advertising's effect on images is likely to last longer than its effect on *sales* (Ross, Tr. 7513).

789. Dr. Brock testified that, because the beliefs for these attributes are high for user and nonuser alike, and are independent of experience with the product, it is reasonable to conclude that these beliefs about Bufferin and Excedrin will [**202**] continue indefinitely for both users and nonusers (Brock, Tr. 8698).

790. In order to change consumer beliefs about products, a corrective message in advertising should be used (Brock, Tr. 8702; Ross, Tr. 7526–28). To increase the chances for successful communication, the corrective message should employ persuasive communication techniques similar to those used to create the beliefs initially. It is also desirable to pre-test a corrective message before use to ensure that the corrective message is being communicated (Brock, Tr. 8705–06). Moreover, the corrective message will be more successful if the other messages in the advertisements do not contradict, conflict, or obscure the corrective message in any way (Jacoby, Tr. 9570–71).

791. Complaint counsel seek corrective advertising directed to consumer beliefs of superior efficacy with respect to Excedrin and Excedrin P.M. and superior speed and safety with respect to Bufferin. Complaint counsel do not seek any corrective advertising with respect to the tension relief images involving Bufferin and Excedrin.

792. In order to support a corrective order provision directed to the so-called establishment claims regarding efficacy or safety of the products involved, complaint counsel must show that consumers currently hold an image that:

(a) it has been established that Bufferin is faster-acting and causes stomach distress less often than aspirin;

(b) it has been established that Excedrin and Excedrin P.M. are more effective than aspirin;

(c) these images are significantly attributable to respondents' advertisements;

(d) these images have caused and are likely to cause consumers to purchase Bufferin, Excedrin or Excedrin P.M.; and

(e) these images will endure for some time after the unlawful advertisements cease in the absence of corrective messages.

793. Complaint counsel have not introduced any direct evidence concerning consumer images specified in (a) and (b) of the preceding Finding, but instead rely on inferences based on inferences: namely that it may be reasonably inferred from the inferred establishment claims regarding Bufferin, Excedrin and Excedrin P.M. that consumers currently hold corresponding establishment images about these products. [**203**]

794. To the extent that the record contains evidence tending to show that consumers held superiority images about Bufferin and Excedrin and to the extent that it may be inferred that the misleading claims alleged in Paragraphs 9 and 10 of the Complaint played a significant role in creating or maintaining these images, it is found that the evidence is not so clear or convincing as to support a conclusion that these images are likely to endure for an appreciable period of time after the advertising claims have ceased.

VII. LIABILITY OF ADVERTISING AGENCIES

A. *Respondent Ted Bates*[7]

795. Respondent Bates actively participated in the creation and dissemination of certain of the challenged advertisements for Bufferin in its capacity as advertising agency for Bristol-Myers, commencing in February 1968 (CX 655C). That participation included development of marketing plans for the promotion and sale of Bufferin as well as creation of certain advertising themes, review of advertisements for appearance, time, position, size and reproduction (CX 655D). Bates was directly involved in the development of advertising themes including the Faster/Gentler-than-aspirin concept (CX 554A) and the "Doctors recommend Bufferin" claim (CX 560).

796. In connection with the development of Bufferin advertisements for Bristol, Bates has relied in good faith upon the judgments of Bristol-Myers' Medical Department inasmuch as Bates does not have in-house medical officers or retain medical consultants (Lanman, Tr. 11431).

797. Bates played a substantial role as Bristol-Myers' ad agency in creating and disseminating the following advertisements for Bufferin between 1968 and 1976: CX 1–7, 22–93, 95, 107, 112–114, 719–722, 751, 761R–V, Z018–020, 760R–V, Z015–016 (CX 655; CX 800). These advertisements were disseminated from 1968 to 1976 and made the representations listed in CX 815, except for Complaint Paragraphs 7A(3) and 9A(3).

798. Despite the fact that Bates created and disseminated advertisements which represented that it was established that Bufferin relieves pain faster than aspirin (Complaint ¶ 7A(1)), internal memoranda reveal that Bates knew that the comparative speed and safety claims to be open to question, although there was some scientific basis for these claims. One memorandum dated April 1969, and titled "Bufferin Briefing", stated that "clinical evidence indicates all [aspirin] work similarly well physiologically" and that all brands of aspirin were very similar in objectively proven effectiveness. It went

[7] References to advertisements disseminated by Bates do not include CX 8–22.

on to add [204] that "Bufferin cannot claim to be the best pain reliever because no one has as yet found a way of measuring time or degree of headache relief objectively. Subjective tests have not been able to substantiate Bufferin's apparent superiority" (CX 563B, C, M; *see also* CX 561).

799. Bates' awareness of the limited support for the "faster" claims for Bufferin is reflected in the following comments from its files: "Everybody agrees we can't document 'best against pain' since that strongly implies relief. There's still some disagreement about being the best" (CX 556, dated 2/13/69).

800. In addition to the internal memoranda, Bates had in its files authoritative documents which specifically addressed the issue of whether faster dissolution of aspirin, and higher blood levels of aspirin, could in fact be correlated with increased or more rapid pain relief. One of these was the Food and Drug Administration's "Fact Sheet on Aspirin" (CX 469), published in November 1972. With respect to Bufferin, it stated that there was "no evidence to indicate speed of onset of its action in relieving pain is significantly increased over plain aspirin." It also concluded that certain advertising claims including the "twice as fast" claim were misleading (CX 469B).

801. Bates also had reviewed the *AMA Drug Evaluations,* Second Edition (CX 512), and expressed concern over its statement that "available evidence does not indicate that buffered aspirin tablets are preferable to plain aspirin" (CX 646B).

802. Bates knew or should have known that, at the time its advertisements were disseminated, the claims relating to comparative freedom from side effects for Bufferin were open to question. Bates had in its files, at the time the advertisements were disseminated, information which indicated that the claims made for gentleness had not been scientifically proven. The FDA Fact Sheet published in 1972 stated, upon comparing Bufferin with plain aspirin, that "[M]ost of the published studies indicate there is little difference in the incidence of stomach upsets after ingestion of Bufferin or plain aspirin" (CX 469B). Also, a Bristol-Myers memorandum and the accompanying Bates analysis of the second edition of the *AMA Drug Evaluation* reveals that Bates was aware of the AMA's conclusion that "results of controlled clinical studies have not conclusively demonstrated that the use of these mixtures results in . . . less gastric upset" (CX 646B). These comments, according to Bristol-Myers' own description, were the same "negative and damaging comments" which appeared in the first edition of the *AMA Drug Evaluations* (CX 646A). Furthermore, soon after Bates acquired the Bufferin account, an article appeared which was "not particularly favorable to Bufferin's medical copy" (CX 493A). That article cited findings by researchers that "people [205]

taking heavy doses of aspirin cannot protect themselves against ulcers by using buffering compounds" (CX 493B). At the very least, these findings contradicted Bates' absolute and comparative claims in the advertisements relating to side effects with Bufferin.

803. Commencing in mid-1969 and continuing through 1970, Bates disseminated a series of Bufferin advertisements which were referred to as the "Sensitive People Campaign." In an internal memorandum reviewing the status of the analgesic market information and the nature of Bufferin advertising written in April 1969, just prior to the dissemination of the advertising campaign (CX 800K–L), Bates concluded that "[T]ension is an area not currently being exploited to the degree it has been—'Sensitive People' may exploit it" (CX 563J).

804. Furthermore, Bates' use of the "Sensitive People" advertisements to "exploit" the tension claims for Bufferin conflicted with the spirit of the NAB Code Advertising Guidelines for Non-Prescription Drugs. Emphasizing the tension relief capacity of Bufferin contradicts the NAB guide that advertising should avoid representing "that a product will alter a user's mood or attitude beyond that reasonably experienced through the relief of symptoms/conditions for which the product has been proven effective" (RX 235, Exhibit A, p. 1).

805. Documents in Bates' files reveal that Bates knew when the advertisements were disseminated that the analgesic ingredient in Bufferin was aspirin. The following comments in an internal memorandum titled "Bufferin Briefing, 4/14/69" make this clear: "Bufferin is a combination of aspirin and two antacids" (CX 563M). The memo also discusses Bufferin's place in the analgesics advertising market and what claims it can make to compete with other aspirin containing analgesics including Anacin, Bayer and Excedrin (CX 563M, N).

806. Notwithstanding Bates' knowledge that aspirin is the chief analgesic ingredient in Bufferin, Bates failed to disclose in its advertisements that Bufferin contained aspirin and suggested that the pain reliever in Bufferin was something other than aspirin. In 1969, Bates even suggested considering disclosure of Bufferin's aspirin content in advertising for the first time (CX 554M). Apparently, this suggestion was not adopted.

807. Regarding the claim that physicians recommend Bufferin more than any other OTC internal analgesic product, Bates knew or should have known that there was no reasonable basis for this claim. This fact is clearly reflected in a memorandum in Bates' files, dated April 1969, which points out that "Although doctors specify Bufferin by brand more than any other brand, they most often recommend plain aspirin" (CX 563J). This fact had been brought to Bates' attention by Walter Law, an official [**206**] of CBS in charge of Program Practices in March of 1969, who, in reviewing copy of certain adver-

tisements, said that "doctors have no reason to specify plain aspirin by brand name. Generic aspirin is specified 4 times more frequently than Bufferin" (CX 560A).

808. Moreover, the supposed basis for these claims, *i.e.*, the National Prescription Audit (CX 364–380) and the National Disease and Therapeutic Index (CX 381–390), were either invalid (NPA data represents solely prescription filling activity without considering nonprescription activity at retail pharmacies) or not supportive of the claim (NDTI showed Tylenol and generic aspirin were recommended more frequently than Bufferin) (F. 708–09, *supra*).

B. *Respondent Young & Rubicam*

809. Respondent Young & Rubicam actively participated in the creation and dissemination of the challenged advertisements for Excedrin and Excedrin P.M. in its capacity as advertising agency for Bristol-Myers since before Dr. Lanman joined Bristol-Myers in 1962 (RX 1; Lanman, Tr. 11430–31). Young & Rubicam assisted its client in the creation and development of advertising strategies; creation and preparation of television and print advertisements and creation of sales promotion programs. Young & Rubicam also supervised the production of advertisements and occasionally conducted market and consumer research (CX 657). Throughout the relevant time period Young & Rubicam relied in good faith upon the judgments of Bristol-Myers' Medical Department inasmuch as Young & Rubicam did not have in-house medical officers or retain medical consultants (YRRX 231, p. 4).

810. With respect to superior efficacy claims for Excedrin, Young & Rubicam knew that there was no clearcut scientific evidence to support these claims. As late as January 9, 1970 an internal report in Young & Rubicam's files clearly stated, in a question and answer format, that "there is no support for this claim [that Excedrin works better than aspirin] and the only explanation in laymen's terms would be the mere definition of synergism" (CX 496A). Elaborating on the possible role of Excedrin's ingredients (*i.e.*, aspirin, salicylamide, acetaminophen and caffeine), the report again states that "there is no clinical efficacy story, but merely one of inference" (CX 496A).

811. In December 1970, presumably after Young & Rubicam was advised of the existence of the Emich Study (CX 425), a letter from Young & Rubicam to Bristol-Myers referring to that study stated: for "the first time ever, an OTC analgesic has been able to make the unique and distinctive claim: 'more effective' " (CX 628A). Young & Rubicam recognized the need for **[207]** a high quality of scientific support for such superior efficacy claims in that same December 1970 letter, where it stated "[W]hen and if the efficacy copy is taken off the

networks, we must realize that there may be great difficulty and reluctance, due to stringent network requirements, to get similar copy approved or reinstated" (CX 628A). This letter confirms that prior to the Emich Study, Young & Rubicam knew it had no adequate clinical data in support of its superior claims for Excedrin.

812. Subsequent to the Emich Study, it was not unreasonable for Young & Rubicam to have accepted the study at face value and relied on it as a reasonable substantiation for the efficacy claims for Excedrin.

813. In disseminating the claim that Excedrin is stronger and more effective than aspirin in relieving pain in certain advertisements for Excedrin (CX 801) and Excedrin P.M. (CX 821), Young & Rubicam represented that the ingredient giving relief was other than ordinary aspirin. In fact, Young & Rubicam impliedly represented that common aspirin was not an ingredient in Excedrin (Complaint ¶ 21). As it knew, however, aspirin was part of the Excedrin formula, it knew that this claim was false (Complaint ¶ 22).

814. With regard to tension-relief claims for Excedrin and Excedrin P.M., it is reasonable to assume that Young & Rubicam relied in good faith upon Bristol-Myers Medical Department's judgment regarding the reasonableness of scientific-medical substantiation found in general biomedical literature. Although these purported authorities were woefully outdated and did not constitute a reasonable basis for the tension relief claim with respect to Bristol-Myers, which knew or should have known that the dated general references could no longer be relied on, at least since 1969, Young & Rubicam had no reason to question Bristol-Myers' judgment in this regard. Under the circumstances, it was not unreasonable for Young & Rubicam to have relied on Bristol-Myers' medical judgment as to the adequacy of medical scientific substantiation for the claim.

DISCUSSION

A. *The Meaning of Advertisements*

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 [208] interpretation is reasonable in light of what appears 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 or misleading, the advertisement may be found to be false or 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.[8] In determining the tendency and capacity of an advertisement to mislead, the Commission looks to the impression an advertisement may make on the average consumer—the gullible and unthinking as well as the trained and sophisticated.[9] 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 modern print or electronic commercials upon the viewer deserves further discussion. The revolutionary insight Marshall McLuhan has provided for contemporary mass communication is that "medium is the message."[10] This insight 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 in the mind of the viewers. A casual viewer of today's television commercials is struck by the element of essential truth in McLuhan's insight. With **[209]** respect to many television commercials that one encounters today, it is fair to say that 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 the commercials (medium) in its totality symbolizes to the psychic and social consciousness of the audience-viewer. The key to true understanding is not literal classifi-

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

[9] *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. 1974); *Rodale Press, Inc.,* 71 F.T.C. 1184, 1237 (1971).

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

cation and differentiation of what the viewer sees or hears, but rather the imagery evoked by the patterned aural-visual symbols.

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 involved in this proceeding. For that task, 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 each advertisement, 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 in the record, I rested. When my initial determination disagreed with that of expert testimony, I reexamined the advertisement in question, and further considered such record evidence as copy tests and verbatim responses contained therein. In any event, I have carefully considered all relevant record evidence before reaching a final determination.

The Findings regarding the meaning of advertisements as related to the claims challenged in the Complaint are self-explanatory. However, several advertising claims challenged in the case merit further discussion.

1. The Twice As Much Pain Relief Claim For Bufferin (Complaint ¶¶ 7A(3) and 9A(3))

Complaint counsel's argument in essence is that a claim that Bufferin relieves pain twice as fast as aspirin (Complaint ¶ 7A(2)) implies a claim that Bufferin relieves twice as much pain as aspirin. However, an examination of the Bufferin **[210]** advertisements cited by complaint counsel in support of this allegation (CPF 20) clearly shows that the central and simple message of these advertisements are twofold: that Bufferin acts twice as fast as aspirin and that it is gentler than aspirin. To the extent that some consumers played back the "twice as

much relief" in a copy test (CX 301), it can arguably be attributed to the claim that Bufferin delivers twice as much pain reliever in the first important (or critical) minutes. However, the "twice as much relief" theme is so remote from what these advertisements can reasonably be said to convey, the verbatim evidence should be dismissed as "noise" in this instance. It follows that there is no basis for the establishment allegation set forth in Complaint ¶ 7A(3).

2. The Faster Pain Relief Claim For Excedrin (Complaint ¶¶ 7B(4) and 9B(4))

Complaint counsel's argument that a claim that Excedrin is more effective or stronger (extra-strength) than aspirin also implies a "faster pain relief" claim is unpersuasive. Most of the Excedrin advertisements complaint counsel cite (CPF 305) contain clear and simple messages that Excedrin is an extra-strength pain reliever, that it acts fast and lasts longer. However, a number of Excedrin advertisements did contain *"faster* pain relief" claim, either expressly or impliedly. *E.g.,* CX 115, 135, 145, 146. And, a comparative claim also implies an establishment claim, for the reasons discussed hereinafter.

3. The Tension Relief Claims For Bufferin, Excedrin and Excedrin P.M. (Complaint ¶ 12A and B)

A number of Bufferin commercials contain an implied claim that Bufferin is also an effective reliever of tension, with or without headache pain, and thus enable persons to cope with the ordinary stresses of everyday life. They include: CX 715, 49–60. While the verbal messages in these advertisements contain the word "headache pain," the overall impression one gets from each of these advertisements is unmistakably that Bufferin is good for tension, with or without headache pain and generally good for tense situations one encounters in everyday life. Indeed, the impact of the visual presentation is so dominant in these TV commercials that any passing reference made to headache pain is entirely submerged, even when one looks at the storyboards with the verbal messages spelled out in print.

A number of Excedrin commercials contain express or implied claims that Excedrin is a good tension reliever. They include: CX 115–116, 120, 121, 124–125, 127–128, 132–133, 135–139, 141–144, 148, 150, 183. Many of them contain clear and direct verbal and pictorial claim that Excedrin has a "tension reliever" and "an anti-depressant" in addition to a pain reliever—as direct and explicit a tension relief claim as any that can be devised. [211]

Two Excedrin P.M. commercials contain an implied claim that Excedrin P.M. is good for tension relief, especially at night time, with or without pain. They are CX 216 and 219. The other ads complaint

counsel cite in CPF 369 present a close question. It is of course arguable that these too contain an implied claim of general tension relief at night time. However, the overall impression of these short ads is unmistakably that the "relaxing" claim is clearly related to a "sleep aid" claim. They are a world apart from the tension relief advertisements reviewed above for Bufferin and Excedrin. As to the remainder of advertisements cited in CPF 369, therefore, I am unable to find an implied general tension claim. The copy test evidence cited in CPF 370 and 375 is not persuasive in these circumstances. In my view, it simply reflects the fact that a mere mention of the word "relax" in any context is likely to evoke in the mind of some consumers an association with general tension. The Excedrin P.M. advertisements should not be indiscriminately condemned for that reason.

4. Claims Related To Ingredients (Complaint ¶ 21)

(a) *The Claim That The Pain Reliever In Bufferin Is Something Other Than Aspirin*

Numerous advertisements for Bufferin contain an implied claim that the pain relieving ingredient or pain reliever in Bufferin is something other than aspirin. Every Bufferin advertisement that refers to faster pain relief or gentleness implies that Bufferin's pain relieving ingredient is not aspirin. In my view, this claim, although not expressly made, is an insidious one and comes through very clearly in these advertisements. These advertisements include all Bufferin advertisements which are listed in Column 14 of CX 816. The fact that the advertisement frequently compares Bufferin with "plain" or "simple" aspirin does not alter the conclusion that most consumers will perceive the comparison to be Bufferin v. aspirin.

(b) *The Claims That The Pain Reliever In Excedrin Is Something Other Than Aspirin and That The Anti-Depressant In Excedrin Is Something Other Than Caffeine*

Numerous advertisements for Excedrin contain an implied yet clear claim that the ingredient that gives longer lasting pain relief or extra-strength pain relief in Excedrin is not aspirin and the anti-depressant contained in Excedrin is not caffeine. They include: CX 115–116, 122–139, 141–167, 169–173, 175–186, 188–191, 193, 202–211. CX 115 and 116 are good examples. A viewing of the TV commercials will persuade the most skeptical. Although the chemical formulas a viewer sees on the screen are in fact true, they are not likely to mean anything to an average viewer but that the long lasting pain reliever in Excedrin is [212] different from aspirin and that the anti-depressant that restores one's spirit in Excedrin is different from caffeine.

Furthermore, a number of Excedrin advertisements which feature the "Excedrin Headache" theme impliedly claim that the pain reliever in Excedrin is special, stronger, and unlike aspirin. They include CX 122–139, 141–152.

5. The Establishment Claims (Complaint ¶ 7))

While a few advertisements in evidence contain an *express* statement that medical research in hospitals and clinics "have established" a proposition (*e.g.,* CX 100, 101), most of the advertisements in evidence do not contain the word "established." The record as a whole shows that the word "established" is not a word commonly used or understood by average consumers. However, the record shows that "established" is not an uncommon term in the biomedical sciences. Also there appears to be a general agreement among clinical pharmacologists and researchers that the term may be used loosely to mean that a study "shows" or "demonstrates" a proposition, or in a narrow, technical sense to mean that a proposition has been scientifically proven or accepted as true by the community of trained and qualified scientists and researchers, based on well-controlled clinical studies. In formal statements filed with the Federal Trade Commission in 1967 and 1968 in connection with a proposed Trade Regulation proceeding involving nonprescription analgesic products, Bristol-Myers used the term "established" in the narrow, technical sense and asserted that superiority of one analgesic product over another is not "established" unless based on a number of clinical pain studies demonstrating such superiority (Tr. 12023–24; CX 908, p. 31; CX 907, p. 14). And a number of complaint counsel's expert witnesses testified to their understanding of the word "established" in a similar, technical sense.

Secondly, a number of advertisements for Bufferin and Excedrin claiming superior speed, efficacy or safety made *express* references to medical-scientific evidence, such as hospital studies, clinical studies, blood level studies, chemical formulas, anatomical models and graphs. *See e.g.,* Bufferin advertisements: CX 2–4, 7, 10, 13, 34, 61–64, 67, 91–96, 98–101, 113–114, 721; Excedrin advertisements: CX 115–116, 118–121, 124–125, 132–133, 138–142, 144, 153–161, 164–167, 170–171, 173, 175–177, 182, 184–185, 202–204, 208, 736. CX 99, a Bufferin print advertisement, displaying a picture of anatomical model and a blood level graph comparing Bufferin and "aspirin," suggests that "Clinical studies prove" (bold types) that Bufferin acts twice as fast as "aspirin" to relieve pain.

Thirdly, there is uncontradicted expert testimony in the record that when consumers see an advertisement containing a scientific or pharmacological claim, they assume that there is a valid scientific basis

for that claim and that such a claim [213] would not be permitted by the authorities unless there was a valid scientific evidence to prove it (Ross, Tr. 7024, 7026, 7036).

Finally, the rationale of the Commission's reasonable basis requirement, as articulated in *Pfizer*,[11] compels a conclusion in the circumstances of this case that, as a matter of marketplace fairness, a superiority claim regarding Bufferin, Excedrin and Excedrin P.M., without more, implies a representation that the claimed superiority, in terms of speed of action, effectiveness or gentleness, has been sufficiently demonstrated by medical-scientific evidence, namely, established.

For all of the foregoing reasons, it is concluded that every advertisement for Bufferin, Excedrin, or Excedrin P.M. which was found to contain a comparative claim as alleged in Paragraph 9 of the Complaint also made the establishment representations alleged in the corresponding subparagraphs of Paragraph 7 of the Complaint.

B. *Pain*

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.[12] 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 [214] some reaction patterns to it are (escape or avoidance), none of these individual statements, nor indeed their sum total, provides a definition of pain.[13]

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

[11] *Pfizer, Inc.*, 81 F.T.C. 23 (1972).
[12] CX 514, at 35350.
[13] CX 514, at 35350–51.

severe and/or protracted pain."[14]

C. *Aspirin and Aspirin Products*

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. Since aspirin was introduced into the American market 80 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.,* blockage of pain impulse generation) and a central nervous system (CNS) effect.[15]

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.[16]

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 **[215]** 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 action by which aspirin produces anti-inflammatory effects is not known.[17]

As a result of the remarkable progress in biomedical sciences during the recent decades, the knowledge and understanding of aspirin's other biological 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

[14] CX 514, at 35351.
[15] CX 514, p. 35351 at 35381.
[16] CX 514, at 35351–52.
[17] CX 514, at 35352.

exhaustive review of available data in biomedical literature, the FDA OTC Internal Analgesics Panel concluded in 1977 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 a pathologic condition and should not be treated with OTC analgesics except under the advice and supervision of a physician.[18]

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.

D. *Headache Pain*

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.[19]

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 in cranial [**216**] 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 are often described by synonymous terms such as muscle contraction and tension headache. Self-medication using 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 conclud-

[18] *Generally see* CX 514 at 35351, 35381–83; Stevenson, Tr. 1481–88; Farr, Tr. 2566–70.

[19] CX 514 at 35352.

ed that the occasional headache is self-limited and requires no medication, it recognized OTC analgesics' usefulness for symptomatic treatment.[20]

F. *Complaint Counsel's Burden of Proof*

The Complaint in this proceeding essentially challenges certain simple or comparative efficacy and safety claims regarding Bristol-Myers' three OTC analgesic products, Bufferin, Excedrin and Excedrin P.M., and alleges that these advertising claims have not been established or did not have a reasonable basis. With respect to Bufferin, the core fact issues are (1) whether Bufferin's faster-pain-relief claim has been established, (2) whether Bufferin's fewer-stomach-upset claim has been established, and (3) whether Bufferin's tension relief claim had a reasonable basis. With respect to Excedrin, the core fact issues are (1) whether Excedrin's superior efficacy claims have been established, and (2) whether Excedrin's tension relief claim had a reasonable basis. With respect to Excedrin P.M., the core fact issues are (1) whether Excedrin P.M's superior and unique (night time pain relief) efficacy claims have been established. With respect to each of these fact issues, complaint counsel have the burden of proving by a preponderance of credible evidence that the challenged advertising claims have not been established or did not have a reasonable basis.

Complaint counsel have attempted successfully in my view, to discharge that burden by showing that these biomedical propositions have not been scientifically demonstrated by two or more well-controlled clinical studies, or (with respect to noncomparative claims) that the propositions did not have a reasonable basis in biomedical sciences. On the other hand, respondent largely relied on failure of proof on complaint counsel's part and sought to show, by clinical and experimental pain studies, expert testimony and references to biomedical literature, that the challenged superiority claims have been [217] established by well-controlled pain studies or serum salicylate concentration studies, that the superiority claims have been generally accepted as valid by the medical-scientific community and that the noncomparative claims had a reasonable basis in scientific facts.[21]

[20] CX 514 at 35353.

[21] A brief general comment from a lay perspective may be in order here with respect to Bristol-Myers' suggestion that no biomedical proposition regarding absolute or comparative efficacy or safety of drugs can be established in the sense of being conclusively proven by objective facts. Apart from epistemological considerations, it is true that the biomedical science is not an "exact" science and that comparative analgesiology is essentially based on a subjective methodology (the subjective pain response model). However, to the extent the biomedical science subscribes to the scientific method of hypothesis testing and statistical analysis, we are not free to bend or modify the concomitant rigors of that method in search of a desired conclusion. For example, a bioassay either shows a statistically significant difference between Excedrin and aspirin, or it does not. Where a bioassay fails to produce a statistically significant difference between Excedrin and aspirin at the conventional 95% level with acceptable confidence intervals, that negative result should be acknowledged for that bioassay with scientific humility; it should not be transformed into Excedrin's "superiority" by statistical or computer manipulations of the same data.

Accordingly, the resolution of the core fact issues outlined above necessitated an evaluation of rather complex and technical biomedical and statistical evidence presented by the parties, with the aid of expert testimony. However, since clinical pharmacology and medicine are not exact sciences, especially when, as here, dealing with such subjective matters as pain and subjective response, a resort to common sense was necessary.

F. *Well Controlled Human Studies Are Required In Order To Establish A Biomedical Proposition Regarding the Efficacy or Safety of A Drug*

The record as a whole clearly shows that, at least since the early 1960's, in order to establish a biomedical proposition regarding the efficacy and safety of drugs in man, well-controlled human clinical studies showing statistical significance are required as a rule, by the medical-scientific community as well as by learned journals and the FDA.

The expert testimony, corroborated by the 1977 final report of the FDA OTC Analagesics Panel, shows that the essential criteria for a well-controlled clinical study include the following: (*see* F. 366, *supra*): [218]

(1) The study should be double blinded;

(2) A protocol should be prepared before a study begins and be adhered to throughout the study;

(3) Test subjects should be randomly assigned to treatment groups;

(4) A placebo control is preferred wherever practicable;

(5) The investigator must be unbiased and experienced;

(6) Appropriate statistical methods contemplated in the protocol should be used to evaluate the data.

The above requirements with respect to a well-controlled clinical demonstration are not a product of the whim of a handful of partisan pharmacologists. On the contrary, they represent a crystallization of slow and deliberate evolution in the development of a scientific method in clinical pharmacology that began in the early 1950's. 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. 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 nonprescription drugs.[22]

Pursuant to the FDA's specific mandate, the FDA's OTC Analgesics Panel set forth the criteria for well-controlled studies which OTC analgesic products must meet in order to establish efficacy. They are virtually the same as those the expert **[219]** witnesses in this processing specified. Specifically, to "establish Category I status for a Category III compound,"[23] the Panel required "at least two studies by independent investigators" (CX 514 at 35445) which conformed to the following criteria:

(1) Allocation of subjects to treatment groups should be done in such a way as to avoid bias;
(2) The double-blind technique should be used;
(3) The randomization procedure should balance out the variables not otherwise controlled in the patient selection;
(4) Suitable controls should be used, including graded doses of an analgesic standard and possibly a placebo as well;
(5) The scoring of pain and relief should be done frequently;
(6) Prior to carrying out an analgesic assay, the appropriate statistical analysis should be defined. (CX 514 at 35444–45).

Unless these requirements were satisfied, the Panel concluded, "any statistical analysis would only impart a false sense of confidence in the results." (CX 514 at 35445).

Respondents' expert witnesses do not dispute the essential validity of the scientific rationale for these requirements, including the principle of replication. Drs. Lanman and Elvers, Bristol-Myers' Medical Director and Associate Medical Director respectively, are in a position to appreciate the practical importance of these requirements with respect to the OTC analgesic products Bristol-Myers markets. And, in my view, the importance of these requirements increases when the question **[220]** becomes one of comparative efficacy or safety rather than simple efficacy or safety.[24]

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[22] 21 C.F.R. 314.111(a)(5)(ii)(a) through (c) and 330.10(a)(4)(ii). In the words of the FDA; the principles underlying these requirements

> 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.* They provide the basis for the determination whether there is "substantial evidence" to support the claims of effectiveness for "new drugs. . . ." (21 C.F.R. 314.111(a)(5)(ii))(Emphasis added).

[23] Three "categories"—Category I, II and III—were used by the FDA Analgesics Panel, as well as all other OTC drug panels. Category I was defined as "generally recognized as safe and effective." Category II was defined as "not generally recognized as safe and effective." And Category III was defined as "[c]onditions for which the available data are insufficient to permit final classification [*i.e.*, Category I or II] at this time." (CX 514 at 35348).

[24] In fact, the FDA OTC Analgesics Panel discussed comparative efficacy issues on a number of occasions. For example, it provided the Category III "faster to the bloodstream" claim for buffered aspirin could be moved to Category I only if clinical studies demonstrated that buffered aspirin provided quantitatively faster analgesia than aspirin (CX 514 at 35480–81). Likewise, the Panel determined that caffeine could be moved to Category I as an adjuvant only if it could be demonstrated that caffeine provided a "statistically significant contribution to the total effect" of 650 mg. aspirin, *i.e.*, that it meaningfully enhanced the analgesia provided by 650 mg. aspirin (CX 514 at 35445).

G. *Excedrin's Superior Efficacy Claim Has Not Been Established*

In my view, complaint counsel have discharged their burden with respect to Excedrin's superior efficacy claims. The record as a whole shows that Excedrin's superior efficacy claims have not been established by well-controlled clinical studies using appropriate subjects. Bristol-Myers attempted to rebut complaint counsel's *prima facie* showing essentially by: (1) showing that the two bioassays conducted for the purpose of determining relative potency estimates of Excedrin as against aspirin (the Emich Study, CX 425, and the Smith Study, CX 453), are well-controlled clinical studies which establish Excedrin's superior efficacy for pain of all types; (2) showing that the experimental study of electric-shock induced dental pulp pain study (the Sherman Study, CX 439) comparing threshold pain elevation effects of Excedrin and aspirin, was a well-controlled study supporting Excedrin's superior efficacy; (3) by showing that, on a pooled basis or on the basis of nonparametric analysis, the two relative potency studies establish Excedrin's superior efficacy; and finally by several references to what relative potency studies purport to show about comparative performance of analgesic products.

1. The Emich Study (CX 425)

The 1968 Emich Study (CX 425) was a bioassay which compared three graded doses (1, 2 and 4 tablets) of Excedrin, 5-grain (about 325 mg.) aspirin and placebo, using female patients with post-partum pain and found relative potency estimates (rho) of 2.27 to 7, depending on the variables used for analysis. However, by conventional variables analysis, only one (based on SPID 5 analysis) of the four rejected the null hypothesis of equipotency (rho of 4.08, with a 95% confidence interval of 1.3 to 3.84×10^{24}). That is, only one analysis shows a statistically significant difference between Excedrin and aspirin at the 95% level of confidence (F. 484). Taking into account the *post hoc* adjustment (% SPID) and additional **[221]** variables analyses increases that number to three out of six. From this, Bristol-Myers argues that the Emich Study supports Excedrin's superiority to aspirin.

The Emich Study's conclusions, however, are clouded by a serious problem of baseline pain imbalance. Apparently after a randomization procedure was followed, more severe pain subjects ended up in the Excedrin treatment groups than in the aspirin groups, thus increasing Excedrin's chances of showing greater pain relief compared to aspirin. Baseline pain imbalance is obviously a fundamental problem, involving as it does the most important variable in a bioassay, and can render the entire study questionable. The investigators in CX

425 used % SPID method in an attempt to adjust or correct the baseline pain imbalance. However, the record as a whole clearly shows that this method, although arguably a statistically defensible procedure, cannot be expected to remove entirely the shadow cast by the baseline pain imbalance and is rarely used in analgesic bioassays,[25] for the simple reason that baseline pain is perhaps the most important variable in a pain study.[26]

In similar circumstances, Dr. Forrest would have started all over again, although he would not have discarded the Emich data entirely. Dr. Brown testified that, although he would not say that the Emich Study was invalid from a methodological point of view, he did not know what to make of the Emich data and that he could not draw any firm conclusions from the Emich Study.

Therefore, the Emich Study (CX 425) does not provide a scientific basis for any firm conclusions regarding Excedrin's therapeutic superiority over aspirin, although it generated some interesting data suggesting the need for further study.

Finally, Bristol-Myers' argument that the requirement for 95% confidence level in analgesic bioassays is not appropriate is rejected. In my view, when the claim involves superior efficacy (not simple efficacy or lack of it), the confidence [222] level becomes more critical and certainly it should not be relaxed. The fact is that the multiple analysis of the same data through a computer model using six variables produced three relative potency estimates that are not significantly different from 1.00 (SPID 4, Total 4 and Total 5).[27]

2. The Smith Study (CX 453)

The Smith Study which commenced in 1970 is a bioassay comparing three graded doses (1, 2 and 4 tablets) of Excedrin, 325 mg. aspirin and placebo, using female patients with post-partum pain at the Boston Hospital for Women, under the direction of Dr. Eugene Smith, a reputable clinical pharmacologist. There is evidence tending to show that the Smith Study was intended to be a long-term study, funded by

[25] Apparently only one analgesic study has been published in biomedical literature that reported statistically significant differences in baseline pain levels among the treatment groups (Tr. 10626–27). In that study, Dr. Louis Lasagna, an eminent clinical pharmacologist, determined that, because of the bias introduced by baseline pain imbalance, he could not come to conclusions about the performance of the tested drugs (Tr. 5903, 9721, 10626–27). Dr. Forrest could not remember any published study which had such imbalances (Tr. 8962).

