FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket 8917]

Bristol-Myers Co., et al.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: This order requires a New York City manufacturer of nonprescription drug products, among other things, to cease advertising that "Bufferin," "Excedrin," "Excedrin PM" or any other nonprescription internal analgesic has been proven to be safer and more effective than other pain relieving products, unless such claim has been substantiated by two well-controlled clinical tests. The manufacturer must have a reasonable basis to support claims of freedom from side effects, or any claim which represents that its pain relievers are therapeutically superior to others. The order prohibits respondents from advertising that its products contain any unusual or special ingredient, when in fact such ingredient is commonly used in similar products; or from making any claim which misrepresents the identity of a product's analgesic ingredient. The manufacturer and the Ted Bates ad agency are further barred from claiming that doctors recommend Bufferin more often than any other pain reliever, or from otherwise falsely claiming any endorsement or recommendation for their products.

DATES: Complaint issued Feb. 23, 1973. Final Order issued July 5, 1983.[1]

FOR FURTHER INFORMATION CONTACT: FTC/PA James H. Skiles, Washington, D.C. 20580. (202) 724-1507.

SUPPLEMENTARY INFORMATION: In the Matter of Bristol-Myers Company, a corporation, Ted Bates & Company, Inc., a corporation, and Young & Rubicam, Inc., a corporation. The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Advertising Falsely or Misleadingly: § 13.10 Advertising falsely or misleadingly; § 13.20 Comparative data or merits; § 13.110 Endorsements, approval and testimonials; § 13.170 Qualities or properties of product or service; § 13.175 Quality of product or service; § 13.205 Scientific or other relevant facts; § 13.280 Unique nature or advantages. Subpart—Claiming or Using Endorsements or Testimonials Falsely or Misleadingly: § 13.330 Claiming or using endorsements or testimonials falsely or misleadingly; 13.330-33 Doctors or medical profession. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements. Subpart—Misrepresenting Oneself and Goods—Goods: § 13.1575 Comparative data or merits; §13.1715 Quality; §13.1740 Scientific or other relevant facts; § 13.1770 Unique nature or advantages. Subpart—Neglecting, Unfairly or Deceptively, To Make Material Disclosure: § 13.1855 Identity; § 13.1895 Scientific or other relevant facts.

List of Subjects in 16 CFR Part 13

Advertising, Analgesics, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45, 52)

The Final Order, including further order requiring report of compliance therewith, is as follows:

In the Matter of Bristol-Myers Company, a corporation, Ted Bates & Company, Inc., a corporation and Young & Rubicam, Inc., a corporation, Docket No. 8917.

Final Order

This matter has been heard by the Commission upon the appeal of counsel for respondents and complaint counsel and upon briefs and oral argument in support of and in opposition to the appeals. The Commission, for the reasons stated in the accompanying Opinion, has granted each appeal in part, and denied each in part. Therefore,

It is ordered that the initial decision of the administrative law judge be adopted as the Findings of Fact and Conclusions of Law of the Commission except as is otherwise inconsistent with the attached opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered that the following Order to Cease and Desist be entered:

Order

I

It is ordered that Bristol-Myers Company, its successors and assigns.

[1] Copies of the Complaint, Initial Decision and the Opinion of the Commission filed with the original documents.

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," "Execedrin," "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 a least to conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

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.

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 orgainzation 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 furthered order 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," 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.

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 respondent herein shall within sixty (60) days after service of this Order upon them, and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which they have complied or intend to comply with this Order.

Paragraphs 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.

Issued: July 5, 1983.

By the Commission.

Emily H. Rock,

Secretary.

Concurring Statement of Chairman Miller [1]

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 situations. Rather, I would encourage the Commission to consider 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.

Issued: July 5, 1983.

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 announces 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, 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

[1] Chairman Miller's Statement also applies to the Commission's Final Order in Sterling Drug Inc., et al. (Dkt. 8919), published in this issue immediately following this document.

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 refrain 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:

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 othert 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 difficutly with that assumption is that "there has never been 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 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 Nutrution*, 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 advetisers 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 consumers 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 interpret such evidence narrowly to provide proof for only a limited portion of the claim." *Sterling Drug, supra*, slip op. at 13, note.

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

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

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 standard 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. *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 case 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.

Issued: July 5, 1983.

Separate Statement of Commissioner Patricia P. Bailey Concurring in Part and Dissenting in Part [1]

Bristol Myers, Docket No. 8917 and Sterling Drug, Docket No. 8919

The Commission today has issued the last two opinions in a three-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* [2] 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.

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

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

[1] Commissioner Bailey's Statement also applies to the Commission's Final Order in Sterling Drug Inc., et al. (Dkt. 8919), published in this issue immediately following this document.

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

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 demanded similarly high standards for claims of comparative effectiveness and safety as are imposed on absolute claims.

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 nigh 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); 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, *Bristol Myers* Slip Op. at pg. 11), 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). At the same time, use of a visual depicting the product's chemical formula can convert the claim into an establishment claim. (*Bristol Myers* Slip Op. at pg. 18). All of this delicate line-drawing may well pose confusing problems of interpretation for those who must comply with the standards enunicated 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.) 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.

Issued: July 5, 1983.

Concurring Statement of Commissioner Douglas [1]

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 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.

Issued: July 5, 1983.

[FR Doc. 83-20596 Filed 7-28-83; 8:45 am]
BILLING CODE 6750-01-M

[1] Commissioner Douglas' Statement also applies to the Commission's Final Order in Sterling Drug Inc., et al. (Dkt. 9319), published in this issue immediately following this document.