aspirin; thus, advertisements for the two specific products which this record shows to have been promoted heavily by misleading statement and omission about their analgesic content will no longer create an erroneous impression that the ingredient is something different from and better than aspirin. Without this specific aspirin disclosure requirement, we are concerned that this respondent—with its

[86] Of course, a claim of the unusualness or specialness of an ingredient is likely also to convey a claim of superior effectiveness (or freedom from side effects), and thus be subject to the requirements of Parts I.A, I.B and V.B.

[87] Caffeine, like aspirin, is a common substance available in many products (F. 387; Ans of AHP, ¶ 23). Thus, if caffeine is commonly used in products intended for the same purpose as the advertised product (as aspirin is used in many products intended for pain relief other than Anacin), the advertisement may not state or imply that it is an unusual or special ingredient. The fact that the ALJ found that caffeine has not been shown to pose a serious public health problem is irrelevant, since the basis for this disclosure requirement is the need to prevent misleading representations about the ingredient.

[88] Because the advertising agency does not bring to this litigation the same history of advertising violations as AHP, we believe that an order covering only OTC internal analgesics will suffice as to Clyne. Nor does the order require Clyne to make affirmative ingredient disclosures.

[89] The order also covers advertisements for any product that includes "Anacin" or "Arthritis Pain Formula" in its name, such as "Maximum Strength Anacin."

striking history of related advertising violations—will devise ways to continue misrepresenting the nature of its product.

D. Tests and Surveys

Part II.C of the order prohibits respondent from misrepresenting any test, study or survey or the results thereof, concerning the efficacy or freedom from side effects of its OTC drug products. In light of the findings that respondent made misleading representations involving tests comparing Anacin with other analgesics (see *supra* at 15–17), as well as a survey of doctors (see *supra* at 41), a prohibition on future misrepresentations of this sort is necessary. Such a prohibition is particularly warranted in light of the order's other provisions requiring tests to substantiate certain claims, to ensure that any tests performed thereunder will not form the basis for further misrepresentations. We are limiting this provision, however, to conform to the types of misrepresentations that respondent made: namely, efficacy and freedom from side effects claims. See *Fedders Corp.*, 85 F.T.C. 38, 74 (1975), *aff'd*, 529 F.2d 1398, 1403 (2d Cir.), *cert. denied,* 429 U.S. 818 (1976).

E. Tension Relief and Other Unsubstantiated Noncomparative Claims

Respondent argues that a cease-and-desist order relating to its unsubstantiated tension relief claims is unwarranted because such claims were abandoned in 1973. It is well established that the Commission has authority to enter an order even where the challenged practices have been voluntarily **[55]**abandoned or revised. See, *e.g.*, *American Medical Ass'n* v. *FTC*, 1980–2 (CCH) TRADE CAS. ¶ 63,569 at 77,028 (2d Cir.) (1980); *Giant Food Inc.* v. *FTC*, 322 F.2d 977 (D.C. Cir. 1963), *cert. denied*, 376 U.S. 967 (1964); *Fedders Corp.* v. *FTC*, 529 F.2d 1398 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976). Here, moreover, respondent ceased its tension relief advertising only after the complaint was issued. As the court stated in *Oregon-Washington Plywood Co.* v. *FTC*, 194 F.2d 48, 50 (9th Cir. 1952), "Parties who have abandoned their challenged practices only after proceedings are brought against them are in no position to complain of a cease-and-desist order. In such a case the discontinuance can hardly be thought to be voluntary." In these circumstances we believe that Part IV of the order, prohibiting tension relief claims for Anacin, is necessary to prevent future recurrence of past practices.

In addition, Part II.D of the order requires respondent to have a reasonable basis, consisting of competent and reliable scientific

evidence, for any other noncomparative representations concerning the effectiveness or freedom from side effects of its OTC drug products. In light of the overall history of advertising violations by AHP, described above, we believe this provision is necessary as a fencing-in measure to prevent respondent from making other unsubstantiated noncomparative claims.[90]

F. Corrective Advertising

This case also raises the question of when corrective advertising is appropriate to dissipate the lingering effects of false or deceptive advertisements. The order entered by the ALJ would include some of the corrective advertising proposed in the notice order accompanying the complaint: a disclosure in future advertising to correct a tension relief image would be required, but a disclosure to correct an "established superiority" image would not. AHP appeals **[56]**from the order to correct the tension relief image (R.A.B. at 73–83), while complaint counsel appeal from the failure to order a correction for the comparative efficacy and side effects claims (C.C.A.B. at 7).

It is well settled that the Commission may order prospective disclosures to correct misleading lingering impressions created or reinforced by previous advertising. *National Comm'n on Egg Nutrition* v. *FTC*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Warner-Lambert Co.* 86 F.T.C. 1398 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978). Once the Commission has determined that a false or deceptive image of a product exists in the minds of consumers, it may order the image corrected if it finds that advertising of the product is the primary source of the image, and that, absent correction, the image is likely to endure even after the advertising has ceased. *Warner-Lambert Co.*, *supra*, 86 F.T.C. at 1503 (1975); *Firestone Tire and Rubber Co.*, 61 F.T.C. 398, 429 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973) (separate statement of Commissioner Jones). In recognition of the nature and purpose of advertising, which is aimed at creating enduring product images, the Commission may in appropriate cases presume a lingering effect on consumers. *Warner-Lambert*, *supra*, 562 F.2d at 762; see also the Commission's Statement in Regard to Corrective Advertising, Trade Reg. Rep. (CCH) ¶ 39,046 (1979). See also *Note, Federal Trade Commission Authority to Order Corrective Advertising*, 1978 Wisc. L. Rev. 605, 624–25 (1978).

We must now apply these principles to the case before us.

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[90] See discussion *supra* at 47–49.

