Administrative Law - Federal Trade Commission - Deceptive Advertising - Disclosure and Substantiation Requirements - Over-the-Counter Internal Analgesics

Dale Elizabeth Walker

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The United States Court of Appeals for the Third Circuit has held that disclosure of common ingredients and clinical substantiation of performance claims or disclosure that certain claims are open to substantial question in the medical community are reasonable requirements to counter the effects of extensive advertising found to violate the Federal Trade Commission Act.

American Home Products Corp. v. FTC, 695 F.2d 681 (3d Cir. 1982).

On February 23, 1973, the Federal Trade Commission (Commission) filed a complaint against American Home Products Corp. (AHP), a Delaware corporation, alleging violations of the Federal Trade Commission Act in its advertisements for Anacin and Arthritis Pain Formula (APF). Specifically, the complaint charged AHP with making false claims about Anacin by advertising its product as a unique pain-killing preparation proven superior in

1. American Home Products Corp. v. FTC, 695 F.2d 681, 683 (3d Cir. 1982). Clyne Maxon, Inc., the advertising agency for AHP, was also named in the complaint. The advertising agency did not petition for a review of those parts of the Order regarding its future obligations, however, because it had gone out of business. Id. at n.1. On the same day, the Commission filed similar complaints against Bristol-Meyers Company and Sterling Drug, Inc., manufacturers of Bufferin and Excedrin, and Bayer Aspirin, respectively. The cases were still on appeal with the Commission and were not considered by the American Home Products court. Id. at 683. See infra note 144, regarding the FTC's decision in these cases.

   § 45(a)(1) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful.
   § 52(a) It shall be unlawful . . . to disseminate any false advertisement . . . [b]y any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in commerce of food, drugs, devices, or cosmetics.
   § 52(b) The dissemination . . . of any false advertisement within the provisions of subsection (a) . . . shall be an unfair or deceptive act or practice . . . within the meaning of section 45.

The court found the definition of "false advertisement" to be very broad, encompassing not only literally untrue advertisements, but also those materially misleading as much for what is said as for what is not said in them. 695 F.2d at 684.

3. 695 F.2d at 683.

4. Anacin is a non-prescription analgesic containing 400 milligrams of aspirin and 32.5 milligrams of caffeine per tablet. Inasmuch as caffeine is not claimed to have any pain-killing properties either alone or with aspirin, the only analgesic component is the aspirin.
effectiveness to all other non-prescription analgesics. The Commission also cited as misrepresentations AHP’s assertions that Anacin is a tension reliever and that APF causes fewer side effects and hence is superior to competing products. AHP responded by stating that it had not made the advertising claims alleged, and that claims it had made were truthful.

Extensive hearings were conducted, culminating in the Administrative Law Judge’s (A.L.J.) initial decision, dated September 1, 1978. The A.L.J. decided most issues in favor of complaint counsel, and on cross appeals, the Commission issued a cease and desist order on September 9, 1981, upholding the A.L.J. in nearly all respects. The A.L.J.’s findings of fact and conclusions of law were adopted by the Commission, but where the A.L.J. spoke of “unfair and deceptive” practices, the Commission limited the Order in terms of deception. The focus in both decisions, however, was on the ability of the advertisements to mislead.

In brief, Part I of the Commission’s Order was applicable to Anacin, APF, and any other of AHP’s non-prescription internal analgesics. Part I(A) required AHP to support representations of established or proven superiority with a minimum of two properly controlled clinical studies. I(B) required such statistical sup-

Id. This compares with 325 milligrams of aspirin in an “ordinary” aspirin tablet. APF is similarly a non-prescription analgesic and contains 486 milligrams of “micronized” (or small particles of) aspirin with two antacids. Id.

5. Id.
6. Id.

The parties were allowed extensive pretrial discovery. Numerous prehearing conferences were held. Joint evidentiary hearings commenced on June 6, 1977 and continued until August 15, 1977 [and] complaint counsel’s case-in-chief . . . began on November 1, 1977 and continued until December 19, 1977. Respondents commenced their defense on January 30, 1978 and continued until March 22, 1978 . . . . Some 40 witnesses, including 27 expert[s] . . . testified. Transcripts of hearing . . . number some 11,600 pages. Some 400 documentary exhibits, including numerous copy tests, penetration and image studies, and medical-scientific studies were received in evidence.

98 F.T.C. at 146, 149.
8. 695 F.2d at 684.
9. Id. An appendix is included in the court’s opinion, id. at 714-16, with key parts of the Commission’s Order which are at issue and extensively discussed in the case. See infra notes 14, 20 & 21.
10. 695 F.2d at 684.
11. Id. The Commission denied a rehearing and noted that the difference in terminology was “more of form than of substance.” Id.
12. Id. The claims of superiority in question were related to effectiveness or freedom from side effects in comparison to other products. Id.
port even when the advertisements were not making overt claims of superiority.\textsuperscript{13} Further, this provision did not allow AHP to make unequivocal claims in the absence of two or more clinical investigations, although it may assert superiority in that instance only if it discloses such a claim as open to substantial question.\textsuperscript{14}

Part II applied to all of AHP's non-prescription drugs and was thus more inclusive than Part I.\textsuperscript{16} Part II(A) prohibited AHP from claiming a product has special or unique ingredients when the actual ingredient is common to other non-prescription drugs of similar usage.\textsuperscript{16} II(B) required AHP to cease falsely representing that any of its non-prescription drugs contained more of a particular active ingredient that its competitors' products.\textsuperscript{17} II(C) proscribed the misrepresentation of test results on product effectiveness or freedom from side effects.\textsuperscript{18} II(D), described as "especially far-reaching,"\textsuperscript{19} required AHP to have a reasonable basis for non-comparative claims of product performance or to cease making such claims altogether.\textsuperscript{20}

\textsuperscript{13} The court noted, that Part I(B) was the only provision not supported unanimously. Commissioner Clanton objected in a separate statement. \textit{Id.} at 684 n.4. See infra notes 76-79 and accompanying text.

\textsuperscript{14} 695 F.2d at 684. Parts I(A) and (B) of the Order state in pertinent part:
\textit{It is ordered, [t]hat . . . American Home Products Corporation . . . in connection with the advertising of "Anacin," "Arthritis Pain Formula," or any other non-prescription internal analgesic product . . . do forthwith cease and desist from:}
A. Making any representation, directly or by implication, that a claim concerning the superior effectiveness or superior freedom from side effects of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations . . . .
B. Making any representation, directly or by implication, of superior effectiveness or freedom from side effects of such product unless:
1. The superior effectiveness or superior freedom from side effects so represented has been established according to the terms set forth in paragraph I.A. of this Order, or
2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the comparative efficacy or side effects claim, or that the claim has not been proven . . . .