[26] Also, from a layman's perspective, the basic objection to baseline pain imbalance in a bioassay of pain relieving drugs is that the study is loaded in favor of one drug. This objection is not satisfied by the suggestion that the problem may have been due to pure chance and that the investigators were not biased in patient assignment to treatment groups.

[27] Again from a layman's perspective, the fact that a comparative pain relief study can show a statistically significant difference in favor of Excedrin for some study variables but not for others is not persuasive that Excedrin has a real, meaningful difference. What a consumer expects from a headache tablet claimed to be stronger and more effective than aspirin is not a technical, now-you-see-now-you-don't difference, but a clearcut superiority demonstrated by definitive studies that are beyond question and accepted by the biomedical scientific community as valid. This observation applies to all pain studies in the record.

Bristol-Myers, for the purpose of estimating the relative potency ratio of Excedrin to aspirin and also of exploring the relative importance of major variables among test subjects. In any event, CX 453, referred to as the Smith Study in this proceeding, is a report based on the data generated from the fall of 1970 through January 1972, which was prepared by Dr. Smith and transmitted to Bristol-Myers.

CX 453 was a well-controlled study. The sample size (about 785) was unusually large, thus increasing the reliability of the results. All variables which could have exerted an influence on the treatment groups were balanced (Smith, Tr. 5434, 5506–07). The Smith Study showed consistent results by all analysis. All of the analyses favored Excedrin over aspirin, but none of them showed a statistically significant relative potency ratio with a 95% confidence interval above 1. *See* F. 506–08.

In every respect, the Smith Study is preferable to the Emich Study in terms of reliability, and its negative findings darken the shadow over the Emich Study discussed hereinabove.

3. Pooled Analysis of Emich and Smith Studies

Bristol-Myers' argument that an examination of the Emich and Smith Studies (CX 425 and 453) on a pooled basis sufficiently demonstrates Excedrin's superior efficacy is not persuasive. To [**223**] begin with, Bristol-Myers' reliance on pooled analysis of the Emich/Smith data is inconsistent with its position that CX 453 is an interim report of an uncompleted study. Furthermore, the pooling of the two studies is subject to a basic objection that the two studies are not comparable and should not be pooled. The situation here is sharply distinguishable from a cooperative project, where the data generated at different hospitals by different investigators under a single protocol are pooled for a uniform and overall analysis. Although it is arguable that the "pooling" procedure employed *post hoc* by Dr. Laska here may be statistically defensible, the proposition that a combination of two studies, each of which is incapable of showing a statistically significant difference by itself, can, through "pooling", produce a statistically significant difference is difficult to accept for a layman. Indeed, there would seem to be little logic in piling up negative results and hoping to come up with an affirmative conclusion. Although Bristol-Myers' argument for "pooling" has some statistical plausibility, it is just as plausible, if not more so, to argue that the pooled results in the record as a whole fail to show a statistically significant difference between Excedrin and aspirin.

Dr. Brown was also emphatic that biomedical researchers do not engage in multiple analyses of the same data in search of statistical significance (Tr. 5014). *Post hoc* data massaging, regardless of wheth-

er through multiple analyses or pooling, only imparts a false sense of confidence and may end in misleading or distorted results. Such procedures should not be relied on as establishing or sufficiently demonstrating a superior efficacy claim.

4. The Sherman Study (CX 439)

The Sherman Study (CX 439), entitled "Comparison of the Effectiveness of Two Analgesic Agents by Laboratory Testing," is the report of a 1962 study of electric-shock induced dental pulp pain, comparing the threshold elevation effects of 2 tablets each of Excedrin and aspirin. The Sherman Study reported that in 65 tests on 14 subjects, Excedrin caused an average pain threshold elevation of 15%, and in 48 tests on 15 subjects aspirin caused an average pain threshold elevation of 2.7%, and concluded that Excedrin is more effective than aspirin in elevating the pain threshold to electrical stimulation to the dental tooth pulp.

The basic problem with the Sherman Study is that, until a few years ago, there was a general agreement among clinical pharmacologists who studied analgesic agents that pain threshold elevation studies of experimental pain (as distinguished from subjective response studies of clinical or pathological pain) are not reliable predictors of the analgesic performance of a drug for clinical pain in man. Although such a renowned clinical pharmacologist as Dr. Beacher of late has begun to [224] take another look at the pain threshold studies *in conjunction with* bioassays, the prevailing view among clinical pharmacologists remains to be that the usefulness of an electric-shock induced dental pulp pain study by itself as a reliable predictor of comparative performance of analgesic agents is seriously limited.[28]

5. Relative Potency Studies and Comparative Efficacy of Excedrin and Aspirin

The concept of dose-response relationship is a pharmacological formulation of the common sense notion that there is a relationship between the amount of drug and the intensity of the drug's biologic effect. The dose-response studies are attempts to quantitate this relationship and are usually expressed graphically, by way of dose-response curves. Thus, the dose-response curve is a graphic expression of the drug's anticipated intensity of action at various dose levels 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

[28] In addition, the Sherman Study appears to have suffered from a number of methodological problems. *See* F. 554–58, *supra*. Also, the authors of CX 439 were at the time careful to limit the applicability of the threshold elevation effects to dental pain or other pain that is transmitted through pathways similar to that of dental pulp pain. The record is not clear whether headache pain, for example, is transmitted through the same pathways as dental tooth pulp pain (F. 550).

of detoxication or excretion, the physical properties of the drug and other specific characteristics of the test subjects. On the other hand, because of the peculiarities of individuals, judgment factors are inevitably involved. The subjective pain response studies using the bioassay technique are attempts to apply this concept to natural or spontaneous pain states.

A relative potency study is a bioassay of graded doses of a standard drug and a test drug for the purpose of estimating the relative potency ratio of the test drug to the standard, from dose-response curves of the standard and test drugs. As such, its product, the relative potency estimate, is generally accepted as a useful statistical ratio in gauging the appropriate dose of the test drug for a given dose of the standard drug (a dose-finding function). Before a relative potency estimate thus derived can be valid, certain underlying assumptions must be shown to be true. They include: (1) the assumption of linearity of the dose-response curves; (2) the assumption of parallel dose-response curves; and (3) the assumption of equianalgesic range.

Thus, the primary purpose of a relative potency bioassay of analgesic drugs is to produce a best relative potency estimate **[225]** of the test analgesic drug to the standard analgesic drug across the dose ranges: It is not to compare their analgesic effectiveness at any specific dose level or to determine the magnitude of the differences, if any. Therefore, relative potency estimates can be misleading when used as an indicator of comparative efficacy of two drugs at specific doses. For example, when the slope of the dose-response curves are shallow or almost flat, the two drugs may be equally effective for all practical purposes in spite of a relative potency estimate indicating significant difference. The reason is simply that when the parallel dose-response curves are shallow, one would find little difference in the effect for an incremental increase in dose, and a large increase in dose is required to obtain a relatively small increase in effect.[29] On the other hand, when the slope of the dose-response curves is steep, assuming identical relative potency estimate as in the example given above, an incremental increase in dose will produce a markedly increased effect. When the results of a relative potency study using bioassays are to be used for the purpose of estimating the comparative efficacy of the two drugs at a specific dose level, it is essential that (1) the best relative potency estimate (rho) be statistically significant at the 95% confidence level *and* (2) the confidence intervals do not enclose 1. Otherwise it cannot be concluded that there is a statistically significant difference in *effectiveness* between the two drugs at a given dose level. *Generally see* F. 418–35.

For all of the foregoing reasons, Bristol-Myers' arguments that

[29] *See* CX 514 at 35364.

bioassay data can be looked at anyway one chooses, that the rigid 95% confidence level is inappropriate in the context of this proceeding, and that pooled analyses of all available bioassay data favoring greater efficacy of Excedrin over aspirin provide adequate demonstration of Excedrin's superior efficacy must be rejected as unpersuasive.

6. The Excedrin Formulation

Bristol-Myers' argument that Excedrin contains larger amounts of analgesic and therefore more effective than aspirin is rejected. Excedrin's analgesic ingredients (aspirin, acetaminophen and salicylamide) amount to 65 grains, compared to 5 grain aspirin. In addition, Excedrin contains caffeine. The record as a whole clearly shows that the proposition "more is better" has no basis in clinical pharmacology as far as mild OTC analgesic products are concerned. And, caffeine's effectiveness as an analgesic adjuvant has not been adequately demonstrated. The three blood level studies introduced by Bristol-Myers (the Booy, Wojcicki, and Dahanukar Studies) are of little value. The Houde and Wallenstein Studies are equivocal and inconclusive by the authors' own characterization. Indeed, it is arguable that [**226**] Excedrin contains a smaller amount of proven analgesic ingredients than a 5 grain aspirin tablet.

7. Is All Pain Alike?

Bristol-Myers' reliance on clinical studies using post-partum pain in this case implicitly assumes that all pain is alike, that what is shown with respect to post-partum pain can be assumed to be true with respect to all types of pain, regardless of particular etiology involved. However, the record strongly suggests that this assumption may not be valid and needs to be demonstrated.

For some years, clinical pharmacologists and researchers have assumed uncritically that if a drug is shown to be effective for the relief of one type of pain it will be effective for other types of pain as well. This convenient assumption is certainly understandable in view of the fact that for many years the researchers in this field have been preoccupied with attempts to develop a satisfactory methodology for measuring analgesic performance. However, the fact that they did not study mixed pain subjects in a study in spite of the fact that patient availability and accessibility often presented major problems, bespeaks their implicit recognition that pain of diverse etiology should not be commingled in a single study. In any event over the years they have come to recognize that some types of pain responds differently to an analgesic drug. Well known examples are migraine headache, uterine cramp pain, and pain accompanied by inflammation. As a result, an increasing number of clinical pharmacologists and re-

searchers, and the FDA, are coming around to the position that at least one study should be done with the type of pain for which the drug is to be used. *See* F. 379, *supra.*[30] However, there appear to be respected clinical pharmacologists [227] who do not support this conservative proposition: They would wait for the day when the contrary proposition (all pain is not alike) is demonstrated by consistence evidence.[31]

The bioassays and experimental pain studies Bristol-Myers relies on in this proceeding do not address the issue of Excedrin's superior efficacy for the relief of headache pain. Bristol-Myers' witnesses agreed that headache pain studies can be done, although they are more difficult than other pain studies. In my view, *the importance of the question whether all pain is alike increases when the issue is comparative efficacy for designated conditions rather than simple efficacy or lack of it.*

8. Excedrin and Aspirin May Be Equally Effective For The Relief of Mild Pain

Finally, none of the studies Bristol-Myers relies on specifically addressed the question of Excedrin's superior efficacy over aspirin for the relief of mild pain. Since OTC analgesic products are indicated for the relief of mild pain, relative potency studies and relative potency estimates are meaningless unless they are shown to be valid for mild pain. The only evidence bearing on this question in the record is the testimony of Drs. Sunshine and Laska regarding what the Emich and Smith data can show with respect to the mild and moderate pain subgroups. (Tr. 9837–40) However, the Emich and Smith studies fail to show statistically significant difference between Excedrin and aspirin for the relief of mild to moderate pain. *First,* the Emich study excluded all mild pain subjects, and the number of moderate pain subjects was too small (less than 15) to provide any meaningful results. *Second,* the number of mild pain subjects in the Smith study was too small to provide statistically significant results, although the Smith study's overall sample size (785) was unusually large. *Third,* of the five relative potency estimates obtained by *post hoc* baseline pain stratification analysis (two from Emich and three from Smith), not

[30] The FDA OTC Analgesic Panel shares this view. In discussing Category III combination products, the Panel states that the clinical test should be related to the symptoms for which the combination is designated. CX 514 at 35371. The NAS/NRC Analgesic Review Committee's recommendations during the 1960's that if an analgesic drug has been shown to be effective in one or two kinds of pain the drug be certified as a general purpose analgesic product in the absence of contrary evidence is often cited as authority for the all-pain-is-alike dogma. The Committee's recommendation was undoubtedly a sound expedience in the massive drug screening project for which the Committee labored long and hard, where the concern was whether a product was an effective analgesic drug, and not whether a product was a more effective analgesic drug than another product for designated conditions. However, that expedience cannot be transformed into a universal scientific proposition that clinical study findings of cancer pain, post-partum pain and post-operative pain apply equally to headache pain or other minor pain. (Tr. 12187; CX 511 H).

[31] From a layman's perspective, the proposition that all pain is alike does not accord with our common experience. Any experienced person will agree that headache is not like post-partum pain or dental pain.

one presents a difference between Excedrin and aspirin that is statistically different from 1.00. (RX 211A). Thus, the results of baseline pain stratification analysis appear to confirm that the intensity of pain to be relieved has an important bearing in evaluating the comparative performance of mild analgesics and that one cannot assume that the relative potency estimate derived from a typical bioassay with mixed (slight to mild to moderate to severe) pain subjects can be reliably used to predict the comparative performance of the two drugs for the relief of mild pain. [228]

In sum, for all the record shows, one could reasonably conclude that Excedrin and aspirin are about equally effective for the relief of mild pain, including headache.[32]

However, this is not to ignore the well known fact that the practice of medicine is not an exact science but an art, and that clinicians often do form personal judgments on the basis of available data short of adequate scientific demonstration. This is as it should be in the practice of medicine. The application of clinical pharmacology to clinical situations inevitably involves the professional judgment of the clinician and is a matter of trial and error based on long experience, insight and wisdom. Obviously, there may be respectable clinicians who are willing to try Excedrin or Bufferin instead of aspirin on their patients on the strength of the evidence contained in the record. However, that fact adds little to the resolution of the issues in this proceeding.

H. *Bufferin's Faster Action Claim Has Not Been Established*

Complaint counsel have carried their burden of showing that the faster action claim for Bufferin has not been scientifically established. In support of its faster action claim for Bufferin, Bristol-Myers essentially relies on blood level studies which show earlier and higher serum salicylate concentrations for Bufferin compared to aspirin. Although there is conflicting evidence regarding the blood level data, the main thrust of complaint counsel's argument is that the proposition that an earlier serum concentration level means faster onset or greater intensity of analgesia has not been scientifically established. Although it has been shown for some drugs that a direct correlation exists between blood levels and biologic effect, the existence and the nature of such correlation for aspirin is not known because of aspirin's unique and complex pharmacokinetic characteristics (Tr. 5942–46, 5957; CX 514 at 35373–74). As plausible as it may sound, such correlation for [229] aspirin remains to be demonstrated.[33] The pre-

[32] It should also be pointed out that these observations regarding pain types and intensity levels apply equally to the pain studies excluded from the record by the administrative law judge.

[33] Dr. Beacher described the problem thus:

(footnote cont'd)

cise nature and degree of such correlation, if any, with respect to aspirin and its metabolites is particularly important in this case where the issue is whether Bufferin acts faster than aspirin or acts twice as fast as aspirin. These are specific comparative claims and demand specific, direct demonstrations.

Bristol-Myers' reliance on the FDA's bioavailability regulations is clearly misplaced. The issue there simply is whether the FDA should require, after the efficacy and safety of a drug compound is established by well-controlled clinical studies, new or additional clinical studies should be required with respect to every subsequent batch produced by the original manufacturer or with respect to a chemically identical compound manufactured by another firm. The FDA took the approach that, in these circumstances, a showing of bioequivalence is enough, only because the efficacy of the compound has already been demonstrated by well-controlled human trials. This common sense approach of the FDA cannot be turned into "the FDA says blood level studies are acceptable proof of efficacy," and much less into "the FDA says earlier and higher blood levels prove faster and stronger effect." In explaining the bioequivalence regulations, then FDA Commissioner explicitly disclaimed such [230] inferences.[34]

I. *Bufferin's Gentler To A Person's Stomach Claim Has Not Been Established*

In support of its comparative safety claims that Bufferin will not upset a person's stomach and that it will cause stomach upset less frequently than aspirin, Bristol-Myers relies on the blood level studies discussed above. Bristol-Myers' argument that since Bufferin is absorbed into the blood stream somewhat faster than aspirin, it will cause less irritation to the stomach than plain aspirin is well grounded in clinical pharmacology. The clinical studies Bristol-Myers relies on, however, are inconclusive. At best they show that, because Bufferin is absorbed into the blood stream somewhat faster than aspirin, Bufferin can reasonably be expected to cause somewhat less gastric discomfort for the small number of consumers in the sub-population who occasionally experience the subjective symptoms of gastric dis-

Now it's quite clear that we have a product which is incompletely absorbed or extraordinarily absorbed compared to a product which is rapidly absorbed, the former may not ever demonstrate any activity at all. However, as the performance—absorption performance of the two products approaches each other, it becomes increasingly debatable as to the importance of the difference in absorption to the actual therapeutic differences seen. *In the case of analgesics, since we don't know the function which connects analgesic activity with blood level—and in the particular case of aspirin, since we don't even know whether it's the unhydrolized aspirin in the blood or the salicylate in the blood or some peculiar combination of both which is responsible for analgesic activity, it is impossible in the current state of the art to say what the significance of such a difference would be in blood levels in terms of speed of onset of analgesic activity.* (Beacher, Tr. 5942-43). (Emphasis added)

[34] The FDA Commissioner stated, "The bioequivalence regulations are not an attempt to equate evidence of bioequivalence with evidence of relative therapeutic effectiveness." (Tr. 11682).

comfort following aspirin ingestion. However, this proposition has not been adequately demonstrated through well-controlled clinical studies. The studies employing the so-called historical controls add little in this regard. Also, the advertising claim that Bufferin will not upset a person's stomach (Complaint ¶ 9A(4)) is patently false.

The FDA Analgesic Panel's final report corroborates the views recited above regarding the potential occasional benefits of buffered aspirin for the small group who may experience dyspepsia with plain aspirin. The Panel reports:

> Current evidence indicates that properly formulated preparations, those within the proposed antacid and dissolution standards, can be expected to . . . decrease the incidence of subjective gastric intolerance in some of the small percentage of persons in the general population who regularly experience gastric intolerance with OTC doses of plain aspirin tablets.
>
> * * * * * * *
>
> . . . [T]he evidence although apparently conflicting seems to indicate that buffered aspirin produces a lower incidence of gastric intolerance in some patients but not in all patients who exhibit gastric intolerance [231] with regular aspirin products. The number of patients who might benefit from buffered aspirin compared to standard [plain] aspirin is probably small. (CX 514 at 35470). *Also see* CX 415A–B.

Furthermore, since Bufferin commercials do not identify the "pain reliever" in Bufferin being compared with "plain aspirin" as aspirin, an advertising claim that Bufferin does not cause or causes less stomach distress than aspirin is highly likely to mislead consumers into a false sense of safety that Bufferin is a product that can be taken without worrying about gastrointestinal side effects. However, aspirin's gastrointestinal side effects are not to be ignored lightly. They are potentially serious, especially when aspirin or aspirin products such as Bufferin are taken in multiple doses or by persons with certain predisposing conditions.

The FDA Analgesic Panel, after reviewing labeling claims for certain buffered and highly buffered aspirin products, including the statements "Faster to the bloodstream" and "Gentle to the stomach," placed in Category II any statement that suggests or represents a buffered product as having a more rapid absorption or as preventing any side effects to the stomach, and recommended that labeling claims be restricted to the following Category III statements: "Faster to the blood stream than plain aspirin" and "Provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label." (CX 514 at 35480) *Also see* CX 514 at 35470, 35474.

J. *Tension Relief Claims For Bufferin, Excedrin and Excedrin P.M. Do Not Have A Reasonable Basis*

The main thrust of Bristol-Myers' argument with respect to the tension relief claims is that its advertisements for Bufferin, Excedrin and Excedrin P.M. did not make those claims. Nevertheless, Bristol-Myers attempted to show that the tension relief claim for Bufferin, Excedrin and Excedrin P.M. had a reasonable basis when made. In my view, the evidence Bristol-Myers relies on is either obsolete or unreliable. The modern view for some years has been that aspirin and/or the other ingredients in Excedrin, or Excedrin P.M., either singly or in combination, are not recognized tension relievers.

The record as a whole clearly shows that Bufferin, Excedrin or Excedrin P.M. will not relieve tension. Dr. Rickels, an eminent authority in the study of psychopharmacologic drugs, testified that aspirin or Excedrin will not relieve tension or emotional anxiety. 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 [**232**] the relief of moderate tension (Rickels, Tr. 6500–17). The medical literature confirms that aspirin cannot be expected to relieve tension. The FDA OTC Internal Analgesics Panel concluded that aspirin was "clearly ineffective" for "nervous tension" (CX 514 at 35355). Also, the FDA OCT Sedative Panel determined that aspirin was "ineffective" as a "day-time sedative" product, which was defined as one claiming "mood-modifying indications such as 'for the relief of occasional simple nervous tension'." (CX 513E, Z002; Tr. 6538). The Sedative Panel reached the same conclusion with respect to acetominophen and salicylamide (CX 513E; Tr. 6540). The NAS/NRC Drug Efficacy Study Group reviewed medical-scientific evidence regarding Bufferin and reached a negative conclusion with respect to Bufferin's tension relieving effect (CX 511F). The medical literature Bristol-Myers relies on is woefully dated and do not constitute a reasonable basis for Bristol-Myers' tension relief claim that continued from the early 1960's through 1970.

With respect to Excedrin P.M., the only difference between it and Excedrin is that it contains methapyrilene fumarate instead of caffeine. The three ingredients Excedrin P.M. has in common with Excedrin (aspirin, acetaminophen and salicylamide) are not effective tension relievers. Methapyrilene is not an effective tension reliever (daytime sedative). Although there is some evidence indicating that methapyrilene may be an effective mild sedative in animals, the FDA Sedative Panel was divided on the issue of methapyrilene's efficacy and safety as a mild OTC daytime sedative in humans. A minority of the Panel considered it to be ineffective, but the majority placed in it

Category III, allowing manufacturers further opportunity to develop favorable clinical studies. However, it was the unanimous opinion of the Panel that the studies would not show methapyrilene's efficacy for the relief of nervous tension. Dr. Rickels, the Panel's chairman, testified that, since no further research on this issue has been forthcoming, all members of the Panel now believe that methapyrilene should be placed in Category II as a daytime sedative (Tr. 6541–51).[35] **[233]**

K. *Unfairness And The Substantial Question Theory*

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

I am persuaded that the substantial question theory outlined hereinabove is, in the particular factual context of this case, a reasonable application 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 & Hutchinson 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.

[35] Apparently Bristol-Myers is in the process of reformulating Excedrin P.M. without methapyrelene since the FDA determined earlier this year that methapyrelene is a carcinogen in animals. *See The Wall Street Journal*, June 7, 1979, p. 23, c. 2–4; June 11, 1979, p. 13, c.1.

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):

> 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 [234] 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 Commission 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.[36] 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.[37] 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.[38]

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. 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. Buffer-

[36] *See id.* at 64.
[37] *Id.* at 64.
[38] *Id.* at 64, 66–67.

in and Excedrin are among the major and heavily advertised aspirin-based OTC internal analgesic products in this country. [**235**] Against this background, what is the reasonable level of substantiation required for a claim that Bufferin is faster acting than aspirin and causes less gastric distress than aspirin and that Excedrin and Excedrin P.M. is stronger than aspirin?

Consumers obviously have no means of verifying the truth of such a pharmacological-clinical superiority claim for themselves. Moreover, consumers are willing to pay, and do pay, a significantly higher price for the alleged superiority of these products. If the alleged superiority is not established, the consumer's evidently widespread self-medication with the allegedly faster/safer, extra-strength OTC analgesic products is not only pharmacologically superfluous and economically wasteful but also is accompanied by significant health hazards (increased potential for adverse side effects).

In my view, in the circumstances of this case, such a comparative 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 on the basis of well-controlled clinical studies.

Furthermore, with respect to Bufferin, a number of advertisements expressly claimed that the alleged superiority of Bufferin "has been established." *E.g.,* CX 99. Also, a number of Bufferin and Excedrin advertisements referred to clinical or hospital tests, and used chemical formulas, graphs, and anatomical models as a support for superiority claims for Bufferin and Excedrin. Therefore, it is reasonable to infer that these advertisements conveyed to the consumer a distinct message that the superior features of Bufferin or Excedrin being discussed in these advertisements have been sufficiently proven by medical-scientific evidence.[39]

The record is clear that, with respect to OTC internal analgesic products, the medical-scientific community requires [**236**] two or more well-controlled clinical studies using appropriate pain models, one of which is a headache pain model.

[39] There is testimony in the record which suggests that consumers generally believe that advertising claims for drug products are supported by adequate medical-scientific substantiation and that otherwise the advertisers would not be permitted to make such claims by the regulatory authorities. (Tr. Ross) *Also see Standard Oil of California,* 84 F.T.C. 1401, 1473 (1974); *Simeon Management Corp.,* 87 F.T.C. 1184, 1230 (1976), *aff'd, Simeon Management Corp.* v. *FTC,* 579 F.2d 1137, 1145–46 (9th Cir. 1978).

It is also clear that the absence of that kind and level of substantiation leaves a substantial question regarding a claim of comparative 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. 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.

Furthermore, the rationale of the substantial question theory as applied to advertising claims for comparative 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.

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 . . . . [237]

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 pro-

vide 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. 366–94. 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 OTC drugs by various panels of experts, including the Panel on Analgesic, Antipyretic and Antirheumatic Products, and when the FDA initiated rulemaking proceedings 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 at trial in this proceeding. More specifically, "to establish Category I status for a Category III compound," the Panel required "at least two studies by independent investigators" which are 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 514 at 35444–45 and F. 366.

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 [**238**] 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 for the Commission to apply the same standard to advertising claims of *comparative* efficacy or safety for OTC analgesic products involved in this proceeding. It would be unreasonable for the Commission to accept for drug advertising a standard which is less than what the FDA requires for labeling.

The "substantial question" standard of unfairness in the context of this proceeding focuses upon the fairness of comparative superiority claims for OTC aspirin products which are therapeutically insignificant modifications of well known aspirin, all having the same general actions or virtually the same efficacy and safety factors when the claimed superiority is not scientifically established but capitalized upon in order to achieve some marketing advantage, by advertisers who know that consumers are not in a position to evaluate the claim and must trust that the superiority claim is scientifically established.

Since the record shows that the standards of clinical testing of analgesics have been well established since the early 1960's, the unfairness of the challenged comparative claims should be determined primarily on the basis of whether the claimed comparative proposition met these standards. Therefore, the fact that the claim is based on sound pharmacological reasoning, or has some support among experts or in medical literature is not enough to meet those specific standards relating to well-controlled clinical demonstration of superior efficacy or safety.

Finally, the presence of aspirin in these products is a material fact from an economic point of view. The record shows that a substantial number of consumers do not know that the analgesic ingredient in Bufferin and Excedrin is aspirin. Obviously, if this fact were known to consumers, that fact would be an important factor in making a choice between higher priced aspirin products and lower priced aspirin. In this sense as well, the presence of aspirin in these products is a material fact which ought to be disclosed in future advertisements. *Also see* section M, *infra.*

L. *The Establishment Claims Related to Bufferin, Excedrin and Excedrin P.M. 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 any sense, a fact is material if non-disclosure of that fact makes a claim patently deceptive and misleading. *E.g., ITT* [**239**] *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 (3d 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 fact that the superiority claims have not been scientifically established or that there is a substantial question among scientists who by training and experience are qualified to evaluate such claims, is a material fact which must be disclosed to consumers. The fact that there is a substantial scientific question about the claim obviously is a vitally important factor for consumers in deciding which OTC aspirin products to buy. The existence of a substantial question is even more material, indeed crucial, in this case because consumers cannot be expected to evaluate the validity of these establishment claims.

Under the provisions of Section 15 of the FTC Act, the failure to disclose facts which are material in light of representations made in drug advertising constitutes a false advertisement in violation of Section 12. The existence of a substantial question regarding the challenged claims of comparative efficacy and safety is a material fact in light of the establishment representations made in the advertisements for Bufferin, Excedrin and Excedrin P.M. The failure to disclose the existence of that substantial question has the tendency and capacity to mislead consumers to believe that the challenged comparative claims can be accepted without qualification. Therefore, the unqualified superiority claims were misleading and in violation of Sections 5 and 12 of the Federal Trade Commission Act.

M. *The Presence of Aspirin In Bufferin, Excedrin and Excedrin P.M. Is A Material Fact Which Should Be Disclosed In Advertisements For These Products*

In the language of Section 15 of the FTC Act, facts may be "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," 15 U.S.C. 55(a)(i). The presence of aspirin in Bufferin, Excedrin and Excedrin P.M. is a material fact in that sense and, therefore, the failure to disclose that fact is a violation of Section 12 of the FTC Act. There is a sharp 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 these products list aspirin as an ingredient, in accordance with FDA labeling regulations. [240]

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. 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 demonstrated over many decades. However, aspirin is also a potent drug and has a number of serious adverse side effects. Several expert witnesses in this case discussed the nature and

extent of the principal side effects (F. 645–671). The FDA OTC Internal Analgesics Panel's report contains a handy compendium of aspirin side effects in eight major areas of concern (CX 514 at 35383–35411). 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. 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 514 at 35392).

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 514 at 35393–94). 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 Bufferin and Excedrin contain aspirin and that a large number of consumers neglect to read labels of such products. These facts, involving important questions of public health, make aspirin ingredient disclosure imperative 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.[40] **[241]**

1. 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, 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, espe-

[40] 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. 662).

cially in persons with certain predisposed conditions such as dyspepsia, gastrointestinal lesions, peptic ulcers or other bleeding problems in the gastrointestinal tract (F. 652).

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 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. 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. Even higher mortality rates are shown in those patients who require surgical intervention to stop the massive internal bleeding (CX 514 at 35392). Furthermore, there is evidence that aspirin can cause gastric ulcers when taken in large doses and aspirin may cause a specific kind of ulcer not seen in its absence. Gastric ulcer is a serious disease with significant morbidity, and often requires surgery on the stomach. By conservative estimate, aspirin ingestion results in 10 out of every 100,000 users developing a gastric ulcer, requiring hospitalization. Levy's Boston Collaborative group study also estimated that one-eighth of all gastric ulcers were aspirin-related (CX 514 at 35390). 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 514 at 35395). The aspirin-related gastrointestinal massive bleeding is compounded by aspirin's recently known anticoagulation effect (CX 514 at 35385).

2. 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 **[242]** asthmatic attacks; effects on the skin such as urticaria, agnioedema, 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. 661). Buffering will not mitigate aspirin's asthmatic side effects (F. 663). 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 514 at 35399).

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 should clearly indicate that the preparation contains aspirin and that aspirin can be harmful to some persons." (CX 514 at 35398; Tr. 2608–13). The FDA OTC Internal Analgesics Panel expressed its agreement with this resolution (CX 514 at 35398–99).[41] 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 (Farr, Tr. 2613, 3650).

Against the unanimous judgment of two responsible professional organizations of specialists and the FDA OTC Internal Analgesics Panel, Bristol-Myers argues that such advertising disclosure is totally unnecessary because (1) the incidence of aspirin intolerance or massive gastrointestinal bleeding is small and (2) to the extent some consumers are susceptible to such side effects, they 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%.[42] 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 [243] 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 Bufferin, Excedrin and Excedrin P.M. contain aspirin is unpersuasive. There is evidence that a substantial portion of consumers do not know that OTC analgesic products, such as Bufferin and Excedrin, contain aspirin. This is not surprising in view of the long history of Bufferin and Excedrin advertisements which carefully avoided any hint that it contains aspirin and suggested by implication that their analgesic ingredient is something special and that it is something other than aspirin. Similarly unpersuasive is respondents' argument that those

[41] 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 514 at 35356).

[42] Tr. 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.

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. Second, the number of consumers who do not read labels before they take an OTC product is as large as, if not larger than, those who read the labels. Similarly, "read-the-label" campaign does not tell consumers that these products contain aspirin. It simply exhorts consumers to read all OTC drug labels. What is needed is a direct and clear statement in all Bufferin/Excedrin/Excedrin P.M. advertising that they contain aspirin.

N. *Caffeine Disclosure Statements In Excedrin Advertisements Are Not Required*

Caffeine has been used widely as a combination ingredient in analgesic products, including Excedrin. When used as an adjuvant, caffeine is safe at a single dose of 65 mg. not to exceed 600 mg. in 24 hours, although its efficacy as an analgesic efficacy has not been sufficiently demonstrated.[43] 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, long known as a central nervous system stimulant, is also 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. Caffeine also inhibits platelet aggregation and its use in patients with gastric bleeding is not recommended.[44] Caffeine is associated with an increase in blood pressure.

However, the record as a whole does not show that the incidence and severity of adverse effects of caffeine are of [244] such magnitude as to make the existence of caffeine in Excedrin a material fact which should be disclosed in Excedrin advertisements. Furthermore, 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 will make the advertisement deceptive or unfair to the consumer or raise a substantial health or safety problem.

O. *Bristol-Myers' Legislative Preclusion Argument Is Without Merit*

Bristol-Myers argues that the legislative history of Sections 12 and 15 of the FTC Act precludes the Federal Trade Commission from imposing upon Bristol-Myers any liability for failing to disclose the

[43] CX 514 at 35482–83.
[44] CX 514 at 35484–85.

existence of substantial question regarding its comparative claims in advertisements containing such claims for Bufferin, Excedrin and Excedrin P.M. (BMM, III, 3–7) At first blush, Bristol-Myers' argument appears plausible. However, a closer examination of the pertinent legislative history leaves no doubt that what Congress had in mind in 1938 was to specify a statutory defense, not to create an exemption, in the amended Act. When Congress was considering the legislation that became section 15 of the amended Federal Trade Commission Act, it contemplated including a statutory defense in cases where there was a division in the medical community as to the truth of a product claim if the advertiser disclosed the existence of the conflicting opinion in his advertisement. However, Congress was persuaded that this was not necessary because in all cases the government will have to carry the burden of showing that, absent such disclosure, the advertisement as a whole is misleading or deceptive. (BMM, III, 4–5) It was understood that nothing in the paragraph of the House version was to be construed as "requiring" the making of such disclosure statement as to the difference of opinions. However, nothing in the legislative history can be reasonably construed to support the proposition that a finding of liability under Sections 12 and 15 is precluded where an advertisement is in fact misleading and deceptive unless the existence of such a question is disclosed in the advertisement. Any other reading of the legislative history would virtually vitiate the central purpose of the 1938 amendment and result in imputing a legislative exemption where none was intended by Congress. The language of the House Report on the Wheeler-Lee Amendment clearly demonstrates a congressional intention to confer upon the FTC a broad mandate to regulate misleading advertising regarding foods and drugs:

> The provisions of this bill covering false advertising are far reaching but we believe entirely warranted, necessary for the effective control of illegitimate advertising and yet drawn with due **[245]** regard to the rights of legitimate advertising.
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> * * * * * * *
>
> The advertisement amendments to this bill revolve around the definitions of a "false advertisement" in Section 15. A false advertisement is defined as one "which is misleading in material respect." Certain specified matters are to be considered in determining whether or not an advertisement is misleading. This definition is very broad. It will be noted that a fraudulent intent is not a necessary element of a false advertisement. The essential elements of a false advertisement are that it is misleading and *misleading in a material respect.* It places on the advertiser the burden of seeing that this advertisement is not misleading.
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> * * * * * * *
>
> The definition is broad enough to cover every form of advertisement deception over which it would be humanly practicable to exercise governmental control. It covers every case of imposition on a purchaser for which there could be a practical remedy.