1. Tension Relief

Although consumer image and penetration studies in the record show that a significant number of consumers perceived Anacin to be effective for relief of tension (see, *e.g.*, CX 455Z027; CX 452Z024), we are not convinced that these images will persist.[91] [57]The studies reveal that consumers did not recall the tension relief theme as readily as other efficacy claims made by AHP. In the 1971 Bates (CX 477) and 1973 Sobel-Chaikin (CX 453) studies, for example, recall of the Anacin tension relief claim was much lower than recall of the pain relief claims (CX 477W (6%); CX 453035 (2%); Smith, Tr. 5876; I.D. at 122). Tension relief seems to have been a secondary image. When compared with other analgesics in the 1967 Glenbrook study, consumers preferred Anacin to other products much more often because of an image of superior efficacy for pain relief than because of an image of tension relief (CX 454Z022, Z029). In the 1969 Excedrin study (CX 462), only 10% of the respondents who stated that they used analgesics to relieve nervous tension used Anacin, as compared to 21% for Bayer (CX 452Z048), and there was little evidence of recall of the tension claim (Ross, Tr. 2216).[92]

There are two possible, related reasons why the evidence of lasting consumer recall of Anacin's tension relief message seems to be relatively weak.[93] First, tension relief appears to be a less important attribute of an analgesic to consumers than the relief of pain. Consumers tend to retain images of attributes that are most important to them, and their purchasing decisions are affected accordingly (Ross, Tr. 2083–84). Although the perceived ability of an analgesic to relieve tension may be significant to those consumers who seek such relief, the record demonstrates that most consumers consider analgesics most effective for pain relief. For example, the 1969 Excedrin study discussed above (CX 462) shows that strength claims penetrate to a far greater degree than other kinds of messages (CX 462Z070) and the 1967 Glenbrook Analgesics study (CX 454) found that speed (34%), strength (26%), and length (28%) of pain

[91] This conclusion does not conflict with our finding above that consumers did perceive such a message in the ads, or suggest that these claims should be allowed to continue if false or misleading. See generally F. 489 for discussion of the difference between evidence of perception of an advertising claim and evidence of retention of a lasting product image.

[92] In the 1975 Leavitt study (CX 457), only 1.4% of the population surveyed held a tension relief image (CX 457M). We do not rely on this study to assess consumer images, however, because of its serious flaws. See F.F. 528–563.

[93] We emphasize that we do not believe corrective advertising may only be imposed where there is an evidentiary basis like that in *Warner-Lambert, supra*. See *National Cmm'n on Egg Nutrition* v. *FTC, supra* at 165; Statement in Regard to Corrective Advertising, Trade Reg. Rep. (CCH) ¶ 39,046 (1979). For example, the Commission may, absent probative evidence one way or the other, infer that a deceptive advertisement will leave a lingering deceptive impression in consumers' minds. Here, however, for the reasons given, we decline to draw such an inference.

relief were far more significant to consumers than tension relief (19%). [58]

Second, the tension relief theme has not been the primary focus of AHP's advertising campaigns; the central theme has been effectiveness of its products for pain relief (CX 454; 462). Indeed, the ALJ found that the dissemination of advertisements containing tension relief claims ceased altogether in 1973 (F. 525). While the cessation of offending claims does not excuse respondent from liability for those claims, see *supra* at 55, the absence of those claims from the media over a period of several years is relevant to the likelihood that consumers have retained the erroneous product image and thus to the need for corrective advertising.

Since we are not convinced on this record that the tension relief claims are likely to endure in consumers' memories, we reverse the ALJ's decision to order correction of the tension relief message.

2. Comparative Claims

Complaint counsel argue on appeal that corrective advertising is necessary to remedy a false consumer belief that Anacin's superiority has been proven or "established," a belief instilled, they assert, by both advertisements expressly claiming proof and other comparative advertisements failing to disclose the existence of a substantial question. C.C.A.B. at 9, 12–13.[94] They ask the Commission to presume that unless corrected the belief in the proof of Anacin's superiority is one which will linger in consumers' minds beyond the life of the advertising which produced it, despite the absence of direct evidence on this claim's endurance (F. 573).

The record does provide considerable evidence indicating the existence, at least at the time the surveys were conducted (1967–70), of a widespread consumer belief in Anacin's superior efficacy. The 1970 Vanquish study (CX 455) shows that an image of extra strength "dominates brand perceptions" and "is highly correlated with market behavior" (CX 455I). The record demonstrates that a substantial number of consumers consider Anacin to be superior to other OTC analgesics for this characteristic; as complaint counsel's experts testified, several studies show that a superior efficacy image exists (Ross, Tr. 2080, 2184, 2193; Rossi, Tr. 1602, 1615). The 1969 Excedrin study (CX 462), for example, found that 53% of analgesics users described Anacin as "speedy" and 34% described it as "long-lasting" (CX 46Z004), as compared to other brands. The percentages

[94] Complaint counsel do not appear to seek a corrective remedy for advertising of APF. In light of our finding that APF ads did not make the "establishment" claim directly, (*supra* at 15 n *), we agree that a correction for APF ads would be less appropriate than one for Anacin ads.

for Anacin users were even higher (73% and 50%) (CX 46Z005). The 1967 Glenbrook study demonstrates similar results (CX 454N). Dr. Ross and **[59]**Dr. Rossi thus both concluded that a substantial number of consumers believe Anacin to be more efficacious than aspirin (Ross, Tr. 2048; Rossi, Tr. 1570).[95]

We are also convinced that the primary source of this consumer belief in Anacin's superiority is the advertising of the product. F.F. 576–84. Respondent argues that this image may just as easily have been created by product usage (Resp. Ans. Br. at 26), and therefore that corrective advertising would be inappropriate (Resp. Ans. Br. at 24). Product usage, however, can be a primary source of a product image only if the consumer has the ability to discriminate objectively between various similar products (Ross, Tr. 2250). Where no objective test is performed, a consumer who believes before use that there is a difference between products is likely to experience a placebo effect, whereby such a difference is perceived when the products are used (Ross, Tr. 2253). Thus if a consumer is unable to evaluate objectively a product's actual efficacy, the role of advertising as a cause of the consumer image is enhanced (Ross, Tr. 2255). The record demonstrates that many consumers cannot determine the efficacy of OTC analgesics through actual usage, due to the possibility of such a placebo effect (Azarnoff, Tr. 626; DeKornfeld, Tr. 2785; see discussion *supra* at 19). And if product usage is not the cause of the consumer's image of these products, the primary source of the image is likely to be the advertising.[96]

We have already concluded that many of respondent's advertisements claiming Anacin's superior efficacy represented expressly and by clear implication that the product's superiority has been proven, and that other superior efficacy claims, when not qualified by a disclosure of the existence of a substantial question, also had a capacity to mislead consumers as to the existence of proof. Therefore, if we were to conclude that **[60]**the image of Anacin's superiority will endure unless corrected, we could logically presume that an image of proven superiority is also likely to linger in consumers' minds, and order the relief sought by complaint counsel.