98 F.T.C. at 423, 425.

\textsuperscript{15} The court in discussing this provision of the Order graphically referred to it as "fencing in," meaning that it is broadly drafted to effectively "close all roads to the prohibited goal." 695 F.2d at 704.

\textsuperscript{16} \textit{Id.} at 684.

\textsuperscript{17} \textit{Id.}

\textsuperscript{18} \textit{Id.}

\textsuperscript{19} \textit{Id.}

\textsuperscript{20} \textit{Id.} Parts II(A)-(D) of the Order state in pertinent part:
\textit{It is further ordered, [t]hat . . . American Home Products Corporation . . . in connection with the advertising . . . of "Anacin," "Arthritis Pain Formula," or any other non-prescription drug product . . . do forthwith cease and desist from:}
A. Making any representation, directly or by implication, that such product contains
The third part of the Commission's Order required conspicuous disclosure of aspirin content whenever an Anacin or APF advertisement makes a performance claim. Part IV, uncontested by AHP, directed the corporation to cease representing Anacin as a tension, nerve, anxiety or depression reliever.

The Order operated prospectively and was designed not to punish for past deceptive practices, but to ensure that public misconceptions about the products derived from years of misleading advertisements were not confirmed or further exacerbated. Additionally, the order was triggered only when AHP made particular kinds of claims and, at that point, imposed an obligation to provide certain information to the public.

AHP's motion for reconsideration was denied on January 21, 1982, although two commissioners stated in separate opinions that the Commission should exercise its discretion and stay the Order or reconsider it in light of the cases pending against AHP's competitors, to guarantee consistency of treatment.

AHP sought review in the United States Court of Appeals for the Third Circuit, asking that Parts I, II(D), and III be vacated, and Parts II(A)-(C) be restricted to Anacin and APF.

Deciding the case on December 3, 1982, Judge Adams began his

any unusual or special ingredient when such ingredient is commonly used in other non-prescription drug products.

B. Making any false representation that such product has more of an active ingredient than any class of competing products.

C. Misrepresenting in any manner any test, study or survey or any of the results thereof, concerning the comparative effectiveness or freedom from side effects of such product.

D. Making any noncomparative representation, directly or by implication, concerning the effectiveness or freedom from side effects of such product unless, at the time such representation is made, respondent has a reasonable basis for such representation which shall consist of competent and reliable scientific evidence.


21. 695 F.2d at 685. Part III of the Order states, in pertinent part:

It is further ordered, [t]hat . . . American Home Products Corporation . . . in connection with the advertising . . . of “Anacin,” “Arthritis Pain Formula,” or any products in which “Anacin” or “Arthritis Pain Formula” is used in the name . . . do forthwith cease and desist from failing to disclose clearly and conspicuously that the analgesic ingredient in such product is aspirin, when such is the case and when the advertisement makes any performance claim for the product.

98 F.T.C. at 426.

22. 695 F.2d at 685.

23. Id.

24. Id.

25. Id.

26. See supra note 1.

27. 695 F.2d at 685.
discussion in this unanimous opinion by addressing AHP's challenges to Part I, which involved clinical support for Anacin and APF superiority claims. AHP denied making claims of proven superiority and charged the Commission with not having substantial evidence to support this finding or the allegation that such claims, if made, were misleading. Further, AHP based its due process challenge on a change in theory of liability as the case made its way through the administrative proceedings.

First, Judge Adams established the standard of review to be followed by the court. He found that 15 U.S.C. § 45(c), as interpreted by the United States Court of Appeals for the Third Circuit and the United States Supreme Court, mandates a deference to Commission findings of fact. He further found that although defining "deceptive practices" is a matter for the judiciary, if the Commission finds particular advertisements are deceptive or have a tendency to mislead, its determination is more a finding of fact than a conclusion of law. Judge Adams determined that the policy supporting such judicial deference was sound because the Commission is uniquely qualified to determine when a practice is misleading to the public based on its years of experience applying the law.

Next, Judge Adams decided in what manner advertising is to be interpreted. He stated that the generally accepted method is to view the advertisement as a whole. Words and phrases are not to be lifted from their context and literal truth or falsity is to give

28. Id.
29. Id.
30. Id. at 685-86. Judge Adams emphasized that the advertisements in question were meant to be taken seriously and were never defended as mere "puffing."
31. See Steadman v. SEC, 450 U.S. 91 (1981); Beneficial Corp. v. FTC, 542 F.2d 611 (3d Cir. 1976), cert. denied, 430 U.S. 983 (1977). The reviewing court is permitted only to decide whether or not the record contains the quantum of relevant evidence a reasonable person would find to be adequate to support a given finding, rather than to actually weigh the evidence. 695 F.2d at 686.
33. 695 F.2d at 686. See Beneficial Corp. v. FTC, 542 F.2d 611, 617 (3d Cir. 1976), cert. denied, 430 U.S. 983 (1977) ("substantial evidence" standard applied to Commission's finding of deceptiveness).
34. 695 F.2d at 686. See FTC v. Colgate-Palmolive Co., 380 U.S. 374, 385 (1965). Judge Adams noted that utilization of the Commission's expertise in this area is critical when the deception found is created by an omission of information from the advertisements under consideration. See, e.g., Simeon Management Corp. v. FTC, 579 F.2d 1137, 1145 (9th Cir. 1978). He further stated that cases relied on by the petitioner did not question the deferential standard of review. 695 F.2d at 686-87 n.8.
36. 695 F.2d at 687.
way to the general impression created by the advertiser.\(^37\) He admitted that on some key points the Commission did not have direct evidence of consumers actually being misled, but he found such evidence is not required.\(^38\) The Commission analyzed the television advertisements with reference not only to the words used, but also to their aural and visual components.\(^39\) Judge Adams found this consistent with the overall impression standard and with the notion that not allowing those parts of the advertising medium to be examined would give advertisers an open-ended opportunity to deceive.\(^40\)

In applying these standards, the court turned to Part I(A) of the Order, which required representations of established or proven superiority to be supported by clinical studies, and asked if the establishment claims\(^41\) had been made by AHP's advertisements. Judge Adams answered the question affirmatively, finding that the survey evidence offered by AHP had been considered in detail by the A.L.J. and reasons were cited for the limited weight given to AHP's proffered expert testimony.\(^42\) Judge Adams compared this process with the semantic analysis which AHP urged upon the

\(^{37}\) See National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 161 n.4 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978) (FTC stated that an advertisement is misleading if even one possible interpretation is false); Resort Car Rental Sys., Inc. v. FTC, 518 F.2d 962, 964 (9th Cir. 1975) (if advertisement can be interpreted in misleading way, it is to be construed against the advertiser); J. B. Williams Co. v. FTC, 381 F.2d 884, 890 (6th Cir. 1967) (FTC not bound to literal interpretation of words); Carter Products, Inc. v. FTC, 323 F.2d 523, 528 (5th Cir. 1963) (FTC may extend its interpretation of advertisements beyond literal meaning of words to overall impact); Bakers Franchise Corp. v. FTC, 302 F.2d 258, 261 (3d Cir. 1962) (deception by innuendo can support finding that advertisement is false); Murray Space Shoe Corp. v. FTC, 304 F.2d 270, 272 (2d Cir. 1962) (factfinder must look at more than technical meanings of phrases; overall impression likely to be made on public is standard). Cf. C. LASCH, THE CULTURE OF NARCISISM 140-41 (1979) (criticizing product advertising for the blurring of falsehood and truth, and not for obvious falsity).