It reaches every case from that of inadvertent or uniformed advertising to that of the most subtle as well as the most vicious types of advertisements.[45]

Respondent's implied exemption argument is also refuted by the fact that where Congress intended to create an exemption **[246]** from the operation of the statute, it did so explicitly.[46]

Furthermore, the Commission's authority under Section 12 of the Act to require an advertiser to disclose the existence of a medical controversy in appropriate cases has been upheld by the Seventh Circuit in 1977. *See National Commission on Egg Nutrition,* 88 F.T.C. 89, 193–94 (1976), *mod. in part,* 570 F.2d 157, 164–65 (7th Cir. 1977), *cert. denied,* 426 U.S. 919 (1978).

We need not dwell on Bristol-Myers' argument that under Section 15(a) of the amended FTC Act, the Commission has no power to require disclosure of any drug ingredient in advertising because the FDA was given an exclusive jurisdiction over labeling of drug products. The issue in this case is not what the contents of any label for Bristol-Myers' OTC analgesic products should be, but whether the existence of aspirin in these products is a material fact which in light of other representations contained in the ads should be disclosed. Simply put, the issue in this case is false or misleading advertising, not misbranding.

P. *Bristol-Myers' Constitutional Objections To The Substantial Question Disclosure Requirements Are Without Merit*

Bristol-Myers' free speech argument in opposition to the requirement that comparative claims for Bufferin, Excedrin and Excedrin P.M. be accompanied by appropriate disclosures regarding the existence of a substantial question, is not well founded. It is now well established that commercial speech is **[247]** entitled to the full protection 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

[45] H.R. Rept. No. 1613, 75th Cong., 1st Sess. (1937) 4–5.

[46] *See, e.g.,* 15 U.S.C. 55(a)(1) (1970):

> The term "false advertisement" means an advertisement, other than labeling . . . No advertisement of a drug shall be deemed false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of the formula showing quantitatively each ingredient of such drug.

See also 21 U.S.C. 502(n)(3)(B) (1970):

> No advertisement of a prescription drug . . . shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of Sections 12 [-] 17 of the [FTC] Act. . . .

(1976), *modified,* 570 F.2d 137 (7th Cir. 1977), *cert. denied,* 426 U.S. 919 (1978).

In the cases involving commercial speech, the First Amendment 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. Bristol-Myers' argument that such a requirement in the context of the substantial question theory would have the effect of chilling truthful speech is therefore without merit.

None of the recent commercial speech cases cited by Bristol-Myers (BMM-VIII) suggests that the Commission under Sections 5, 12 and 15 of the FTC Act may not require an affirmative disclosure to prevent a claim from being misleading or that the Commission must prove a claim to be false before imposing restraints on future dissemination of that claim. In fact, the Court in recent years has reaffirmed the view set forth in *Virginia State Board,* 425 U.S. at 771–72, n. 24.[47] Most recently, in *Friedman* v. *Rogers,* 47 U.S.L.W. 4151 (Feb. 20, 1979), the Court stated: **[248]**

> . . . Equally permissible are restrictions on false, deceptive, and misleading commercial speech. *Id.* at 4153.
>
> Regarding the permissible extent of commercial speech regulation, the Court observed in *Virginia Pharmacy* that certain features of commercial speech differentiate it from other varieties of speech in ways that suggest that "a different degree of protection is necessary to insure that the flow of truthful and legitimate commercial information is unimpaired." [citation] * * * Commercial speech, because of its importance to business profits, and because it is carefully calculated, is also less likely than other forms of speech to be inhibited by proper regulation. These attributes . . . indicate that it is "appropriate to require that a commercial message appear in such a form . . . as [is] necessary to prevent its being deceptive. . . . They may also make inapplicable the prohibition against prior restraints." [citations omitted] *Id.* at 4154.

Also, the constitutional challenge against the reasonable basis requirement in this case is misdirected for the reason that the tension

[47] In *Young* v. *American Mini Theatres,* 427 U.S. 50 (1976):

> [R]egulatory commissions may prohibit businessmen from making statements which though literally true, are potentially deceptive. *Id.* at 68–69 n. 31.

And again in *Bates* v. *State Bar of Arizona,* 433 U.S. 350 (1977):

> We do not foreclose the possibility that some limited supplementation, by way of warning or disclaimer or the like, might be required . . . so as to assure that the consumer is not mislead. *Id.* at 380.

relief claims related to Bufferin and Excedrin not only lacked a reasonable basis but also were untrue. While the free speech protection extends to commercial speech and truthful speech may not be banned outright under a claim of substantial governmental interest, what is being proscribed here is not "truthful speech" by any stretch of the imagination but affirmative medical-scientific claims for drug products which are based on some favorable clinical studies and at times simply on pharmacological theory. Clearly there is an important distinction between "truthful speech" and a product claim based on medical-scientific theory or on questionable experimental data. Free speech is a keystone of free political institutions and must be guarded with steadfast vigilance. However, it may not be invoked to insulate from proper regulation commercial speech which is misleading and unfair to the consumer.

Q. *Product Images of Bufferin, Excedrin And Corrective Advertising*

Complaint counsel contend that: (1) a substantial number of consumers have an image of Bufferin as a faster and gentler pain reliever than aspirin and an image of Excedrin as a faster and more effective pain reliever than aspirin; (2) these images are **[249]** due in substantial part to Bristol-Myers' misleading advertising claims made over a period of many years; (3) these product images will persist in the absence of corrective advertising designed to convey to consumers a corrective message that these products' superior speed, efficacy or safety is not scientifically established. Respondents vigorously dispute complaint counsel's argument. It is my determination that (1) the record is devoid of any evidence from which it may reasonably be inferred or which tends to show that any consumer is likely to have an "establishment" image about any product involved in this proceeding; (2) although the record shows that a substantial number of consumers had an image of Bufferin and Excedrin as tension relievers, the empirical evidence in the record suggests that Bristol-Myers' advertisements may not have played a substantial role in creating or maintaining that image; and (3) in any event the tension advertisements for Bufferin and Excedrin ceased by 1970 and there is no solid basis for requiring any corrective advertising in this case.

1. Product Images, Their Sources And Duration

The mere fact that Bristol-Myers made the challenged advertising claims for a long period of time supports a fair inference that consumers will have an image of Bufferin as a faster and gentler pain reliever than aspirin and an image of Excedrin as a faster and more effective

pain reliever than aspirin.[48] This inference is further confirmed by some empirical data in the record.

The record as a whole clearly supports the conclusion that consumers have had these product images about Bufferin and Excedrin for some years. The five commercial market research studies (CX 310, 346, 1058 and 1059) conducted between 1967 and 1970 by various reputable firms for different marketers of aspirin products (including Bristol-Myers), together with the 1975 Leavitt Study (CX 349), produced fairly consistent results which support that conclusion. Although they were not perfect surveys, they were in general of the kind and quality normally used by business firms to help guide their marketing efforts. An analysis of the data pertaining to efficacy- and safety-related product attributes shows that consumers for some years have believed that Bufferin and Excedrin were superior to aspirin in those respects claimed by the advertisements. Thus, these penetration/image studies confirm what common sense and experience suggest, namely, that Bristol-Myers' dissemination of the challenged advertising claims over a long period of time led **[250]** to consumer images that Bufferin is faster and gentler than aspirin and Excedrin is faster and more effective than aspirin.

Next, the Commission has consistently rejected the argument that the image consumers may have about a product is the result of many and varied causative factors and that advertising cannot be singled out as the primary factor in the absence of empirical evidence which establishes a causal relationship between advertisements and consumer images.[49] The remarkable correspondence between advertising claims and consumer images shown in this record is further indication that advertising played a significant role in creating or reinforcing those images.

With respect to the duration issue, the record as a whole supports the conclusion that the consumer images about Bufferin and Excedrin that have been found to exist will endure for some time and will tend to be reinforced either by subsequent advertising or by subsequent use.[50]

2. 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 correc-

[48] *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).

[49] *See e.g., Warner-Lambert Co., supra*, 86 F.T.C. at 1501–02, 1503 (1975), 562 F.2d at 762; *Walthum 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).

[50] *Cf. Warner-Lambert Co., supra*, 86 F.T.C. at 1501–03, 562 F.2d at 762; *National Commission on Egg Nutrition* v. *FTC, supra.*

tive 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 argue that the finding that some of respondents' advertisements contained an implied establishment claim of superior efficacy and safety and the finding that some consumers held corresponding superiority images about Bufferin and Excedrin 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 [**251**] *establishment* image or that such an inference is fair in the circumstances of this case. It is one thing to find an implied establishment claim in certain of respondents' advertisements and to require in future advertisements containing such establishment claims, an affirmative disclosure of the material fact that a substantial question exists. It is entirely another matter to find an implied establishment claim and require a corrective advertising saying essentially that the past establishment claims were false in cases where, as here, the claimed product performance characteristics (faster, stronger, or gentler) are not alleged to be false. Indeed, the record contains substantial evidence which indicates that the superiority claims involved in this case, although not "established," are based on sound pharmacological rationale and are not outright falsehoods. Furthermore, if a finding of "establishment" image among consumers is to be logically inferred from the fact of superiority image about Bufferin and Excedrin, the basis for doing so in this case is less than substantial, for the evidence of consumer images itself is less than overwhelming. Finally, as a practical matter, the disclosure requirements regarding the existence of aspirin in Bufferin and Excedrin as well as the existence of a substantial question in future advertisements will sufficiently inform consumers of the fact that Bufferin and Excedrin are aspirin-based products and that any comparative claim being made about them is not scientifically established, and by so doing may have the further effect of causing some consumers to modify accordingly their image of superiority of Bufferin and Excedrin. On balance, it is determined that on the basis of this record, corrective advertising directed to comparative images of Bufferin and Excedrin is not justified.[51] [**252**]

[51] In theory a corrective advertisement provision may be justified on the basis of Complaint Paragraphs 9 and (footnote cont'd)

With regard to the tension claim, there is evidence tending to show that consumers have a tension relief image about OTC headache tablets as a class and that Bristol-Myers' tension relief claims may have played a significant role in reinforcing them with respect to Bufferin and Excedrin, if not in creating them in the first place. However, in view of the fact that Bristol-Myers' tension relief claims ceased some ten years ago, a corrective advertising requirement directed to the tension reliever image appears unnecessary.

R. *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).

1. The Reasonable Basis Provision Is Justified

Part I of the Order would prohibit simple and noncomparative efficacy or safety claims or recommendation claims that are not supported by a reasonable basis. This prohibition is based on the findings that Bristol-Myers made tension reliever claims for Bufferin, Excedrin and Excedrin P.M. and endorsement or recommendation claims for Bufferin without adequate substantiation. Although the tension reliever claims ceased in 1970, the provision is necessary to prevent a renewal of that claim as well as any other claims concerning any non-prescription drug product not supported by a reasonable basis.

Inclusion of all OTC drug products in the reasonable basis requirement provision is appropriate in this case. Bristol-Myers appears to have been involved in a number of Section 5 proceedings which resulted in cease and desist orders, consent orders or stipulations involving misrepresentation of a number [253] of OTC drug and cosmetic

10, for the reason that respondents' unqualified and misleading superiority claims made over many years played a significant role in creating and reinforcing corresponding consumer images of superiority of Bufferin and Excedrin over aspirin and that, in the absence of a clear corrective message in future advertisements, these images are likely to endure. However, the focus of complaint counsel's arguments in support of corrective advertising was placed upon "false establishment images." *See* CCM, at 209–11, 223–26, 239–40. In any event, although the evidence supports a finding that consumers held superiority images about Bufferin and Excedrin during the years 1967–70 and 1975, the evidence is not so clear and convincing as to support a finding that, but for a corrective message in every future advertisement, these images are likely to endure *after the offensive advertisements have ceased.* In my view, this case is clearly distinguishable from *Warner-Lambert,* where the cold-preventive image of Listerine was shown to be about three times as high as that of competitive products. 86 F.T.C. at 1503.

products.[52] In *Grove Laboratories,* Grove (owned by Bristol-Myers) was found to have falsely represented the therapeutic effect of a hemorrhoid preparation, and was ordered to cease misrepresenting the ability of any "drug" to prevent or treat hemorrhoids. The Commission found that it was obligated to include all drug products in the order, saying,

> [W]e are convinced that we would be derelict in our responsibilities if we were to limit the prohibitions of the order against false representations solely to hemorrhoidal preparations having the same or similar ingredients. The ease with which such orders can be avoided has been amply demonstrated by the Commission's experience with this respondent alone. We are equally convinced that it is essential that this order also "fence this respondent in" in connection with all of its future advertising of drug preparations. It is our judgment that in the circumstances of this case and of this respondent, it is essential that the order which we are entering cover all drug products sold by respondent. 71 F.T.C. at 847–48.

The Commission's order also broadly prohibited respondent from "misrepresenting the efficacy of any drug" (418 F.2d at 497). The Fifth Circuit reversed the all-drugs-products order coverage on the grounds that it was a "close question" whether the past history of Grove and Bristol-Myers warranted broad product coverage. It is my view that now is the time to place Bristol-Myers under a broad proscription with respect to all OTC **[254]** drug products marketed by it. Furthermore, the proscription here is narrower and is related to the particular types of claims involved in this case.

2. Substantial Question Disclosure Requirement Should be Limited to OTC Analgesic Products

Part III A of the order would prohibit Bristol-Myers from making comparative efficacy and safety claims of any OTC internal analgesic products without disclosing the existence of a substantial question unless the claim is not scientifically established. The 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

[52] *See Bristol-Myers Co.,* 36 F.T.C. 707 (1943) (efficacy claim of "Sal Hepatica"); *Bristol-Myers Co.,* 46 F.T.C. 162 (1949), *aff'd,* 185 F.2d 58 (4th Cir. 1950) (therapeutic claim of a toothpaste); *Bristol-Myers Co.,* 47 F.T.C. 1441 (1950) (efficacy claim of "Resistab"); *Grove Laboratories, Inc.,* 71 F.T.C. 822 (1967), *rev'd in part,* 418 F.2d 489 (5th Cir. 1969) (efficacy claims of a hemorrhoidal preparation); *Bristol-Myers Co.,* 74 F.T.C. 780 (1968) (safety claim of Bufferin). In addition, Bristol-Myers has entered into six stipulations regarding the advertising of its products. 24 F.T.C. 1546 (1937) (relating to health claims for "Vitalis"); 24 F.T.C. 1554 (1937) (relating to health claims for Ipana toothpaste); 24 F.T.C. 1558 (1937) (relating to health claims for "Sal Hepatica," a laxative); 25 F.T.C. 1626 (1937) (relating to claims for "Minit-Rub," an alleged cold remedy); 27 F.T.C. 1602 (1938) (relating to skin claims for "Ingram's Milkweed Cream"); 27 F.T.C. 1609 (1938) (relating to health claims for "Ingram's Shaving Cream").

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 (CM, 193–96).

With respect to the product scope of this provision, I am now of the view that the substantial question disclosure should be limited to OTC internal analgesic products for the reason that the record provides an insufficient basis for concluding that the implied establishment claim/substantial question theory discussed in this case would be equally valid for all OTC drug products. There is some evidence from which it can be inferred that the considerations discussed in connection with the establishment/substantial question issue related to OTC analgesic products may be equally valid with respect to all OTC drug products. For example, the FDA's requirements for clinical demonstration of efficacy and safety by two or more well-controlled studies apply to all new drugs. In establishing the monograph procedures for certain classes of OTC drugs, including OTC analgesics, the FDA incorporated similar standards for labeling purposes.

However, in the final analysis, the establishment/substantial question theory in this case is essentially anchored in the reasonable basis doctrine. What constitutes a reasonable basis for an advertising claim is a question of fact to be determined on a case-by-case basis and depends on, among other things, the nature of the product and the type of claim involved.[53] Although it is eminently plausible to conclude that the essential rationale of the substantial question disclosure requirement with respect to headache tablets will be valid for OTC drug products of other classes, I am not persuaded [255] that this adjudicative record involving OTC internal analgesic products provides a sufficient basis for extending the establishment/substantial question disclosure provision of the Order to all OTC drug products. For the same reasons, the fencing-in argument, valid with respect to the reasonable basis provision of the Order, is inappropriate with respect to the establishment/substantial question disclosure provision.[54]

S. *Liability of Advertising Agencies*

The law is well-settled that an advertising agency may be held liable for false advertising if it "actually participated in the deception. . . In order to be held a participant in such deception, the agency must know or have reason to know of the falsity of the advertising." *Doherty, Clifford, Steers and Shenfield, Inc.* v. *F.T.C.*, 392 F.2d 921,

[53] *Pfizer*, 81 F.T.C. at 64, 66–67.

[54] This view represents a modification of my views expressed in the Initial Decision in *American Home Products Corporation*, Docket No. 8918, filed 9/1/78 [98 F.T.C. 136], regarding the propriety of an "all drug products" coverage with respect to a similar disclosure requirement in the order therein.

918 (6th Cir. 1968); also *Carter Products, Inc.* v. *F.T.C.*, 323 F.2d 523, 534 (5th Cir. 1963); *ITT Continental Baking Co., Inc.*, 83 F.T.C. 865 (1973).

In determining liability, the agency will be strictly held to know what claims are made in advertisements. *In re Merck & Co.*, 69 F.T.C. 526, 559 (1966), *aff'd*, 392 F.2d 921 (6th Cir. 1968). *ITT Continental, supra.* Since it is undisputed that Bates and Young & Rubicam actively participated in the creation and dissemination of the challenged advertisements for Bufferin, Excedrin and Excedrin P.M., the remaining issues regarding their respective liability are whether each knew or should have known that the advertisements they disseminated were false due to failure to disclose material facts of the presence of aspirin and the existence of a substantial question in the medical scientific community concerning the validity of the "establishment" claims regarding these products.

Complaint counsel argue that both respondents' absolute and comparative efficacy (and related) claims for Bufferin, Excedrin, and Excedrin P.M. were false because, having represented these claims as being "established" by scientific evidence, Ted Bates knew or should have known that the data supporting the claims were subject to "substantial question" among experts and that the existence of such substantial question was a material fact which should have been disclosed to consumers. A similar allegation is made with respect to Bufferin's "Doctors Recommend" advertisements, the "antidepressant" claims imputed to Excedrin, and the "mild sedative" claims imputed to Excedrin P.M. Complaint counsel **[256]** also argue that the failure of both respondents to include the presence of aspirin in these analgesics was false because both advertising agencies knew, or should have known, that since aspirin may cause undesirable side effects in certain users, implicit promotion of these analgesics as containing ingredients other than aspirin and failure to disclose the presence of aspirin was false advertising by virtue of the fact that the presence of aspirin is material fact, knowledge of which may cause some consumers to change their purchase decisions.

It is my determination that the record as a whole: (1) fails to support allegations in the complaint relative to the imputed "antidepressant" and "mild sedative" claims for Excedrin and Excedrin P.M., respectively; (2) supports the complaint allegations that the failure to disclose the presence of aspirin in all three analgesics constituted knowingly false advertising relative to the imputed claims for Bufferin, Excedrin and Excedrin P.M. that the analgesic ingredient in these products was something other than aspirin for which respondent advertising agencies should be held liable; and (3) supports the conclusion that both respondents' good faith reliance on the substantiation

information with respect to the comparative efficacy and safety claims for Bufferin, Excedrin, and Excedrin P.M., as well as the tension relief claims was reasonable under the circumstances.

With respect to the tension relief claim, although the dated medical literature on which Bristol-Myers relied on did not constitute a reasonable basis for Bristol-Myers which was in a position to evaluate the nature and reliability of the purported substantiation, I am unable to conclude that it was not reasonable for the advertising agencies to have relied on Bristol-Myers Medical Department's judgment as to medical-scientific substantiation for the claim. In other words, what may not be a reasonable basis for a medical-scientific claim for a drug manufacturer may be a reasonable basis for an advertising agency which relied in good faith on the client drug manufacturer's judgment regarding the adequacy of substantiation, unless the purported substantiation was unreliable on its face. However, in view of the specific findings made herein with regard to the inadequacy of medical substantiation for the tension relief claim, the advertising agencies should be prohibited in the future from continuing to make such claims until the day something more than what was relied on by respondents in this case is forthcoming.

With respect to advertising agency's liability under the establishment/substantial question theory, it is my determination that the same standards applicable to drug manufacturing firms are not appropriate for advertising agencies in this case. Here, as in my Initial Decision in *American Home Products,* Docket No. 8918, dated 9/1/78 (p. 225) [98 F.T.C. at 340], respondents are found to have acted reasonably in relying in good faith on [**257**] the substantiation data provided by Bristol-Myers. As the record in this case amply demonstrates, scientific analysis or verification of the accuracy of clinical data is a highly complex, technical process, one for which the two advertising agencies are not, and may not reasonably be expected to be, equipped. Even where complaint counsel have shown the advertising agencies to have been aware of some questions concerning the validity of their unqualified representations, respondents were not obligated to perform statistical or clinical analyses of their representations to determine the "substantiality" of the question or its "materiality." I reiterate my conclusions in *American Home Products* [98 F.T.C. at 340]:

> 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 [advertising agency] cannot be reasonably charged with the duty to conduct an independent investigation that the claim is scien-

tifically 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.

Conclusions of Law

1. The Federal Trade Commission has the jurisdiction over the advertising of Bufferin, Excedrin and Excedrin P.M. under Section 5 of the Federal Trade Commission Act.

2. Respondents' false and misleading advertising representations as alleged in the Complaint and as herein found to have been made, with the exception of Paragraphs 7A(3), 9A(3), 12C and 14A (as relates "twice as strong" claim), have had and now have the capacity and tendency to mislead consumers [258] into the mistaken belief that the said representations are true and into purchasing substantial quantities of Bufferin, Excedrin and Excedrin P.M. by reason of said mistaken belief. In the absence of an appropriate cease and desist order, including appropriate affirmative disclosure requirements, consumers will continue to be misled by respondents' advertisements that certain advertising representations being made regarding efficacy or safety of said products are supported by medical-scientific evidence generally accepted by the scientific community as establishing such propositions or have 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 Sections 5 and 12 of the FTC Act.

4. The Complaint is hereby dismissed: (A) as to all respondents insofar as it relates to the advertising representations alleged in Complaint Paragraphs 7A(3), 9A(3), 12C and 14A as relates to "Bufferin is twice as strong as aspirin" claims; and (B) as to Ted Bates & Company and Young & Rubicam, Inc. insofar as it relates to the allegations in Complaint paragraphs 10, 11, 15 and 16.

5. The accompanying order is necessary and appropriate for the purpose of prohibiting the continuation of the proscribed acts and remedying the injury and unfairness to the consuming public. [259]

Order

I.

It is ordered, That respondent Bristol-Myers Company, a corporation, its successors and assigns and respondent's officers, agents, rep-

resentatives 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 any nonprescription drug 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, that such product relieves nervousness, tension, anxiety or depression or will enable persons to cope with the ordinary stresses of everyday life; or

B. Making any statements or representations, directly or by implication, concerning the effectiveness or freedom from side effects of such product; or

C. Representing that any group, body or organization endorses or recommends such product;

unless at the time such statement or representation is made respondent has a reasonable basis for such statement or representation, which shall consist of competent and reliable scientific evidence.

II.

It is further ordered, That respondent Bristol-Myers Company, a corporation, its successors and assigns and respondent's [260] 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 Bufferin, Excedrin, Excedrin P.M. or any other nonprescription drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing 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 nonprescription analgesic products.

B. Referring, directly or by implication, to aspirin, caffeine or any commonly known ingredient by any word or words without disclosing the common, or usual, name of such ingredient.

C. Failing to disclose in the advertising of any nonprescription drug product intended for internal use, the presence of aspirin when such product contains aspirin.

D. Misrepresenting in any manner any test, study or survey or any results thereof.

III.

It is further ordered, That respondent Bristol-Myers Company, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection [**261**] with the labeling, advertising, offering for sale, sale or distribution of Bufferin, Excedrin, Excedrin P.M., 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. 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 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 comparative freedom from side effects it is represented to have, and (2) that such comparative effectiveness or comparative freedom from side effects 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 conducted on any pain or condition [**262**] referred to, directly or by implication; or, if no specific pain or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two types of pain or conditions 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 must 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;

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. **[263]**

3. 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 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 must 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.

B. Making any statement or representation, directly or by implication, concerning the comparative effectiveness or comparative freedom from side effects of such product, when there exists a substantial question, recognized by experts **[264]** qualified by scientific training and experience to evaluate the efficacy and safety of such drug product, as to the validity of any such statement or representation, unless respondent discloses the existence of such substantial question by including in the same advertisement a clear and conspicuous disclosure statement conforming to the following:

1. The disclosure statement regarding comparative efficacy [and/or safety] for Bufferin should state "Bufferin has not been proven to be a faster pain reliever [and/or gentler to the stomach] than aspirin," or comprise such other statement approved by the Federal Trade Commission in advance or as respondent can demonstrate (based on consumer surveys whose design is adequate and previously approved by the Federal Trade Commission) will convey the same message to consumers.

2. The disclosure statement regarding comparative speed [and/or efficacy] for Excedrin should state "Excedrin has not been proven to be a faster [and/or stronger] pain reliever than aspirin," or comprise such other statement determined and approved as set forth in 1 hereinabove.

3. The disclosure statement regarding comparative efficacy for

Excedrin P.M. should [265] state "Excedrin P.M. has not been proven to be stronger pain reliever than aspirin," or comprise such other statement determined and approved as set forth in 1 hereinabove.

4. 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.

5. 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 occur. Each such disclosure shall be presented in the language principally employed in the advertisement.

IV.

It is further ordered, That respondent Ted Bates & Co., 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 labeling, advertising, offering for sale, sale or distribution of Bufferin in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from: [266]

A. Representing, directly or by implication, that Bufferin will not upset a person's stomach, unless respondent has a reasonable basis for such representation consisting of competent and reliable scientific evidence;

B. Representing, directly or by implication, that Bufferin will relieve nervous tension, anxiety or irritability or will enable persons to cope with the ordinary stresses of everyday life, unless respondent has a reasonable basis for such representations.

C. Referring to the ingredient aspirin by any word or words other than "aspirin";

D. Failing to disclose, clearly and conspicuously, that the product contains aspirin; or

E. Representing, directly or by implication, that physicians recommend Bufferin more than any other nonprescription internal analgesic product, unless respondent has a reasonable basis for such representation consisting of competent and reliable surveys of physicians.

V.

It is further ordered, That respondent Young & Rubicam, 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 labeling, advertising, offering for sale, [**267**] sale or distribution of Excedrin or Excedrin P.M. 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, that Excedrin or Excedrin P.M. will relieve tension, nervousness, anxiety or irritability or will enable persons to cope with the ordinary stresses of everyday life, unless respondent has a reasonable basis for such representations.

B. Referring to the ingredient aspirin in Excedrin or Excedrin P.M. by any other word or words other than "aspirin";

C. Failing to disclose, clearly and conspicuously, that the products contain aspirin; or

D. Representing, directly or by implication, that physicians recommend such products, unless at the time of such representations respondent has a reasonable basis for such representation consisting of competent and reliable surveys of physicians.

VI.

It is further ordered, That respondents herein 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. [**268**]

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.

Paragraphs Seven A(3), Nine A(3), Twelve C and Fourteen A as relates to "Bufferin is twice as strong as aspirin" claim, of the Complaint are hereby dismissed as to all respondents. Paragraphs Ten,

Eleven, Fifteen and Sixteen of the Complaint are hereby dismissed as to Ted Bates & Company, Inc. and Young & Rubicam, Inc.

OPINION OF THE COMMISSION

BY CLANTON, *Commissioner:*

I. INTRODUCTION AND HISTORY OF THE CASE

Announcer:	Excedrin headache #94102: The Parking Attendant.
Man 1:	This is a red sedan.
Man 2:	Yes it is. Take your red sedan and move it out on the street, or we'll push it out . . . .

Thus begins an ad for Excedrin, an over-the-counter (non-prescription or "OTC") aspirin-based analgesic (pain reliever) produced by the Bristol-Myers Company ("Bristol-Myers"). From 1971 to 1973, consumers spent an average of $85 million annually to purchase Excedrin, Bufferin, and Excedrin P.M., all of which are manufactured by Bristol-Myers. During that same time, Bristol-Myers spent approximately $20 million each year to promote the sale of these three products with television, radio, and print advertisements. That some of these ads were very clever (such as the [2] "Excedrin headache #__" campaign mentioned above) or very effective (as demonstrated by Bristol-Myers' sales) is unquestioned. What is at issue in this proceeding is whether the claims made for these products violate the law.

The issues involved here are very similar to those involved in *American Home Products Co.*, 98 F.T.C. 136 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982), and in *Sterling Drug, Inc.*, Docket No. 8919 (also announced today) [102 F.T.C. 395]. In each of these three companion cases, we are required to determine (a) what claims were made by various analgesic advertisements, (b) what level of evidence should be required to substantiate those claims, and (c) whether the evidence possessed by the advertisers measures up to that required level. Each case involved a number of advertising claims, made in a large number of separate advertisements.

In brief, in this case (as in the others), we find that respondent made some claims for which it lacked a reasonable basis, in violation of the doctrine of *Pfizer, Inc.*, 81 F.T.C. 23 (1972). We also find that in a larger number of advertisements respondent represented that claims had been scientifically established even though respondent's evidence did not bear out this contention. However, we decline to follow our prior decision in *American Home Products,* insofar as it found consumers believe every comparative performance claim has been scientifically established (the "substantial question" theory). Thus, in this

case and in *Sterling Drug,* we hold the advertiser to the level of evidence required to convince the relevant scientific community of the claim's truthfulness only when the advertisement expressly or implicitly represents that the claim's truth has been scientifically established.

The Commission issued the complaint against Bristol-Myers and against Ted Bates & Company, Inc., and Young & Rubicam, Inc., Bristol-Myers' advertising agencies, on February 23, 1973.[1] The complaint charged that respondents' advertising violated Sections 5 and 12 of the Federal Trade Commission Act (15 U.S.C. 45, 52) by making advertising claims regarding Bufferin's efficacy, freedom from side effects, ability to relieve tension, and ingredients and regarding Excedrin and Excedrin P.M.'s efficacy, ability to relieve tension and ingredients. Ted Bates and Company, Inc. was charged with responsibility for all ads relating to Bufferin and Young & Rubicam, Inc. was charged with responsibility for the claims relating to Excedrin and Excedrin P.M. **[3]**

This case was assigned for hearing to Administrative Law Judge Montgomery K. Hyun, who rendered an initial decision finding against respondent Bristol-Myers on all charges except those relating to claims that Bufferin is twice as strong as aspirin (Comp. ¶ 7(A)(3), 9(A)(3), and part of 14(A) and that Excedrin P.M. is an effective sedative (Comp. ¶ 12(C)). With respect to the advertising agencies, Judge Hyun found that they had adequate substantiation for all comparative safety and efficacy claims but found them liable for failing to disclose the presence of aspirin in the products.

This matter is now before the Commission on the appeal of all three respondents and complaint counsel. Respondent Bristol-Myers' principal contentions on appeal are: (1) the ALJ erred in interpreting the meanings of the challenged ads; (2) the ALJ erred in finding that Bristol-Myers lacked substantiation for the claims made in its advertisements; (3) there is no legal support for the clinical testing standard which the ALJ's order requires as substantiation for comparative claims; and (4) the ALJ's order is overbroad and violates Bristol-Myers' constitutional rights. Both advertising agencies appeal on the grounds that they acted reasonably in relying on Bristol-Myers' substantiation and the ALJ erred in entering any order against them. Complaint counsel support the ALJ's order and findings in most respects but raise the following issues on appeal: (1) corrective advertising should have been ordered; and (2) the ALJ erred by not finding the ad agencies liable for establishment claims.

[1] On the same date, the Commission issued a complaint against American Home Products Corporation regarding its advertising of Anacin and Arthritis Pain Formula and a complaint against Sterling Drug, Inc., regarding its advertising of Bayer Aspirin, Bayer Children's Aspirin, Cope, Vanquish, and Midol.

In our discussion below, we will review each claim in turn, first determining whether the claim was made by the advertisements and then describing the standard by which the respondent's substantiation is to be judged. At the end, we discuss the liability of the two advertising agencies.[2] [4]

II. COMPARATIVE EFFICACY AND SIDE EFFECTS CLAIMS

A. *Legal Standards for Interpreting Claims*

Paragraphs 7 through 11 of the complaint contain two sets of allegations regarding respondent Bristol-Myers' comparative performance claims for Bufferin, Excedrin, and Excedrin P.M. and we deal with these claims in this section. In Part B below, we consider the representations made by respondent's advertisements. First, however, we consider the manner in which the meaning of advertisements is interpreted under Section 5 of the F.T.C. Act.

Interpreting advertising claims is not a mystical process; it involves the exercise of common sense and good judgment. *F.T.C.* v. *Colgate-Palmolive Co.,* 380 U.S. 374, 385 (1965); *Porter & Dietsch,* 90 F.T.C. 770, 862 n.3, *aff'd as modified,* 605 F.2d 294 (7th Cir. 1979). It is well settled that the Commission can determine the meaning of an advertisement without necessarily resorting to assessments of consumer perception or other expert testimony. *American Home Products* v. *F.T.C.,* 695 F.2d at 687, and cases cited at n. 10; *The Kroger Company,* 98 F.T.C. 639, 728 (1981). However, when extrinsic evidence on the meaning of an ad has been introduced, that evidence must be considered by the Commission in reaching its conclusion. *Cinderella Career and Finishing Schools, Inc.* v. *F.T.C.,* 425 F.2d 583, 588 (D.C. Cir. 1970); *The Kroger Company,* 98 F.T.C. at 729 n. 11. While that evidence will not necessarily supplant the Commission's common sense judgment, it will assist us in reaching a sound decision. *Firestone Tire and Rubber Co.,* 81 F.T.C. 398, 454 (1971), *aff'd* 481 F.2d 246 (6th Cir. 1973), *cert. denied,* 414 U.S. 1112 (1973); *Crown Central Petroleum Corp.,* 84 F.T.C. 1493, 1540 (1974). There also may be instances where claims cannot be inferred from a facial examination of the advertisements and resort to extrinsic evidence is necessary. *See e.g., Leonard F. Porter, Inc.,* 88 F.T.C. 546, 626 (1976).