There is some basis in this record for concluding that the superiority image, and thus the implicit proven superiority image,

[95] Respondent argues that a study of data gathered by NPD Research, Inc. (RX 176–185) shows that any image consumers hold of Anacin's superior efficacy does not result in loyalty to the Anacin brand. Resp. Ans. Br. at 30. As the ALJ found, however, these data form a weak basis for conclusions about enduring consumer beliefs. F.F. 602–606, 609.

[96] We also reject respondent's theory that corrective advertising may only be required when advertising is the *sole* source of product images (Resp. Ans. Br. at 24). We need only find that the advertising played "a substantial role in creating *or reinforcing* in the public's mind a false belief about the product * * *." *Warner-Lambert, supra* 562 F.2d at 762 (emphasis added).

will endure. For example, the survey results appear to have been stable over several years, F.F. 503, 521, 568–9; and expert witnesses testified that the superiority image would last, F.F. 594–5. The Commission can also reasonably draw inferences about the endurance of the image from factors including the salience of the claim to consumers, the extent of dissemination, the forcefulness of the persuasive techniques used, and the likelihood that product usage will affect the image held. See F.F. 585–6, 590, 593, 597.

Corrective advertising need only be ordered, however, if we determine that it is the only way to ensure that the image of established superiority will not persist. Here, we believe that other remedial provisions in our order will do the job. A belief in the proven superiority of Anacin is most likely to continue if comparative claims continue to be made in Anacin advertising. But under this order, any future comparative efficacy or side effects claims must be effectively qualified—*i.e.*, corrected as to the lack of proof—unless the requisite proof actually exists, in which case there will be no further deception. Moreover, the order will prevent respondent from conveying an erroneous impression of the product's superiority (proven or not) by means of claims about the unusualness of the ingredient in the product, in that it will prohibit false unusualness claims and will require the disclosure, in many Anacin ads, of the familiar name of aspirin.

We believe that in the face of all of these measures, there is little likelihood that a false or unsubstantiated image of proven superiority will survive. Therefore, we affirm the ALJ's rejection of a corrective advertising provision for comparative efficacy claims.

G. Labeling

The ALJ's order would apply to the labeling as well as the advertising of respondent's products. Respondent argues that this requirement is unwarranted because its labeling practices were not at issue during the proceeding and because **[61]**the FDA has jurisdiction over labeling. While we believe that an order relating to labeling could properly be entered as a fencing-in provision, we do not believe that this is an appropriate instance for such an order. Our liaison agreement with the FDA recognizes that primary responsibility for labeling rests with the FDA, 36 FR 18539 (1971), and that agency is currently engaged in reviewing labeling claims for OTC drugs. In view of these circumstances, the attached order does not cover labeling.

H. Competitive Impact

AHP has requested in motions filed throughout this proceeding that the three cases instituted by the Commission involving advertising claims for OTC analgesic products should be a matter for a joint decision.[97] (*Bristol-Myers*, Docket No. 8917, involves claims for Bufferin and other products; *Sterling Drug*, Docket No. 8919, involves claims for Bayer Aspirin and other products.) AHP has argued that issuance of any Commission order adverse to it would cause it severe competitive injury, and that, at the very least, any such order entered prior to disposition of the other analgesics cases should take effect only upon the entry of final orders in the other cases. We find that the arguments offered by AHP in these motions do not justify the requested relief.

In several cases, respondents have sought to stay prosecution of Commission cases on the grounds that they will suffer competitive harm if prohibited from engaging in practices that are open to their competitors. The courts have held in such cases that the Commission has the discretionary authority to enter an order against one firm, even when its competitors are alleged to be engaged in the same practices and the **[62]**Commission has not similarly proceeded against any of them. See *FTC* v. *Universal Rundle Corp.*, 387 U.S. 244 (1967); *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411 (1958). The Commission's discretion in this area is limited only to the extent that it cannot institute proceedings which will arbitrarily destroy one of many alleged law violators in an industry. See *FTC* v. *Universal-Rundle Corp.*, *supra*, 387 U.S. at 251.

These principles are certainly applicable here, where proceedings against AHP's competitors are already pending before the Commission[98]—though of course there is no certainty whether or to what extent those proceedings will result in orders covering AHP's competitors, as any such orders will depend solely on the evidence adduced therein. We note, moreover, that AHP's allegations of competitive harm were based in substantial part on the assumption that the Commission would adopt the corrective advertising provision of the ALJ's order[99]—a provision which we have rejected. In these circumstances, we believe that the public interest will be best

[97] See Motion of American Home Products Corporation For Stay of this Proceeding Pending Consolidation of All Three Pending Analgesic Cases on Appeal (Dec. 19, 1979); Response of American Home Products To Complaint Counsel's Motion Requesting Expedited Decision (March 14, 1979); Motion of American Home Products Corporation to Stay the Appeal For the Purpose of Consolidating on Appeal All the Analgesic Proceedings (Sept. 29, 1978); Motion of American Home Products Corporation to Dismiss the Complaint or in the Alternative Suspend the Proceeding Due to Changed Circumstances (April 29, 1977).

[98] The Commission heard oral argument in *Bristol-Myers* in April, 1980; an initial decision was filed in January, 1981 in *Sterling Drug*.

[99] Motion of American Home Products Corporation to Stay the Appeal for the Purpose of Consolidating on Appeal All the Analgesic Proceedings, at p. 8 (Sept. 29, 1978).

served by issuing the cease and desist order in this proceeding for immediate effect.