\(^{38}\) 695 F.2d at 687. See Resort Car Rental Sys., Inc. v. FTC, 518 F.2d 962, 964 (9th Cir. 1975). See also Simeon Management Corp. v. FTC, 579 F.2d 1137, 1146 n.11 (9th Cir. 1978) (stating the FTC need not produce consumer testimony because it has the expertise to determine if advertising will be deceptive to the public).

\(^{39}\) 695 F.2d at 688.

\(^{40}\) Id. See Standard Oil Co. of California v. FTC, 577 F.2d 653 (9th Cir. 1978) (predominant misleading visual message not corrected by verbal message in ad); FTC v. Colgate-Palmolive Co., 380 U.S. 374, 385-86 (1965) (product demonstration creates false impression when viewers not told it has been recreated by use of "mock-ups").

\(^{41}\) 695 F.2d at 688. When Judge Adams referred to "establishment claim" he meant AHP's representations of the proven superiority of Anacin. He pointed out that establishment claims were not found by the Commission in APF advertisements and that petitioner did not challenge the language in I(A) which encompassed APF and claims of proven superior freedom from side effects. Id. n.12.

\(^{42}\) Id. at 688-89.
court and which the court rejected in favor of a "pragmatic" approach.\footnote{Id. at 689 n.13. The pragmatic analysis does not deal with words in their literal sense, rather with what those words imply when uttered in a given context. Id.}

Sample Anacin advertisements from magazines were reproduced in the opinion.\footnote{Id. at 689-90. Pertinent portions of the first advertisement considered read as follows: "[T]he has now been proven beyond a doubt that today's Anacin delivers the same complete headache relief as the leading pain relief prescription . . . . Doctors know Anacin contains more of the specific medication they recommend most for pain than the leading aspirin, buffered aspirin, or extra-strength tablet." Id. at 689.} The court agreed with the A.L.J. and the Commission's statement that the first of the advertisements could reasonably be construed by consumers to mean Anacin is equivalent in effectiveness to prescription drugs, and since it is claimed to have more pain reliever than non-prescription products, that Anacin is proven to be more effective than the latter.\footnote{Id. at 690. "What's best to take for tension and headache pain? . . . [T]ake the fast acting pain-reliever doctors recommend most . . . Anacin Tablets . . . . Next time a tension headache strikes, see if medically-proven Anacin doesn't work better for you." Id.}

Considering the second of the two advertisements,\footnote{Id. at 691. According to the Court, AHP apparently agreed that some of its product claims were misleading, although it maintained that none of them was an establishment claim. Id. n.16.} the court again contrasted the literal reading with the reading it was reasonable to assume consumers would make.\footnote{Id. at 691.}

The next question addressed by the court, was whether or not the establishment claims were deceptive.\footnote{Id. at 691.} Although AHP never disclosed the actual ingredients in its advertisements, the superiority of Anacin was apparently based on the idea that the relatively higher dosage of aspirin made it more effective as a pain reliever.\footnote{Id. at 691-92. A dose response curve relied upon by AHP was also found to be insufficient to support its claims because most points on the curve could not be proven by}

The Commission found that AHP's evidence was inadequate to support the superiority claims and that the types of data required by scientists to prove such claims involve criteria which are not disputed by the scientific community.\footnote{Id. n.16.} Again, the court stated it was unable to find the action of the Commission unreasonable.\footnote{Id. at 691-92. The pragmatic analysis does not deal with words in their literal sense, rather with what those words imply when uttered in a given context. Id.}
Judge Adams cited numerous appellate decisions which allow the Commission to order substantiation of advertising claims, and offered *Porter & Dietsch, Inc. v. FTC* as an example of even more far-reaching court-approved requirements.

AHP's next claim, denial of administrative due process, was also rejected by the court. AHP believed that the theory underlying Part I(B) of the Order, requiring disclosure of a substantial question when advertising claims lack clinical support, was changed following the initial complaint. AHP charged that notice of the change had not been given and that the A.L.J. excluded evidence which was relevant to the theory on which AHP was found liable. Judge Adams found that AHP's evidence of a change in theory was clinical studies. *Id.* at 692. Anacin contains 150 mg. more aspirin than common aspirin, and at dosage levels above a given point (600 mg.) it is found that substantial increases are required to produce small increases in relief from pain. The Commission also rejected Anacin's favorable comparison claims with Darvon Compound 65, which is a leading prescription analgesic. *Id.* n.19. Other evidence in the record showed expert witnesses did not believe Anacin to be superior and in fact might be inferior to ordinary aspirin because the caffeine in it could either increase perception of pain or further worsen aspirin's gastrointestinal side effects. *Id.* at 692.

52. Sears, Roebuck and Co. v. FTC, 676 F.2d 385 (9th Cir. 1982) (reasonable substantiation of major appliance performance claims upheld); Litton Indus., Inc. v. FTC, 676 F.2d 364 (9th Cir. 1982) (substantiation of product claims part of order not appealed to FTC, therefore not properly before the court); Jay Norris, Inc. v. FTC, 598 F.2d 1244 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979) (requirement of substantiation is clearly permissible method of regulation); Fedders Corp. v. FTC, 529 F.2d 1398 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976) (part of order forbidding air-conditioning capability claims unless based upon competent scientific or engineering material upheld by court); National Dynamics Corp. v. FTC, 492 F.2d 1333 (2d Cir.) *cert. denied*, 419 U.S. 993 (1974) (FTC order requiring battery-additive manufacturer to support performance claims with laboratory tests found reasonably related to misrepresentations); Firestone Tire & Rubber Co. v. FTC, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973) (court affirmed FTC order requiring Firestone to substantiate certain claims of tire performance with competent scientific testing).

53. 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (the order restricted representations concerning any food, drug, cosmetic, or device and required health risk warnings for specific products).

54. 695 F.2d at 693.