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

F.	– Initial Decision, Finding No.
I.D.	– Initial Decision
CX	– Complaint Counsel's Exhibit No.
RX	– Respondents' Exhibit No.
Tr.	– Transcript of Testimony, Page No.
RAB	– Bristol-Myers Appeal Brief
C.A.B.	– Complaint Counsel's Appeal Brief
C.R.A.B.	– Complaint Counsel's Revised Answering Brief

When the Commission interprets an ad, it must consider the net impression that the ad makes on consumers. *American Home Products* v. *F.T.C.*, 695 F.2d at 688; *National Bakers Services, Inc.* v. *F.T.C.*, 329 F.2d 365 (7th Cir. 1964). Thus, an ad may violate the law if an implied representation which it conveys is not properly substantiated, even though the statements in the advertisement taken literally are true. *Carter Products, Inc.* v. *F.T.C.*, 323 F.2d 523, 528 (5th Cir. 1963). But the Commission may not inject novel meanings into ads and then strike them down as unsupported; ads must be judged by the impression they make on reasonable members [5] of the public. *Ward Laboratories, Inc.* v. *F.T.C.*, 276 F.2d 952, 954 (2nd Cir. 1960), *cert. denied* 364 U.S. 827 (1960); *International Parts Corporation* v. *F.T.C.*, 133 F.2d 883 (7th Cir. 1943); *Heinz W. Kirchner*, 63 F.T.C. 1282, 1290 (1963), *aff'd* 337 F.2d 751 (9th Cir. 1964). If an ad conveys more than one meaning to reasonable consumers and one of those meanings is false, that ad may be condemned. *National Commission on Egg Nutrition* v. *F.T.C.*, 570 F.2d 157, 161 n.4 (7th Cir. 1977), *cert. denied* 439 U.S. 821 (1978).

Finally, the challenged claims must be material to the purchase decision; in other words, the claims must be of the type that consumers are likely to rely upon in deciding whether to purchase a particular good or service. *F.T.C.* v. *Colgate-Palmolive Co.*, 380 U.S. at 386.[3] (Respondent does not dispute the materiality of the claims it is charged with making. However, it does dispute the materiality of its failure to disclose the presence of aspirin in ads for Bufferin and Excedrin.) With this background, we now turn to Bristol-Myers' ads.

B. *Representations of Comparative Efficacy and Freedom from Side Effects in Bristol-Myers' Ads*

Complaint paragraphs 7–11 charge respondent with making numerous claims of superior efficacy and freedom from side effects for Bufferin, Excedrin, and Excedrin P.M. Paragraphs 7 and 8 charge that the ads represented that the claims had been established. Paragraphs 9–11 allege that where there was no representation of establishment, respondents failed to disclose the existence of a substantial question regarding the claims' validity.

In the Initial Decision, Judge Hyun found that respondent had made 14 of the 15 challenged claims of superior performance or freedom from side effects and that it had represented that all 14 of these claims had been established.[4] We agree [6] with respect to ten of the

[3] Under Section 15 of the F.T.C. Act, materiality is an essential element of a false advertising charge involving drugs. 15 U.S.C. 55(a).

[4] F. 233–363. Judge Hyun found that respondent did not make the claims alleged by complaint paragraphs 7(A)(3) and 9(A)(3) (that a recommended dose of Bufferin relieves twice as much pain as a recommended dose of aspirin will relieve and that that fact has been established) (I.D. pp. 209–210). Complaint counsel have not appealed this and we see no reason to reverse the ALJ's decision on this point.

performance claims and seven of the establishment claims.[5] We disagree, however, with Judge Hyun's finding that every ad that makes a comparative claim also represents that the claim has been established.[6]

In analyzing the claims involved in this case, it will help to keep in mind three different categories of claims. The first consists of "puffing" claims, which are not capable of measurement or which consumers would not take seriously—for example, an advertisement touting a foreign sports car as "the sexiest European." These claims do not require any substantiation. *See Pfizer, Inc.,* 81 F.T.C. at 64 (1972).

The second and third categories consist of claims which, under the *Pfizer* doctrine, do require some level of substantiation. If an advertisement represents that a particular claim has been scientifically established—what we will refer to here as an "establishment claim" —then, under *Pfizer,* the advertiser must possess the level of proof claimed in the ad. When an advertiser makes an establishment claim, it must possess evidence sufficient to satisfy the relevant scientific community of the claim's truth. If an ad does not assert that a claim has been established, then the advertiser is only required to have a "reasonable basis" for believing that the claim is true. As we discussed in *Pfizer,* the evidence required to constitute a "reasonable basis" in such a case will depend on various factors including the importance of the claim being made, the consequences to consumers if the claim is false, and the ease with which more reliable evidence could be acquired.

A key issue, then, is whether each advertisement represents that a given claim has been scientifically established. Although an establishment claim may be made by such words and phrases as "established," "here's proof," and "medically proven," *see American Home Products,* 98 F.T.C. at 374; *Standard Oil Co. of California,* 84 F.T.C. 1401, 1472 (1974), *modified on other grounds,* 577 F.2d 653 (9th Cir. 1978), it may also be made through the use of visual aids (such as scientific texts or white-coated technicians) which clearly suggest that the claim is based upon a foundation of scientific evidence.[7] *See American Home Products,* 98 F.T.C. at 375. Furthermore, the representation of establishment need not [7] be made explicitly in an ad but may be implicit. *American Home Products* v. *F.T.C.,* 695 F.2d at 689–690.

[5] We find that some of the ads used by the ALJ as examples to support claims which were made do not support those claims. Although we find a smaller number of violative ads than did the ALJ, there is certainly an adequate number to support the order provisions which we enter today. *See Fedders Corp.,* 85 F.T.C. 38, 71–72 (1975).

[6] F. 266, 357; I.D. p. 213.

[7] This is not to say that every reference to a test necessarily gives rise to an establishment claim. The key, of course, is the overall impression created by the ad. *Cf. Pfizer,* 81 F.T.C. at 59.

1. Claims that Bufferin relieves pain faster than aspirin and that it relieves pain twice as fast as aspirin.[8]

Although Bristol-Myers argues there was no showing the ads in question made this claim, (R.A.B. 47–48), we agree with the ALJ that numerous ads made the representation that Bufferin was faster acting. Furthermore, we believe that consumers would reasonably conclude that the claim of superior speed had been established.

First, Bristol-Myers has admitted its ads represented Bufferin relieves pain faster than aspirin.[9] Of course, this representation is also made by ads which represent that Bufferin relieves pain twice as fast as aspirin because this statement simply is a more extreme version of the claim. For example, CX 3 states:

> In the first important 30 minutes Bufferin delivers twice as much pure pain reliever as the best known aspirin. Twice as much.[10]

Although read literally, this ad states twice as much Bufferin is going to work, consumers could reasonably have understood this to mean Bufferin relieves pain twice as fast as aspirin. And, in fact, this is confirmed by a copy test in the record which measured viewer reactions to an ad containing this language (CX 301 M). The same representation was made more directly by advertisements which state Bufferin goes to work in half the time. For example, CX 22 states:

> Bufferin can cut the waiting time in half. Half the time. That's Bufferin time. Because in the first critical minutes, Bufferin acts twice as fast as simple aspirin to speed more of its active pain reliever to your headache. Bufferin goes to work in half the time.[11]

Once again, consumers could reasonably infer from this that Bufferin relieves pain faster and this is confirmed by a copy test in the record. *See* CX 245. [8]

We are unable to agree with the ALJ that every ad making a comparative performance claim also represented that superiority had been established. However, we find that some of respondent's ads do make that claim. For example, CX 61 states:

> Scientific tests show that in the first critical moments Bufferin delivers twice as much pain reliever as simple aspirin.[12]

As another example, CX 34 states:

[8] Complaint paragraphs 7(A)(1), (2) and 9(A)(1), (2).
[9] Answer of Bristol-Myers, paragraph 7.
[10] Similar language was used in CX 2, 4, 7, 10, 12, 13, 15, 61, 63, 64, 67.
[11] Similar language was used in CX 1, 23–39.
[12] Similar language appears in CX 63, 64.

Tests show Bufferin's high-speed formula rushes its pain reliever to your headache twice as fast as aspirin.

Other ads represent that it has been established that Bufferin relieves pain faster (not necessarily twice as fast) as aspirin. For example, CX 91 states:

Bufferin laboratory tests show most of its pain reliever gets in the bloodstream 10 minutes sooner than plain aspirin.[13]

None of Bristol-Myers' ads actually uses the word "established."[14] However, this is immaterial because the ads create the impression that the claims have been established. (*See supra* p. 6.) *American Home Products* v. *F.T.C.*, 695 F.2d at 690. The impression conveyed by these ads comes not only from the words but also from visual images which have been used. For example, in CX 61, 63, and 64, a computer typewriter prints out a column made up of the words "Bufferin" and "aspirin" on graph paper at the same time as the announcer speaks about scientific tests. The column representing Bufferin prints out twice as fast and twice as high as the column for aspirin. It appears to be printing the results of the scientific test in a graphic form showing Bufferin to be superior. Consumers could reasonably conclude that proof acceptable to scientists underlies the claim made in the advertisement.

We disagree, however, with the ALJ regarding some of respondent's ads. Although the computer typewriter enhances the implication of establishment in the three ads discussed [9] above, we do not think that it alone can create the impression of scientific support for the claim.[15] Similarly, we do not think that glass models of people with Bufferin and aspirin tablets crumbling in their stomachs and reforming in their heads indicates that Bufferin's superior speed has been scientifically established.[16] Although these props are effective in conveying the claim of Bufferin's superior speed, they do not add an aura of scientific establishment to the claim.[17] Thus, we find that the ads which contain only these props do not make a representation of establishment.

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[13] Similar language appears in CX 761Z018.

[14] The word "established" was used in two magazine advertisements for Bufferin during the 1950s. *See* CX 100, 101.

[15] CX 2, 4, 7, 67; *see* F. 270.

[16] CX 68–77; *see* F. 270.

[17] This is not to say that props alone can never create a representation of establishment. Indeed, a depiction of test apparatus or the use of an announcer in a white technician's coat, in the right context, might constitute a representation of scientific establishment.

2. Claims that Bufferin will not upset a person's stomach and that it does so less frequently than aspirin.[18]

Respondent has admitted its ads represent Bufferin will not upset a person's stomach as often as aspirin,[19] and our examination of the ads shows that this message is plainly conveyed.[20] Respondent's ads also represented that Bufferin will not upset a person's stomach. This message is contained in CX 2, "Bufferin doesn't upset my stomach the way plain aspirin sometimes did."[21] Other ads use the following phrases, "without the stomach upset plain aspirin can cause," and "without fear of stomach distress."[22] A copy test in the record also confirms that consumers received the "no stomach upset" message from the ads. (CX 301N) **[10]**

The ALJ found that three of the challenged advertisements made establishment claims that Bufferin will not upset a person's stomach (CX 61, 63, 64). We are unable to agree with this conclusion. These ads deal primarily with Bufferin's ability to provide pain relief and contain language similar to the following:

> Scientific tests show that in the first critical minutes, Bufferin delivers twice as much pain reliever as simple aspirin. Bufferin relieves arthritis, minor pain, and stiffness for hours. So hands and fingers regain flexibility.... And Bufferin can prevent the stomach upset aspirin often causes. (CX 61)

As explained above, we agree that this ad represents that Bufferin's superior speed has been established. The ALJ apparently concluded that the reference to scientific testing imbued *all* subsequent claims with the aura of medical-scientific authority. We are not convinced this is the impression consumers would receive. Although complaint counsel's expert witness stated consumers would infer that scientific tests supported the series of claims that followed, including the gentleness claim (Tr. 7019–7020), we are unable to reach that conclusion without further evidence of consumer beliefs. Indeed, the reference to stomach upset is preceded by a pause which separates it from claims represented to be supported by scientific proof. The pause signals a change of subject. We, therefore, cannot find that respondent represented it has been established Bufferin will not upset one's stomach.

However, respondent clearly represented it had been established that Bufferin will upset the stomach less frequently than aspirin. CX 109 states, "It has been clinically observed that Bufferin was gentler to the stomach than plain aspirin." Although, once again, the word

[18] Complaint paragraphs 7(A)(4), 7(A)(5), 9(A)(4), and 9(A)(5).

[19] Answer of Bristol-Myers Company paragraph 7.

[20] For example, CX 11 states, "without the stomach upset plain aspirin can cause." This ad, and others like it, represent both that Bufferin upsets the stomach less than aspirin and also that Bufferin does not upset the stomach. Other ads which represent that Bufferin upsets the stomach less than aspirin are, *e.g.*, CX 2–7, 17, 19, 41, 43–46.

[21] *See also* CX 3–7, 40, 41, 43, 66.

[22] *See* CX 11, 17, 19, 44, 46, 96.

"establishment" is not actually used, we believe consumers receive an impression of scientific proof from this ad.

3. Claims that Excedrin relieves twice as much pain as aspirin and more pain than any other over-the-counter analgesic.[23]

The ALJ found respondent had made both these claims[24] and we agree. In some advertisements Excedrin is represented as able to relieve more pain than aspirin. For example, CX 115 states, "Tablet for tablet, Excedrin is 50% stronger than aspirin for the relief of headache pain."[25] [11] Although this ad actually says that Excedrin is stronger for the relief of pain than aspirin, consumers could reasonably interpret this ad to say that Excedrin relieves more pain. In addition, this claim is made by those ads which represent that Excedrin relieves twice as much pain as aspirin. CX 153 says:

> It would take more than twice as many aspirin tablets to give the same pain relief as two Excedrin. Not three aspirin. Not even four. But more than double the recommended dosage to give the same pain relief as two Excedrin.[26]

Again, read literally this ad does not say that Excedrin relieves twice as much pain. Nevertheless, that claim is a natural implication of the ad's explicit assertions regarding the relative potency of Excedrin and aspirin.

None of respondent's ads compares Excedrin to all other over-the-counter analgesics. However, numerous ads make a comparison to other "leading tablets." For example, CX 169 states, "Excedrin has more pain relievers, more total strength than any other leading tablet."[27] Consumers could reasonably infer that a tablet which is a leading tablet has achieved that status, at least in part, through its ability to relieve pain. Since Excedrin is represented as being better than its leading competitors, consumers could assume that Excedrin is the best of all. *See American Home Products,* 98 F.T.C. at 372.

The ALJ found that the challenged ads made establishment claims that Excedrin relieves more pain than either aspirin or any other OTC analgesic and that Excedrin relieves twice as much pain as aspirin. We find that respondent did make the claim alleged with respect to Excedrin's superiority over aspirin. For example, CX 203 states:

> What's better than aspirin? New clinical evidence says Excedrin. In a major hospital study, two Excedrin worked better in relieving pain than twice as many aspirin tablets.

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[23] Complaint paragraphs 7(b)(1), (2) and 9(B)(1), (2).

[24] F. 274–277, 289–292.

[25] Some other examples of this claim are CX 116, 162, 163.

[26] Some other examples of this claim are CX 154–161, 170, 171, 202–204.

[27] Other examples of this claim are CX 122, 123, 126–128, 134, 136, 137, 174, 178.

Indeed, a series of television commercials focuses totally on the results of the "major hospital study."[28] These ads are set in Atlantic City and start: **[12]**

This is where it all happened. At a medical convention right here in Atlantic City. Here doctors heard new clinical evidence that there is a difference in how pain relievers perform. . . . (CX 155)

Another ad in the series discusses the history of such medical tests (CX 176) and still others discuss some of the details of the study (*e.g.*, CX 167, 182). Finally, the ads stress that consumers should rely on the results of this study, "With that kind of medical evidence, isn't it time you tried Excedrin?" (CX 173).

However, we disagree with the ALJ's finding that Bristol-Myers made an establishment claim that Excedrin relieves more pain than *all* other OTC analgesics. The ALJ cites 11 ads which he believes make this representation (F. 321). However, upon examining these ads, we cannot conclude that they represent that Excedrin relieves more pain. All 11 ads are similar. All contain a graphic representation of Excedrin's formula and language similar to the following:

The modern Excedrin formula gives you quick relief, long-lasting relief, a tension-reliever to relax you, an antidepressant to help restore your spirits. Four ingredients . . . not just one or two. That's Excedrin . . . the Extra-Strength pain reliever. (CX 132)[29]

Although we believe that this ad does compare Excedrin to other products, the comparison is with respect to overall efficacy, not just pain relief (*see infra* pp. 15–16). Furthermore, the ad does not represent that Excedrin is the only extra-strength OTC analgesic available. Finally two copy tests in the record (CX 289, 290) relate to ads containing this language and both indicate that only a small number of viewers received the impression that Excedrin was the strongest pain reliever.[30] **[13]**

4. Claims that Excedrin relieves pain faster and for a longer period of time than aspirin or any other OTC analgesic.[31]

We are unable to agree with the ALJ that respondent made either of these representations in its advertisements. The ALJ found that the faster-acting claim was made by two types of ads. The first

[28] CX 153–161, 164–167, 170, 171, 173, 176, 182, 184, 185, 202–204.

[29] The other ten ads are CX 115, 116, 124, 125, 133, 138, 139, 141, 142, 144.

[30] The record contains numerous surveys ("copy tests") which measure viewer reactions to ads. Because of the way in which these studies are conducted (F. 185–215) participants tend to focus only on the primary idea of the ad being tested and the results are not statistically projectable to the population at large. While this does make the copy tests less useful for our purposes, they are of help to us in confirming whether our interpretation of certain claims is reasonable. *See American Home Products* v. *F.T.C.*, 695 F.2d at 687.

[31] Complaint paragraphs 7(B)(3), (4) and 9(B)(3), (4).

type states that Excedrin "has a special type of ingredient for quick relief."[32] There is, however, no comparison in the ad between Excedrin's speed and the speed of any other product.[33] We are unwilling to read such an implication into those ads without some strong evidence that consumers receive the "faster acting" message from an ad which merely says "fast acting."[34] The ALJ also found that any ad that claimed that Excedrin was stronger made an implicit representation that Excedrin was faster acting. He based this conclusion upon the expert testimony of Dr. Ivan Ross. Dr. Ross' comments were conclusory in nature and we do not find them persuasive based upon consumer response to the ads.

The ALJ found noncomparative ads such as CX 125 claimed Excedrin provided longer lasting relief. That ad states, "The modern Excedrin formula gives you . . . long lasting relief . . . ." Although the Initial Decision refers to tests of consumer reactions to advertisements (F. 294), these tests do not show that any significant number of consumers derived a "longer lasting pain relief" message from the ads. Once again, without such evidence, we are unable to reach the conclusion drawn by the ALJ. The ALJ concluded that the "longer lasting" message was conveyed by any ad that represented Excedrin as being either stronger or more effective. The only evidence in the record to support this proposition is the testimony of complaint counsel's expert Dr. Ross (Tr. 7058–9, 7066, CX 819). As we stated above, we do not find this evidence adequately convincing to permit us to conclude that consumers would receive the impressions from the ads. **[14]**

5. Claims that Excedrin reduces fever more effectively than aspirin.[35]

We agree with the ALJ that this claim was made in three ads, each of which indicates that Excedrin has more "fever reducers." (CX 162, 163, 186) We believe that reasonable consumers could infer that the presence of more "fever reducers" in the product implies that the product is more effective at reducing fever. None of these ads claims that Excedrin's superior fever-reducing capacity has been established and the ALJ concedes as much (F. 288). Since, as we indicated above (p. 8), we are unable to conclude that every claim of comparative superiority implies that the superiority has been established, we find that respondent did not make the challenged establishment claims.

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[32] *E.g.*, CX 115, 116, 124, 125, 137–139, 141, 142, 144.

[33] Some of the ads do make very specific fast-acting claims. For example, CX 115 features an endorsement of a user whose headache disappeared in ten minutes. Nonetheless, there is no comparison with other products.

[34] The record contains two tests of consumer reactions to the fast acting claim. In one test 3% of the viewers inferred a faster acting claim (CX 290). In the other, 15% drew the inference (CX 289). We do not find this to be strong enough evidence to conclude that a significant number of reasonable consumers would draw the inference from the ad.

[35] Complaint paragraphs 7(B)(5) and 9(B)(5).

6. Claims that Excedrin is a more effective pain reliever than aspirin or any other OTC analgesic and that it is more effective because it has four ingredients.[36]

Respondent has admitted representing that Excedrin is a more effective pain reliever than aspirin.[37] The ALJ found that respondent had represented not only that Excedrin was more effective than aspirin, but also that it was more effective than any other OTC analgesic. We agree. Statements such as "Excedrin is made stronger against pain and stronger against its tension than any other leading headache tablet," (CX 122) and "Excedrin has more pain relievers, more fever reducers, more total strength than any other leading tablet," (CX 186) proclaim that Excedrin is a more effective pain reliever than any other OTC analgesic.[38] As explained above, (*supra* p. 11), a comparison between Excedrin and "any other leading tablet" could be viewed by consumers as a comparison with all other anagesics. Furthermore, we find that ads which promote Excedrin's superior strength are, in fact, representing that **[15]** Excedrin is a superior pain reliever. The fact that consumers receive this impression is supported by copy test results in the record. (CX 288)

We also find that respondents represented that Excedrin is a more effective pain reliever because it has four ingredients. (Of course, each ad which makes this claim also makes a claim of superior efficacy as discussed in the preceding paragraph, since the four-ingredient claim merely adds an explanation of the reason for the superiority.) However, we find that respondent offered this reason only in representing that Excedrin was only more effective than aspirin, and not in representing that it was more effective than all other OTC analgesics. For example, CX 115 states:

> Look: this is the formula for aspirin. The heavily-advertised product that talks of a new stronger formula merely adds caffeine to plain aspirin. But Excedrin has the strength of four medically-endorsed ingredients. You get quick relief . . . long-lasting relief, . . . a tension reliever to relax you, . . . an anti-depressant to restore your spirits.[39]

As these lines are being spoken, there is a video depiction of benzene rings showing, first, aspirin's formula, then the "heavily advertised product's" formula, and then Excedrin's formula with four ingredients. The message conveyed by this ad is that Excedrin is stronger, based on the reference to the "strength of four medically-endorsed

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[36] Complaint paragraphs 7(B)(6), (7) and 9(B)(6), (7).

[37] Answer of Bristol-Myers, para. 7. Examples of this claim are CX 116, 153–167, 176, 179–182, 188–191, 199–208, 752–759. A claim of superior effectiveness relative to aspirin was also made by any ad which stated that Excedrin relieved more pain or twice as much pain as aspirin, as discussed above at pp. 10–12.

[38] Examples of similar representations are contained in CX 123, 126–128, 136, 137, 169, 172, 174, 178, 186, 737, 738, 740, 741.

[39] Other similar ads are CX 116, 200, 201.

ingredients," and enhanced by the video comparison which shows Excedrin with more benzene rings than either of the other two products.

Our interpretation of these ads is consistent with our interpretation of similar ads in *American Home Products.* There we held that an ad (CX 15) which showed Anacin's formula made a representation of superior efficacy because the ad showed Anacin as having more of the pain relieving ingredient. 98 F.T.C. at 375. We find that in ads like CX 115 respondent depicts Excedrin as having four ingredients to provide strength. The ad thereby represents that Excedrin is a more effective pain reliever than aspirin. However, CX 115 specifically mentions and depicts the formulas of the two analgesics to which Excedrin is being compared and in the context of this ad, the comparison is clearly limited to those two. Consumers would not infer that Excedrin is being compared to all OTC analgesics. **[16]**

However, we are unable to agree with the ALJ that this same message was conveyed by every ad which mentioned Excedrin's four ingredients. For example, CX 125 closes with a graphic depiction of Excedrin's formula and the following language:

> The modern Excedrin formula gives you quick relief, long lasting relief, a tension reliever to relax you, an anti-depressant to help restore your spirits. Four ingredients, not just one or two.[40]

Although this ad does imply that Excedrin is better, the message conveyed by the language is that it is better because it performs more functions—not only does it relieve pain, but it also relieves tension and contains an anti-depressant. Only two of the ingredients are devoted to pain relief; one provides quick pain relief and the other provides long-lasting relief. Thus, unlike CX 115, this ad does not say that the four ingredients make it a better pain reliever; it says only that Excedrin is better because it has four ingredients which enable it to cure a variety of problems that cannot be cured by an analgesic containing only one or two ingredients.

We also find that CX 115 makes an establishment claim that Excedrin is a more effective pain reliever than aspirin because it has four ingredients. This representation is conveyed by the description of the ingredients as "medically endorsed" ingredients and by the use of the graphic display of Excedrin's chemical formula. The use of the language and the image imbue the ads with an aura of scientific support which we believe reasonable consumers would perceive. These two ads also necessarily represent that it has been established that Excedrin is a more effective pain reliever than aspirin. There are other ads

[40] Similar language is used in CX 124, 132, 133, 138, 139, 141, 142, 144.

which make this same representation. For example, CX 155 states that at a medical convention doctors were presented with clinical evidence which showed that Excedrin was a more effective pain reliever. The use of the words "clinical" and "evidence" and the reference to a "major hospital study" imply that the claim in the advertisement is backed by a level of substantiation which would satisfy doctors. Thus, consumers would infer from the ad that Excedrin's superior efficacy over aspirin has been established.[41] However, we find no ads which represent that it has been established that Excedrin is a more effective pain reliever than any other OTC analgesic. **[17]**

7. Claims that Excedrin P.M. will relieve more pain than a recommended dose of aspirin and that it is a more effective pain reliever than aspirin because it has three analgesic ingredients.[42]

We agree with the ALJ that respondent represented that Excedrin P.M. will relieve more pain than aspirin. For example, CX 236 states, "Well, let me tell you about Excedrin P.M. It has more pain relievers than simple aspirin. . . ."[43] As we found in connection with representations regarding Excedrin (*supra* p. 11), consumers could reasonably infer that a product which contains more pain relievers than aspirin would relieve more pain than aspirin. However, we find that some of the ads cited by the ALJ as representing Excedrin P.M.'s ability to relieve more pain contain no comparison, either direct or implied, to aspirin. We find the same to be true of all ads cited by the ALJ as representing that Excedrin P.M. is a superior pain reliever because it contains three analgesic ingredients. Although these ads mention the ingredients in Excedrin P.M., none mentions aspirin. For example, CX 233 compares Excedrin P.M. only with Excedrin and CX 244 mentions no other product. Our conclusion is supported by copy test results in the record which show that consumers did not infer a claim of comparative efficacy from ads which did not mention other products. (*See* CX 263.) Thus we find that respondent did not represent that Excedrin P.M. is a more effective pain reliever than aspirin because it has three analgesic ingredients.

We also find that respondent made no establishment claims to the effect that Excedrin P.M. relieves more pain than aspirin. None of the ads which represent that Excedrin P.M. relieves more pain than aspirin contains any reference to medical proof.

[41] Numerous ads make the same establishment claim. Among them are CX 153, 154, 156–161, 164–167, 170, 171, 202–206.

[42] Complaint paragraphs 7(B)(8), (10) and 9(B)(8), (10).

[43] CX 235 contains similar language.

8. Claim that Excedrin P.M. is more effective for the relief of nighttime pain than aspirin or any other OTC analgesic.[44]

We find that respondent did not make this comparative claim. Some of the ads cited by the ALJ do not compare Excedrin P.M. with any other product (*e.g.*, CX 233, 240, 243). Other ads cited by the ALJ state that Excedrin P.M. is a superior product not because it relieves nighttime pain more effectively, but because it contains a sleep-inducing ingredient. For example, CX 228 states: [18]

> Because at night when it's quiet, even a tiny pain can hurt a lot. You could take a simple pain reliever. But it doesn't have anything extra to help you sleep. Excedrin P.M. does. It combines pain relievers with an additional ingredient to gently help you sleep.[45]

There is no indication in this ad that the pain reliever in Excedrin P.M. is special or different from the pain relievers in other products. Furthermore, the evidence in the record confirms that consumers who saw this ad inferred from it that Excedrin P.M. was a product to take at night because it had a sleep-inducing ingredient. (*See* CX 262, 263.) Thus we find that respondent did not represent (and did not represent that it had been established that) Excedrin P.M. is more effective for the relief of nighttime pain than aspirin or any other OTC analgesic.

C. *Required Substantiation for Establishment Claims*

1. Nature of an establishment claim.

In Part B we found that respondent has represented in its advertisements that the truth of certain superior efficacy and freedom from side effects claims has been established. Paragraph 25 of the complaint alleges that these claims have not been established and that the ads, therefore, are false and misleading and in violation of Sections 5 and 12 of the FTC Act. Bristol-Myers appears to argue that an excessive level of substantiation is being required of it and that complaint counsel are applying a new and different interpretation of the law in this case. (RAB pp. 8–9) In fact, however, the theory is based on the straightforward notion that when an advertiser represents that there is scientific proof or support for a claim, such proof—proof that is generally accepted by the relevant scientific community—must exist.

In previous cases, the Commission has treated similar claims in like manner. For example, in *Porter & Dietsch, Inc.*, we found that claims such as "medically recognized" and "clinic tested" not only implied the existence of substantiation, but they also represented that this

[44] Complaint paragraphs 7(B)(9) and 9(B)(9).
[45] Similar ads are CX 229, 235, 236.

substantiation consisted of competent scientific proof. 90 F.T.C. at 865. Similarly, in *Standard Oil Co. of California,* we found that claims of "Here's [19] proof" and "You're about to see proof" clearly invited the assumption that the evidence which followed was based "on tests or other reliable substantiation." 84 F.T.C. at 1472. The Commission went on to conclude that the advertisements "represent that tests had been conducted which proved the claims made in the advertisements." *See also Crown Central Petroleum Corp.,* 84 F.T.C. at 1549. Although the claims in this case (and in the two companion cases) are referred to as "establishment" claims, the underlying legal theory is no different and no more stringent than the theory of the above cited cases.[46]

Of course, we are not committed to the notion that consumers actually understand the details of comparative drug testing. However, consumers have been led by respondent's ads to believe the scientific community regards Bufferin and Excedrin to be superior. For this reason it is necessary to analyze the requisites of establishment for OTC analgesics claims and determine whether the respondent's evidence does, in fact, establish those products' superiority.

2. Requisites of establishment for OTC analgesic claims.

In *Firestone Tire & Rubber Co.,* the Commission concluded that:

> a scientific test is one in which persons with skill and expertise in the field conduct the test and evaluate its results in a disinterested manner using testing procedures generally accepted in the profession which best insure accurate results. 81 F.T.C. at 463. [20]

Thus, the issue is whether the evidence relied upon by Bristol-Myers is generally accepted by the relevant scientific community. The record in this case reveals the elements of proof necessary to establish scientifically an analgesic's comparative superiority. With this perspective in mind, we examine the record and find no reason to alter the decision we reached in *American Home Products* regarding the sort of evidence necessary to substantiate a claim of established superiority for analgesics.

There is, unfortunately, no way to measure objectively the amount of pain felt by an individual. (Forrest, Tr. 8916) Therefore, the next best method for comparing the effectiveness of analgesics is to elicit

[46] In this connection, we note respondent's contention that an establishment claim requires only "some basis in fact, or in medical or scientific fact." (R.A.B. p. 47) Respondent has derived this standard from complaint counsel's witness, Dr. Ivan Ross (Tr. 7008), but we believe it is a misreading of his testimony. Indeed, an examination of his testimony regarding the establishment claims for Bufferin (Tr. 7006–7055) shows that his position is simply that an establishment claim alleges a basis in medical fact (not merely "some" basis), a position which is in accord with our decisions discussed above. It is not entirely clear what respondent means by "some" basis in fact, but even if we accept respondent's characterization of the establishment standard, we believe that it necessarily implies the existence of credible evidence that is probative of the claims in question. As we discuss below, the evidence offered in support of the claims here falls short of that standard.

the responses of subjects regarding the relief they have obtained after the administration of the analgesics being compared. (Forrest, Tr. 8908–09; Moertel, Tr. 5534) In order to do this, well-controlled clinical tests are conducted in which human subjects report the changes in their symptoms (Azarnoff, Tr. 9179; Grossman, Tr. 7767; Forrest, Tr. 8952, 8908), and this methodology has been employed since the early 1950s, *American Home Products,* 98 F.T.C. at 376. When the goal of the test is to compare the efficacy of two drugs, scientists have normally tested the drugs head-to-head. (Beaver, Tr. 6056; Moertel 5528–29; Forrest, Tr. 8898)

Numerous expert witnesses testified in this proceeding, and there was general agreement among them as to the elements of a well-controlled clinical test. First, the test must involve subjects who are experiencing the appropriate type of pain. In general, the appropriate type of pain is the pain for which the use of the drug is intended. (Evans, Tr. 6353; Moertel, Tr. 5535–36; Forrest, Tr. 8911; Azarnoff, Tr. 9185). If, for example, a claim is made regarding an analgesic's ability to relieve headache pain, at least one of the studies required to establish the claim normally should employ subjects with headaches. (Smith, Tr. 5442) Bristol-Myers challenges this proposition (R.A.B. pp. 66, A.8–A.10) and argues that studies on headache pain are not truly necessary—*i.e.,* "pain is pain." Two of respondent's experts, Drs. Sunshine and Lanman, support this proposition. (Tr. 9754, 12187) Respondent also argues that it is virtually impossible to perform studies on headache pain. However, Bristol-Myers' arguments are weakened by their own witness' testimony. As early as 1968, Bristol-Myers agreed that if studies are to be used to support claims concerning superiority in relieving headache pain, those studies must focus on headache pain. In comments filed in a proposed rulemaking proceeding [21] Bristol-Myers argued that analgesics may function differently in relieving different kinds of pain and that tests on subjects experiencing pain other than headache pain (such as post-partum pain) are not transferrable. (Lanman, 12013–14)[47] Also, respondent's witness, Dr. Sunshine, testified that FDA guidelines regarding tests of new drugs (guidelines which he assisted in preparing, but with which he claims no longer to agree; Tr. 9824–25) provide that studies should be performed on more than one kind of pain because there is no certainty that the mechanism causing a drug to relieve one kind of pain will be applicable to relief of another kind of pain. (Sunshine,

[47] Respondent argues that its position in 1968 should not be given much weight because it was not written by scientists but "was written and submitted by Bristol's lawyers in the course of a legal proceeding," and furthermore the lawyers were merely exercising "their lawyer-type efforts . . . ." (R.A.B. p. A–10) While we understand the nature of legal advocacy, we note that the position taken by Bristol-Myers in 1968 was based not only upon the efforts of its lawyers, but also upon the opinions of numerous experts including Drs. John Seed, Max Sadove, Louis Lasagna, and Walter Modell. (Lanman, Tr. 12020–26).

Tr. 9823–25) Taking all this into account and based upon the testimony of complaint counsel's four witnesses, we find that the preponderance of evidence in the record shows that well-controlled clinical tests for measuring an analgesic's comparative efficacy must involve subjects experiencing the type of pain for which the drug is intended. This is in accord with *American Home Products*, 98 F.T.C. at 378.

Moreover, the record does not support Bristol-Myers' contention that studies cannot be conducted on headache pain. Although more difficult to perform because they are outpatient studies (Sunshine, Tr. 9651–52), such studies are feasible and six such studies are mentioned in the record, one of which was performed in 1967. (CX 514, pp. 35382–83)[48] In fact, Bristol-Myers relied on two outpatient studies in [22] this proceeding, one of which examined headache pain. (Lanman, Tr. 11512–17, 12066–67, 12083–84)

With respect to other characteristics of a well-controlled clinical study, the record shows that there should be a written protocol which describes the conduct of the study and its analysis. (Moertel, Tr. 5531, 5542; Azarnoff, Tr. 9180, 9183) Subsequent deviation from the protocol leads to a strong suspicion of bias in the study. (Moertel, Tr. 5542–3) Another possible source of bias is the investigator conducting the study. To minimize this problem, the investigator should generally be both experienced and independent. (Moertel, Tr. 5533–34) Additionally, the persons who administer the test (be they medical personnel or the subjects themselves) should be adequately trained to assure accuracy in recording test results. (Brown, Tr. 4976–77; Moertel, Tr. 5541–42; Forrest, Tr. 8921, 9123–24)

There is virtually no disagreement that test subjects must be randomly assigned to the treatment groups within the study. (Brown, Tr. 4858–60, 4911; Moertel, Tr. 5544; Grossman, Tr. 7768; Evans, Tr. 6342; Forrest, Tr. 8912; Azarnoff, Tr. 9179–80; Laska, Tr. 10166) The purpose of randomization is to make certain that uncontrolled variables are balanced among treatment groups and that subsequently observed differences between treatment groups are attributable to the analgesics being tested and not to the inherent characteristics of the groups. (Beaver, Tr. 6019–22; Forrest, Tr. 8916; Azarnoff, Tr. 9180; Sunshine, Tr. 9864) Failure to randomize the test subjects renders questionable the validity of the study and all subsequent analysis (Brown, Tr. 5083–84; Forrest, Tr. 9114–15), although statistical techniques may be available to correct the imbalance if the importance of the imbalanced variable and the magnitude of the imbalance are not

[48] If such tests were impossible to conduct, this would not necessarily militate in favor of permitting inadequately substantiated claims; at a minimum it would require close scrutiny of secondary sources of support and possible qualification of the claims being made.

significant. (Brown, Tr. 4911–12, 5086–87, 8052–54; Moertel, Tr. 5544; Forrest, Tr. 9121; Laska, Tr. 10269).