APPENDIX

ALJ's Interpretation of the Advertisements

Respondent AHP contends that the ALJ's findings on the meaning of the challenged advertisements were based on an improper analysis of the record evidence (R.A.B. at 30–33).[1] Administrative law judge is authorized to use his own accumulated expertise in determining the meaning of advertisements (R.A.B. at 30). AHP urges, however, that the law judge erroneously failed to consider certain extrinsic evidence on the meaning of the challenged advertisements, and that he based his interpretations on a one-sided, selective use of the record (R.A.B. at 30–33). For the reasons stated below, we conclude that the ALJ properly considered the record evidence and determined the weight to be accorded the evidence with respect to each of the challenged advertising claims.

A. Relevance of Extrinsic Evidence in General

The legal test for determining whether advertising has violated Section 5 is whether the challenged representations have the capacity and tendency to deceive.[2] The Commission (and its ALJ) is authorized to make that determination without resort to expert testimony or consumer survey data, which constitutes a "surrogate form of direct consumer testimony."[3] Consistent with that standard, the ALJ primarily relied on his own experience and expertise in determining what direct or indirect representations were contained in the challenged advertising, but he [2]also considered the relevant extrinsic evidence in the record[4] (I.D. p. 165; F. 45), and properly

[1] The specific representations disputed on appeal by AHP are the alleged claims that: (1) AHP's products are superior to *all other* OTC analgesics; (2) the superiority of AHP's products has been established; (3) the analgesic ingredient in Anacin or APF is unusual, special, or stronger than aspirin; (4) Anacin relieves tension; and (5) within 22 seconds after taking Anacin a person may expect relief from headache pain. We have evaluated each of these alleged representations in turn, *supra*.

[2] See, *e.g.*, *Murray Space Shoe Corp.* v. *FTC*, 304 F. 2d 270, 272 (2d Cir. 1962); *United States Retail Credit Ass'n* v. *FTC*, 300 F.2d 212, 221 (4th Cir. 1962); *Rhodes Pharmacal Co.* v. *FTC*, 208 F.2d 382, 387 (7th Cir. 1953), *rev'd on other grounds* 348 U.S. 940 (1955).

[3] *Ford Motor Co.*, 87 F.T.C. 756, 794 (1976); See *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 391–92 (1965); *Standard Oil Co.*v. *FTC*, 577 F.2d 653, 659 (9th Cir. 1978); *J.B. Williams & Co.*v. *FTC*, 381 F.2d 884, 890 (6th Cir. 1967); *Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 454 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 112 (1974); *Carter Products, Inc.* v. *FTC*, 323 F.2d 523, 528 (5th Cir. 1963).

[4] In addition to the advertisements themselves, the evidence consists of (a) the testimony of experts in the

(Continued)

determined its probity and weight based on a number of factors, including the qualifications and experience of respondents' expert and the format, methodology, and relevance of the consumer research upon which respondents' expert relied.[5] F. 46–48, 50, 59, 62–65, 486, 488–90, 492–93, 500, 525, 588; I.D. pp. 164–65.

B. Testimony of Dr. Smith

Among the extrinsic evidence considered by the ALJ was the testimony of respondents' expert witness, Dr. Joseph Smith, and certain consumer survey data upon which his conclusions were based. I.D. pp. 164–65. The ALJ specifically considered the mode of analysis used by Dr. Smith; determined the relevance and weight of his testimony based on established legal standards; and, on that basis, rejected his conclusions [3]on the meaning of the challenged advertisements. F.F. 47–48; I.D. pp. 164–66. Respondent claims, however, that the ALJ erroneously failed to credit Dr. Smith's testimony (*e.g.*, Tr. 5664–67; 5755–58) relating to the representations conveyed in the challenged advertising.

We find that the ALJ's decision not to credit Dr. Smith's testimony was entirely proper, and consistent with established principles of advertising interpretation. Dr. Smith's analysis of the challenged advertisements relied heavily on consumer survey data—"penetration" and "image" studies (Smith, Tr. 7442–49, 7454–58, 7518, 7562). These studies, however, do not address the question of whether or not a particular advertisement conveyed a particular claim.[6] Yet it is

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fields of consumer psychology and behavior, marketing, and marketing research; (b) AHP internal memoranda relating to AHP's awareness that certain advertising techniques were effective; (c) copy tests on Anacin television commercials, including the verbatim comments of consumers; (d) consumer studies relating to consumer perceptions of certain attributes of OTC analgesics; (e) "image" studies of consumer attitudes and beliefs about the Anacin brand and its competitors; and (f) "penetration" studies designed to evaluate consumers' ability to recall Anacin advertising themes. The only evidence bearing on the meaning of APF advertising is expert testimony and the APF advertisements themselves.

[5] Thus, the ALJ's use of such extrinsic evidence as exists in the record was consistent with our observation in *ITT Continental Baking Co.*, 83 F.T.C. 865, 954 (1973), *modified on other grounds*, 532 F.2d 207 (2d Cir. 1976), that while extrinsic evidence should be taken into consideration, its probity or weight will depend on the "qualification and experience of the particular expert involved and the validity and soundness of methodology utilized in the survey." Similarily, in *Cinderella Career & Finishing Schools, Inc.*v. *FTC*, 425 F.2d 583, 588–9 (D.C. Cir. 1970), and *Universal Camera Corp.*v. *NLRB*, 340 U.S. 474, 494–96 (1951), both cited in respondents' brief (R.A.B. at 36), the courts merely indicated that the Commissioners and the Board could not disregard entirely the examiner's findings of fact and conclusions of law and the evidence upon which they were based. In *Giant Food, Inc.* v. *FTC*, 322 F.2d 977, 982 (D.C. Cir. 1963), *appeal dismissed* 376 U.S. 967 (1964), the court held only that such extrinsic evidence as existed in the record supported the Commission's conclusion on the meaning of the term "manufacturer's list price."