55. AHP relied on 5 U.S.C. § 554(b)(3) (1976) which requires timely notice of matters of law, and on Rodale Press, Inc. v. FTC, 407 F.2d 1252 (D.C. Cir. 1968), where it was stated that "it is well settled that an agency may not change theories in midstream without giving respondents reasonable notice of the change." 695 F.2d at 693 n.21. The essence of AHP's charge was that the Commission's complaint alleged a "substantial question" regarding proof of Anacin and APF superiority claims and that failure to disclose this information in advertisements was misleading. *Id.* at 693. AHP believed this expressed theory was actually a subterfuge for the "reasonable basis" doctrine of Pfizer, Inc., 81 F.T.C. 23 (1972), where advertisers were required to possess and rely on an adequate reasonable basis for product claims. 695 F.2d at 693. The question was seen to be a factual issue in Pfizer, and the possibility of valid scientific or medical studies being required to support some claims was noted. *Id.* at 693-94.
derived from a particular statement in the A.L.J.'s opinion,\textsuperscript{56} and decided that this was a strained interpretation in light of its context.\textsuperscript{57} According to the court, the Commission, in affirming the A.L.J.'s decision, took a different approach to the "substantial question" theory which underlies Part I(B).\textsuperscript{58} Complaint counsel and the A.L.J. had characterized the doctrine as something new, but the Commission, citing Pfizer, Inc.,\textsuperscript{59} saw it merely as a logical elaboration of the "reasonable basis" theory,\textsuperscript{60} and decided two or more well-controlled clinical tests would be the acceptable method of supporting drug performance claims.\textsuperscript{61} Because the Commission determined that an advertiser could, in certain situations, lack a "reasonable basis" for a claim when there was a "substantial question" concerning its truth, any evidence tending to establish the former without tending to eliminate the latter would not have been relevant.\textsuperscript{62}

Turning to the merits of Part I(B), the court found AHP's objections were analogous to those made against Part I(A) and, employing a similar analysis, concluded that, according to a valid Commission interpretation, the superiority claims were made and that such claims were deceptive.\textsuperscript{63} The court dealt at considerable length with the deception issue, beginning with a caveat indicating that it would support only the Commission's narrow application of

\textsuperscript{56} The excerpt from the A.L.J.'s opinion upon which AHP based its denial of due process argument reads: "against this background, what is the reasonable level of substantiation required under the fairness doctrine for a claim that Anacin is more effective than aspirin . . . ?" Id. at 694 (emphasis added).

\textsuperscript{57} Id. Judge Adams stated that the A.L.J. only used the term "reasonable" to frame the issue. The A.L.J. had actually applied the "substantial question" test because he found that consumers of over the counter analgesics are deceived by superiority claims which experts recognize as being open to substantial question. The A.L.J. found it reasonable to require two clinical studies to support superior effectiveness claims. Id.

\textsuperscript{58} See supra note 55.

\textsuperscript{59} See supra note 55.

\textsuperscript{60} The Commission stated that lack of a reasonable basis to support certain product claims is deceptive and that failing to disclose the nonexistence of support which presumably underlies some claims would, by mere elaboration, also be a deceptive practice. 695 F.2d at 694.

\textsuperscript{61} Id. at 695. The court did not think the case had been decided on a "reasonable basis" theory, however, and pointed out that no allegation had been made that the Commission had abused its discretion by setting forth the "substantial question" doctrine in an adjudicative rather than a rulemaking setting. Id. at 695 n.22.

\textsuperscript{62} Id. at 695. AHP also claimed the experts called by the Commission were not queried about the "substantial question" issue, but the court disagreed, observing that AHP could not have failed to understand due to the nature of the testimony regarding acceptable scientific procedures that the issue was indeed being addressed. Id.

\textsuperscript{63} Id. at 696.
the ruling rather than holding that such a provision could apply to any product claims for any drugs.64

Judge Adams refuted AHP's assertion that Part I(B) is obscure by stating as its central idea that consumers should be able to assume that when a factual, verifiable statement is made in an advertisement in no uncertain terms, the appropriate tests to support such a claim have been conducted.65 AHP further disagreed with the Commission over how much support is required when failure to reveal the nonexistence of the support would be misleading, and apparently believed two clinical studies constituted too stringent a requirement.66 The court found AHP's challenges went to an issue of fact, and reiterated the canon of judicial deference to Commission findings of fact.67

The policy reasons behind a high level of proof, which the court held justifiable, were grouped into two categories based on the particular nature of the product and AHP's conduct.68 Petitioner's behavior was found to warrant the measures imposed by the Commission, because AHP had conducted a very long and successful campaign to convince the public of Anacin's and APF's superior-

64. Id. The court quoted the Commission on this point as follows: "When an analgesic advertiser claims its product to be superior in performance, even without the additional explicit claim that it has been so proven, it is reasonable for consumers to construe that claim to be the assertion of a fact that is generally accepted, within the scientific community, as established." The court did not think the Commission could require the advertiser to indicate a substantial question existed in all cases. Id.

65. Id. at 697. The court also stressed the fact that certain claims of drug performance, such as superior effectiveness or freedom from side effects, are factual and testable. Id.

66. Id.

67. Id.

68. Id. The court found that prescription and, by reasonable extension, non-prescription drugs are subject to wide-ranging government regulation and that consumers would tend to expect that performance and safety claims were based not on the advertiser's opinion, but on the results of FDA evaluation of the product. See Simeon Management Corp. v. FTC., 579 F.2d 1137, 1145 (9th Cir. 1978). The court also noted that another reason to allow a high standard of substantiation for comparative effectiveness and safety claims for pain relief products was the consumer's inability to easily evaluate the claims by using the products. 695 F.2d at 698. The factors for this evaluation problem include: 1) pain which is not extreme eventually goes away whether or not the consumer takes anything for it; 2) memory problems could preclude product comparison; 3) intensity of pain varies, also interfering with reliable personal judgment when comparing products; and 4) a placebo effect had been found in clinical studies where pain relief was experienced with pharmacologically inactive drugs between 30% and 60% of the time. Id. Health risks associated with use of aspirin were also cited by the court. Id. at 698-99. Gastrointestinal bleeding with a 4% to 10% mortality rate and gastric ulcers requiring hospitalization, thought by the court to be particularly serious side effects, made AHP's representations of gentleness to the stomach without disclosure of its products' main ingredient a real hazard to those sensitive to aspirin. Id. at 699 n.31.
ity.\textsuperscript{69} Part I(B) was designed to undo damage previously done without being overly intrusive and to prevent any future infliction of damage.\textsuperscript{70}