Whenever possible, tests comparing two mild analgesics should also compare those drugs against a pharmacologically inert placebo. (Moertel, Tr. 5539–41; Beaver, Tr. 5979–81; Forest, Tr. 8922; Azarnoff, Tr. 9181) The use of the placebo provides a measure of the study's sensitivity; if the study cannot detect the difference between a standard and the placebo, it cannot be relied upon to detect the difference between the analgesics being tested. (Moertel, [23] Tr. 5539–41; Beaver, Tr. 5979–80; Forrest, Tr. 8923, 9008–09; Azarnoff, Tr. 9181; Lanman, Tr. 12092–93)[49]

A further typical characteristic of a well-controlled clinical test is double-blinding. That is, neither the test subject nor the person administering the test should be able to tell which treatment is being administered. (Moertel, Tr. 5538; Evans, Tr. 6354, 6357; Grossman, Tr. 7768; Forrest, Tr. 8912; Azarnoff, Tr. 9180; Sunshine, Tr. 9676–77; Laska, Tr. 10166). To achieve double-blinding, it is important that the treatments all look and taste the same. If double-blinding is not used, subjects' responses may be influenced by their own pre-existing biases and by the expectations of those administering the tests. (Beaver, Tr. 6014; Moertel, Tr. 5538; Evans, Tr. 6341, 6357–62)

Respondent objects to the necessity for double-blinding (R.A.B. p. 52, Bristol-Myers Reply Brief p. II–12 - II–13), but offers no expert testimony to support its position. First, it argues that it is not a requirement of FDA regulations that double-blinding be used in testing a drug's efficacy, citing 21 C.F.R. 314.111(a)(5)(ii) in support of that proposition.[50] Respondent reads this regulation too narrowly. The regulation states that clinical investigations are essential to support efficacy claims (21 C.F.R. 314.111(a)(5)(ii)), and that as part of such an analysis, "methods [must be] used to minimize bias on the part of observers and analysts of the data." (21 C.F.R. 314.111(a)(5)(ii)(a)(4)). The regulations recognize that for certain sorts of tests, double-blinding is not possible or appropriate and other methods must be used to minimize bias.[51] However, in connection with comparative efficacy claims for analgesics, the evidence indicated that double-blinded tests are feasible and appropriate for minimizing bias. [24]

Respondent's second argument is that double-blinding is not appropriate because it will "eliminate the actual and real clinical effect of

[49] As we noted in *American Home Products*, 98 F.T.C. at 377, the rate of response to a placebo is as high as 60% in some studies. We also took note of the placebo effect in *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).

[50] The pertinent parts of 21 C.F.R. 314.111 are identical to 21 C.F.R. 130.12 which was in effect at the time the complaint in this action was filed.

[51] For example, double blinding is not possible in a study comparing an oral analgesic with acupuncture. It is not appropriate in a test of a new drug which offers the only chance of survival to terminally ill patients and must, therefore, be administered to all test subjects.

expectation . . ." (Bristol-Myers Reply Brief p. II–12) We have faced this argument before and rejected it. "The Commission cannot accept as proof of a product's efficacy a psychological reaction stemming from a belief which, to a substantial degree, was caused by respondent's deceptions." *Warner-Lambert Co.*, 86 F.T.C. at 1496. Indeed, were we to hold otherwise, advertisers would be encouraged to foist unsubstantiated claims on an unsuspecting public in the hope that consumers would believe the ads and the claims would be self-fulfilling.

After the clinical tests are completed, the results should be analyzed to determine their clinical and statistical significance. The procedures for this analysis should be set forth in advance (Moertel, Tr. 5542) and should be adhered to in order to guard against bias caused by a premature conclusion of the study at a time when the data appear to produce a favorable result. (Moertel, Tr. 5542–43) The statistical analysis serves to determine the probability that any apparent differences in efficacy are due to the treatments being tested and are not due to chance. (Brown, Tr. 4867–69; Moertel, Tr. 5545) Scientists generally will accept the differences as being real and not due to chance if analysis shows a 95% level of statistical significance (*i.e.*, there is no greater than a 5% likelihood that the results were produced by chance). (Brown, Tr. 5143; Moertel, Tr. 5545–46; Forrest, Tr. 8912; Azarnoff, Tr. 9182)

Respondent objects to the use of the 95% level of statistical significance to test hypotheses regarding drugs. First, it argues that scientists do not always submit the results of studies comparing drugs to statistical analysis. (Bristol-Myers Reply Brief, p. II–3 - II–4) It is true that when using test results for some purposes (such as determining the proper dosage of a new drug), scientists do not test statistical significance.[52] However, when those same tests are used to establish the comparative superiority of one drug over another, it is essential to determine the statistical significance of the results (Brown, Tr. 4934–35, 4939, 5137–38; Forrest, Tr. 8899–8901; Sunshine, Tr. 9688–90; Laska, Tr. 10426–28). If this is not done, it is impossible to reject **[25]** the hypothesis that the drug which may appear superior in the test is, in fact, of only equal (or even lesser) effectiveness.[53]

[52] When scientists use a bioassay (*see infra* pp. 33–34) to determine the proper dose of a new drug, a decision has already been made to use the new drug and the function of the test is solely to determine dosage. They are not concerned with the ability of the study to reject to a 95% degree of certainty the hypothesis that the new drug is no more effective than the standard drug against which it is being tested.

[53] We reject respondent's argument that the data should be tested against the hypothesis that respondent's products are more effective than others and that if this hypothesis cannot be rejected, the Commission should find no violation. (R.A.B. p. 9–10) Respondent's ads represented that it has been established that its analgesics are more efficacious. The complaint alleges that these claims are false. Thus, to meet its burden of proof, complaint counsel must show that the relevant scientific community does not accept the superiority of respondent's products as proven. Since the weight of expert testimony indicates that comparative superiority can only be established if tests reject the hypothesis that respondent's products are equally effective as others on the market, complaint counsel can meet its burden of proof by showing that tests do not reject that hypothesis.

Respondent's second objection is that even if test results are to be analyzed for statistical significance, the 95% confidence level represents an arbitrary standard. (R.A.B. p. A–2 n.2) This standard, however, was not selected by the ALJ or by the Commission; it was selected by scientists who perform clinical tests on drugs. And, among both complaint counsel's and respondent's experts, there is a consensus that the appropriate level of significance is 95%. (Brown, Tr. 5143; Laska, Tr. 10551–52)[54]

The next step is to determine whether a statistically significant difference between two drugs is clinically significant. A difference is of no clinical significance if scientists regard the difference as being so small as to be of no importance. (Beaver, Tr. 5971–72)

Finally, in order to establish the comparative efficacy of an analgesic, two well-controlled studies meeting all the criteria set forth above are required. (Brown, Tr. 4878, 8160–61; Moertel, Tr. 5530, 5850–51; Grossman, Tr. 7769; Forrest, Tr. 8917; Azarnoff, Tr. 9185–86) Replication reduces the possibility that the results are due to chance and reduces the effect of flaws in the design of any one study. (Moertel, Tr. 5850–51; Grossman, Tr. 7769; Brown, Tr. 8161; Azarnoff, Tr. 9185). According to Dr. Moertel, replication is especially important for clinical studies of OTC analgesics because of the subjective nature of participants' responses and because of the presence of other variables which are [**26**] difficult to quantify but could influence test results. (Tr. 5849–51)

As we indicated in *American Home Products,* 98 F.T.C. at 378–381, the criteria set forth above are consistent with regulations adopted by the Food and Drug Administration to implement the 1962 amendments to the Food, Drug, and Cosmetic Act of 1938. (Pub. Law No. 87–781, 76 Stat. 780) These amendments imposed the requirement that there be substantial evidence that a new drug is effective (as well as safe) before it can be introduced on the market. Substantial evidence is defined in the Act to mean:

> 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 that the drug will have the effect it purports . . . . 21 U.S.C. 355(d) (1976)

In promulgating implementing regulations, the FDA pointed out that the criteria necessary to show substantial evidence of a drug's efficacy "have been developed over a period of years and are recog-

[54] Although the 95% level of statistical significance appears to be necessary to establish unqualified analgesic claims of therapeutic superiority made to the general public, we note that a lesser standard may be appropriate to support claims that have been adequately qualified or that are made to a limited audience capable of understanding levels of statistical significance.

nized by the scientific community as the essentials of adequate and well controlled clinical investigations. 21 C.F.R. 314.111(a)(5)(ii). These criteria 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 recording methods, including steps taken to minimize bias on the part of the subject or observer; (4) a comparison of results with a control; 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).[55]

It is the consensus of the experts who testified in this proceeding that at this time well-controlled tests meeting the criteria set out above are necessary to establish comparative superiority for OTC analgesics. However, we recognize that the elements of establishment may change with time. We further recognize (*see* provision I(D) of the order we enter today and p. 67 *supra*) that relevant experts might in some cases regard a proposition as established even if the well-controlled tests did not meet all of the criteria **[27]** set forth above. But as we discuss below, the evidence possessed by Bristol-Myers was not adequate to establish comparative superiority to the satisfaction of the scientific community.

Respondent further argues that the FDA does not mandate that a proponent of a new drug perform more than one study to establish that drug's efficacy. (R.A.B. p. 52) However, the FDA normally requires at least two tests demonstrating a new drug's efficacy. The regulations provide that a new drug application must include "full reports of clinical *investigations* that have been made to show whether or not the drug is safe for use and effective in use." (21 C.F.R. 314.1(C) (1980) (emphasis added)). The regulations further provide that a new drug application will be denied if "there is a lack of substantial evidence [of efficacy] consisting of adequate and well-controlled investigations, including clinical *investigations*. . . ." 21 C.F.R. 314.111(a)(5)(i) (1980) (emphasis added). Thus, the requirement of more than one test is perfectly consistent with FDA regulations.

Respondent additionally contends that FDA regulations do not mandate that study results be tested for statistical significance at the 95% level. It is true that the regulations do not specifically refer to the 95% level of statistical significance. (Nor, for that matter, does the order which we enter today.) However, the regulations do state that the evidence to support a new drug's efficacy must consist of investigations on the basis of which scientific experts could conclude that the drug will have the effect it purports to have. 21 C.F.R. 314.111(a)(5)(i).

[55] These criteria have been 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 evidence in the record from the expert witnesses provides ample support for the conclusion that scientific experts ordinarily will not draw a conclusion of superior efficacy from a test unless the results of that test are statistically significant at the 95% level. Thus, in effect, the regulations do mandate that test results meet that confidence level, since that is the level of significance relied upon by experts in the field.

Finally, respondent asserts that the standards employed by the FDA to determine drug efficacy should not be applied to comparative performance claims where the basic efficacy of the product is not in question. It argues that FDA regulations must be stringent because they are designed to guard public health and safety by preventing the marketing of ineffective drugs. Once that initial threshold has been crossed, it is no longer necessary to apply such a strict standard to claims of comparative superiority. (R.A.B. p. A–11) Although these FDA standards do not speak directly to the question of comparative efficacy claims, they are entirely consistent with the other evidence, including the [28] considerable expert testimony introduced in this case concerning the kind of support needed to establish such claims. In addition, the reference to FDA regulations shows the extent to which the criteria for well-controlled tests are widely and uniformly accepted in the relevant scientific community.[56] By contrast, there is little or no evidence in the record of scientific support for an alternative approach. In requiring that establishment claims be substantiated with well-controlled clinical tests, we are not creating a new stringent standard; we are merely applying the standard generally accepted by the scientific community.

D. *Evidence of Establishment.*

Our analysis of the advertisements in Part B above showed that respondent had represented that it has been established that:

1) Bufferin relieves pain faster than (and in some ads, twice as fast as) aspirin;

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

3) A dose of Excedrin relieves more pain than (and in some ads, twice as much pain as) a dose of aspirin;

4) Excedrin is a more effective pain reliever than aspirin or any other OTC analgesic (and in some ads, more effective because it has four ingredients).

[56] Although we are only using FDA regulations as one indication of what experts require before they will regard a claim of superior efficacy as established, we note that in 1979 the same standards set forth in 21 C.F.R. 314.111(a)(5) were made applicable to comparative safety and efficacy claims made in prescription drug advertising. 44 FR 37434, 37466–67 (June 26, 1979).

We must now determine whether these claims have been established —that is, whether the respondent's establishment representations are correct.

1. Claims regarding Bufferin's speed.

Respondent has supplied no clinical evidence in support of claims regarding the speed of analgesia (pain relief) provided by Bufferin. Instead, it has supplied numerous studies which show that Bufferin is absorbed into the bloodstream twice as fast as aspirin. (F. 566–583) There is little question that an analgesic must be absorbed into the blood before it can begin to relieve pain. However, according to [29] all of the experts who testified in this case, it has yet to be shown that there is a correlation between the rate of absorption of an analgesic into the blood and the rate of onset of pain relief. (Moertel, Tr. 5801–05, 5817–18, 5860; Beaver, Tr. 5945–46; Forrest, Tr. 8987–90; Azarnoff, Tr. 9189–90) It may appear logical to infer speed of relief from speed of absorption, but complaint counsel's experts agree that such an inference is at best a hypothesis which must remain a hypothesis until proven in well-controlled clinical tests. No data exists to prove that inference. As Dr. Beaver stated, "The problem with analgesics is that that data just isn't there and there are certain data which suggest that this correlation is not at all simple." (Tr. 5952; *see also* Moertel, Tr. 5800–06, 5817–18, 5860; Beaver, Tr. 5947–48, 5957–58, 5961–64; Forrest, Tr. 8980, 8987–90, 9035, 9043–45; Azarnoff, Tr. 9195, 9225)

Respondent's only witness in support of Bufferin's superior speed was Dr. Lanman, the former medical director of Bristol-Myers, who was not qualified as an expert in the area of pharmacokinetics. His testimony in this proceeding was contradicted by a memorandum he wrote in 1969 which admitted that there was no known correlation between the rate of an analgesic's absorption and the rate of onset of analgesia. Furthermore, in 1967, the National Research Council, a subsidiary of the National Academy of Science, reviewed Bristol-Myers' substantiation for the claim that Bufferin provides pain relief faster than aspirin and found that the claim was "ambiguous and misleading." The report also found that there was "no evidence" that Bufferin provided significantly faster relief than aspirin. (CX 511F)[57] This same claim was considered by the FDA's Advisory Review Panel on OTC Analgesics after reviewing extensive submissions from Bristol-Myers. (Lanman, Tr. 12115–16; CX 506) The Panel concluded that it was

[57] The NAS/NRC panel was composed of a number of well-known experts in the field of pharmacology (Beaver, Tr. 5903), and it operated under the aegis of the FDA. Its purpose was to evaluate the efficacy of drugs that had been introduced on the market prior to 1962. In 1972, the Panel's findings were published in the *Federal Register.* (Beaver, Tr. 5899; Tr. 5925)

unaware of any data that demonstrate that buffered aspirin [such as Bufferin] provides a more rapid onset, a greater peak of intensity or a more prolonged duration of analgesic effectiveness than unbuffered aspirin. (CX 514 at 35378)[58] **[30]**

Respondents argue that the FDA OTC Analgesics Panel found several analgesics to be effective based solely upon blood absorption data (R.A.B. p. 49). This argument appears to us to be irrelevant. While the Panel may well have considered blood absorption data for some purposes, it is clear that they did not find it adequate to demonstrate a more rapid onset of analgesia for Bufferin. The fact is that many experts (including those on the FDA OTC Panel) have considered the blood absorption studies offered by Bristol-Myers and have not been able to conclude that Bufferin provides faster relief from pain than aspirin. That is the issue before us here. Thus, we cannot conclude respondent's claims of superior speed of pain relief have been established. Since it has not been established that Bufferin provides faster pain relief than aspirin, it has also not been established that it provides pain relief twice as fast.

2. Claims that Bufferin will upset a person's stomach less frequently than aspirin.

Some individuals suffer gastric intolerance to aspirin (*see* p. 55 infra) and, in certain instances, doctors prescribe that these individuals take antacid in conjunction with aspirin in order to reduce the chances of stomach upset. This is the theory behind the formulation of Bufferin which contains 5 grains of aspirin and about 150 mgs. of antacid. Dr. Morton Grossman, complaint counsel's expert in the field of gastroenterology stated that, "the small amount of buffering that is present in Bufferin . . . would not be expected to have any effect upon the secreted acid in the lumina of the stomach." (Tr. 7772) Furthermore, he indicated that if a patient were suffering gastrointestinal problems from aspirin, he would "place the patient on a full antacid regime to be taken along with the aspirin," and he would prescribe a dosage of antacid 75 times larger than that contained in Bufferin. (Tr. 7773–74) In addition, he noted that the antacid in Bufferin would have no effect on stomach upset which occurs after aspirin enters the blood. (Tr. 7772–73) Finally, he stated that only well-controlled clinical studies could establish that Bufferin causes less stomach upset than aspirin. (Tr. 7769–71) Thus, the composition of a Bufferin tablet and the speed with which it enters the blood do not establish that Bufferin causes less stomach upset than aspirin.

Bristol-Myers presented no expert testimony in support of Bufferin's freedom from side effects but did supplement the evidence

[58] This view is also shared by the experts who prepared the *AMA Drug Evaluations* (CX 512H, 518G).

regarding chemical composition and speed of absorption with four studies comparing Bufferin's side effects with aspirin. However, none of these studies is a well-controlled clinical study. Two of those studies use a historical control (the Paul Study, CX 786, and the Tebrock Study, *see* Lanham, Tr. 11478, 11486), which means that the subjects [31] were given Bufferin and then asked to compare its side effects with what they remembered to be the side effects associated with aspirin. It is impossible to know whether the test subjects accurately remembered and related past experiences with aspirin or whether they were able to distinguish the side effects caused by aspirin from side effects generated by other possible causes. As further evidence of the inappropriateness of this method of testing, FDA regulations permit historical controls only where it would be unacceptable to leave the disease being studied untreated or to treat it by a means other than the test treatment. 21 C.F.R. 314.111(a)(5)(ii)(a)(4).[59] Also, Dr. Grossman indicated that he would reject the two studies because they "were open trials without randomization and without double-blind controls." (Tr. 7961)

The third study presented by Bristol-Myers, the Fremont-Smith Study, was also flawed. Subjects were not randomly assigned to treatments and aspirin was given to most of them first. This failure to randomize the order can produce "very, very misleading" results (Laska, Tr. 10433) due to the physiological and psychological "carry over" problems where only one drug is given during a particular period of a test. Furthermore, the test patients were arthritis sufferers, many of whom were subject to a variety of gastric abnormalities. (Lanman, Tr. 12050) Thus, even if this test had been well-controlled, it would be generalizable only to those suffering similar abnormalities.

The fourth study, the Sher Study, was conducted in a prison and was never published. (Lanman, Tr. 12054, 12061) Evidence regarding the claim of less stomach upset was reviewed in 1967 by the NAS/NRC Panel (the Sher Study was among the studies they considered) and the Panel concluded that it indicated little difference in the incidence or intensity of side effects from Bufferin or plain aspirin. (CX 511F) The same conclusion was reached in *AMA Drug Evaluations* (CX 512, 518) and by the FDA OTC Analgesics Panel. Thus, the record shows that it has not been established that Bufferin causes less stomach upset than aspirin. [32]

[59] Respondent's witness Dr. Lanman argues that although the methods used to conduct these two tests might not be appropriate now, they were appropriate in 1949 and 1952 when the tests were conducted. (Lanman, Tr. 11477–78) However, by the 1960s, other methods of testing had been developed (*supra* p. 24) and were being used by experts in the field of pharmacology. What is relevant in this case is whether the claims regarding Bufferin, in light of available learning, were established at the time they were made in the late 1960s and early 1970s. It thus seems clear in this case that tests done 20 years earlier could not establish those claims.

3. Claims regarding Excedrin's superior efficacy.

Respondent presented three types of evidence relating to Excedrin. The first relates to Excedrin's formula. Excedrin contains 3 grains of aspirin, 1.5 grains of acetaminophen, 2 grains of salicylamide, and 1 grain of caffeine. We agree with the ALJ's finding (F. 478) that the number and quantity of ingredients in an analgesic is not evidence alone which can establish the superiority of one product over another. There must be some demonstration of or explanation for the differences. Indeed, complaint counsel's witness Dr. Forrest, an eminent expert in the field of clinical testing of analgesics, stated that adding ingredients may work to the betterment of a drug but may also work to its detriment. Only good clinical data can support the proposition that more is better. (Tr. 8977–78) In fact, Excedrin contains only 4.5 grains of ingredients recognized as analgesics (aspirin and acetaminophen) compared to a normal 5-grain aspirin tablet. Furthermore, the FDA OTC Analgesic's Panel concluded that the amount of salicylamide in Excedrin is ineffective as an analgesic. (CX 514, p. 35441) Caffeine, also, has not been established as an analgesic and its value as an adjuvant (*i.e.,* an ingredient that assists) to aspirin and acetaminophen is unclear. (Forrest, Tr. 9107) The studies presented by respondent regarding caffeine's value are at best ambiguous (F. 477) and the FDA OTC Analgesic's Panel considered much of the evidence presented in this case by Bristol-Myers and was unable to conclude that caffeine contributed an adjuvant effect. (CX 514, p. 35441, 35484)

The second type of evidence regarding the Excedrin claims consists of a study based upon experimentally induced pain, the Sherman study (CX 439). This study compared the ability of Excedrin and aspirin to raise the threshold at which subjects could first feel pain caused by an electric shock to their tooth pulp. The major problem with this study is that results relating to pain induced experimentally are not considered to be applicable to naturally occurring pain. This is the opinion expressed in the writings of Drs. Beecher, Chapman, and Mumford, all of whom were recognized as experts by respondent's witness Dr. Elvers. (Elvers Tr. 11111, 11166, 11163–64) Indeed, the methods employed by Dr. Sherman produced results that were inconsistent with clinical literature, with clinical tests, and with bioassay studies. (F. 545) Furthermore, in the draft report of the Sherman Study, the authors recognize the limited applicability of the study when they state "aspirin might be more effective in relieving other types of pain" than that induced by electric shock to tooth pulp. (CX 450G) At the instruction of Dr. Elvers (who was then Associate Medical Director of Bristol-Myers Product Division), this statement was

omitted from the final version of the report. (CX 449D) Nevertheless, in the final version of their report, the authors still admit that the results of their study may be limited to [33] types of pain similar to the type being studied (CX 439L), and respondents concede this point. (RAB p. A2)

The Sherman Study also suffered from methodological flaws which were described in some detail by Dr. Evans, complaint counsel's witness, who was qualified in this proceeding as an expert in pain, experimental pain and the response of pain to treatment. (F. 33) First, the study measured only the ascending threshold of pain rather than averaging the ascending and descending thresholds, which is considered the appropriate scientific procedure. (Evans, Tr. 6377) Indeed, Dr. Wolff, an expert in experimental pain research recognized by Dr. Elvers, agrees that the ascending and descending thresholds must be averaged. (Elvers, Tr. 11140) Second, the Sherman Study tested the subjects' pain threshold only, rather than measuring the supra-threshold (point at which pain becomes intolerable). Both Drs. Evans and Wolff regard tests of the supra-threshold as a better indicator of analgesic efficacy than the pain threshold because the supra-threshold is more likely to be affected by analgesics. (Evans, Tr. 6382–85; Elvers, Tr. 11127) Third, Dr. Sherman eliminated 30% of the subjects from the test without gathering data on these subjects, which is considered to be an unacceptable procedure. (Evans, Tr. 6395; CX 439C) Fourth, Dr. Elvers was unable to explain fully the fact that large amounts of electrical current (in one instance, more than 300 times the normal amount) were required to reach the subjects' pain thresholds. (Tr. 11212–36) Finally, Bristol-Myers was unable to replicate the results of the Sherman Study. (Elvers, Tr. 10897–10901)

Although respondent refers to eight other studies using experimental pain (R.A.B. p. A1, A2; Bristol-Myers Reply Brief p. II–7 - II–8), none of these studies was introduced into evidence and none was evaluated by the various experts who testified in this proceeding. Thus, these studies do not establish Excedrin's superiority.

The third type of evidence submitted by Bristol-Myers consists of two bioassays; one performed by Dr. Emich and the other by Dr. Smith. It is this evidence that comes closest to establishing the claims regarding Excedrin. A bioassay is a study of complex design whose purpose is to determine the amount of a test drug necessary to equal the analgesia produced by a standard drug (in this case, aspirin). The result of a bioassay is the "relative potency" of the test drug. (Brown, Tr. 4849; Forrest, Tr. 8884) The relative potency of two drugs is different from their relative efficacy. Relative potency produces a conclusion about the amount of a test drug necessary to produce a desired amount of analgesia; relative efficacy is a comparison of the effective-

ness of equal doses of the test drug and the standard drug. (Brown, [34] Tr. 4853–54; Laska, Tr. 10417) Although a bioassay is normally used to draw conclusions about relative potency, its results may also be used to compare the efficacy of drugs. (Forrest, Tr. 8885–8807; Laska, Tr. 10487) However, when using the results of a bioassay to compare efficacy, the data must be analyzed in a different fashion than if the data are used to determine relative potency. When determining drug dosage, scientists are interested in the "best estimate" of relative potency. (Sunshine, Tr. 9670, 9689; Laska, Tr. 10206–08) Both respondent's and complaint counsel's experts agree that when comparing efficacy (and attempting to show the superior efficacy of one drug over another), scientists analyze the data to determine whether the possibility that the drugs are equally efficacious may be excluded. (Forrest, Tr. 8899–8902; Brown, Tr. 8078; Laska, Tr. 10426–27, 10519–25)[60]

Respondent argues repeatedly and strenuously about the appropriate method of analyzing the results of a bioassay. (R.A.B. pp. 5, 9, 12 n.1, A5–A6) Respondent contends that scientists do make use of and do draw conclusions from bioassay results in which the possibility of equal efficacy has not been excluded to a 95% degree of certainty. To support this, they refer to no expert testimony but do cite a published article reporting the results of a bioassay performed by complaint counsel's expert witness Dr. Brown, entitled "Assay of Aspirin and Neoproxin Analgesia." (R.A.B. p. A.5 – A.6) In this bioassay, a conclusion was drawn from the data even though it was not possible to reject the possibility of equipotency to a 95% degree of certainty. Thus, respondent contends that for purposes of substantiating advertising claims regarding Excedrin, the bioassays should not be subject to statistical analysis. Respondent has failed to distinguish between the two uses to which bioassays may be put. The primary purpose of a bioassay is dose selection—the recommended dose must be determined for a new drug. This was the purpose of the bioassay performed by Dr. Brown. If the confidence interval surrounding the best estimate of relative potency is not too large, that best estimate will be used to recommend a dose. (F. 428–429) Scientists normally do not use bioassays to compare the efficacy of analgesics. (Laska, Tr. 10405–07) However, when they do, they then analyze the results to determine whether they can reject the possibility that the drugs are equally effective. The record contains only one example of a published bioassay used to compare efficacy. The article was authored primarily by Dr. Louis Lasagna (respondent's expert Dr. Laska is listed as a co-author) and it states that the results of the bioassay do not permit a

[60] As explained above, this is the appropriate hypothesis to test because Excedrin's advertising claimed that Excedrin was more efficacious.

conclusion of differing efficacy [35] because it was not possible to reject the hypothesis of equal efficacy to a 95% degree of certainty. (Tr. 10521–22) Furthermore, substantial expert testimony in the record supports the conclusion that this is the proper method of interpreting bioassay results when attempting to draw a conclusion regarding comparative efficacy. (Brown, Tr. 4934–35; Forrest, Tr. 8899–8901; Laska, Tr. 10426–27)

The Smith Study is a bioassay on patients suffering post-partum pain which compares three doses of Excedrin, aspirin, and a placebo. The author of the study, Dr. Smith, stated that he did not believe his study showed any statistically significant difference between Excedrin and aspirin. (Tr. 5422–24) However, respondent contends it supports Excedrin's superior efficacy. As in most bioassays, the performance of the products was assessed by measuring the reduction in the subjects' pain intensity at various time intervals after administration of the drugs and by measuring the amount of pain relief they received during the same intervals. (F. 406–409) The Smith Study was well-controlled and well-designed in all respects. (Brown, Tr. 8150) For all six parameters analyzed in the study, Excedrin showed a relative potency slightly exceeding 1.0 (meaning that a somewhat smaller dose of Excedrin was necessary to produce the same amount of analgesia as a given dose of aspirin). However, as explained above, in order to compare effectiveness, the data have to be tested against the hypothesis of equal effectiveness, and for all six parameters, the data showed that it was impossible to reject, to a 95% degree of certainty, the possibility that Excedrin and aspirin were equally effective. (Indeed, the data were so equivocal that for four of the six parameters it would be impossible to reject the hypothesis that Excedrin was only two-thirds as effective as aspirin.) According to Dr. Brown, who was qualified as an expert biostatistician in this proceeding, the results of the Smith Study are quite consistent with the results that would be obtained in a bioassay where the true relative potency of the two compounds was, in fact, equal. (Brown, Tr. 5009, 8157–58)

Respondent cites Dr. Laska (an expert in the testing of analgesics) in support of the proposition that the Smith Study is acceptable evidence that Excedrin is stronger than aspirin. (R.A.B. p. A5) However, what Dr. Laska actually says is that the Smith Study cannot be used to reject the hypothesis that Excedrin is more effective than aspirin. (Tr. 10295) He later also concedes that the Smith Study does not reject the hypothesis that Excedrin and aspirin are equally effective (Tr. 10518), and Dr. Sunshine, respondent's expert in clinical pharmacology drew the same conclusion (Tr. 9751). Finally, Dr. Laska states that his experience does not permit him to generalize the results of the

Smith Study to any kind of pain other than post-partum pain. (Tr. 10306–07) **[36]**

The second bioassay submitted by respondent was the Emich Study. (This study was also performed exclusively on women suffering from post-partum pain.) The Emich Study was a less reliable estimate of relative potency than the Smith Study because it employed fewer subjects and was methodologically flawed. (Brown, Tr. 8150) The same six parameters that were analyzed in the Smith Study were analyzed by Emich and they showed a relative potency ranging from 2.27 up to 7.1 (meaning that Excedrin ranged from 2.27 to 7.1 times as potent as aspirin). (F. 484) However, statistical analysis showed that for three of the six parameters, the Emich Study was unable to reject the hypotheses that Excedrin was equally or less potent than aspirin. Nevertheless, Dr. Laska, respondent's statistician, stated that the Emich Study provided "compelling evidence of superiority" of Excedrin over aspirin (Tr. 10185), and Dr. Sunshine, respondent's expert in clinical pharmacology, stated that the Emich Study gives "strong scientific evidence that Excedrin is stronger and more effective than aspirin on a tablet for tablet basis." (Tr. 9660)[61]

The major flaw in the Emich Study was baseline pain imbalance. More patients initially having severe pain were assigned to the group given Excedrin. (Brown, Tr. 5174; Sunshine, Tr. 9662) The authors of the Emich Study noted that "the response of an individual patient to a given medication was closely related to her starting level." (CX 425N) This means that Excedrin had a greater opportunity to relieve pain than did aspirin. (Brown, Tr. 4904, 5174) For this reason, respondent's expert Dr. Laska admitted that he would have no confidence in using those parts of the data from the Emich Study which measured the reduction in subjects' pain intensity. (Laska, Tr. 10440)

To overcome this problem, the authors of the Emich Study performed a *post hoc* statistical analysis to correct for the initial pain imbalance. (In fact, two of the three parameters which rejected the hypothesis of equal effectiveness were produced in this analysis. The third parameter was a measure of reduction in pain intensity in which even Dr. Laska would have no confidence.) In the opinion of respondent's statistician, this analysis corrects the imbalance. (Laska, Tr. 10199–10201) However, Dr. Laska conceded that if the subjects in the study were not assigned to treatment groups in an unbiased fashion, the entire study would be seriously compromised. (Tr. 10590–94) And because he felt such bias was present, complaint counsel's statistician Dr. Brown stated that the *post hoc* analysis was inappropriate. Indeed, **[37]** the record shows that if true randomization had been

[61] Dr. Sunshine's subsequent testimony, however, indicates that he was not concerned with whether the Emich Study could be used to reject the hypothesis that Excedrin and aspirin are equally effective. (Tr. 9863–77)

present in the Emich Study, the baseline pain imbalance would occur only 2% of the time. (Brown, Tr. 4903, 4921; Forrest, Tr. 8960) Because of this imbalance, both Drs. Forrest and Brown concluded that they would not rely on the Emich Study as credible evidence regarding the superiority of Excedrin over aspirin. (Brown, Tr. 8108, 8149–50, 8154–55; Forrest, Tr. 8960–61, 9121–23)[62]

Finally, even accepting respondent's attempts to correct for methodological flaws, the results are, at best, equivocal in that for some parameters the Emich Study rejects the hypothesis of equal effectiveness and for others it does not. (F. 500) In part to compensate for this, respondent combined the results of the Emich and Smith Studies in order to produce another analysis of their results. However, pooling the two studies does not produce a third study; it merely reduces two independent studies into one. (Brown, Tr. 8159–63; Forrest, Tr. 8965–68) Not surprisingly, the results of the pooled study are also equivocal and are able to reject (just barely) the hypothesis of equal effectiveness for only two of the five parameters. (F. 521)

In order to establish that Excedrin is a more effective pain reliever than aspirin, scientists require the proposition to be demonstrated by two well-controlled clinical tests. The Smith Study is such a well-controlled study but for all parameters analyzed, it could not reject the hypothesis of equal effectiveness. Since it was done on post-partum pain, respondent's statistician stated that its results were not generalizable. The Emich Study was also performed on post-partum pain and its authors also admit that its results are not generalizable to other forms of pain (such as headache pain for which Excedrin is promoted). Furthermore, this study was less well-controlled than the Smith Study creating questions of bias in the initial assignment of patients. Although these two studies may present some evidence of Excedrin's superiority, they clearly are unable to establish [38] it. The additional nonclinical evidence submitted by respondent also does not establish superiority.[63]

E. *The Substantial Question Issue*

The second set of allegations related to respondent Bristol-Myers' comparative performance claims is contained in paragraphs 9 – 11 of the complaint. These paragraphs set forth the same 15 comparative performance claims contained in paragraph 7 and allege that even in

[62] The testimony shows that there was only one published analgesic study (the Emich Study was not published when its authors failed to answer adequately a question regarding its applicability to other types of pain (Lanman, Tr. 12095–97)) in which there was significant baseline pain imbalance and the author of that study, Dr. Louis Lasagna (who was cited by respondent in its 1968 comments to the F.T.C. (Lanman, Tr. 12023–24)) indicated that because of the imbalance he could come to no conclusion about the tested drugs. (Laska, Tr. 10626–27)

[63] The evidence submitted by respondents compared Excedrin only to aspirin. Thus, there is no evidence comparing Excedrin to all other OTC analgesics and it has not been established that Excedrin is superior to them in any respect.

those instances in which the ads did not indicate that the truth of the claims had been established, respondent violated the law by failing to disclose the existence of a substantial question as to the claims' validity. The complaint also alleges that respondent failed to disclose the existence of a substantial question regarding the validity of two additional claims contained in paragraph 14.[64] Although a majority of the Commission found that respondent in *American Home Products* had violated the law by failing to disclose the existence of a substantial question with respect to certain claims, we have reconsidered that theory of liability and can no longer endorse it. For that reason, we dismiss all allegations in paragraphs 9 – 11 and 14 – 16 of the complaint. [**39**]

The "substantial question" doctrine (and our reasons for rejecting it here) can best be understood by comparing it to the "reasonable basis" standard enunciated in *Pfizer, Inc.*, 81 F.T.C. 23 (1972). In *Pfizer,* the Commission ruled that it was an unfair act or practice for an advertiser to make a claim without having a reasonable basis for believing that the claim was true. The amount of evidence required to provide a reasonable basis was left to be determined on a case-by-case basis, for the Commission recognized that the reasonableness of an advertiser's supporting evidence would depend on a number of factors. Among the factors recognized as relevant in the *Pfizer* opinion were:

> (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 consumer product, other consumer product; (3) the possible consequences of a false claim—*e.g.*, personal injury, property damage; (4) the degree of reliance by consumers on the claim; (5) the type and accessibility of evidence adequate to form a reasonable basis for making the particular claim.[65]

However, in *American Home Products Corp.*, 98 F.T.C. 136 (1981), the Commission took a somewhat different approach to the relationship between an advertiser's claims and the evidence supporting them. That case, like this one, involved claims that an analgesic possessed properties which had not been established by generally

[64] Complaint paragraph 14A alleges that respondent advertised that tests or studies prove that Bufferin is twice as fast and twice as strong as aspirin. As we indicated in Part B, (*supra* pp. 9–11), ads such as CX 31, 61, 63 and 64 state that tests show Bufferin is twice as fast as aspirin. The ALJ found no ads which state Bufferin is twice as strong as aspirin and we agree with that finding. Paragraph 14B alleges that respondent advertised that tests or studies prove Excedrin is more than twice as strong and more effective than aspirin in relieving pain. As we indicated in Part B (*supra* pp. 16–18), Excedrin ads do claim that studies show Excedrin is more effective than aspirin. (*E.g.*, CX 205, 206) Also, Excedrin ads state that it would take more than twice as many aspirin to equal the pain relief of Excedrin. (*E.g.*, CX 176) Although ads such as this do not actually state that Excedrin is more than twice as strong as aspirin, consumers would reasonably infer this. Thus, we find that respondent made the claims alleged in paragraph 14B and part of the claim alleged in 14A.