[6] Dr. Smith himself testified that "penetration" studies are designed to test consumers' recollection, over a period of time, of an advertiser's promotional themes rather than consumer understanding of particular advertisements (Smith, Tr. 7443–45). The recollection of consumers over time, as measured by a penetration study, inevitably takes into account a myriad of factors other than the message content of individual ads, including the extent of dissemination and the memorability and pertinence of the various advertising themes (Smith, Tr. 7445). Dr. Smith also observed that "image" studies, which evaluate consumer beliefs and attitudes (*e.g.*, quality, price) about a particular product and its competitive profile without regard to the source of such views, are not designed

(Continued)

beyond dispute that effective Section 5 enforcement requires that advertisers be held accountable for each advertisement on an individual basis.[7]

Moreover, Dr. Smith considered competitors' advertising claims to be relevant to an understanding of the representations contained in the challenged advertisements for Anacin and APF. He stated, for example, that the use of similar words or themes by competitors would either reduce substantially [4]the likelihood that the alleged message about Anacin would be perceived in the Anacin ads, or enhance the likelihood that if the message were perceived it would be "displaced" quickly (Smith, Tr. 5650–51). The ALJ properly determined that this testimony was entitled to little weight.[8] As we stated above, each challenged advertisement must be evaluated individually. Moreover, even if the meaning of Anacin ads as perceived by some consumers could have been affected by claims made in ads for competitors' products, *every* consumer perception of the Anacin messages alleged in the complaint would not have been "displaced" in the manner suggested.[9]

Dr. Smith also largely disregarded the nonverbal components of the challenged advertising in formulating his conclusions on their meaning (Smith, Tr. 7493–94). The ALJ correctly observed that this failure to assess the net impression of the advertisements diminished the probative value of the testimony. I.D. p. 164. [5]

C. ASI Copy Tests

Other extrinsic evidence considered by the ALJ consisted of the results of twenty copy tests conducted by Audience Studies, Inc. (ASI) that were placed into evidence by complaint counsel. CX 402, 404–07, 409, 412, 414, 415. These studies designed to elicit data from

to provide evidence on all of the possible meanings consumers take from specific advertisements of the product whose image is being studied (Smith, Tr. 5549–52; see also Sen, Tr. 7178–79, 7327–28).

[7] Thus, the legal determination as to whether an advertisement is deceptive is not based on its effectiveness relative to truthful ads in selling products (*Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 450 (1972), *aff'd* 481 F.2d 246 (6th Cir. 1973) *cert. denied*, 414 U.S. 112 (1974)), and the fact that nondeceptive ads may be part of an ad compaign is no basis for ignoring the ads which are deceptive (*Chrysler Corp.*, 87 F.T.C. 719, 751–52 (1976)).

[8] Respondent also claims that the ALJ erred in refusing to admit certain competitors' advertisements and in limiting the testimony of both Dr. Smith and Mr. DeMott (an AHP executive) addressing such advertisements (R.A.B. at 29). For the reasons given in the text, we believe the ALJ's actions were correct. Respondent misconstrues certain statements of complaint counsel in the Joint Hearings, which, respondent argues, constituted a concession that a competitor's advertising is relevant. The question discussed was whether a consumer survey reporting recall figures for Anacin, Excedrin and Bufferin should be admitted in the Bayer Aspirin portions (Joint Tr. 956–60) of *Sterling Drug*, Docket No. 8919. Complaint counsel stated that the data would serve as a basis for comparison for similar studies of Bayer advertising and specifically added: "I am not saying that you have to look at the advertisements of other products to understand the advertisement of Bayer * * *" (Joint Tr. 960).

[9] Advertisements frequently convey more than one meaning, but if one of them is misleading, the advertiser is liable for the misleading variation. See *e.g., National Comm'n on Egg Nutrition* v. *FTC*, 570 F.2d 157, 161 n. 4 (7th Cir. 1977); *cert. denied*, 439 U.S. 821 (1978) *Murray Space Shoe Corp.* v. *FTC*, 304 F.2d 270, 272 (2d Cir. 1962).

representative samples of consumers on the meanings conveyed by individual advertisements.[10] Respondents urge that the ALJ improperly failed to credit Dr. Smith's analyses of the verbatim responses elicited in the ASI tests. One of these analyses (RX 123–26) was performed in an attempt to determine whether the challenged advertising claims caused consumers to switch their purchasing preference or intent (Smith Tr. 7476). To prove that a deceptive claim has been made, however, complaint counsel need not show that it would have been likely to cause consumers to buy a product which they otherwise would not have purchased. *Firestone Tire & Rubber Co., supra,* 81 F.T.C. at 451. Dr. Smith himself conceded that his "switching" analysis shed no light on the question whether the advertisements conveyed the representations alleged (Smith, Tr. 7476).[11]

Respondent points also to Dr. Smith's analysis of the verbatim responses (RX 271) as conclusive proof that the claims alleged were not conveyed in the challenged advertising (R.A.B. at 31–32). That analysis is flawed, however, because Dr. Smith's approach was to code a response as a "directly-related recall" only if it recited the precise language of the alleged representation. See, *e.g,* Smith, Tr. 7541. We believe this to be an overly restrictive use of copy test results. Other expert testimony in the record shows, moreover, that a low response rate of verbatims falling into a particular category is meaningless without an assessment of the advertisement tested and all surrounding circumstances, and that even after such analysis it may be impossible to determine **[6]**conclusively that a given message was not communicated. (Lukeman, Tr. 241–44, 247–48; Seltzer, Tr. 367–68). In addition, the open-ended questioning technique used by ASI does not elicit an exhaustive playback from consumers of all the representations that may be perceived in the tested advertising. In sum, while such surveys can be a useful aid in advertising interpretation, and the ALJ used them for such assistance (I.D. p. 164), their limitations tend to diminish the significance of the absolute response rate for each advertising claim.

D. Other Objections

[10] In the copy tests involved here, audience members filled out their responses to a page of questions about their comprehension of the advertisements immediately after viewing the films. Approximately 30 to 40 minutes later, the audience members were presented with a recall document which asked them to write down all that they could remember about the advertisements. These "verbatim" responses were then tabulated and coded. Only twenty of the television advertisements, and none that appeared in print or were broadcast on radio, were subjected to ASI testing.

[11] Of course, the likelihood that consumers would alter their purchasing decisions on the basis of a claim or omission in advertising is relevant in determining the materiality of the claim, after it has been found to be deceptive or to have a capacity to deceive. See *supra* at 8–11 and 32–33.