The court cited and discussed \textit{National Commission on Egg Nutrition v. FTC},\textsuperscript{71} \textit{FTC v. Colgate-Palmolive Co.},\textsuperscript{72} \textit{Warner-Lambert Co. v. FTC},\textsuperscript{73} and \textit{Simeon Management Corp. v. FTC},\textsuperscript{74} to support the proposition that the Commission has been given wide latitude when ordering advertisers to make disclosures limiting or countering certain claims.\textsuperscript{78}

Judge Adams addressed Commissioner Clanton's dissent from Part I(B) of the Order,\textsuperscript{76} finding that Commissioner Clanton objected because he thought that the majority had adopted a per se rule which would require that any comparative drug claim be backed by scientific proof.\textsuperscript{77} Commissioner Clanton maintained drug claims should be considered on a case by case basis.\textsuperscript{78} The court, however, did not find the Commission had adopted such a rigid rule, and indicated the lengths to which the Commission had gone in shaping its Order to fit the specific facts of the case at hand.\textsuperscript{79}

The court then turned to Part II of the Order and examined AHP's contention that the provisions prohibiting certain claims

\begin{itemize}
  \item \textsuperscript{69} \textit{Id.} at 699.
  \item \textsuperscript{70} \textit{Id.}
  \item \textsuperscript{71} 570 F.2d 157 (7th Cir. 1977), \textit{cert. denied}, 439 U.S. 821 (1978). The FTC ordered egg producers to accompany representations about egg consumption and heart and circulatory disease with a conspicuous disclosure indicating medical experts link increased egg consumption (i.e., dietary cholesterol) to the risk of heart disease. The Seventh Circuit upheld the order despite the absence of a long history of deception.
  \item \textsuperscript{72} 350 U.S. 374 (1965). The Commission had found that televised “tests” were misleading because of undisclosed use of props, and gave the advertiser alternatives similar to those given to AHP under Part I(B). The Supreme Court agreed and affirmed.
  \item \textsuperscript{73} 562 F.2d 749 (D.C. Cir. 1977), \textit{cert. denied}, 435 U.S. 950 (1978). The Commission required the makers of Listerine to employ corrective measures until a specified amount had been spent on advertising. The Order was more burdensome than in AHP's case, however, because disclosures about the product not preventing colds or lessening their severity had to accompany any advertising claim.
  \item \textsuperscript{74} 579 F. 2d 1137, 1146 (9th Cir. 1978) (safety and effectiveness of weight loss program found to violate Federal Trade Commission Act even though no claim was made that a government agency approved the program).
  \item \textsuperscript{75} 695 F.2d at 700-01.
  \item \textsuperscript{76} \textit{Id.} at 701. 98 F.T.C. at 417 (Commissioner Clanton, dissenting).
  \item \textsuperscript{77} 695 F.2d at 701. \textit{See} 98 F.T.C. at 420 (Commissioner Clanton, dissenting).
  \item \textsuperscript{78} 98 F.T.C. at 420-21 (Commissioner Clanton, dissenting).
  \item \textsuperscript{79} 695 F.2d at 701. Judge Adams remarked that an unyielding use of the “substantial question” provision in another case might be cause for judicial modification of a Commission order in the future. \textit{Id.} at 701-02.
\end{itemize}
were unsupportably broad and that the part requiring a reasonable basis for non-comparative claims was ambiguous and should be vacated in its entirety. Judge Adams first discussed the findings of fact underlying this part of the Order, which applied to all non-prescription drugs, noting AHP never defended itself during the proceedings by claiming Anacin or APF contained special or unique pain-killing ingredients. The Commission determined that the advertisements for these products, since they were specifically designed to differentiate the products from ordinary aspirin, had the capacity to mislead consumers by failing to reveal aspirin content. The claims of AHP’s use of more active ingredients as compared with competitors’ products were also found to be false. The facts supporting Part II(C) included AHP’s misrepresentations of product comparison test results and surveys of doctors. Underlying the broad II(D) provision was the rather narrow Commission finding of the lack of a reasonable basis for AHP’s non-comparative claim that Anacin offers relief from tension. There was no basis for such a claim and the court decided AHP advertisements would lead consumers to believe this claim was being made.

Another preliminary question addressed by the court was whether or not the Commission had discretion to “fence in” violators. Judge Adams cited several cases which support the principles that: (1) the Commission has responsibility for fashioning or-

80. Id. at 702. See supra note 20 and accompanying text.  
81. 695 F.2d at 702.  
82. A sample advertisement quoted by the court reads in pertinent part: “Anacin tablets are so effective because they are like a doctor’s prescription . . . . Anacin contains the pain reliever most recommended by doctors plus an extra active ingredient not found in leading buffered aspirin . . . . The big difference in Anacin makes a difference in the way you feel.” Id.  
83. Id. Expert testimony and consumer surveys on which the Commission relied, show that many consumers had no idea Anacin contains aspirin and believed it to be superior to aspirin. Id.  
84. Id. Arthritis Strength Bufferin, Midol, Cope, and Arthritis Pain Formula contain larger doses of aspirin. Id. at 703. Similarly, claims conveying an impression that Anacin has twice as much pain reliever as other non-prescription products were deemed even more misleading. Id.  
85. Id. at 703.  
86. Id. In this regard, the court noted AHP did not challenge Part IV which proscribes tension relief claims, although AHP had suggested such a provision was moot because it was no longer making such assertions in its advertisements. The court found this behavior had not been voluntary, however, in that AHP discontinued such advertisements following initiation of the Commission proceedings against it. Id. n.38.  
87. Id. at 704.  
88. Id. at 704-06. See supra note 15 and accompanying text.
ders; 89 (2) violators must expect to be "fenced in" 90 because ways of avoiding proscriptions are limited only by human inventiveness; 91 and (3) the courts should not be quick to modify Commission orders. 92 The court observed that deference to the Commission's discretion is limited where the remedy selected has no reasonable relation to the existing illegal conduct. 93 A second limitation was found in Colgate-Palmolive, 94 where the Supreme Court stated that an order's prohibitions had to be framed in language as clear and precise as circumstances permit. 95

Further, Judge Adams noted "fencing in" could take the form of multiple product orders and stated the Supreme Court had upheld in Colgate-Palmolive 96 an all-product order in a situation where only three advertisements for a single product were involved. 98 The question to be answered by a court when deciding if such an order is justified is: whether or not the advertiser is likely to commit the type of conduct proscribed by the order. 98 According to the court, factors important to this issue include the deliberateness and seri-

90. Id. at 431.
91. See Sears, Roebuck and Co. v. FTC, 676 F.2d 385, 391 (9th Cir. 1982) (in striking balance between violations found and effective orders, FTC fences in violators out of necessity due to range of human inventiveness in transferring misleading advertising campaigns from product to product).
92. See FTC v. Colgate-Palmolive Co., 380 U.S. 374, 391 (1965) (courts should not lightly modify orders because FTC has wide discretion in and primary responsibility for fashioning orders).
93. 695 F.2d at 704. See Jacob Siegel Co. v. FTC, 327 U.S. 608, 612-13 (1946), where the Court stated:

The Commission is the expert body to determine what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed. It has wide latitude for judgment and the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.