[65] *Pfizer, Inc.*, 81 F.T.C. at 64. In subsequent decisions, we ruled that it was legally deceptive (as well as unfair) for an advertiser to make a claim without a reasonable basis, because consumers *expected* advertisers' claims to be supported by a reasonable basis. *See infra* pp. 41–42.

acceptable scientific evidence. The case might have been pled and argued on the theory that, under the criteria set forth in *Pfizer*, only generally acceptable scientific evidence (*i.e.*, two well-controlled clinical tests) would suffice to provide a reasonable basis for such claims. However, this was not the theory on which the case was argued or decided. Instead, what the Commission actually ruled was that the absence of such scientific evidence created a "substantial question" about the truth of the advertiser's claims—and that the existence of this substantial question was a material fact which consumers ought to know. Making such claims without disclosing the absence of authoritative scientific proof was therefore deemed legally deceptive. **[40]**

This theory of liability was subsequently upheld by the Third Circuit in *American Home Products Corp.* v. *FTC.* In reasoning similar to that used by the Commission, the court emphasized that consumers could not judge for themselves the effectiveness of competing pain relievers, that drugs were heavily regulated as to safety and efficacy by the federal government, and that American Home's advertising campaign was so intensive and long-lasting that consumers might well come to believe that the claims being made had been established as a matter of scientific proof. Thus, while the court was reluctant to assume that consumers expected *every* analgesic claim to be backed by scientific proof (695 F.2d at 697–699), it ruled that the Commission could reasonably infer that consumers had expected such proof in the case of American Home's claims.

The practical difficulty with this doctrine, however, is that it is difficult to see where it stops. In effect, the substantial question doctrine eliminates any difference between the claim, "Our product works better than aspirin," and the claim, "Scientific tests *prove* that our product works better than aspirin." It has always been recognized that the latter claim is deceptive if the scientific tests referred to in the claim do not exist, or do not prove the truth of the claim. Under the substantial question doctrine, though, the former claim must also be proven with the same level of scientific evidence, or it will be deemed deceptive for failure to disclose the existence of a "substantial question" regarding the truth of the claim. The level of proof that is legally required will thus be the same whether the advertisement specifically refers to scientific proof or not.

There might, of course, be cases where consumers do in fact interpret both of the above claims as implying the same level of scientific certainty. The presence or absence of any reference (express or implied) to scientific tests would then be irrelevant, if consumers interpreted the claim the same way in either case. The difficulty, however, is that there has never been any evidence to confirm this somewhat

counterintuitive reading of consumer expectations. The factors relied on by the Commission in *American Home Products—i.e.,* the persuasive regulation of drug safety and efficacy, and the fact that consumers cannot judge such issues for themselves—would apply with equal strength to *every* drug claim.[66] [41] If these factors alone are enough to warrant an inference that consumers expect authoritative scientific proof for a claim, then there is no way to avoid drawing a similar inference in every other drug case (where the same factors will always be present), and the Third Circuit's concerns about an across-the-board application of the substantial question doctrine would be realized.

Thus, we are not ruling out the possibility that, in some future case, a proper showing might be made that consumers did expect unequivocal scientific proof even when the advertisements made no express or implied reference to such proof. We decline, however, to impute such expectations to consumers solely on the basis of the general characteristics of the drug market such as pervasive regulation or consumers' inability to test the claims themselves. To this extent, our decision here departs from our prior ruling in *American Home Products.*

Instead, we hold today that such cases ought to be judged (absent stronger evidence of some higher level of consumer expectations) under the "reasonable basis" standard of *Pfizer.* We thus are not ignoring the fact that there is also a difference between the claim, "Our product works better than aspirin," and the claim, "We think our product works better than aspirin but we have no proof of it." *See American Home Products,* 98 F.T.C. at 387. The latter claim implies virtually no supporting evidence; the former implies that the advertiser has at least some measure of support for the claim. But unless we have more direct evidence of what measure of support consumers actually expect, the measure that would be appropriate (or "reasonable") can only be determined by reference to factors such as those discussed in the *Pfizer* opinion.

This conclusion is entirely consistent with the Commission's other post-*Pfizer* substantiation decisions. While we have often ruled that the failure to possess a reasonable basis can be deceptive as well as unfair (on the grounds that consumers expect advertisers to possess a reasonable basis), we have never tried to set the measure of a reasonable basis exclusively directly by reference to consumers' expectations. As we said in *National Dynamics Corp.,* 82 F.T.C. 488, 550

[66] We also question the notion that an advertiser should be held to a higher standard of proof if it has made claims in a large number of advertisements over a long period of time. An intensive and long-lasting campaign is probably more likely to be remembered by consumers, and may well be more effective for that reason. Consequently, the duration of the campaign may be relevant to the need for a corrective advertising requirement (*see infra* pp. 75–76), or to other issues concerning the appropriate scope of a cease and desist order. However, there is no evidence at all to suggest that consumers expect a higher level of proof in long-lasting campaigns than in other contexts.

n. 10 (1973), *aff'd in part, remanded in part,* 492 F.2d 1333 (2d Cir. 1974), *cert. denied,* 419 U.S. 993 (1974):

> [P]erformance claims lacking a reasonable basis in fact may be found deceptive within the meaning of [42] Section 5 of the F.T.C. Act. . . . Whether an advertisement is analyzed from the standpoint of unfairness or deception, however, the standard for evaluating the substantiating material and test which is applied is the same—does the substantiation provide a reasonable basis to support the claim.[67]

Had such an analysis been performed in this case, it might well have led to the conclusion that a reasonable basis for these claims would in fact have required two well-controlled clinical tests. That is, the *Pfizer* analysis might well have led to the same conclusion as the "substantial question" doctrine, and provided an independent basis for finding a violation here.[68] Certainly the fact that consumers cannot judge analgesic claims for themselves would be one factor to take into account in that analysis, along with such other factors as the cost of testing, the extent to which lower levels of testing would reduce the certainty that a claim that survived the tests was in fact true, and the extent of the injury consumers would suffer if the claim turned out not to be true.[69] However, the difficulty with this rationale is that no such analysis has been conducted in this case. The complaint did not allege that Bristol-Myers' comparative claims were not supported by a reasonable basis, and the parties did not argue the case on that theory either before the Commission or before the ALJ. That issue therefore is not properly before us, and we are unable to rule on that theory of liability.

In short, on the record before us we can only find that the failure to possess two well-controlled clinical tests in [43] support of a claim of comparative superiority violated the FTC Act when the advertisement in some way referred to or implied the existence of scientific proof. This approach is in accord with a long line of previous Commission decisions. For example, in *Firestone Tire & Rubber Co.,* 81 F.T.C. 398 (1972), we required the respondent to substantiate its claims with scientific tests because its advertisements represented that its 25% quicker stopping claim was backed by scientific tests. (Indeed, respondent conceded that such representations had been made. 81 F.T.C. at 450.) Similarly, in *Standard Oil Co. of California,* the advertisements in question contained white-jacketed technicians perform-

[67] *See also Porter & Dietsch, Inc.,* 90 F.T.C. 866 at n.11; *National Comm'n on Egg Nutrition,* 88 F.T.C. 191 at n.14.

[68] The *Pfizer* opinion itself acknowledged such a possibility, noting that "there may be some types of claims for some types of products for which the only reasonable basis, in fairness and in the expectations of consumers, would be a valid scientific or medical basis." 81 F.T.C. at 64.

[69] *Pfizer, Id.* In some cases, the benefits consumers would receive if the claim were in fact true may also be relevant (especially if they are far greater or far less than the harm consumers would suffer if the claim turned out to be false), as this will affect the cost of setting too high or too low a standard of evidence.

ing a demonstration and used such phrases as "Here's proof" and "You're about to see proof." 84 F.T.C. at 1472. In *Litton Industries, Inc.*, 97 F.T.C. 1 (1981), we required Litton to substantiate its claims with competent and reliable surveys or tests because its ads mentioned surveys and tests, thereby implying a measure of support for the claims which did not exist. Finally, in *National Commission on Egg Nutrition,* we required respondent to disclose the existence among medical experts of a substantial question regarding the relation of egg consumption to heart attacks. 88 F.T.C. at 193. However, respondent had represented in its ads that scientific evidence supported the view that eating eggs was safe. In each of the above cases, we required the respondent to substantiate advertising claims with particular kinds of proof (or to disclose that the proof was not as one-sided as represented) because the ads in question represented that the proof existed.[70] [44]

We apply the same test in this case. Numerous ads for Bufferin and Excedrin represent that there exists scientific proof establishing the product's superiority. As we discussed above in Parts B, C and D, these claims must be substantiated by two well-controlled tests. For all non-establishment superiority claims, we dismiss those portions of the complaint which allege that respondent failed to disclose the existence of a substantial question among experts regarding the validity of such claims. Although our order includes a reasonable basis requirement for non-establishment analgesic claims, we decline to conclude at this time that two well-controlled clinical tests constitute the only acceptable substantiation for these claims.

III. TENSION RELIEF CLAIMS

Complaint paragraph 12 alleges that Bristol-Myers represented that Bufferin, Excedrin, and Excedrin P.M. relieve tension and that it lacked a reasonable basis for making those claims. The ALJ found that the claims had been made (F. 247–252, 328–336, 358) and that respondent lacked a reasonable basis for making them. (I.D. 231–232)[71] From these findings, Bristol-Myers has appealed.

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[70] In *Simeon Management Corp.*, 87 F.T.C. 1184 (1976), *aff'd*, 579 F.2d 1137 (9th Cir. 1978), we found it to be deceptive for an advertisement to omit the fact that the drug used in the advertised course of treatments had not been approved as safe and effective for that purpose by the FDA. However, even in that case there had been affirmative claims which the respondent conceded represented that the treatment had been "medically approved." 87 F.T.C. at 1230; *see also Id.* at 1208 ("Lose weight safely . . . through our *proven* weight reduction program") (emphasis added). Moreover, in *Simeon* the omitted fact did not relate merely to the level of substantiation possessed by the advertiser, but rather to the absence of formal governmental approval (approval which would have been legally required had the drug been marketed directly rather than as part of a treatment program). In this case, Bristol-Myers' products have all been approved by the FDA as safe and effective for their advertised purposes—and if that had not been the case, the failure to disclose that lack of approval would clearly be deceptive under *Simeon.*

[71] Complaint paragraph 12 also alleges that respondent lacked a reasonable basis for claims that Excedrin P.M. is an effective mild sedative. This portion of paragraph 12 was dismissed by the ALJ. Complaint Counsel have not appealed the dismissal and we see no reason to reverse the ALJ on this point.

First, it is necessary to determine whether respondent represented that the products will relieve tension. Respondent argues that the ads in question claim the products will relieve headache pain and thereby relieve the tension caused by that pain, or that by relieving headache pain they will lessen the tension exacerbated by that pain. (R.A.B. pp. 22–23) However, tension can exist separate from headache pain and we find that respondent has made broader claims about the tension relief characteristics of Bufferin and Excedrin.

In CX 53, respondent represented that Bufferin will relieve tension. The ad depicts a confrontation between a college dean and a student. The tension of the situation is conveyed by a close-up view of the student's clenched fist and by the student's threatening posture. Although part of the audio portion of the ad speaks of headache pain, the visual impression of the ad is that Bufferin should be taken to produce **[45]** a calming effect after a tense situation.[72] Given the language of this ad, some consumers could infer only that Bufferin relieves headaches caused by tension. However, the copy tests provide strong evidence showing that a substantial number of viewers (54%) received the impression that Bufferin relieves tension and we find that this claim was made by the ad.[73]

Respondent's advertising also represented that Excedrin will relieve tension. This claim is made by those ads which depict Excedrin's chemical formula and state that one of Excedrin's four ingredients is "a tension reliever to relax you."[74] A portion of most of these ads is devoted to Excedrin's ability to relieve headaches. However, in each instance, the depiction of the chemical formula (and the tension relief claim) is separated from the first portion of the ad. Furthermore, these ads stress that Excedrin has four discrete ingredients each of which performs a discrete function. Thus, it is reasonable to conclude these ads make the claim that Excedrin will relieve tension.

The ALJ also found that certain other ads depict headache sufferers in tense situations and thereby imply that Excedrin relieves tension. For example, CX 127 states:

> What is an Excedrin headache? Well, if you suddenly discover a whole pile of unpaid bills .... That's a headache. If four of them are from the electric company ... [the scene goes dark], that's an Excedrin headache. And for Excedrin headaches, you want Exce-

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[72] Similar tense situations are depicted in CX 48, 49, 52, 54–60.

[73] Respondent argues that the 54% figure is misleading because test subjects may not distinguish between "free-floating" tension and tension caused by pain. (R.A.B. p. 30) However, the verbatim portion of the copy test makes it clear that a substantial number of viewers received the impression that Bufferin has a calming effect. The ALJ quoted five of these verbatim responses in F. 251. Respondent apparently misinterpreted this finding and concluded that there were only five viewers who believed that Bufferin would relieve tension. In fact, 29 of the verbatim responses relate to Bufferin's ability to relieve tension and appear to distinguish that ability from Bufferin's ability to relieve pain. (*See* CX 299H–Q.)

[74] For example, CX 115, 116, 124, 125, 132, 133, 135–137, 143.

drin strength. Excedrin, made stronger against pain and stronger against its tension . . . ."[75] [46]

While this is a close call, we agree with the ALJ that this ad implies that Excedrin will relieve tension. The ad shows, somewhat humorously, a tense situation and then indicates that Excedrin will provide complete relief by relieving both headache and tension. At the close of the ad, the video portion depicts an Excedrin bottle. Superimposed over the bottle are two phrases, "Stronger against pain," and "Stronger against tension." This enhances the impression that Excedrin performs discrete functions, one of which is the relief of tension. Therefore, we find that consumers would reasonably infer that this ad and others like it represent that Excedrin is able to relieve tension. Further support for this is CX 288, a copy test of a similar ad which shows that 23% of the viewers found Excedrin's ability to relieve tension to be a major idea communicated by the ad.

We are unable to agree with the ALJ that respondent represented that Excedrin P.M. will relieve tension. The ALJ found that this representation was made in CX 216 and 219. But the message conveyed by these ads is not that Excedrin P.M. relieves tension; rather it is that the product will relieve the headache pain which causes tension. The ads also represent that Excedrin P.M. has an ingredient "that gently helps you to sleep." However, none of these ads represents that Excedrin P.M. will relieve tension *per se.*

Respondent presented some evidence which it contended constituted a reasonable basis for the tension relief claims. However, the ALJ did not agree with respondent, and we concur. *Pfizer* sets forth several criteria which must be considered in determining whether respondent has a reasonable basis for its tension relief claims. These claims advise consumers to take aspirin-based analgesics for relief of a specific symptom—tension. If Bufferin and Excedrin are unable to provide tension relief, then consumers may forego effective remedies and are needlessly being encouraged to consume aspirin, a drug with potentially hazardous side effects (*see infra* p. 53). Furthermore, as with other performance claims related to analgesics, it is virtually impossible for consumers to verify whether or not an analgesic is able to relieve tension. Thus, these considerations should be taken into account in determining the adequacy of respondent's substantiation.

Respondent called no expert witness to support its tension relief claims but instead has relied upon six pieces [47] of evidence, including the results of four studies (none of which were funded by Bristol-Myers (F. 690), and one article and one section from a textbook. The 1957 report on the study by Boyd, Gittinger, and Schimmer does not provide a reasonable basis for respondent's claims because it tested a

[75] Examples of other similar ads are CX 128, 135–137, 143.

drug called Effisin which contained no component in common with Bufferin and contained only salicylamide in common with Excedrin. Respondent never claimed any tension relieving properties for salicylamide. (Lanman, Tr. 11509–10, 12149–51.) The 1959 report by Boyd, *et al.* was reviewed by Dr. Rickels, complaint counsel's expert on pharmacology and tension, and he pointed out that the authors tested subjects who had pain (not just tension) and the study's results might be attributable to the pain relieving properties of aspirin. (Rickels, Tr. 6593) He also stated that he had "great doubts about the results" of the study because they showed Bufferin's tension relieving abilities as exceeding those of most prescription drugs prescribed for tension relief. (Rickels, Tr. 6591–95) Two studies reported in 1964 and 1965 by Krumholtz and Merlis also do not constitute a reasonable basis because the authors recognized the data's deficiencies. (Lanman, Tr. 12258) Furthermore, Dr. Rickles noted that these studies were not randomized and had numerous other flaws. (Rickels, Tr. 6572–80)

Respondent also submitted a 1954 textbook and a 1957 review article. Neither was based on clinical trials. Dr. Rickels noted that the FDA Panel on OTC Sedatives, Tranquilizers and Sleep-Aid Drug Products (which he chaired for three years) did not consider such textbooks and articles as evidence of a drug's efficacy. (Rickels, Tr. 6547–48) In 1965, when all evidence submitted by respondent was extant, Dr. Beaver, an expert in the field of analgesics and the clinical testing of analgesics (F. 20), conducted a review of all evidence—including evidence solicited directly from Bristol-Myers—on the pharmacological properties of analgesics. (Beaver, Tr. 5897–5900) As a result of his review (which specifically considered the 1964 and 1965 studies by Krumholtz and Merlis), Dr. Beaver concluded that there was "no good evidence" that mild analgesics have tension relieving properties. (Beaver, Tr. 5897–98; Lanman, Tr. 12151–54) The adequacy of respondent's evidence has been subsequently cast into further doubt by a well-controlled 1973 study which showed that aspirin was not significantly different from a placebo in its ability to relieve tension (Rickels, Tr. 6500, 6511–14, 6517) and by the FDA OTC Analgesics Panel which concluded that aspirin is "clearly ineffective" for "nervous tension." (CX 514, p. 35353) [48] Thus, in light of the kind of claims made by respondent (and their potential impact), the limited relevance of evidence submitted by respondent and the expert testimony, we find that respondent did not possess a reasonable basis for claims that Excedrin and Bufferin relieve tension.[76]

[76] Indeed, Excedrin contains caffeine, a substance which is contraindicated for the relief of tension (Rickels, Tr. 6530–31) and which is described as "nerve-jangling" and "sleep-disturbing" in a 1968 ad for Bufferin. (CX 106)

IV. THE DOCTORS RECOMMEND CLAIM

Paragraphs 17 and 18 of the complaint allege, and the ALJ found, that respondent's ads represent that physicians recommend Bufferin more than any other nonprescription internal analgesic and that there is no reasonable basis for the claim. Respondent does not contest that it lacks a reasonable basis for the claim that physicians recommend Bufferin more than any OTC analgesic.[77] However, it argues that the ads represent only that physicians recommend Bufferin more than any other *leading brand* of OTC analgesic and that the evidence it has presented constitutes a reasonable basis for that claim. Thus, we must determine what is represented by the ads in question.

We find that in numerous ads respondent has represented that doctors recommend Bufferin more than any other OTC analgesic. For example, in CX 3, the video portion states, "Doctors specify Bufferin most." At the same time the announcer states, "Of all leading brands of pain reliever you can buy for minor pain, doctors specify Bufferin most."[78] **[49]** Although the literal message contained in the audio portion is that Bufferin is specified more frequently than leading *brands,* consumers could reasonably infer that Bufferin is recommended more frequently than all other OTC analgesics. (Certainly consumers cannot be expected to realize that the product doctors recommend most, aspirin, is not a brand.) This is also the message in the video portion. We believe the open-ended statement, "Doctors specify Bufferin most" would reasonably be interpreted to mean that doctors specify Bufferin more than any other OTC analgesic and the audio portion might not override that impression.[79]

Thus, we find that respondent's ads represent that doctors recommend Bufferin more than any other OTC analgesic, and that respondent lacked a reasonable basis for making that claim.

V. REPRESENTATION THAT BUFFERIN AND EXCEDRIN CONTAIN OTHER THAN ORDINARY ASPIRIN; FAILURE TO DISCLOSE THE PRESENCE OF ASPIRIN

Paragraph 21 of the complaint charges respondent with representing that the analgesic ingredient in Bufferin is other than ordinary

[77] Respondent submitted portions of two surveys in support of the "doctors recommend" claim. (CX 364–390) These data do show that from 1967 through 1971 doctors recommended Bufferin more than Bayer, Excedrin and Anacin. (*See* CX 838J–R) However, these data also show that for pain relief, doctors recommend Tylenol, Ascriptin and generic aspirin more often than Bufferin. (*See* CX 822Y–Z)

[78] Similar ads are CX 2, 4–7, 41–46, 65–67, 97, 107.

[79] Respondent argues that the copy test of CX 3 does not show that a substantial number of consumers received the impression that doctors recommend Bufferin more than any other OTC analgesic. (CX 301) However, as we indicated above (*supra* p. 12), although a copy test may verify the primary theme of an ad, it is less likely to demonstrate the presence of secondary themes. Since the ad makes several claims (including speed, efficacy, less stomach upset, long-lasting relief) in addition to the "doctors recommend" claim, the copy test might well not accurately measure the extent to which consumers received a particular message from an ad which contained a number of messages.

aspirin, that the ingredient in Excedrin which provides long-lasting relief is other than ordinary aspirin, and that the antidepressant in Excedrin is other than caffeine. Paragraph 19 charges that respondent failed to disclose that Bufferin, Excedrin, and Excedrin P.M. contain aspirin and that Excedrin contains caffeine. **[50]**

Respondent argues that its ads do not indicate that its products contain an analgesic other than aspirin. It claims that the ads for Bufferin contrast the total product of Bufferin with aspirin. It further claims that Excedrin ads compare its ingredients to aspirin but in no way imply that Excedrin does not contain aspirin. Finally, respondent argues that the presence of aspirin in Bufferin and Excedrin is not material to consumers and that the ALJ's order requiring disclosure of aspirin is improper. Specifically, it argues that aspirin is harmful to only a small group of consumers and these consumers already know that Bufferin and Excedrin contain aspirin.

We disagree with respondent and find that its ads do represent that Bufferin and Excedrin contain other than ordinary aspirin. All three products, Bufferin, Excedrin, and Excedrin P.M., contain aspirin and no ad for any of them discloses that fact.[80] In addition, numerous ads for Bufferin attempt to differentiate its analgesic ingredient from aspirin. This is accomplished by several means. First, through the use of strained syntax, ads make it appear that Bufferin contains something other than aspirin. For example, CX 7 states:

> In the first 30 minutes Bufferin delivers twice as much pure pain reliever as the best known aspirin.

This ad compares Bufferin's analgesic ingredient, and not its total formula, with aspirin. In no ad for Bufferin is its analgesic ingredient referred to as aspirin. Instead, it is called "pain reliever" (CX 33), "pure pain reliever" (CX 13), "active pain reliever" (CX 27), "high-speed formula" (CX 34), and "strong medicine" (CX 52). These characterizations, in and of themselves, would not necessarily lead to deception. **[51]** However, in each of these ads aspirin is specifically mentioned and is carefully differentiated from Bufferin. In addition,

[80] The active ingredients of one tablet of each of the three preparations are:

Bufferin:	aspirin	5 grains
	magnesium carbonate	97.2 mgs.
	aluminum glycinate	49 mgs.
Excedrin:	aspirin	3 grains
	acetaminophen	1.5 grains
	salicylamide	2 grains
	caffeine	1 grain
Excedrin P.M.:	aspirin	3 grains
	acetaminophen	2.5 grains
	salicylamide	2 grains
	methapyrilene fumarate	25 mgs.

ads create the impression that Bufferin is different from aspirin by contrasting Bufferin's analgesic performance with aspirin. For example, CX 39 states:

> What a time for a headache. You could have taken aspirin . . . but Bufferin goes to work in half the time of simple aspirin. Look. Simple aspirin takes 20 minutes to give you the pain reliever Bufferin gives you in 10.

As another example, CX 50 states, "Plain aspirin's fine, but Bufferin goes to work much faster." Always, Bufferin is distinguished from aspirin. By virtue of the wording of these ads, consumers would reasonably infer that the analgesic in Bufferin is other than ordinary aspirin.

Although no ad for Excedrin discloses that it contains aspirin, several ads affirmatively disguise that fact. For example, CX 115 contains a graphic representation of the chemical formulas of Excedrin and one of its competitors. The ad first depicts the competitor's formula and identifies its ingredients as aspirin and caffeine. Below that, Excedrin's formula is displayed. However, Excedrin's ingredients are not identified. They are merely referred to as "four medically endorsed ingredients" providing "quick relief, long-lasting relief, a tension reliever to relax you, an antidepressant to restore your spirits." The second ingredient, the one providing "long-lasting relief" is, in fact, aspirin. Its formula is placed below caffeine in the competitor's formula. Thus, a viewer may be unlikely to realize that aspirin is contained in Excedrin. Indeed, by virtue of the juxtaposition of ingredients, it appears that Excedrin does not contain aspirin. The same technique is used to disguise the presence of caffeine. Caffeine is referred to as "an antidepressant to restore your spirits." Its formula is not placed below caffeine in the competitor's product and consumers could be led to believe that Excedrin contains no caffeine.[81]

CX 141 creates the impression that Excedrin does not contain aspirin by stressing the aspirin content of its competitors. It states: [52]

> This pain reliever says it works wonders. And it does. It's plain aspirin. This pain reliever says it has more of the ingredient doctors recommend most. And it does. They mean plain aspirin. [Excedrin] says it's the extra strength pain reliever and it is. Excedrin's four ingredient formula gives you quick relief, long lasting relief, a tension reliever to relax you. An antidepressant to help restore your spirits.

The failure to disclose the presence of aspirin in Excedrin in the context of this ad makes it appear that Excedrin does not contain aspirin.

Thus, we find that consumers could reasonably infer from the ads

[81] CX 116 is similar.

discussed above that Bufferin and Excedrin do not contain ordinary aspirin.[82] Our analysis of these ads is similar to that in *American Home Products,* 98 F.T.C. at 365–367, and, as in that decision, we conclude that the representations in these ads had the capacity to mislead consumers. Nevertheless, a misleading claim or omission violates the FTC Act only if the omitted information would be a material factor in the consumer's decision to purchase the product. *F.T.C.* v. *Colgate-Palmolive Co.,* 380 U.S. at 392. "Materiality" is defined in Section 15 of the FTC Act, 15 [53] U.S.C. 55, the section which defines "false advertisement."[83] It provides that an omission of fact may be material "in the light of representations made or suggested . . . or . . . with respect to consequences which may result from the use" of the product.

In light of the "representations made or suggested" in the advertisements discussed above, there can be little doubt that the presence of aspirin in Bufferin and Excedrin is material to consumers. Indeed, the fact that ads for Excedrin and Bufferin carefully differentiate their formulas from aspirin and then use these apparently special formulas as principal selling messages strongly implies that knowledge of the presence of aspirin would be material to consumers. Furthermore, the presence of aspirin in Bufferin and Excedrin is made all the more significant by virtue of aspirin's potential side effects. As we found in *American Home Products* 98 F.T.C. at 368–369, and as was testified to in this case by Dr. Grossman and Dr. Donald Stevenson (an immunologist who is an expert in the area of asthma and allergy), aspirin may have numerous side effects. It may cause dyspepsia and gastrointestinal bleeding and it may exacerbate or even cause ulcers. (Grossman, Tr. 7724–28, 7741–45, 7821, 7985) Aspirin can cause asthmatics to suffer attacks which may be severe or even life threatening. (Stevenson, Tr. 1480, 1489) It can also cause skin reactions such as hives and swelling. (Stevenson, Tr. 1512)

Although respondent recognizes that these side effects may occur, it argues that since only a very small percentage of users actually suffer these side effects, the disclosure of aspirin's presence is not

[82] However, we find that some of the Excedrin ads cited by the ALJ do not disguise the presence of aspirin. For example, CX 132 makes no comparison between Excedrin and aspirin. Aspirin is never mentioned in the ad and Excedrin's ingredients are not described as special or different. Thus, although this ad and others like it (*e.g.,* CX 122–131, 133, 134, 136–139, 142–152) do not disclose the presence of aspirin, we do not believe that they create the misimpression that Excedrin does not contain aspirin.

Respondent argues that there has been no showing that the aspirin contained in Bufferin and Excedrin is "ordinary." (R.A.B. pp. 37, 38; Bristol-Myers Reply Brief pp. VIII–1 – VIII–2.) However, complaint paragraph 21 alleges that respondent misled consumers by creating the impression that Bufferin and Excedrin did not contain aspirin, a common, well-known analgesic. Thus, as used in paragraph 21, the word "ordinary" refers to the fact that aspirin is well-known. It does not refer to the quality of the particular type of aspirin used in Bufferin and Excedrin.

[83] The definition of "false advertisement" in Section 15 applies to that term as it is used in Section 12. Since respondent is charged with violating both Sections 5 and 12, the definition in Section 15 is directly relevant to the case.

material. Nevertheless, as we found in *American Home Products,* 98 F.T.C. at 367, the actual number of individuals who may be adversely affected is significant. Furthermore, the disclosure of aspirin's presence is material not only to individuals who actually suffer adverse effects but also to those who *may* suffer effects. For example, immunologists generally warn all asthmatics to avoid aspirin (Farr, Tr. 2601, 2606), and some studies indicate that more than 10% of the population suffers from asthma. (Stevenson, Tr. 1498; Farr, Tr. 2589–2605) For this portion of the population, the presence of aspirin is material.

Respondent next argues that disclosing the presence of aspirin in ads for Bufferin and Excedrin is unnecessary because consumers who may be allergic to aspirin (such as **[54]** asthmatics) have been warned by their physicians to avoid aspirin and to read labels. The labels for Bufferin, Excedrin, and Excedrin P.M. do disclose the products' aspirin content. (R.A.B. p. 42, 44)[84] However, the nondisclosure of aspirin is material in light of both "the consequences which may result" from aspirin's use and respondent's representations regarding aspirin.[85] As discussed above, numerous ads for Bufferin and Excedrin create the impression that those products do not contain aspirin. Consumers receiving that impression might feel no need to examine the label. The importance of this misleading initial contact is recognized in *Carter Products, Inc.* v. *F.T.C.,* 186 F.2d 821 (7th Cir. 1951), which held that when the first contact between a seller and a 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. In this case, of course, we have no assurance that consumers do actually read labels. And, even if consumers do subsequently read the label, they may have already purchased the product unnecessarily, thereby causing themselves economic harm. **[55]**

Respondent argues that the legislative history of the FTC Act precludes finding the nondisclosure of aspirin to be material. Specifically, it cites a portion of the conference report regarding Section 14 of the Act, 15 U.S.C. 54, which states that criminal sanctions are not to be imposed for false advertising if the commodity which is falsely

[84] The ALJ found that studies show a substantial number (in excess of 60%) of consumers do not know that Bufferin and Excedrin contain aspirin. (F. 673–679) This conclusion was based upon numerous consumer surveys in the record including CX 314, 333, 347, 348, 810, 1058, and 1059. The record also contained (and the ALJ relied upon) an analysis of these surveys by Dr. Ivan Ross, complaint counsel's expert in marketing research, and he concluded that "a substantial number of people are not aware that aspirin is an ingredient of either Bufferin or Excedrin." (Ross, Tr. 7456) Respondent disputes the methodology of four of the surveys relied on by the ALJ (R.A.B. p. 43 n*) but does not question the other three. Furthermore, respondent has offered no expert testimony to dispute the ALJ's finding. Thus, we believe the ALJ correctly concluded that evidence shows a substantial number of consumers do not know that Bufferin and Excedrin contain aspirin.