AHP also urges that the ALJ erroneously precluded testimony of AHP's Whitehall Laboratories Division president, George DeMott, relating to the meaning of the challenged advertisements. (R.A.B. at 29). The ALJ's action in this instance was entirely correct because while Mr. DeMott was allowed to testify as to the general objectives of the company in designing its advertising strategies,[12] he was not offered as an expert qualified in advertising interpretation (Tr. 4689).

Finally, AHP contends that the ALJ committed reversible error by looking to certain post-complaint advertisements, which were admitted only for the purpose of assessing the appropriateness of any remedy and the currency of the advertising claims challenged in the complaint (Tr. 162–63, 674–77), to determine whether the alleged representations were made (R.A.B. at 30). The ALJ could not have used the post-complaint advertisements for assessment of the remedy, however, without first determining what representations they conveyed. In addition, most of the ALJ's findings cited by respondent rely on ads disseminated before the complaint issued, along with some disseminated later. In any event, there is no prejudice to respondent, because none of our conclusions with respect to claims made by respondents' advertising relies primarily on advertisements aired or printed after the complaint issued.

Thus, we hold that the ALJ engaged in a proper evaluation of the representations alleged to have been made in respondents' advertising.

SEPARATE STATEMENT OF COMMISSIONER CLANTON CONCURRING IN PART AND DISSENTING IN PART

I concur in the Commission's order and opinion except for the portion that deals with the substantial question issue. On that point, I dissent.

The majority holds that American Home Products violated Section 5 of the FTC Act by failing to state in its advertisements that there was a substantial question in the scientific community as to the veracity of its comparative performance claims for Anacin and APF. The majority's holding is based on the conclusion that consumers reasonably believe that any comparative drug performance claim is

[12] Tr. 4651–59. See *supra* at 5–6.

backed, not merely by reasonable substantiation, but by data that will be accepted as proof within the scientific community. Unfortunately, the majority can cite practically nothing in the record that indicates what consumers are likely to believe is adequate substantiation for comparative drug claims. It is one thing to infer consumer beliefs where advertising expressly claims, or clearly implies, that scientific proof exists. But it is something else entirely to decide that consumers believe such proof exists where the advertisements are silent on the issue.

A brief review of complaint counsel's theory concerning the substantial question disclosure will explain the dearth of relevant evidence on consumer perceptions; it may also illuminate the majority's own, different approach to this issue. In brief, complaint counsel have argued that it is unfair for a drug advertiser to make a comparative performance claim with anything less than scientific proof as substantiation. In making this assertion, complaint counsel state candidly that they are not relying on the reasonable basis test set forth in *Pfizer*, 81 F.T.C. 156 (1972). They observe, in fact, that this case was tried differently from a reasonable basis case. CCAB at 48 n. 104. Specifically, the trial did not focus on whether respondent's substantiating evidence was reasonable under the criteria listed in *Pfizer*. Instead, complaint counsel have urged that the Commission move beyond the reasonable basis test and develop a new standard that is more appropriate to "the specific problems encountered in a particular market." CCAB at 47. Citing the FDA's standards for determining the efficacy and safety of drugs, complaint counsel arrive at the conclusion that fairness requires that comparative drug performance claims should be substantiated by two well-controlled, clinical tests. [2]

Complaint counsel then suggest that *National Dynamics*, 82 F.T.C. 488, 546 (1973), *aff'd* 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974), and its progeny have established that if an advertiser's performance claims are unfair because they are not adequately substantiated, they are also deceptive because a performance claim must, as a matter of law, imply exactly the same level of substantiation that fairness requires. Under complaint counsel's approach, extrinsic evidence as to consumer assumptions about an advertiser's level of support appears to be wholly irrelevant; the implied claim of substantiation is legally determined by the standard necessary to avoid unfairness.

The ALJ evidently accepted complaint counsel's reasoning:

> [T]he consumers of OTC analgesic products are entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a sufficient kind and level of

substantiation for the claim. In the circumstances of this case, the only sufficient substantiation for the claim is that the claim is accepted by the medical-scientific community. . . .

It is also clear that the absence of that kind and level of substantiation leaves a substantial question regarding a claim of comparative or superlative efficacy or safety, and that the existence of such a question is a material fact, of which the failure to disclose will render an advertisement deceptive. . . . (I.D. p. 212–13.)

Although the ALJ's analysis of marketplace fairness seemingly is derived, at least in part, from *Pfizer* (*see* I.D. pp. 210–16), complaint counsel disavowed reliance on *Pfizer* and it is clear that respondent was given no opportunity to address the "reasonableness" of its substantiating data.

In my view, the approach taken by complaint counsel and the ALJ is deficient in several respects and the majority has properly declined to follow it. As articulated, the deception (or material omission) theory advanced by complaint counsel is not dependent upon actual or probable consumer beliefs; rather, it depends entirely upon some independent notion of fairness that is distinct from the reasonable basis doctrine of *Pfizer*. Such an approach does violence to the legal concepts of both deception and unfairness. [3]

To be sure, the substantiation doctrine is predicated upon both a deception and an unfairness rationale. *Jay Norris Corp.*, 91 F.T.C. 751, 854 (1978), *aff'd*, 598 F.2d 1244 (2d Cir. 1979). Thus the Commission has indicated that it is reasonable for consumers to assume that objective product or service claims are backed by some kind of substantiation and that merchants are in a better position than consumers to verify the claims made on behalf of their products or services. That analysis also recognizes that substantiation requirements may vary, depending on a variety of factors which are set forth in *Pfizer*. But that kind of approach hardly warrants use of an abbreviated unfairness test to justify inferences about specific consumer beliefs concerning the level of substantiation that the Commission feels is appropriate in a given case. Such an exercise produces an artificial deception standard that is divorced from the reality of reasonable consumer expectations; it also misperceives the nature of our unfairness jurisdiction, which requires that challenged practices be analyzed in terms of both public policy and consumer injury. *See Commission Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction* in letter to Senators Danforth and Ford, December 17, 1980.