Id. The American Home Products court, in addition, cited other cases applying the Jacob Siegel "reasonable relation" test. 695 F.2d at 704.
94. 380 U.S. at 392.
95. 695 F.2d at 704-05. The policy favoring specific language in Commission orders was elucidated in terms of problems with meaning and application for reviewing courts when general language is employed, and the possibility that penalties and enforcement procedures set out in the Federal Trade Commission Act could be altered when the courts are asked to penalize those violating Commission orders without the benefit of the agency hearing process. See Litton Indus., Inc. v. FTC, 676 F.2d 364, 371 (9th Cir. 1982); Standard Oil Co. of California v. FTC, 577 F.2d 653, 661 (9th Cir. 1978); see also Colgate-Palmolive, 380 U.S. at 392.
96. 380 U.S. at 394-95.
97. 695 F.2d at 705.
98. Id. at 706. See Litton Indus., 676 F.2d at 370.
ousness of the violation subject to present consideration, the advertiser's past record in the area of deceptive or unfair trade practices, the transferability of such a practice to other products, and the consequences of a failure to fence in a violator. Of the latter criterion, the court stated that potential health hazards flowing from drug use could be the foundation for justifiable breadth in Commission orders. Having dealt with the underlying facts and the law controlling the Commission's discretion when drafting orders, and finding all of the above enumerated factors to be present, the court decided Parts II(A)-(C) should stand as written.

Judge Adams found the violations to be both serious and deliberate, noting AHP's long-standing and massive campaigns to convince the public that Anacin differed from and was superior to common aspirin and its competition. He also found AHP to have a prior record of habitual violations of the Federal Trade Commission Act, and that the types of claims it made were readily trans-

99. 695 F.2d at 706. See Sears, Roebuck, 676 F.2d at 392. Judge Adams quoted further from Sears, Roebuck to show that the Commission would be wasting its resources if it were required to institute separate proceedings each time an advertiser transferred successful but illegal techniques from product to product. 695 F.2d at 706 n.41.

100. 695 F.2d at 706. The court opined that predictions regarding future behavior were dependent upon determinations which the Commission, rather than the courts, was in the better position to make. Id.

101. Id. The court examined the cases which AHP cited in support of its attack on Parts II(A)-(C) and decided such precedents were not applicable to the instant case. Id. at 708-09. See Standard Oil Co. of California v. FTC, 577 F.2d 653, 661-63 (9th Cir. 1978). In that case only three advertisements for a single product were misleading and the order applied to thousands of diverse products. Judge Adams noted that the violators had made a good faith effort to eliminate the misleading implications in their advertisements. 695 F.2d at 709. See also American Home Products Corp. v. FTC, 402 F.2d 232 (6th Cir. 1968). The Preparation H case appeared to hold that a multi-product order could not stand based on a violation involving a single product unless habitual violation of the Act had been established, but the Ninth Circuit Court of Appeals in Sears, Roebuck held the courts "regularly refused to follow such reasoning." Judge Adams also discussed the cases which AHP tried to distinguish, Litton Indus., Inc. v. FTC, 676 F.2d 364 (9th Cir. 1982) and Sears, Roebuck, but found AHP's effort to be unavailing. 695 F.2d at 709. Judge Adams stated that the multi-product orders involved in these two cases were comparable to the present order against AHP, and that the relationship of order coverage and the total number of products sold was not a relevant issue. 695 F.2d at 709.

102. The court reproduced the A.L.J.'s findings that AHP had spent $210 million on Anacin advertisements in print and broadcast media between 1960 and 1970. 695 F.2d at 708 n.43. The sample offending advertisements in this opinion were generally introduced as representative of dozens of others. See supra notes 44, 46 & 82.

103. 695 F.2d at 707.

104. Three prior litigated cease and desist orders against AHP for similar violations of the Act were: American Home Products Corp., 70 F.T.C. 1524 (1966), aff'd in part, modified in part, American Home Products Corp. v. FTC, 402 F.2d 232 (6th Cir. 1968) (representations that Preparation H could provide anything more than temporary relief found to be
ferable to its other products. 105

Section III(D) of the court’s opinion addressed the challenge made by AHP to Part II(D) of the Commission’s Order and advanced the grounds for supporting that challenge. The phrase “reasonable basis,” since it had not been adequately defined by the Commission and since it covered any non-prescription drugs and any non-comparative claims of effectiveness or freedom from side effects, was struck down for vagueness and overbreadth. 106 The court found the Commission’s justification for an all-encompassing provision to be based on AHP’s comparative claims and the one non-comparative claim that Anacin relieves tension. 107 Judge Adams feared an order approaching the scope of statutory provisions would shift enforcement from the Commission to the courts. 108 He also stated that the Commission did not adequately support its contention that AHP was likely to make false non-comparative claims. 109 Further, Judge Adams could find no explanation by the Commission for such an imprecise proscription. 110

With respect to Part III of the Order, 111 AHP argued that since other parts of the Order would ensure an end to deceptive claims about Anacin and APF ingredients, a disclosure requirement that the products contain aspirin would be a violation of first amendment guarantees of free speech. 112 The Commission had justified such a measure on the basis that public misconceptions about the products needed correction and AHP’s history of related advertis-
ing violations indicated that AHP had many ways of misrepresenting the contents of its products. The court upheld the Commission's judgment on the basis of the Jacob Siegel "reasonable relation" test and "fencing in" precedents.

AHP alleged that Part III was a burdensome prior restraint and only an affirmative misrepresentation could be barred as deceptive. The court found, however, it would be less of a burden for AHP to admit that Anacin and APF contain aspirin than to continue the practice of going on at length in its advertisements concealing that fact. The court further stated that this provision is triggered only when AHP is making performance claims, thus other kinds of advertising could be exempt from its strictures.

Judge Adams found that the commercial free speech cases relied upon by AHP were no help to its cause, for in general, they promote the concept of requiring qualifying explanatory language as opposed to excision of offending claims. He also pointed out that the extension of first amendment protection to commercial speech was intended to enhance the "clean" flow of information, and that AHP's intent to conceal the nature of its product would be a subversion of that doctrine.