[85] Despite aspirin's harmful side effects, we are unprepared to hold that the mere failure to disclose the presence of aspirin in advertising for aspirin-based analgesics renders that advertising materially misleading. Respondent's affirmative misrepresentations (both express and implied) that Bufferin and Excedrin *do not* contain aspirin are essential elements to our finding of liability.

advertised is injurious to consumers' health only because of peculiar idiosyncracies or allergic conditions. (R.A.B. p. 38)[86] It argues that this section of legislative history also applies to Section 15 because Sections 14 and 15 share some wording in common.[87] However, respondent's argument regarding Section 15 is inappropriate for two reasons. First, we have found respondent's advertisements misleading not merely because of the nondisclosure of aspirin, but because of the combined effect of affirmative statements implying that the products do not contain aspirin *and* the failure to disclose aspirin. Both elements, affirmative statements and nondisclosure, are essential to our finding of materiality in this case. Indeed, in the order we enter today, we do not require respondent to disclose the presence of aspirin in every ad for Bufferin and Excedrin, only in those ads which contrast the product's ingredients with an aspirin-containing product. Second, arguments regarding Section 14 (such as the one made by respondent) do not necessarily apply by analogy to Section 15. Section 14 imposes criminal sanctions and Section 15 does not. That fact alone is reason for applying a different standard under Section 15. There is also no reason to believe that Congress intended to restrict the definition of misleading advertisements in the same way it restricted the imposition of criminal sanctions. The legislative history of Section 14 quoted by respondents refers to penalization and there is no similar language in the legislative history interpreting Section 15. [56]

Respondent also argues that by virtue of dissimilarities between Section 15 of the FTC Act and portions of the Food, Drug, and Cosmetics Act, its advertisements should not be found to be false advertisements as that term is defined in Section 15. Bristol-Myers points out that the same Congress which enacted Section 15 also enacted amendments to the FDCA which apply to misbranded drugs. These amendments state that a drug is misbranded if its label does not disclose its ingredients. 21 U.S.C. 352(e)(ii). Respondent argues that since Section 15 does not mention disclosure of ingredients, Congress did not intend that failure to disclose ingredients would constitute false advertising. It is true that Section 15 does not say that every ad which fails to disclose ingredients violates the law. But, once again, we have found respondent's ads misleading because of affirmative statements *and*

[86] House of Representatives Report No. 1774, February 8, 1938. Conference Report, page 10.

[87] Section 14 states that criminal sanctions may be imposed if:

> . . . the use of the commodity may be injurious to health because of results of such use *under the conditions prescribed in the advertisement thereof or under such conditions as are customary or usual* . . . .

Section 15 states that in determining whether an ad is misleading in a material respect, the Commission must take into account:

> . . . consequences which may result from the use of the commodity to which the advertisement relates *under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.*

The section of the conference report cited by respondents comments on the underlined portion of Section 14.

nondisclosure. This is not a case of simple nondisclosure; therefore, respondent's argument is not germane.[88]

VI. CLAIM THAT EXCEDRIN P.M. CONTAINS A SPECIAL INGREDIENT

Complaint paragraphs 23 and 24 allege, and the ALJ found, that respondent has falsely advertised that Excedrin P.M. contains a special sedative or sleep-inducing agent available only in Excedrin P.M. when in fact the ingredient, methapyrilene fumarate, is available in several other OTC drugs. We disagree with the ALJ's finding and conclude that this representation was not made by respondent's advertising.

According to the ALJ, numerous ads represent that Excedrin P.M.'s sleep-inducing ingredient is unique. (F. 359) However, we find that, at most, these ads represent that the formulation of Excedrin P.M. is unique. For example, CX 218 states, in its entirety:

> There's a new idea for bedtime headaches. It's more than a pain tablet but it's not a strong sleeping pill. It's new Excedrin P.M., the night-time pain reliever. It combines pain relief with a special night time ingredient that gently helps you sleep. Excedrin P.M. is a new idea. Excedrin P.M., the night-time pain reliever.

The message in this ad is that Excedrin P.M. is new and different, not that the sleep-inducing ingredient is unique. Although that ingredient is referred to as "special," in the context of this ad, that appears to suggest that the ingredient has a special purpose, a purpose other than pain relief. [57] After considering all the ads cited by the ALJ, it is our conclusion that in no instance do those ads represent that the sleep-inducing ingredient is unique. Thus, we dismiss the allegations of complaint paragraphs 23 and 24.[89] [58]

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[88] The ALJ determined that the record in this case did not show that the presence of caffeine in Excedrin is a material fact which should be disclosed in ads. (I.D. 243–244) Complaint counsel did not appeal this point and we see no reason to reverse the ALJ's decision.

[89] In addition to substantive objections discussed in Sections II - VI above, Bristol-Myers objects to numerous evidentiary rulings by the ALJ. (R.A.B. pp. 18–20, 75–77) First, it contends that certain medical documents (CX 510, 511, 512, 514, 518) should not have been admitted into evidence because it was not given an opportunity to depose the authors or probe into underlying data. It is not necessary for us to resolve this issue because we do not believe that any error which may have occurred regarding these documents substantially prejudiced respondent's rights. No portion of our decision is based on these documents. Indeed, our decision makes no reference to CX 510, and the few references we have made to the other documents are only to provide additional support for propositions which are adequately supported by expert testimony on the record. Similarly, we do not believe that the inclusion of documents contradicting the testimony of Dr. Azarnoff prejudiced respondent since each reference to his testimony is accompanied by a reference to at least one other expert witness.

Bristol-Myers also objects to the ALJ's refusal to accept into evidence a study on Excedrin performed by Dr. Sunshine. The ALJ excluded this study because it was not listed by Bristol-Myers on its pre-trial document list. (Tr. 9626–9635) We decline to overturn the ALJ's decision on this point because it was an appropriate exercise of the ALJ's duty to manage fairly and efficiently the progress of a complex lawsuit. Without full pre-trial disclosures, it would be impossible to conduct an orderly trial in a case such as this one. Furthermore, this rejected study was one of a group of studies rejected by the ALJ. Bristol-Myers was subsequently given the opportunity to introduce one of the studies but chose not to do so unless all would be accepted into evidence. Apparently respondent believed that it was the pooled results of all the studies which supported Excedrin's superiority. (Tr. 11616–18) Nonetheless, the ALJ did permit respondent's experts to refer to the pooled results. In addition, the record shows that none of these studies was among the evidence submitted by Bristol-Myers to either the FDA OTC Analgesics Panel or the

(footnote cont'd)

VII. ADVERTISING AGENCIES' LIABILITIES

The ALJ concluded that Ted Bates & Company, Inc. and Young & Rubicam, Inc., two advertising agencies employed by Bristol-Myers, were also liable for certain of the advertising claims regarding Bufferin, Excedrin, and Excedrin P.M. We concur with certain parts of the ALJ's decision but have modified the order to reflect our areas of disagreement.

In order to hold an advertising agency liable for false advertising, the agency must have been an active participant in preparing the violative advertisements, *Doherty, Clifford, Steers & Shenfield, Inc.* v. *F.T.C.*, 392 F.2d 921, 927 (6th Cir. 1968); *American Home Products*, 98 F.T.C. at 396, and it must have known or had reason to know that the advertisements were false or deceptive. *Doherty*, 392 F.2d at 927; *Standard Oil Co.*, 84 F.T.C. at 1475. It is undisputed in this case that the advertising agencies actively participated in the preparation and dissemination of certain of the challenged ads in this proceeding. Furthermore, an advertising agency is held to know the claims made in the advertisements which it has prepared. *In re Merck & Co.*, 69 F.T.C. 526, 559 (1966), *aff'd*, 392 F.2d 921 (6th Cir. 1968). Thus, what remains to be determined is whether the agencies knew, or had reason to know, that the ads in question were false or deceptive due to the failure to disclose material facts, the lack of a reasonable basis, or the lack of scientific establishment.

In determining whether an advertising agency knew or had reason to know that an ad was false or deceptive, it is necessary to examine carefully the claim made in the challenged ad and the type of substantiation necessary to support the claim. Surely, an advertising agency cannot be required to conduct an independent investigation to determine whether a scientific claim has been established. However, with respect to certain claims, it may be that the disparity between the claims and the substantiation is so great as to preclude a conclusion that the ads in question were conceived through reasonable reliance on the substantiation provided by the manufacturer of the product. *Standard Oil Co. of California*, 84 F.T.C. at 1474–75. **[59]**

A. *Ted Bates & Company, Inc.*

Respondent Ted Bates & Company, Inc., (Bates) actively participated in the creation and dissemination of advertisements for Bufferin beginning in 1968. Thus, Bates was responsible for making the same claims regarding Bufferin which we found were made by respondent

AMA Drug Evaluations to support claims of Excedrin's extra strength. (Lanman, Tr. 12116–17; Sunshine, Tr. 9702–06) Thus, we are not able to conclude that the ALJ abused his discretion in excluding these studies. Similarly, we think that the ALJ correctly refused to accept into evidence those portions of the new drug application for Extra Strength Tylenol and certain additional blood level data regarding Bufferin submitted by respondent.

Bristol-Myers. Bates has not denied that it participated in the creation and dissemination of any of the ads listed in F. 797 and CX 800. But it has appealed the ALJ's conclusion that the ads make the challenged representations. (Ted Bates Appeal Brief pp. 7–10, 12–16, 17–19) However, we find no reason to alter any of the conclusions which we reached above regarding the Bufferin advertisements and we find that Bates is responsible for the ads which make false or deceptive claims regarding Bufferin.

The ALJ determined that with respect to the claims of Bufferin's established superior efficacy, respondent Bates reasonably relied on the substantiation provided by Bristol-Myers and was, therefore, not liable for the fact that those claims had not been established. From this determination, complaint counsel have appealed. Complaint counsel contend that documents from Bates' files (*e.g.,* CX 469B, 556) demonstrate that Bates knew the establishment claims were open to substantial question. (CAB p. 54) They point out that Bates was not required to perform any analysis of the support presented by Bristol-Myers since the documents in their files should have demonstrated the falsity of the claims they were making. Therefore, complaint counsel contend that Bates' reliance on the substantiation provided by Bristol-Myers was not reasonable.

We are unable to agree with complaint counsel on this point. Although we found that the comparative efficacy claims regarding Bufferin had not been established, there definitely was some evidence supporting Bufferin's claims of superior speed (*see e.g.,* F. 592, 606–607) and superior freedom from side effects (F. 634). This evidence provided at least some facial support for the claims but did not establish them. A major drug company, such as Bristol-Myers, may be expected to perform the sort of analysis necessary to determine whether a claim has been established; an advertising agency is far less capable of performing such a task. That task is a complicated one (as demonstrated by Section II of this opinion) requiring both scientific and statistical expertise and demanding familiarity with work done by other experts in the field. We are unwilling to require that Bates perform this sort of examination of the universe of knowledge related to analgesics. **[60]**

It is true that some documents in Bates' files do question Bufferin's superiority. However, this fact alone would not preclude a finding that Bates reasonably believed that the claims had been established since we have found that Bates possessed other evidence which provided some scientific basis for the claims that were made in the ads. We concluded from the expert testimony and other evidence in this case that in order to establish the comparative claims made for Bufferin, scientists generally would require two well-controlled clinical

tests. But even if a claim has been established, that does not mean that the claim is unanimously regarded as correct. There will always be disagreements and documents reflecting that disagreement. While we might expect an advertiser to determine whether conflicting opinions would negate a finding that a claim had been established, we would not require an advertising agency to perform the same level of analysis. We, thus, find that the documents in Bates' files do not render Bates liable for the lack of support for the establishment claims.

This decision is not inconsistent with our past decisions finding ad agencies liable for inadequately substantiated advertising. In *Merck & Co., Inc.,* 69 F.T.C., 526, 558–559 (1966), *aff'd sub nom. Doherty, Clifford, Steers and Shenfield, Inc.* v. *F.T.C.,* 392 F.2d 921 (6th Cir. 1968), we found an advertising agency liable for deceptive ads because it developed an advertising campaign which went far beyond the substantiation provided by the drug company. In *ITT Continental Baking Co.,* 83 F.T.C. 865, 968–969 (1973) *order modified in part,* 532 F.2d 207 (2d Cir. 1976), we held an advertising agency (by coincidence, Ted Bates & Co., Inc.) liable for false advertising claims which lacked any substantiation. The agency argued that it had no reason to know that the claim was deceptive. In response to this, we affirmed that an agency does have a duty to ascertain the existence of substantiation for the claims which it makes. However, as we also stated, "No issue is raised in the instant case of agency reliance on the accuracy of a scientific test conducted by third parties." *Id.* at 969. Once again, in *Standard Oil Company of California,* 84 F.T.C. 1401, *order modified* 577 F.2d 653 (9th Cir. 1978), we found an advertising agency liable because its advertised claims "went far beyond even the most favorable interpretation of test results or other research data available when the advertisements were created and distributed." *Id.* at 1474. Finally, in *American Home Products,* 98 F.T.C. at 309, we held that "when presented with a facially inadequate study as substantiation, an advertising agency may not ignore the study's defects." **[61]**

In this case (unlike any of the above-cited cases), the substantiation possessed by respondent Bates did tend to support the claims in the Bufferin advertisements and the studies were not facially inadequate. We found Bristol-Myers liable because it did not possess substantiation of the type and quantity necessary to establish the claims it made. We do not intend to require an advertising agency to perform the inquiry necessary to determine what level of substantiation relevant experts require to establish a comparative claim regarding OTC drugs. Thus, we find that complaint counsel failed to show that the evidence in the record was sufficient to put Bates on notice that

adequate substantiation was lacking and respondent Bates is not liable for the violations charged in paragraphs 7 and 8 of the complaint.

Respondent Bates appeals from paragraph IV A of the ALJ's order which would prohibit it from representing that Bufferin will not upset a person's stomach unless it possesses a reasonable basis for making that claim. Bates argues that the order provision was improper because the complaint raised no issue as to the reasonableness of the "no stomach upset" claim. (Ted Bates Appeal Brief p. 10) This is true (*see* Tr. 11613–14), and we find that paragraph IV A of the ALJ's order is inappropriate.

Bates next objects to paragraph IV B of the ALJ's order, which prohibits it from representing without a reasonable basis that Bufferin will relieve tension. Bates argues that since the ALJ found that Bates had a reasonable basis for the tension-relief claim (I.D. 256), entry of the order provision was improper. Complaint counsel do not oppose deletion of this provision. (C.R.A.B. p. 55) As the ALJ observed in discussing the issue of Bates' liability:

> what may not be a reasonable basis for a medical-scientific claim for a drug manufacturer may be a reasonable basis for an advertising agency which relied in good faith on the client drug manufacturer's judgment regarding the adequacy of substantiation unless the purported substantiation was unreliable on its face. (I.D. 256)

We find that the substantiation for the tension relief claim did constitute a reasonable basis for Bates (although not for Bristol-Myers). Since Bates did not violate the FTC Act with respect to the claims of tension relief, paragraph IV B of the ALJ's order is inappropriate. *ITT Continental Baking Co., Inc.* v. F.T.C., 532 F.2d 207, 221 (2d Cir. 1976). [62]

Respondent Bates also objects to paragraphs IV C and D of the ALJ's order. These provisions would prohibit Bates from referring to aspirin by any name other than aspirin and would require it to disclose in advertisements that Bufferin contains aspirin. Bates contends: (1) that the ads do not imply that Bufferin contains something other than aspirin, and (2) that even if they do, Bates neither knew nor had reason to know that the presence of aspirin in Bufferin is a material fact.

First, as we explained above, a substantial number of ads for Bufferin do imply that Bufferin does not contain aspirin and that its formula is somehow special (*supra* pp. 50–51). Second, we find that Bates had reason to know that the presence of aspirin in Bufferin was a material fact.[90] Bates developed numerous ads which create the impression

[90] Bates argues that paragraphs IV C and D of the ALJ's order are inappropriate because it has not been shown that (1) Bates knew that consumers were unaware of the presence of aspirin in Bufferin: and (2) Bates knew that aspirin might be injurious to health. (Ted Bates Appeal Brief, p. 19) However, it is not necessary for complaint

(footnote cont'd)

that Bufferin does not contain aspirin. This false inference was central to these ads, and these ads were central to the advertising campaign for Bufferin. From this we infer that Bates knew (or at least should have known) that knowledge of the presence of aspirin in Bufferin would be material to consumers and that it was, therefore, important to disguise that fact and even to create the impression that aspirin was not a component of Bufferin. Thus, we find that respondent has committed the violations alleged in paragraphs 19–22 of the complaint.

Finally, respondent Bates objects to paragraph IV E of the ALJ's order. (Ted Bates Appeal Brief pp. 21–22) This provision would prohibit Bates from representing that doctors recommend Bufferin more than any other OTC analgesic unless Bates has a reasonable basis for making the claim. First, Bates argues that it did not develop the "doctor recommend" campaign. That may be so. However, Bates clearly participated actively in the preparation of ads making the claim even if the claim was initially developed by another advertising **[63]** agency. To hold Bates liable for the claim, it is not necessary to establish that it was the original developer of the campaign. Second, Bates argues that the ads only represent that doctors recommend Bufferin more than other leading brands. However, as we explained above (*supra* pp. 48–49) consumers could reasonably infer from the ads in question that Bufferin is recommended more frequently than all other OTC analgesics. Bates' third argument is that no ad made the "doctors recommend" claim after 1971 and it would be inappropriate to enter an order provision related to a campaign long discontinued. The mere fact that an unlawful practice has been discontinued does not bar the entry of a cease and desist order. *Fedders Corp.* v. *F.T.C.*, 529 F.2d 1398, 1403 (2d Cir. 1976), *cert. denied*, 429 U.S. 818 (1976). Indeed, abandonment will not constitute a defense to an order provision unless it was done voluntarily and the record contains assurance that the practice will not be resumed. *Rubbermaid, Inc.* v. *F.T.C.*, 575 F.2d 1169, 1172 (6th Cir. 1978). Since the record in this case contains no assurance that the circumstances under which the ad claims were dropped provide a basis for inferring that the "doctors recommend" claim will not be resumed in the future, we have entered an order provision similar to paragraph IV E of the ALJ's initial order.

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counsel to demonstrate either of these propositions. We have already determined that the presence of aspirin in Bufferin is a material fact by virtue of the health hazards associated with aspirin and the misleading claims that were made for the product (*supra* p. 53). To find the advertising agency that developed the ads liable, all that remains to be determined is whether it knew or had reason to know of that materiality.

B. *Young & Rubicam, Inc.*

Respondent Young & Rubicam, Inc. has actively participated in the creation of advertisements for Excedrin and Excedrin P.M. since prior to 1962. Thus, Young & Rubicam was responsible for making the same claims regarding Excedrin and Excedrin P.M. which we found were made by respondent Bristol-Myers. Young & Rubicam has not denied that it was an active participant in the creation and dissemination of the advertisements for Excedrin and Excedrin P.M. It does contest whether some of the ads make the challenged representations. (Young & Rubicam Appeal Brief pp. 11–12) However, once again, we find no reason to alter our interpretation of any of the Excedrin or Excedrin P.M. ads.

As he did with respect to Bates, the ALJ determined that Young & Rubicam reasonably relied on substantiation provided by Bristol-Myers supporting the comparative efficacy claims regarding Excedrin and Excedrin P.M. (I.D. p. 256). Complaint counsel have appealed this finding. They contend that prior to Young & Rubicam's receipt of the results of the Emich study in 1970, Young & Rubicam knew that its claims of superior efficacy for Excedrin lacked adequate support. (CAB p. 60) They cite two documents obtained from Young & Rubicam's files which they contend demonstrate Young & Rubicam's knowledge that the pre-1970 claims were false. (CX 469, 628) Thus, they have requested that the ALJ's order against Young & Rubicam be amended to prevent such unsubstantiated comparative efficacy claims in the future. **[64]**

We decline to amend the order in this fashion. First, as we indicated above in connection with the discussion of the liability of Ted Bates, Inc. (*supra* pp. 60–61), we are unwilling to require an advertising agency to perform independently the inquiry necessary to determine the level of substantiation required by experts to establish a claim of superiority regarding an OTC drug. Furthermore, we agree with the ALJ that "it was not unreasonable for Young & Rubicam to have accepted the [Emich] study at face value and relied on it as reasonable substantiation for the efficacy claims for Excedrin." (F. 812) We also find that prior to 1970, Young & Rubicam possessed the Sherman study (*see supra* pp. 32–33) which is evidence, albeit not clinical evidence, that tended to show that Excedrin was superior to aspirin. Although we agree with the ALJ that CX 496[91] is of questionable materiality in this case (Tr. 3956), we believe that in conjunction with CX 628[92] it raises the question of whether Young & Rubicam knew its

[91] CX 496 is an unsigned review of a January 1970 Excedrin research and development meeting which casts doubts on Excedrin's superior efficacy. It was obtained by complaint counsel from Young & Rubicam's files.

[92] CX 628 is a copy of a letter dated December 1970 from Young & Rubicam to Bristol-Myers which appears to state that the Emich Study represents the first evidence of Excedrin's superior efficacy.

claims were inadequately substantiated. However, as we noted before, the mere fact that questions have been raised to an advertising agency regarding advertising claims does not automatically establish that the agency should have known the claims were not adequately substantiated. In this instance, Young & Rubicam possessed some substantiation for the comparative performance claims prior to 1970. Moreover, the evidence shows that only two ads prior to 1970 represented that Excedrin's superiority had been established, and that subsequent to early 1970 the Emich study constituted adequate facial support for the comparative claims made by Young & Rubicam. In light of these facts, we decline to enter any order provision against respondent relating to comparative performance claims for Excedrin.

Young & Rubicam has raised three issues on appeal. First, it argues that paragraph V D of the ALJ's order is inappropriate. (Young & Rubicam Appeal Brief pp. 5–7) This paragraph would prohibit Young & Rubicam from representing that doctors recommend Excedrin or Excedrin P.M. unless they possess a reasonable basis for making the claim. Young & Rubicam contends that this paragraph should be removed from the order because no such claim was ever made regarding either Excedrin or Excedrin P.M. and Young & Rubicam was never charged with making such a claim. Our examination of the advertisements in evidence in this case shows that no "doctors recommend" claim was ever made regarding either Excedrin or Excedrin P.M. Since the prohibitions in a **[65]** remedial order must bear a reasonable relation to the respondent's conduct, *Jay Norris, Inc.* v. *F.T.C.*, 598 F.2d 1244, 1249 (2d Cir. 1979), *cert. denied*, 444 U.S. 980 (1979), we agree that paragraph V D of the order is inappropriate.

Young & Rubicam next argues that paragraph V A is inappropriate. (Young & Rubicam Appeal Brief pp. 8–9) This provision would prohibit respondent from representing that either Excedrin or Excedrin P.M. will relieve tension unless Young & Rubicam possesses a reasonable basis for such a claim. Respondent argues that since the ALJ found that Young & Rubicam did possess a reasonable basis for the tension relief claims which it made (I.D. 256), the order provision is inappropriate. The facts regarding this order provision are identical to the facts regarding order paragraph IV B discussed above (*supra* pp. 61–62) and for the same reasons we dismiss paragraph V A.

Young & Rubicam's final objection is to order paragraphs V B and V C. (Young & Rubicam Appeal Brief pp. 10–12) These provisions would prohibit Young & Rubicam from referring to aspirin by any name other than aspirin and would require advertisements to disclose that Excedrin and Excedrin P.M. contain aspirin. Young & Rubicam argues that these provisions are not appropriate unless it can be shown that respondent knew or had reason to know that: (1) aspirin

is a health hazard; (2) consumers are unaware that Excedrin and Excedrin P.M. contain aspirin; and (3) the presence of aspirin constitutes a material fact, the knowledge of which is likely to affect consumers' purchasing decisions. Further, Young & Rubicam argues that since it reasonably relied on substantiation provided by Bristol-Myers regarding Excedrin's safety, it cannot be shown that it knew or had reason to know that aspirin is a health hazard.

We are unable to agree with Young & Rubicam's formulation of the law. First, no ad for Excedrin discloses the presence of aspirin and several ads actually create the impression that Excedrin does not contain aspirin. (*See supra* pp. 51–52) Second, as we explained in our discussion of the liability of Ted Bates, Inc., it is only necessary for complaint counsel to show that respondent Young & Rubicam knew or had reason to know that the presence of aspirin in Excedrin constituted a material fact (*supra* p. 62). That respondent had, or should have had such knowledge as demonstrated by the advertising campaign it created for Excedrin, a campaign based upon ads which create the impression that Excedrin does not contain aspirin. For this reason, we have entered order provisions similar to Paragraphs V B and C of the ALJ's order. **[66]**

VIII. RELIEF

The order which we enter in this case proscribes the violations committed by the three respondents and also encompasses related violations, the prohibition of which we believe is necessary in order to prevent respondents from violating the law in the future. *FTC* v. *Ruberoid Co.,* 343 U.S. 470, 473 (1952); *American Home Products,* 98 F.T.C. at 398. This order diverges substantially from the order entered by the ALJ. First and foremost, the ALJ's order requires that any ad containing a comparative performance claim for an internal analgesic must either be substantiated by clinical tests or must contain a notice reflecting the lack of such substantiation. Our order imposes a clinical testing requirement only for those ads which claim that the analgesic's comparative superiority has been scientifically established. Second, the ALJ's order imposes a reasonable basis requirement on all efficacy or side effects claims respondent makes regarding *any* OTC drug. We have limited this provision so that it applies only to analgesics. Third, our order narrows the scope of the aspirin disclosure requirement imposed by the ALJ, limiting the disclosure of the presence of aspirin to those ads for analgesics which contrast the product with other aspirin-containing products. Also, our order does not cover labeling but is limited to advertising claims.

The order we have entered also requires Bristol-Myers to cease representing that common ingredients are unusual or special and to

cease representing that any group recommends a product unless respondent possesses a reasonable basis for such claim.

With respect to the advertising agencies, the order will prohibit both Ted Bates & Company and Young & Rubicam, Inc. from representing that any nonprescription internal analgesic contains an unusual or special ingredient when such is not the case. This is an expansion of the ALJ's order, which only imposed the requirement on ads for Bufferin, Excedrin, and Excedrin P.M. In addition, both agencies are required to disclose in advertisements contrasting analgesics with aspirin that the product contains aspirin. Finally, Ted Bates will be prohibited from representing that any group endorses an analgesic unless it possesses a reasonable basis for making the claim.

A. *Establishment Claims*

Part I of the order sets forth the level of substantiation which Bristol-Myers must possess before it can advertise [67] that the superior effectiveness or freedom from side effects of a nonprescription internal analgesic product has been established. Specifically, these ads must be substantiated by two adequate well-controlled clinical studies. The criteria for such studies are specified in Paragraphs A-C of Part I of the order; they represent the criteria which the record shows that the relevant expert community requires to establish a claim of superior performance or superior freedom from side effects (*supra* pp. 19–28).[93] Paragraph D of Part I provides that failure to comply with each and every specification of Part I will not result in a violation if Bristol-Myers can show that the substantiation it possesses would still be generally recognized by the scientific community as sufficient evidence to establish the truth of the claims. The purpose of this provision is to avoid penalizing Bristol-Myers for purely technical instances of noncompliance with the detailed provisions of Part I, if it can show that the scientific community would not regard the technical violations as affecting the measure of support for the claims provided by the tests.

Our decision in this case also explains in some detail which advertisements will trigger the clinical testing requirement. In brief, advertisements that claim the product's superiority has been proven or established or which create that impression through the use of visual aids and language must be substantiated by well-controlled clinical tests.[94]

This order applies the clinical testing requirement to establishment claims made by Bristol-Myers for any nonprescription internal

[93] We applied the same testing requirement in the order which we entered against *American Home Products Corp.*, 98 F.T.C. 136, 424–425.

[94] *See supra* pp. 18–19.

analgesic product. Complaint counsel have argued that this requirement should apply not only to establishment claims promoting analgesics, but also to establishment claims made by Bristol-Myers for any nonprescription drug. (CAB pp. 41–48) We reject complaint counsel's argument and we decline to extend the reach of this order provision beyond nonprescription internal analgesics. As we held in *American Home Products,* 98 F.T.C. at 402–403, it is possible that establishment claims for other drug products may be [68] substantiated by other than two well-controlled clinical tests. On this point we find no reason to alter the decision we reached in *American Home Products.*

However, we do believe that this provision of the order should not be restricted merely to establishment claims for Bufferin and Excedrin. The appropriate breadth of this portion of the order is dependent upon a determination of the likelihood that the practices will be repeated. Factors that may be considered are the extent of the current violation, the transferability of the practice to other contexts, and whether the respondent has a past history of violations. *American Home Products,* 98 F.T.C. at 401; *see Sears, Roebuck and Co.* v. *F.T.C.,* 676 F.2d 385, 391–392 (9th Cir. 1982). But in the final analysis, we must look to the circumstances as a whole and not to the presence or absence of any single factor.

First, respondent's current violations were widely disseminated over several years on radio and television and in magazines at a cost of millions of dollars per year (F. 5).[95] Second, as we indicated in *American Home Products,* 98 F.T.C. at 401, it would be a simple matter for a manufacturer of analgesics to make inadequately substantiated establishment claims regarding other analgesics. Indeed, the prevention of this sort of transfer of an unfair trade practice is a proper goal of the Commission's remedial work. *Sears, Roebuck and Co.* v. *F.T.C.,* 676 F.2d at 394.

Respondent Bristol-Myers has an extensive history of dealings with the FTC which include the entry of three litigated orders[96] and the acceptance of seven stipulations[97] [69] based upon false and deceptive advertisements. The first two litigated orders applied only to the

[95] In *F.T.C. v. Colgate-Palmolive Co.,* 380 U.S. 374 (1965), an all products order was upheld based upon three different commercials produced by the respondent all of which employed the same deceptive practice.

[96] *Bristol-Myers Co.,* 36 F.T.C. 707 (1943) (false and deceptive advertising claims regarding the laxative "Sal Hepatica"); *Bristol-Myers Co.,* 46 F.T.C. 162 (1949), *aff'd* 185 F.2d 58 (4th Cir. 1950) (false therapeutic claim for "Ipana" toothpaste and false claim that dentists recommend it); *Grove Laboratories, Inc.,* 71 F.T.C. 822 (1967), *rev'd in part,* 418 F.2d 489 (5th Cir. 1969) (false and deceptive advertisements regarding "Pazo Formula" a hemorrhoid preparation).

[97] 24 F.T.C. 1546 (1937) (health claims regarding "Vitalis" hair oil); 24 F.T.C. 1554 (1937) (health claims regarding "Ipana" toothpaste); 24 F.T.C. 1558 (1937) (health claims regarding the laxative "Sal Hepatica"); 25 F.T.C. 1626 (1937) (health claims for an alleged cold remedy, "Minit-Rub"); 27 F.T.C. 1602 (1938) (false claims for "Ingram's Milkweed Cream"); 27 F.T.C. 1609 (1938) (health claims for "Ingram's Shaving Cream"); *Bristol-Myers Co.,* 47 F.T.C. 1441 (1950) (complaint dismissed and stipulation accepted regarding an alleged cold remedy, "Resistab").

specific product which had been falsely and deceptively advertised. However, in 1967 the Commission found that Bristol-Myers (through its Grove Laboratories Division) had disseminated false and deceptive advertisements regarding "Pazo Formula," a hemorrhoid preparation and we entered a two-part order, one part which applied to advertisements for any hemorrhoid preparation. We noted that:

> . . . we are convinced that we would be derelict in our responsibilities if we were to limit the prohibitions of the order against false representations solely to hemorrhoidal preparations having the same or similar ingredients. The ease with which such orders can be avoided has been amply demonstrated by the Commission's experience with this respondent alone. *Grove Laboratories, Inc.*, 71 F.T.C. 822, 847–848 (1967), *rev'd in part* 418 F.2d 489 (5th Cir. 1969).

Furthermore, in a 1968 proceeding we found that ads placed by Bristol-Myers misrepresented the freedom from side effects of Bufferin. *Bristol-Myers Co.*, 74 F.T.C. 780 (1968). We entered no order at that time but merely admonished Bristol-Myers to heed the guidance of the opinion and to avoid disseminating misleading advertisements. Given this history and the facts of this case, we believe that the order provisions should fully address the kinds of claims and products at issue here. Although we are in no position to extend the requirement that establishment claims be substantiated by two well-controlled clinical studies to all drugs, it is entirely reasonable to extend the order to establishment claims made for all nonprescription internal analgesics.

Respondent Bristol-Myers argues that the requirements of Part I of the order would unconstitutionally abridge its First Amendment free speech rights. It contends that the substantiation requirement may "chill" protected truthful speech. (R.A.B. p. 12, 14, 69–74) However, the Supreme Court has made it clear that the First Amendment does not protect false advertising. *Va. State Board of Pharmacy* v. *Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976). Since we have found that respondent falsely represented that the superiority of its products had been established, there is no constitutional impediment to an order provision prohibiting such false advertising in the future.

Respondent argues that *Friedman* v. *Rogers*, 440 U.S. 1 (1979), prevents imposition of a substantiation requirement. **[70]** It argues that *Friedman* would protect from regulation truthful advertising. (R.A.B. pp. 66–70) We are unable to agree with Bristol-Myers' interpretation of that case. *Friedman* upheld against constitutional challenge a total ban on the use of trade names by optometrists. Although the Court pointed out that truthful commercial speech, such as price advertising by pharmacists, was entitled to constitutional protection, it

stressed that "much commercial speech is not provably false, or even wholly false, but only deceptive or misleading. We foresee no obstacle to a State's dealing effectively with this problem." *Friedman,* at 9–10. The substantiation which we require in Parts I and II of this order is a constitutionally appropriate remedy designed to curtail Bristol-Myers' false and deceptive ads. Indeed, a reasonable substantiation requirement fosters rather than impairs First Amendment objectives because it helps 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. 1979), *cert. denied* 444 U.S. 980 (1979). Thus, we see no constitutional bar to these parts or to any other part of the order we enter today.

B. *Reasonable Basis Provision*

Paragraph II of our order requires respondent to possess a reasonable basis for all therapeutic performance and freedom from side effects claims regarding OTC internal analgesics. In those instances in which Bristol-Myers represents that such claims have been established, paragraph I of this order applies. However, in those instances in which respondent makes a "non-establishment" performance or side effects claim, this provision of the order imposes on respondent the more general reasonable basis standard of substantiation.

The order entered by the ALJ would have imposed a similar requirement for claims regarding *any* OTC drug. While we are not willing to go this far, we believe that a reasonable basis requirement is appropriate for all future OTC analgesic claims. Most of the claims in this case were establishment claims and we found that Bristol-Myers did not possess adequate substantiation for any of these claims.[98] Our concern is that this violation, the making of inadequately substantiated claims, can easily be transferred to other sorts of claims, including non-establishment claims. In addition, the number and frequency of such violations, combined with the other factors (such as the history of past violations) discussed in the previous section, make it clear that order Paragraph II represents a fencing-in requirement that is reasonably related to the violations. [71]

Moreover, some of the claims in this case were in fact judged under the "reasonable basis" standard (because they were not embellished with establishment representation), and respondent's evidence was again found wanting. At least 11 of respondent's ads represented that Bufferin relieves tension, and another ten ads made similar claims for Excedrin.[99] These violations alone could well justify a reasonable basis requirement extending to all products or all claims. *See, e.g.,*

[98] Even if respondent had not represented that its claims had been scientifically established, we might still have found that respondent lacked a reasonable basis for many of the claims. For example, respondent produced no evidence at all in support of its claim that Bufferin would not upset a user's stomach.

[99] *See supra* pp. 44–46.

F.T.C. v. *Colgate-Palmolive Co.*, 380 U.S. 374; *National Dynamics Corp.* v. *F.T.C.*, 492 F.2d 1333; *Sears, Roebuck & Co.* v. *F.T.C.*, 676 F.2d 385. Instead, we have limited the reasonable basis requirement here to therapeutic performance and freedom from side effects claims for OTC analegics—*i.e.*, to the exact kinds of claims and products that were involved in this case.