With respect to the unfairness issues, the problem with complaint counsel's arguments and the ALJ's reasoning is that they fail to balance the factors relevant to an unfairness case. Mention is made

in complaint counsel's answer brief and in the ALJ's initial decision that FDA regulations endorse the standard of two well-controlled clinical tests for safety and efficacy claims; this fact evidently provides some public policy justification for requiring similar proof in drug advertising. But the analysis cannot stop there. Regard must also be given to other relevant issues, such as the type and accessibility of data sufficient to constitute proof, or the type of consumer injury that would be risked if the advertiser possessed some lesser basis for its claims than scientific proof. It is thus impossible to declare that the substantiation the respondent did have on hand for its comparative advertisements was inadequate under an unfairness rationale.

The majority has not followed complaint counsel's approach. Rather, it attempts to imply a proof claim simply because the advertising at issue involves drugs. It is true, of course, that the Commission need not refer to consumer surveys or similar extrinsic evidence to interpret the meaning of an advertisement. *FTC* v. *Colgate Palmolive Co.*, 380 U.S. 374 (1965). Similarly, actual deception need not be shown by complaint counsel to carry its burden of proof. It is necessary only that the advertisement have the tendency or capacity to deceive. *Charles of the Ritz Dist. Corp.* v. *FTC*, 143 F.2d 676, 680 (2d Cir. 1944); *Firestone Tire and Rubber Co.*, 81 F.T.C. 398, 441 (1972), *aff'd* 481 F.2d 246 (6th Cir. 1973), *cert. denied* 414 U.S. 112 (1974). Still, [4]these precedents do not give the Commission a carte blanche to assume that an advertisement makes every claim that it might theoretically imply. Nor do they give the Commission the expertise to define, without the aid of extrinsic evidence, the particular expectations that consumers bring to a challenged advertisement. Rather, the Commission's interpretation of an advertising claim must be reasonably grounded on the expressions in, and format of, the advertisement. *National Dynamics*, *supra* at 548; *see Standard Oil Co. of California* v. *FTC*, 577 F.2d 653 (9th Cir. 1978).[1]

In this case, however, the majority has decided that a proof claim is implied by *any* comparative drug advertisement, regardless of the wording or format involved. Moreover, on closer analysis of the majority's opinion, one finds that the majority does not even cite the comparative nature of the advertising to support its conclusion that consumers believe drug performance claims are supported by proof.

[1] In *Simeon Management Corp.* v. *FTC*, 579 F.2d 1137 (9th Cir. 1978), the Ninth Circuit upheld a Commission determination that some consumers would reasonably believe that the government exercised control over the promotion and use of prescription drugs. *Id.* at 1146. This determination was evidently made without the benefit of extrinsic evidence. However, there is an obvious difference between prescription drugs and such commonplace medicines as aspirin. It can hardly be assumed that consumer beliefs regarding prescription drugs also apply to aspirin. Furthermore, the Commission did not reach any conclusions in *Simeon Management Corp.* concerning the *type* of substantiation that might be required before an advertiser claimed that its drugs were safe and effective.

Instead, the majority opinion suggests that consumers are entitled to believe that the drug advertiser has proof simply because the sale of drugs raises safety and health issues.

This assumption about consumer beliefs is not clearly implied by drug advertising in general. Neither is it supported by previous Commission determinations on the meaning of advertisements. The Commission has, of course, held on several occasions that consumers would reasonably believe that an advertiser had conducted scientific tests or surveys to support its claims. *Standard Oil Co. of California* v. *FTC, supra*; *Litton Industries*, Dkt. No. 9123 (filed January 5, 1981); *Crown Central Petroleum Corp.*, 84 F.T.C. 1493 (1974). Those cases are readily distinguishable, however. The proof and testing claims in *Standard Oil, Crown Central* and *Litton* were made explicitly. Better analogues to the advertising in this case may perhaps be found in the comparative claims at issue in *Firestone Tire and Rubber Co., supra.* The advertisements there claimed the Firestone tires "stopped 25% quicker" than competing brands. [5]We held that this assertion implied that scientific tests had been conducted to support the claim. In so ruling, we noted that a specific percentage was used to make the superiority claim and that the claim directly addressed significant safety concerns. By contrast, in this case, product performance was typically not compared in specific objective terms. Furthermore, the comparative claims did not raise safety issues. In the absence of such considerations or more direct evidence of consumer beliefs, I think the Commission should be loath to speculate as to what consumers may independently think about a product or the type of data needed to support claims concerning it.[2]

I am also concerned that the majority's attempt to limit its substantial question analysis to comparative drug advertising will prove untenable in the future. There is nothing in the majority's reasoning to suggest that proof-type substantiation would not also be required for noncomparative drug claims. Furthermore, there are many comparative performance claims outside the drug area that, if the majority's reasoning is followed, consumers would have equal reason to believe are substantiated by scientific proof. For example, if consumers believe that there are scientifically acceptable tests to

[2] Of course, if surveys or expert testimony showed that consumers actually believed, or were likely to believe, that the advertising made proof claims, some type of action might be appropriate. Here, however, the majority can point to no such evidence. The majority opinion notes that respondent conceded that a simple comparative performance claim for drugs would suggest that the underlying substantiation should be acceptable to responsible medical experts. The majority also notes that Dr. Smith, respondent's expert, admitted that consumers are likely to expect that drug product claims will have greater substantiation than other types of claims. See note 53 on page 31 of majority opinion. But these admissions fall far short of accepting the argument that consumers would assume that any comparative drug claim must be proven scientifically before it is advertised.

support the claim that one aspirin is better than another, it would be reasonable to assume that they believe similarly rigorous evidence supports any comparative claim that touches on health or safety issues. It is not clear where the line should be drawn under the proposed substantial question doctrine, which is a good reason why this test should not be used at all.