Judge Adams concluded that the Order should be enforced as modified by the deletion of the part requiring a reasonable basis for non-comparative claims of product performance. In the interest of fairness, he thought the Commission should exercise its discretion and grant a stay of at least the part involving disclosure of a

113. Id. See 98 F.T.C. at 405-06.
114. 695 F.2d at 712. See supra notes 88-95 and accompanying text.
115. 695 F.2d at 712 n.49.
116. Id. at 712-13.
117. Id. at 713.
118. Id. See Beneficial Corp. v. FTC, 542 F.2d 611, 618-20 (3d Cir. 1976) (court overturned excision of phrase sought by FTC, stating that qualifying explanatory language is preferred remedy). See also In re R.M.J., 455 U.S. 191 (1982) (attorney advertising case in which Court reiterated that it is preferable for states when regulating misleading advertising to require disclaimers and explanations); Bates v. State Bar of Arizona, 433 U.S. 350 (1977) (recognizing warnings or disclaimers might be required in attorney advertising to assure consumers are not misled); Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976) (pharmacist permitted to advertise prescription drug prices which, if found to be misleading, could be dealt with effectively by state).
119. See National Comm'n on Egg Nutrition, v. FTC, 570 F.2d 157, 162 (7th Cir. 1977) (first amendment does not prohibit intervention by State when advertising is misleading or deceptive); Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 772 (1976) ("the [f]irst [a]mendment . . . does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely").
120. 695 F.2d at 714.
substantial question in the absence of clinical support, until the resolution of proceedings against AHP's competitors.121

The FTC has been regulating advertising since its creation by the 63rd Congress in 1914, pursuant to its broad mandate to prevent unfair methods of competition.122 The courts early on tried to restrict the Commission's jurisdiction to cases where injuries to competitors could be demonstrated,123 but Congress responded in 1938, with the Wheeler-Lea Amendments, clearly delegating to the FTC a power of enforcement for the protection of consumers.124 At the same time, the Commission's arsenal of regulatory devices was broadened with authority to obtain a temporary injunction when it reasonably believed an advertisement for foods, drugs, or cosmetics was false.125

The one power withheld from the Commission, that of promulgating rules beyond mere housekeeping and definition of unlawful practices, has meant that the Commission has had to establish its interpretative and specific standards one case at a time.126 According to various studies conducted at intervals during the Commission's existence,127 this method, combined with a Commission failure to establish priorities, led to crowded dockets involving trivial offenses, orders affecting single violators only, and standards evolv-

121. Id.
122. Developments in the Law-Deceptive Advertising, 80 Harv. L. Rev. 1005, 1019 (1967) (the first case heard by a court involving the FTC, Sears, Roebuck & Co. v. FTC, 258 F. 307 (7th Cir. 1919), concerned advertising practices found to be injurious to trade).
123. See, e.g., FTC v. Raladam Co., 283 U.S. 643 (6th Cir. 1931) (the Commission lacks jurisdiction where it can not show, in addition to injury to the public, that competition has been adversely affected).
126. See 1 R. Callman, The Law of Unfair Competition Trademarks and Monopolies §18.3 (1967); Developments in the Law-Deceptive Advertising, supra note 122, at 1064. But see National Petroleum Refiners Ass'n v. FTC, 340 F. Supp. 1343, rev'd, 482 F.2d 672 (D.C. Cir), cert. denied, 415 U.S. 951 (1972). Judge J. Skelly Wright broke new ground by deciding, contrary to what Congress and the FTC had always believed, that the FTC does have the power to promulgate substantive rules. This was not an advertising case.
127. See E. Cox, R. Fellmuth & J. Schulz, “The Nader Report” on the Federal Trade Commission, 44-45 (1969) (quoting the critical studies made of the FTC by G. Henderson in 1924, the Hoover Commission in 1949, and Auerbach in 1964. But see Developments in the Law-Deceptive Advertising, supra note 122, at 1024 (finding there is judicial reluctance to overrule Commission orders for lack of sufficient public interest because an important legal principle or the credibility of the FTC may be at stake in even the most minor cases).
ing in a piecemeal fashion.\textsuperscript{128} Herein, perhaps, lies an explanation for the lengthy opinion rendered by the Third Circuit Court of Appeals in the instant case. Judge Adams conducted an exhaustive study of deceptive advertising standards, writing, in effect, a treatise which emphasizes unanimity with decisions in other circuits and, perhaps, attempts to provide an antidote to a history of what commentators have viewed as the FTC’s failures and the judicial complicity in that result.\textsuperscript{129}

The courts have been viewed as the branch of government responsible for preventing abuses by a growing administrative power and presence.\textsuperscript{130} Administrative agencies are regarded as necessary to the mediation of disputes between groups, hopefully before they even arise, in a rapidly changing urban industrial society.\textsuperscript{131} The “fourth branch of government,” with its unique combination of executive, judicial, and legislative powers was originally hailed for its flexibility, expertise in specific fields, and potential for speedy recognition and control of complex problems.\textsuperscript{132} In practice, however, as exemplified by American Home Products Corp. v. FTC,\textsuperscript{133} hear-

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\item Contra Handler, Introduction to Symposium, The Fiftieth Anniversary of the Federal Trade Commission, 64 Colum. L. Rev. 385, 388 (1964) (finding the FTC provides “yeoman” service for consumers and honest businessmen).
\item See 1 R. Callman, supra note 126, at § 18.3 (“[t]hough the Commission has often been criticized, it is true, as Professor McLaughlin stated, ‘it must be conceded that the courts have overlooked few reasonable opportunities to contribute to that result.’”) (quoting McLaughlin, Cases on Federal Anti-Trust Laws 692 (1933)).
\item See generally R. Pound, Administrative Law (1942). Pound did not dispute the need for administrative agencies and their exercise of power, rather, he addressed his arguments against those who wanted to free agencies from judicial review and the constraints of due process. He outlined legislative safeguards which would maintain the balance among the branches of government and emphasized review of administrative action by the courts. A recent major decision by the Supreme Court, INS v. Chadha, 103 S. Ct. 2764 (1983), affirming, 634 F.2d 408 (9th Cir. 1981), seems to have definitively reserved to the courts the exclusive power to check the regulatory actions of federal agencies where Congress tries to by-pass proper procedure and vetoes such action.
\item See R. Pound, supra note 130, at 20-21. See also F. Frankfurter, The Public & Its Government (1930) (Justice Frankfurter strongly believed that government and administrative agencies were crucial to the functioning of an industrial society); and W. Douglas, Democracy and Finance 246 (1940) (the administrative agency is “the mechanism of democratic government whereby capitalism can discipline and preserve itself . . . . [I]t is in its infancy, but it is here to stay”).
\item W. Douglas, supra note 131, at 241.
\item 695 F.2d 681 (3d Cir. 1982). See also Nader Report, supra note 127, at 75 (“an investigation of the deceptive claims of analgesic companies began over a decade ago. [It] resulted, primarily in four dismissed complaints, after years of tests and years of still continuing deceptive ads”) (citing FTC news summaries, April 13, 1965, July 7, 1967, and November 30, 1967).
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ings drag on for years as the economic climate changes and the official record becomes a Draconian form of punishment for those required to read it.  