Paragraph II thus has a much closer relation to the violations than did the reasonable basis provision that was deleted on appeal in *American Home Products* v. *F.T.C.*, 695 F.2d at 710–711. That provision was much broader in its product coverage, applying to all nonprescription drugs manufactured by American Home Products, including such products as topical anesthetics, antacid powders, hemorrhoid preparations, wart removers, denture cleansers, medicated shampoos, acne medications, corn removers, depilatories and breath fresheners. By contrast, Paragraph II of this order applies only to Bristol-Myers' OTC internal analgesics, the exact type of product involved in this case. According to information submitted by respondent to the 1982 edition of the *Physicians' Desk Reference*, respondent makes only 10 different OTC internal analgesics.

In general, the amount of substantiation necessary to constitute a reasonable basis must be determined case-by-case. In part for that reason, and in part because we did not evaluate all of the claims in this case under a reasonable basis standard, the order does not describe in detail the amount and kinds of evidence necessary to constitute a reasonable basis for Bristol-Myers' future claims. It is clear, however, that two well-controlled clinical tests, the amount of evidence necessary to establish a claim, would constitute a reasonable basis for any therapeutic performance or side effects claim. Thus, Paragraph II states that that amount of evidence will be deemed to provide a reasonable basis for such claims.

Whether any lesser amount of evidence could also constitute a reasonable basis is more difficult to determine. The experts **[72]** who testified in this case indicated that the scientific community requires two well-controlled clinical tests to evaluate therapeutic claims. Thus, even if some lesser amount of evidence were appropriate for non-establishment claims, it is difficult to see where that level could possibly be set. Nonet less, we cannot rule out the possibility that other types of evidence might be adequate on the record before us in this case.[100] Accordingly, order Paragraph II does permit respondent to substantiate its claims with evidence other than two clinical tests if

[100] A different standard of evidence might be appropriate for different types of claims. For example, in some situations the FDA will permit a drug to be marketed without clinical testing if non-clinical tests show the drug to be as effective as another drug whose effectiveness has already been established by clinical tests. *See* 45 FR 77807–08 (1980). However, this non-clinical evidence is used to show that the drugs are equivalent, not that one is superior to another.

it can show that such evidence is sufficiently reliable to support a good faith belief in the truth of the claim. Such a showing must be based on the factors set forth in the *Pfizer* line of cases—the nature of the claim, the degree of consumer reliance on the claim, the consequence to consumers if the claim is, in fact, false, and the accessibility of various types of evidence.

Concededly, permitting such a showing creates some ambiguity regarding the absolute minimum amount of evidence necessary to provide a reasonable basis for respondent's future claims. But this is inherent in any reasonable basis order by virtue of the factors set forth in *Pfizer*. As we noted in that case, the reasonable basis standard can only be determined on a case-by-case basis. 81 F.T.C. at 64. Indeed, it is settled that Commission orders are required only to be "as specific as the circumstances permit," *F.T.C.* v. *Colgate-Palmolive Co.*, and courts have upheld reasonable basis requirements, including those in orders having broader coverage than this one. *E.g., Sears, Roebuck and Co.*

In fact, in this case there are several methods whereby Bristol-Myers can resolve uncertainty regarding the level of substantiation required by the order. First, it can be assured of compliance with the order by conducting two well-controlled clinical tests as described in Paragraph I. Second, pursuant to Rule 2.41(d) of the Commission's Rules of Practice, Bristol-Myers may seek an advisory opinion from the Commission. Third, even if Bristol-Myers does not possess adequate support to constitute a reasonable basis for a broad, unqualified claim, it may still make the claim by carefully qualifying it so that it discloses the level of support actually possessed. As we have indicated in numerous cases, we require advertisers [**73**] to possess a reasonable basis for their claims because that is what consumers expect and they will be deceived if that level of support does not exist. *See, e.g., Porter & Dietsch, Inc.*, 90 F.T.C. 770; *National Dynamics Corp.*, 82 F.T.C. 488. This deception can be avoided if the ad is properly qualified so that consumers know the nature and limitations of the support the advertiser actually possesses for the claim.

For the above reasons, we believe that the relief provided by Paragraph II is directly related to Bristol-Myers' violations and that it adequately balances the goals of preventing future violations and providing Bristol-Myers with notice as to what conduct is prohibited.

C. *Ingredient Claims and Omissions*

As we explained above, Bristol-Myers' advertisements falsely represent that "Bufferin" and "Excedrin" contain special or unusual ingredients. (*Supra* pp. 49–52) Under Part III A of the order, Bristol-Myers may not represent that a product contains any special

or unusual ingredient when that ingredient is commonly used in other nonprescription drug products for the same purpose. To determine the scope of this section of the order, we have applied the same considerations discussed in connection with Part I and Part II. The violations in this case are extensive and respondent Bristol-Myers has a history of past dealings with the Commission. These facts justify broad coverage. Furthermore, the practice of falsely representing that ingredients are unusual could easily be applied to other drug products. Indeed, two of the stipulations entered in the past by Bristol-Myers required it to cease and desist from representing that its drugs contained unusual ingredients. In the first of these stipulations, Bristol-Myers agreed to cease and desist representing that the cold remedy "Minit-Rub" was a special analgesic or contained drugs other than those commonly used in analgesics. 25 F.T.C. 1626 (1937). The second stipulation required Bristol-Myers to cease representing that a facial cream, "Ingram's Milkweed Cream," contained special ingredients not found in other creams. 27 F.T.C. 1602 (1938). For these reasons, Part III A of the order applies to advertising for any nonprescription drug product.

Part IV of the order differs substantially from Part III A. The latter provision prohibits respondent from falsely representing that its analgesics contain special or unusual ingredients. The purpose of the paragraph IV is to prevent respondent from passing off its aspirin-based analgesic products as being different [74] from aspirin or from otherwise misrepresenting the identity of any analgesic ingredient. The principal means by which this deception has been accomplished in the past has been to contrast some unspecified analgesic ingredient in respondent's product with aspirin, or with the ingredient in a competing aspirin-based analgesic. Such a contrast inevitably implies that the unidentified analgesic ingredient in the first product is different from aspirin. To prevent this practice, paragraph IV prohibits any misrepresentation that the analgesic ingredient in an aspirin-containing product is different from aspirin. To prevent closely related violations, the order prohibits misrepresentations regarding the identity of any analgesic ingredient in respondent's products. The order also makes clear that any attempt to contrast the ingredient in an aspirin-based analgesic without disclosing that the ingredient in respondent's product is aspirin will violate the order.

This aspirin disclosure requirement differs from the comparable provision in the order entered by the ALJ which would have required this disclosure in any ad for an aspirin-based analgesic. We are unprepared to state on the basis of the record in this case that the mere failure to disclose the presence of aspirin in an advertisement for an analgesic is an unfair or deceptive practice. However, respondent

Bristol-Myers' advertising was deceptive because it contrasted its own aspirin-based analgesics with other aspirin-based products without disclosing the presence of aspirin in its products. This created the false impression that the analgesics advertised did not contain aspirin. The disclosure required by this part of the order will prevent this deceptive sort of comparison. Indeed, it is possible that without a provision such as this one, respondent would devise new ways to capitalize on the public's ignorance of the ingredients in Bufferin and Excedrin. *See American Home Products* v. *F.T.C.,* 695 F.2d at 712.

D. *"Doctors Recommend" and Tension Relief Claims*

Part III B of the order is necessary in light of our finding that Bristol-Myers falsely represented that doctors recommend Bufferin more than any other nonprescription internal analgesic. It will prohibit Bristol-Myers from representing that any group recommends any nonprescription drug product unless Bristol-Myers possesses a reasonable basis for making such a claim. This order provision applies to any nonprescription drug product because this sort of representation easily could be made about any product and [**75**] respondent has made similar representations in the past regarding toothpaste.[101]

E. *Corrective Advertising*

Corrective advertising is a remedy available to the Commission to correct misleading impressions created by previous advertising. *Warner-Lambert Co.* v. *F.T.C.,* 562 F.2d 749, 756–759 (D.C. Cir. 1977), *cert. denied,* 435 U.S. 950 (1978). Two inquiries must be made in order to determine if the remedy is appropriate: (1) did the advertisements in question play a substantial role in creating or reinforcing a false belief in the public's mind regarding the product; and (2) will the belief remain after the advertising ceases? *Warner-Lambert Co.* v. *F.T.C.,* Id. at 762. Complaint counsel devote a substantial portion of their appeal brief to a request that we include a corrective advertising requirement in the order which we enter against Bristol-Myers. (CAB pp. 12–39) They argue that absent such relief, consumers will continue to believe that Bufferin's and Excedrin's comparative superiority have been established. The ALJ was unwilling to conclude that consumers have an image of *established* superiority for Bufferin and Excedrin. (I.D. p. 251) However, complaint counsel contend that this image may be inferred from the challenged advertisements or from consumers' expectations regarding the substantiation which an advertiser should possess prior to comparing one analgesic to another.

[101] Bristol-Myers agreed in a stipulation to cease representing that dentists usually prescribe "Ipana" toothpaste to patients with gum disorders. 24 F.T.C. 1554 (1937). In a subsequent litigated order, Bristol-Myers was required to cease representing that more dentists recommend "Ipana" than any other two toothpastes combined. *Bristol-Myers Co.,* 46 F.T.C. 162 (1949).

They also contend that the presence of the image is demonstrated by consumer research in the record.

It is our conclusion that corrective advertising is not a proper remedy in this case. Although we have found that numerous ads do represent that Excedrin's and Bufferin's superiority have been established, we decline to infer that that image will persist. While the record does demonstrate that the public has held the belief that Bufferin and Excedrin are superior to aspirin (F. 757), there is no evidence that consumers will retain an image that this superiority has been established. Finally, we will not infer that the public will retain an image of *established* superiority from the fact that it currently has an image of Bufferin's and Excedrin's superiority. As we explained above (*supra* pp. 40–41), we [**76**] are unwilling to conclude that consumers believe that advertisers possess the degree of substantiation for every comparative performance claim which would satisfy relevant experts.[102] Indeed, we have reached no conclusion as to whether Bristol-Myers did or did not possess a reasonable basis for its comparative performance claims. Thus, we cannot infer from the record that an establishment image will persist and, therefore, corrective advertising is an inappropriate remedy.

F. *Labeling*

The order entered by the ALJ would apply not only to respondents' advertising, but also to the labeling for its products. As we stated in *American Home Products,* 98 F.T.C. at 411, our liaison agreement with the FDA recognizes that primary responsibility for the labeling of nonprescription drugs rests with it. For the reasons set forth in that opinion, the order which we enter does not apply to labeling.

G. *Advertising Agencies*

The extent of the liability of Ted Bates & Company, Inc., and Young & Rubicam, Inc., has been discussed above (*supra* pp. 58–65), and we have entered appropriate order provisions regarding the two advertising agencies. The order prohibits both agencies from falsely representing that an advertised analgesic contains an unusual or special ingredient and requires both agencies to disclose presence of aspirin in an analgesic when an ad contrasts the product's analgesic ingredients with aspirin. In addition, Ted Bates may not represent that any

[102] *Compare Warner-Lambert Co. v. F.T.C.* in which survey evidence showed that consumers would retain a false image regarding Listerine. 562 F.2d at 762. We note that survey evidence is only one factor to be considered in determining whether corrective advertising is appropriate in a particular case. Other factors to be considered are the amount of exposure consumers have had to the false claim, the persuasive characteristics of the claim, the manner in which the claim is presented, and the nature of the audience. Even considering all of these factors, we do not think corrective advertising is appropriate in this case.

group endorses a product unless it has a reasonable basis for the representation. [77]

The order provisions regarding the advertising agencies apply to ads for any nonprescription internal analgesic. The deceptive practices employed by the respondents could easily be used in advertisements for other analgesics. It is, therefore, essential that we enter an order which will prevent this. *ITT Continental Baking Co., Inc.* v. *F.T.C.*, 532 F.2d at 222. In addition, respondent's violations were not isolated instances but were the basis of extensive advertising campaigns. For these reasons, our order applies to ads for all analgesics.[103]

IX. CONCLUSION

For the reasons set forth above, the initial decision of the administrative law judge is modified as described. An appropriate order is appended.

CONCURRING STATEMENT OF CHAIRMAN MILLER*

I concur with the decisions reached by the majority in these two cases and wish to compliment Commissioner Clanton for his thorough review of the records and for his insightful commentary. But while joining in the majority decisions, I wish to note three caveats.

First, although I agree with the outcomes of these cases, including the individual charges of liability, I do not necessarily agree with each and every argument that is advanced. This is, of course, an occupational hazard. Majority decisions are inherently "consensus documents" and should be read with that in mind.

Second, in a particular application of the point just made, I take issue with the majority's differentiating between an "establishment claim theory" and a "reasonable basis theory." To me, the overarching goal of our law enforcement efforts in this area is to encourage truthful advertising; specifically, to eliminate unfairness and deception. The Commission's celebrated, and controversial, reasonable basis standard, first enunciated in *Pfizer* over a decade ago, is a useful tool for the Commission in achieving that end. I am troubled by any communication, such as that implicit in these opinions, that the Commission will apply one standard (*i.e.*, reasonable basis) in cases generally, and another standard (*e.g.*, establishment claim) in specific [2] situations. Rather, I would encourage the Commission to consider

[103] In addition, twice in the past Ted Bates has had litigated cease and desist orders entered against it. *ITT Continental Baking Co., Inc.*, 83 F.T.C. 865, (misrepresentations regarding the extent to which Wonder Bread contributes to growth); *Colgate-Palmolive Co.*, 59 F.T.C. 1452 (1961), *remanded* 310 F.2d 89 (1st Cir. 1962), *remanded* 326 F.2d 517 (1st Cir. 1963), *rev'd reinstating Commission's order*, 380 U.S. 374 (1965) (use of mock-ups to falsely prove the quality of shaving cream).

* Chairman Miller's Concurring Statement also applies to *Sterling Drug Inc., et al.*, (Dkt. 8919) 102 F.T.C. 395.

whether the reasonable basis test, or some variant of it, were not the appropriate standard for universal application, thus reducing uncertainty in the private sector and, possibly, avoiding double jeopardy.

Third, because of the importance of these cases it would have been desirable to have the benefits of the Commission's review of its ad substantiation program, as well as the staff's efforts to develop a protocol defining deception, before these cases were made final. However, I am well aware that both cases are over a decade old and agree with the adage, "Justice delayed is justice denied." Thus, I believe that expeditious treatment of these opinions wins out in any weighing of the equities. This is not to say, of course, that in the future the Commission should not articulate a somewhat different, more comprehensive, standard for claims of these types.

SEPARATE STATEMENT OF COMMISSIONER PERTSCHUK CONCURRING IN PART AND DISSENTING IN PART

I concur with most of the Commission's Opinion and Order. For the reasons discussed below, however, I cannot join with the majority's decision to reverse the "substantial question" doctrine announced so recently in *American Home Products Corporation,* 98 F.T.C. 136 (1981), *aff'd,* 695 F.2d 681 (3d Cir. 1982). Accordingly, I dissent from the Commission's decision to dismiss paragraphs 9 through 11 and 14 through 16 of the complaint.

Together with our opinion in *Sterling Drug, Inc.* (D. 8919), also announced today [102 F.T.C. 395], these three cases represent the culmination of a decade-long attempt to curb allegedly deceptive advertising in the multi-million dollar over-the-counter ("OTC") aspirin-based pain reliever market. That deception, now documented by three lengthy adjudicative records, has stemmed from a marketing strategy, adopted by each of the major makers of pain relievers named in these cases, to portray *their* particular pain reliever as being different and more effective than any other, including plain aspirin. Unfortunately, such a strategy is at its heart deceptive, since the most assiduous efforts of company counsel in each of these three cases have failed to unearth conclusive evidence that any one aspirin-based product is in fact any better than any other in doing what people buy analgesics for—relieving pain. As a result, the claims made by these leading makers that there are differences in effectiveness among aspirin-based pain relievers have largely been a fraud on the American public.

In *American Home Products,* the Commission found unequivocal claims of analgesic superiority made by American Home Products ("AHP") for Anacin to be deceptive. There, we required AHP to re-

frain from such claims unless it either proved through two well-controlled clinical tests that in fact Anacin was more effective in relieving pain, or else disclosed that there was a "substantial question" about the claim.

The analysis used to reach that decision was straightforward. First, the Commission considered the context in which consumers are exposed to claims for OTC pain relievers. Taking notice of the public's concern with the special health risks associated with therapeutic drug products, the inability of the public to verify objectively the consequences of therapeutic drug use, and the reasonable consumer expectation that the marketing of drug products claims is carefully regulated by the government, the Commission held that: [2]

> when an advertiser has made unequivocal, unqualified claims about a drug product's effects . . . 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. *American Home Products, supra,* at 386.

The Commission then determined that the scientific community considers one analgesic drug to be more effective than another only when its superiority is demonstrated by two well-controlled clinical tests. *Id.* at 373–381. In the absence of such supporting evidence, the scientific community would view any such claim as being open to doubt. Since AHP had no such tests to support its claims, and therefore did not possess the level of proof consumers reasonably would expect, the Commission held that it was deceptive for AHP to claim that Anacin was more effective than other OTC internal analgesic drug products, without qualifying the claim by disclosing that there was a substantial question about its validity. The Commission's findings, analysis, and order addressing this problem were affirmed by the Third Circuit in a well-reasoned and scholarly opinion. *American Home Products* v. *FTC,* 695 F.2d 681 (3d Cir. 1982)[1]

The majority in today's opinion retreats from the "substantial question" principle established in *American Home Products.* In doing so, the majority argues that the substantial question analysis eliminates any difference between "establishment claims" (claims which refer to scientific proof), and "superior efficacy claims" (claims which do not refer to any type or quality of proof). The majority rejects the assumption made by the Commission in *American Home Products* that an unequivocal superior efficacy claim could reasonably lead consumers to believe that it was supported by scientific proof. In the majority's view, the difficulty with that assumption is that "there has never been

[1] The Third Circuit reversed one subparagraph portion of the Commission's Order which is not relevant here.

any evidence to confirm this somewhat counterintuitive reading of consumer expectations." Slip op. at 40.

The absence of extrinsic evidence about consumer expectations has never barred the Commission from making informed, considered judgments about what consumers could reasonably be expected to believe about a given claim. As the courts have recognized, "[d]etermining whether an advertisement is deceptive draws upon the FTC's familiarity with the public's expectations." *Litton Indus., Inc.* v. *FTC,* 676 F.2d 364, 369 (9th Cir. 1982). Indeed, underlying the "reasonable basis" doctrine itself is the fundamental proposition that "consumers are likely to assume that when a product claim is advanced which is in theory subject to objective verification, the party making it possesses a reasonable [3] basis for so doing, and that the assertion does not constitute mere surmise or wishful thinking on the advertiser's part." *Nat'l Commission on Egg Nutrition,* 88 F.T.C. 89, 193 (1976), *modified,* 570 F.2d 157 (7th Cir. 1977), *cert. denied,* 439 U.S. 821 (1978). Absent any reference in a claim to the evidence on which the claim is based, the Commission routinely assumes that consumers expect advertisers to possess and rely upon whatever type of evidence is appropriate to substantiate the claim. It does not require extrinsic evidence of those expectations, although such evidence, if produced, will be considered. *See, e.g., Fedders Corp.,* 85 F.T.C. 38 (1975), *aff'd,* 529 F.2d 1398 (2d Cir.), *cert. denied,* 429 U.S. 818 (1976); *Sears, Roebuck & Co.,* 95 F.T.C. 406 (1980), *aff'd,* 676 F.2d 385 (9th Cir. 1982); *Jay Norris,* 91 F.T.C. 751 (1978), *modified,* 598 F.2d 1244 (2d Cir.), *cert. denied,* 444 U.S. 980 (1979).

If it is reasonable to find without extrinsic evidence proof that consumers expect claims to be supported by evidence sufficient to substantiate the claim, it seems hardly "counterintuitive" to find similarly that consumers expect claims comparing the medical benefits of various drugs to be supported by appropriate scientific evidence. In affirming the Commission's decision in *American Home Products,* the Third Circuit upheld that assumption, noting:

> Of course the Commission is not committed to the unrealistic notion that consumers understand the clinical details of comparative drug testing or the exact mechanisms of government regulation. It merely asserts that consumers reasonably assume that the proper governmental authorities will take steps to ensure that unqualified claims of a drug's superiority are supported by whatever proof the appropriate medical or scientific experts consider sufficient. *American Home Products* v. *FTC,* 695 F.2d 681, 698 (footnotes omitted).

Indeed, the Commission's analysis of the "establishment" claims in the instant case rests on an assumption about consumer expectations scarcely distinguishable from that made by the Commission in *American Home Products.* No proof was offered in these cases that consum-

ers understand a mere reference to a scientific test or a computer print-out to mean the claim has been established as scientific fact to the satisfaction of the relevant scientific community. Nevertheless, the Commission today assumes that consumers could reasonably be led to believe from direct and indirect references to a scientific study in ads for Bufferin and Excedrin that "the scientific community regards Bufferin and Excedrin to be superior." Slip op. at 19. The only justification for this assumption is the observation that "[w]here scientific evidence is cited in support of a claim, absent some explicit qualification it is unlikely that consumers would [4] interpret such evidence narrowly to provide proof for only a limited portion of the claim." *Sterling Drug, supra,* slip op. at 13, note. [102 F.T.C. at 755]

It appears, then, that the Commission is willing to make assumptions about consumer expectations which are certainly as reasonable as the assumption that consumers expect therapeutic efficacy claims for drugs to be scientifically supported. The majority's concern about *American Home Products* therefore seems to stem not so much from the "unreasonableness" of the assumption made there as from a concern about the scope of that theory. In the majority's view, the same factors cited by the Commission in *American Home Products* in support of the assumption that consumers reasonably expect superior therapeutic efficacy claims to be backed by scientific proof would exist with respect to *any* drug performance claim. As a result, application of that assumption, according to the majority, would necessarily lead the Commission to require all drug performance claims to be backed by two well-controlled clinical tests.

While the Commission's opinion in *American Home Products* was carefully limited to the facts in that case,[2] I believe it is entirely appropriate for the Commission to assume consumers generally expect therapeutic efficacy claims for drugs to be supported by scientific fact. In an age when consumers are told that drugs are constantly monitored by the government and industry through careful scientific tests for safety and efficacy, consumers quite reasonably expect drug products to provide the therapeutic benefits claimed for them. This belief is particularly justified because consumers are frequently unable to determine the therapeutic value of a drug for themselves by simply using it. They do not expect such claims to be based on hunches, or on informed guesses, or on untested scientific theories, but on accepted scientific fact.

While the Commission's rationale for adopting the substantial question doctrine in *American Home Products* is, at least in my view, applicable generally to any therapeutic efficacy claim for an OTC drug, it does *not* follow—as the majority implies—that all such claims must be supported by the strict two well-controlled clinical test stan-

[2] *See, American Home Products* v. *FTC, supra,* 695 F.2d at 701.

dard which the Commission adopted in *American Home Products.* As the majority recognizes, the Commission does not depend on consumer expectations to determine precisely what type of evidence is necessary to substantiate a given claim. Slip op. at 41. Determining the appropriate level of evidence is essentially a factual inquiry, one which must weigh a number of considerations and which can only be determined on a case-by-case basis. [5] *Pfizer, Inc.,* 81 F.T.C. 23, 64 (1972). Consequently, we might find from the facts in a different case that a level of proof less than the two well-controlled clinical test standard would be appropriate for other types of drug product therapeutic efficacy claims.

The majority's decision, unfortunately, may leave unsolved the central problem that our trilogy of analgesics cases was designed to address—the profusion of mutually inconsistent claims by analgesic makers that each produces the most effective pain reliever. By refusing to extend the "substantial question" doctrine to these cases, the Commission creates unnecessary uncertainty about what evidence each maker has to possess to claim that its product is the best pain reliever. Under today's order, the makers must substantiate such claims with "competent and reliable scientific evidence." While the opinion makes clear that two well-controlled clinical tests suffice to meet that standard, and suggests further that such tests may well be the *only* data which could meet such a standard, the opinion expressly leaves open the question whether evidence short of such tests would be sufficient. (Slip op. at 71–72) That uncertainty creates a potential for Bristol-Myers to claim that Excedrin is more effective than Anacin or Bayer aspirin, and for Sterling Drug to claim that Bayer aspirin is more effective than Excedrin or Anacin. And American Home Products, should the substantial question provisions of the order against it be modified, in fairness, to conform to the Commission's order here, may be able to claim that Anacin is more effective than Bayer aspirin or Excedrin. Purely as a matter of logic, only one of these advertisers can possibly be telling the truth. And the chances are that *none* is—because the evidence in these three cases suggests that there is probably no clinically significant difference among any of these products.

SEPARATE STATEMENT OF COMMISSIONER PATRICIA P. BAILEY CONCURRING IN PART AND DISSENTING IN PART*

The Commission today has issued the last two opinions in a three-

* Commissioner Bailey's Separate Statement also applies to *Sterling Drug Inc., et al,* (Dkt. 8919) 102 F.T.C. 395.

part series of cases challenging the national advertising of several major over-the-counter (OTC) analgesics products. In both cases, I concur in the majority's findings of liability, as far as they go. However, because portions of the Commission's *American Home Products*[1] decision are overturned by the decisions issued today, I must register my dissent from those aspects of *Bristol Myers* and *Sterling* which are inconsistent with the holdings in *American Home Products.*

In that earlier opinion, the Commission concluded that any claim that Anacin was more effective than any other OTC analgesic implied that such a claim was "established" by evidence generally acceptable to the scientific community. Therefore, we decided, it was deceptive to make such a claim unless the advertiser possessed adequate substantiation for it. Having ruled in that opinion (and in these) that an "establishment" claim requires substantiation by two competent and reliable clinical tests, the same substantiation level was required in *American Home Products* when comparative performance claims were made. Absent possessing such substantiation, the advertiser would have to disclose the existence of a "substantial question" as to the comparative effectiveness claim. [2]

In these two opinions today, the Commission reaffirms its decision in *American Home Products* that an "establishment" claim requires substantiation by two competent and reliable clinical tests. But the majority here decides that this two-test substantiation requirement will not be triggered by "establishment" implications inherent in a comparative performance claim. Instead, these opinions hold that the two-test requirement will only be triggered when the advertiser makes affirmative express or implied claims that its product's effectiveness has been "established".

I disagree with the majority's limitation of the establishment theory in this way and dissent from its decision to dismiss those portions of the complaint in these two cases which depend on the original theory articulated in *American Home Products.* As the Third Circuit stated in upholding the Commission's decision in *American Home Products:*

> Pervasive government regulation of drugs, and consumer expectations about such regulation, lend drug claims all the more power to mislead. The Commission's reasoning on this point. . . . is similar to that approved in *Simeon Management Corp.* v. *FTC.* . . . The Commission in these proceedings reasonably extended the ideas approved in *Simeon* from prescription to non-prescription drugs, and from absolute representations about safety and effectiveness to comparative representations. Non-prescription as well as prescription drugs are subject to the FDA's requirements that absolute safety and efficacy be demonstrated by well-controlled clinical tests. And the Commission concluded that many consumers could reasonably believe that the federal government de-

[1] *American Home Products Corporation,* 98 F.T.C. 136 (1981), *aff'd* 695 F.2d 681 (3rd Cir. 1982).

manded similarly high standards for claims of comparative effectiveness and safety as are imposed on absolute claims. [3]

Of course the Commission is not committed to the unrealistic notion that consumers understand the clinical details of comparative drug testing or the exact mechanisms of government regulation. It merely asserts that consumers reasonably assume that the proper governmental authorities will take steps to ensure that unqualified claims of a drug's superiority are supported by whatever proof the appropriate medical or scientific experts consider sufficient.

Another consideration in favor of holding comparative effectiveness and safety claims for analgesics to high standards of substantiation is the difficulty for the average consumer to evaluate such claims through personal experience, and the consequent tenacity of advertising-induced beliefs about superiority. (emphasis in original) 695 F.2d at 697–698.

I would also note that the revised theory of liability adopted by the majority depends on the identification of express or implied establishment claims in an advertisement. The lines drawn by the majority providing guidance as to when such claims are present are exceedingly fine. Thus, the advertising industry is told that the depiction of a computer typewriter, by itself, does not constitute an establishment claim, but that the same visual, coupled with a certain kind of text, does (*Bristol Myers* Slip Op. at pgs. 10–11) [102 F.T.C. at 324–325]; that a mortar and pestle or glass figures of people with tablets crumbling in their stomachs do not communicate an establishment claim (*Sterling* Slip Op. at pg. 20, [102 F.T.C. at 760] *Bristol Myers* Slip Op. at pg. 11) [102 F.T.C. at 325], and that a pause between sentences of an otherwise questionable establishment claim may be enough to cure it of its establishment implication (*Bristol Myers* Slip Op. at pg. 12) [102 F.T.C. at 326]. At the same time, use of a visual depicting the product's [4] chemical formula can convert the claim into an establishment claim. (*Bristol Myers* Slip Op. at pg. 18) [102 F.T.C. at 331] All of this delicate line-drawing may well pose confusing problems of interpretation for those who must comply with the standards enunciated in these opinions and I hope the Commission will be able to provide necessary guidance to those who are perplexed.

Finally, I would hope some of the Commission's interpretations of particular advertisements are not carried too far and misinterpreted. In particular, while I do not disagree with Commissioner Clanton's analysis of the specific advertisements touting the superiority of the process used by Sterling in the manufacture of various Bayer aspirin products, I believe these interpretations must be carefully confined to the entire context of the advertisements in question. (*See Sterling* Slip Op. at pgs. 15 and 16). [102 F.T.C. at 756 and 757] Certainly, claims that an advertiser utilizes a special manufacturing process can often

amount to a claim of superior efficacy and it would be most unfortunate if advertisers misinterpreted the opinion to permit such deceptive representations.

CONCURRING STATEMENT OF COMMISSIONER DOUGLAS*

I concur in the Commission's finding of liability and its choice of remedies in these two matters. Commissioner Clanton's majority opinions have carefully analyzed the numerous specific claims addressed at trial. In my view, the majority opinions make a commendable effort to draw upon available evidence of consumer views in interpreting specific advertising claims. For the future, I hope the Commission will rely increasingly upon such extrinsic evidence in determining the meaning of advertisements when implied claims are at issue. The soundness of the interpretations the Commission ultimately adopts can be enhanced substantially by resort to evidence, beyond our individual and collective judgments, which suggests how consumers themselves interpret the advertisements in question.

Our experience with these cases also underscores the desirability of pleading future advertising cases more narrowly. The abundance and variety of claims raised by the complaints here appear to have hindered the expeditious adjudication of the relevant issues and encumbered the Commission's efforts to analyze the disputed claims. I expect that the Commission's ongoing examination of both its advertising substantiation program and the standards by which it identifies deception will produce important refinements in the way in which the agency pleads and decides advertising cases. This process of review and analysis [2] may yield useful adjustments in the standards the Commission employs to evaluate advertising claims. While I support the result achieved in these decisions, I do not endorse all elements of the reasoning in the majority opinions, nor do I foreclose the possibility of doctrinal changes as the Commission completes its review of its advertising enforcement program.

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

* Commissioner Douglas' Concurring Statement also applies to *Sterling Drug Inc., et al.*, (Dkt. 8919) 102 F.T.C.

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: [2]

ORDER

I

It is ordered, That Bristol-Myers Company, its successors and assigns, and its 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 "Bufferin," "Excedrin," "Excedrin P.M.," 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:

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: [3]

A. The subjects must be selected by a method that:

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

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

3. 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 test drugs.

B. 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.

C. The plan or protocol for the investigations and the report of the results shall include the following:

1. A clear statement of the objective of the investigation;

2. 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 the subject and observer;

3. 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;

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

D. A test or investigation which is not conducted in accordance with these procedures may be used to establish a claim only if respondent can show that, notwithstanding the failure to satisfy these procedures, the test or investigation would still be generally accepted by the relevant scientific community as sufficient to establish the truth of the claim. [4]

II

It is further ordered, That respondent Bristol-Myers Company, its successors and assigns, and its 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 "Bufferin," "Excedrin," or any other nonprescription internal analgesic, in or affecting commerce, as "commerce"

is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any therapeutic performance or freedom from side effects claim for such product unless respondent possesses a reasonable basis for making that claim. A reasonable basis for such a claim shall consist of competent and reliable scientific evidence supporting that claim. Well-controlled clinical tests conducted in accordance with the criteria set forth in Order Paragraph I shall be deemed to constitute a reasonable basis for a claim.

III

It is further ordered, That respondent Bristol-Myers Company, its successors and assigns, and its 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 "Bufferin," "Excedrin," "Excedrin P.M.," or any other nonprescription 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 representations, directly or by implication, that such product contains any unusual or special ingredient when such ingredient is commonly used in other nonprescription drug products intended for the same use or uses as the product advertised by respondent.

B. Representing that any group, body, or organization endorses or recommends such product unless at the time such statement or representation is made, respondent has a reasonable basis for such statement or representation.

IV

It is further ordered, That respondent Bristol-Myers Company, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device in connection with the [5] advertising, offering for sale, sale or distribution of "Bufferin," or "Excedrin," or any other nonprescription internal analgesic in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin or otherwise misrepresenting the identity of any analgesic ingredient. It shall be a violation of this paragraph to contrast the analgesic ingredient of a product which contains aspirin with the analgesic ingredient of

another product if that product also contains aspirin, unless respondent discloses clearly and conspicuously that the analgesic ingredient in its product is aspirin.

V

It is further ordered, That respondent Ted Bates & Company, Inc., a corporation, its successors and assigns, and its 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 "Bufferin" 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 such ingredient is commonly used in other nonprescription drug products intended for the same use or uses as the product advertised by respondent.

B. Falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin or otherwise misrepresenting the identity of any analgesic ingredient. It shall be a violation of this paragraph to contrast the analgesic ingredient of a product which contains aspirin with the analgesic ingredient of another product if that product also contains aspirin, unless respondent discloses clearly and conspicuously that the analgesic ingredient in its product is aspirin.

C. Representing that any group, body, or organization endorses or recommends such product unless at the time such statement or representation is made respondent has a reasonable basis for such statement or representation. [6]

VI

It is further ordered, That respondent Young & Rubicam, Inc., a corporation, its successors and assigns, and its 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 "Excedrin," "Excedrin P.M.," 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 such ingredient is commonly used in other nonprescription drug products intended for the same use or uses as the product advertised by respondent.

B. Falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin or otherwise misrepresenting the identity of any analgesic ingredient. It shall be a violation of this paragraph to contrast the analgesic ingredient of a product which contains aspirin with the analgesic ingredient of another product if that product also contains aspirin, unless respondent discloses clearly and conspicuously that the analgesic ingredient in its product is aspirin.

VII

It is further ordered, That respondents Bristol-Myers Company, Ted Bates & Company, Inc., and Young & Rubicam, Inc., shall notify the Commission at least thirty (30) days prior to any proposed change in their respective corporate respondent such as a 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.

VIII

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. [7]

Paragraphs Seven A.3, Seven A.4, Seven B.3, Seven B.4, Seven B.5, Seven B.8, Seven B.9, Seven B.10, Nine, Ten, Eleven, Twelve C, Fourteen, Fifteen, Sixteen, Twenty-Three, and Twenty-Four of the Complaint are hereby dismissed.