Finally, it should be obvious that a substantial question analysis is an ungainly tool for measuring deception in the instant case. The situation here is quite dissimilar from that in *National Commission on Egg Nutrition*, 88 F.T.C. 89 (1976), *modified in part*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978), where the respondent made affirmative claims that no scientific evidence linked the [6]consumption of eggs with increased risk of heart attack. The existence of just such a diet-health link was, in fact, the subject of lively debate among interested doctors, nutritionists, and researchers. In those circumstances, it was entirely appropriate to require that the fact of that debate be disclosed. Here, the notion of a substantial question regarding Anacin's and APF's superiority is more artificial. There is no actual debate in the medical and scientific communities about the relative efficacy of different analgesics. Rather, the record suggests that most researchers would simply dismiss a respondent's purported substantiation as inadequate to establish anything scientifically. Thus, ironically, to allow respondent to say even that there is a substantial question regarding its proof may actually countenance deception.

The most sensible manner of analyzing the substantiation for comparative drug advertisements that do not make establishment claims is simply to ask whether there is a reasonable basis to support them. It does not assume much, I think, to believe that consumers generally regard product performance claims to have some reasonable support. The Commission is then in a position to identify the precise level of support that is reasonable in each instance by referring to the criteria set forth in *Pfizer*. This analytical approach is flexible enough to permit respondents an opportunity to submit evidence on the feasibility of conducting scientific tests or research. As *Pfizer* suggests, however, in some circumstances the only reasonable basis may be medical or scientific proof. We might very well have reached that conclusion here. Unfortunately, we cannot resolve that question because the case was not tried on the theory that respondent's comparative claims lacked any reasonable basis. That omission may have been unfortunate, but we should not cure the problem by seeking to ground liability on a theory that has

inadequate record support and by ordering a remedial disclosure that is inappropriate to the circumstances of this case.

FINAL ORDER

This matter has been heard by the Commission upon the appeal of counsel for respondents and complaint counsel and upon briefs and oral argument in support of and in opposition to the appeals. The Commission, for the reasons stated in the accompanying Opinion, has granted each appeal in part, and denied each in part. Therefore,

It is ordered, That the initial decision of the administrative law judge be adopted as the Findings of Fact and Conclusions of Law of the Commission except as is otherwise inconsistent with the attached opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered, That the following Order to Cease and Desist be entered:

ORDER

I

It is ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or [2]through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that a claim concerning the superior effectiveness or superior freedom from side effects of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness or comparative freedom from side effects of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness or freedom from side effects that it is represented to have, and (2) that such comparative effectiveness or

freedom from side effects is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. The investigations shall be conducted in accordance with the procedures set forth below:

At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be conducted on any disease or condition referred to, directly or by implication; or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

1. The subjects must be selected by a method that:

a. Provides adequate assurance that they are suitable for the purposes of the investigation, and diagnostic criteria of the condition to be treated (if any); [3]

b. Assigns the subjects to the test groups in such a way as to minimize bias; and

c. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity or duration of disease or condition (if any), and use of drugs other than the test drugs.

2. The investigations must be conducted double-blind, and methods of double-blinding must be documented. In addition, the investigations shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

3. The plan or protocol for the investigations and the report of the results shall include the following:

a. A clear statement of the objective of the investigation;

b. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subject's response and steps taken to minimize bias on the part of subject and observer;

c. A comparison of the results of treatments or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data.

d. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

B. Making any representation, directly or by implication, of superior effectiveness or freedom from side effects of such product unless:

1. The superior effectiveness or superior freedom from side effects so represented has been established according to the terms set forth in paragraph I.A. of this Order, *or* [4]

2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the comparative efficacy or side effects claim, or that the claim has not been proven. Such a disclosure may consist of a clear and conspicuous statement that the claim is "open to substantial question," or that the claim "has not been proven." If other language is used by respondent to convey the required message, respondent shall maintain, for a period of three (3) years after the dissemination of any advertisement containing such disclosure, records sufficient to demonstrate that the required message is effectively conveyed to the advertisement's intended audience.

II

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription drug product, in or affecting commerce, as "commerce" and "drug" are defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that such product contains any unusual or special ingredient when such ingredient is commonly used in other non-prescription drug products intended for the same use or uses as the product advertised by respondent.

B. Making any false representation that such product has more of an active ingredient than any class of competing products.

C. Misrepresenting in any manner any test, study or survey or any of the results thereof, concerning the comparative effectiveness or freedom from side effects of such product.

D. Making any noncomparative representation, directly or by implication, concerning the effectiveness or freedom from side

effects of such product unless, at the time such representation is made, respondent has a reasonable basis for such representation which shall consist of competent and reliable scientific evidence. **[5]**

III

It is further ordered, That respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any products in which "Anacin" or "Arthritis Pain Formula" is used in the name, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from failing to disclose clearly and conspicuously that the analgesic ingredient in such product is aspirin, when such is the case and when the advertisement makes any performance claim for the product.

IV

It is further ordered, That respondent American Home Products Corporation, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, that Anacin relieves nervousness, tension, anxiety or depression or will enable persons to cope with the ordinary stresses of everyday life.

V

It is further ordered, That respondent the C.T. Clyne Company, Inc., a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising of "Arthritis Pain Formula" or any other nonprescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that

such product contains any unusual or special ingredient when respondent knows or has reason to know that such ingredient is commonly used in other non-prescription internal analgesic products for the same use or uses as the product advertised by respondent. [6]

B. Making any representation, directly or by implication, of superior freedom from side effects of such product, unless:

1. Respondent knows or has reason to believe that the superior freedom from side effects so represented has been established according to the terms set forth in paragraph I.A. of this Order, *or*

2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the claim, or that the claim has not been proven. Such a disclosure may consist of a clear and conspicuous statement that the claim is "open to substantial question," or that the claim "has not been proven." If other language is used by respondent to convey the required message, respondent shall maintain, for a period of three (3) years after the dissemination of any advertisement containing such disclosure, records sufficient to demonstrate that the required message is effectively conveyed to the advertisement's intended audience.

VI

It is further ordered, That respondents American Home Products Corporation and the C.T. Clyne Company, Inc. shall notify the Commission at least thirty (30) days prior to any proposed change in their respective corporate respondent 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 their respective corporation which may affect compliance obligations under this Order. [7]

VII

It is further ordered, That the respondents herein shall within sixty (60) days after service of this Order upon them, and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which they have complied or intend to comply with this Order.

Paragraphs Eight A.4, Eight B.2, and Ten B. of the Complaint are hereby dismissed.