Judge Adams read the lengthy record and followed the standard of judicial review which has evolved, beginning with the decision in *Universal Camera Corp. v. NLRB*, requiring analysis of the substantial evidence in the record as a whole, when Commission findings of fact are at issue. In a case where a battle of the experts emerges and the meanings of words are disputed, the court is forced to sift through the data almost as thoroughly as the Commission does; but the court is required to defer to Commission judgment where a weighing of evidence is necessary. This deference has been criticized in the area of deceptive advertising which some compare to the old common law action of deceit, certainly well within the expertise of the judiciary. The courts agree, however, that evidence of consumer beliefs is not required in FTC advertising cases, essentially because of the burden it would place on a limited Commission budget; and hence, the courts have decided to rely on Commission interpretations. Judge Adams made

134. See *A Bitter Pill for Aspirin Makers*, Bus. Wk., July 5, 1982, at 78. Tylenol, a non-aspirin analgesic, since its introduction in the 1960's as a non-prescription drug, has steadily eroded aspirin's share of the market. By 1981, Tylenol sales represented 37% of the $850 million spent on over-the-counter analgesics. Further, the recently discovered link between Reyes Syndrome, a children's disease with a 20-30% mortality rate, and the use of aspirin is expected to have an impact on the industry if warnings are required on packaging.

135. See supra note 7. The A.L.J.'s findings and the Commission's opinion run several hundred pages at 98 F.T.C. 136 (1981), and petitioner's and respondent's briefs cite hundreds of pages of appendix references in their arguments.


137. 15 U.S.C. § 45(c) (1976) provides: "[t]he findings of the Commission as to the facts, if supported by the evidence, shall be conclusive." See FTC v. Colgate-Palmolive Co., 380 U.S. 374, 385 (1965); and cases cited by Judge Adams in *American Home Products*, 695 F.2d 681 at 686-87 n.6. See also Millstein, supra note 124, at 470.

138. See 1 R. Callman, supra note 126, at 656; *Developments in the Law-Deceptive Advertising*, supra note 122, at 1039.

139. See Charles of the Ritz Distributors Corp. v. FTC, 143 F.2d 676, 680 (2d Cir. 1944) (order not improper on account of lack of consumer testimony, since actual deception need not be shown in FTC proceedings) (citing FTC v. Winsted Hosiery Co., 258 U.S. 483, 494 (1922) and other cases). But see Pollay, Deceptive Advertising and Consumer Behavior: A Case for Legislative and Judicial Reform, 17 Kans. L. Rev. 625, 636 (1969) (urging, in fairness to innocent advertisers, that research on how consumers actually do interpret advertising should be required).

140. See *Developments in the Law-Deceptive Advertising*, supra note 122, at 1058.

141. Id. at 1039.
no departure from this practice in his opinion.\textsuperscript{142}

It is entirely possible that Commission findings of fact are influenced by considerations beyond those appearing in the record. By routinely deferring to agency expertise, the courts are not taking notice of the role that improper ex parte communications sometimes play in agency findings and decisions.\textsuperscript{143} Where the agency has made a determination profoundly affecting the party it is investigating, however, such a danger would appear to be of minimal importance with respect to the Commission's function as a public watchdog.\textsuperscript{144}

Judge Adams upheld those parts of the Order substantially supported by the record as a whole and reasonably related to the violations found, and he struck down the one part which appeared to lack such support.\textsuperscript{145} The excised part might have become a restraint on the rest of the over-the-counter drug industry, but because its relation to Anacin advertising was tenuous, the court overruled it.\textsuperscript{146}

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142. See supra notes 31-34 and accompanying text.
143. Nelson, Two, Three, Many Rita Lavelles, 236 Nation 394 (1983) (describing the ways in which ex parte meetings influence actions taken by the Environmental Protection Agency and the Occupational Safety and Health Administration). See also E. Freund, Administrative Powers Over Persons and Property 403 (1928) ("[t]he repression of private action upon the basis of vaguely defined economic principles makes a considerable demand upon administrative impartiality").
144. See Final Order, 48 Fed. Reg. 34,419 and 34,424 (1983) (FTC decisions regarding AHP's competitors). It is interesting to note that the FTC retreated from the more rigorous "substantial question" requirements of its Order against AHP. Sterling Drug, Inc. and Bristol Myers Co. need not reveal the existence of a substantial question in the scientific-medical community with respect to certain advertising claims, but may make such claims if possessing a reasonable basis to support them. Commissioners Pertchuk and Bailey dissented from this new majority position and indicated it is a reversal of the American Home Products doctrine and necessarily reverses parts of the American Home Products decision. The return to the Pfizer standard means advertisers will be able to continue to make comparative claims, distinguishing virtually identical products. Id. at 34,423.
145. See 695 F.2d at 710-711 (discussing Part II(D) of the Order which prohibited any non-comparative claims of effectiveness or freedom from side-effects for non-prescription drug products unless there is a reasonable basis for such claims). See supra notes 106-109 and accompanying text for the court's treatment of Part II(D) of the Commission's Order.
146. See generally FTC Staff Report, Advertising for Over-the-Counter Drugs (prepared May 22, 1979) (to be codified at 16 C.F.R. pt. 450). This report reviews research done by the FTC staff and hearings conducted during the same period the FTC was proceeding against AHP, involving some of the same experts and similar issues. The outcome of this endeavor was a proposed Trade Regulation Rule which would require ads for non-prescription drugs to convey the same information as that approved by the Food and Drug Administration on product labels and packaging, concerning indication-for-use claims. The report, in places, argues along the same lines as respondent's brief and may have been the impetus behind Part II(D) of the Order. If this part had withstood petitioner's challenge it would have approximated the impact on over-the-counter drug advertising of the proposed regula-
The due process and first amendment discussions in the case are familiar concerns in false advertising litigation. Here, the court was in traditional judicial territory and it can and did ensure that the party before the A.L.J. received a fair hearing and was subject only to constitutionally permissible restraints. It is true, as AHP argued, that the substantial question theory places a greater burden on advertisers and that it is different from the Pfizer standard. It is also true that the cases support an agency's power to develop interpretative standards which are prospective in operation during an adjudicative procedure. If affirmed by the court, the standards achieve precedential value in further litigation. From the standpoint of the regulated industry, this is not a satisfactory legal background against which to devise an ad campaign, for one could never be sure if a particular advertising stratagem were within the bounds of the law. On the other hand, it would encourage advertisers to avoid the outer limits of false and deceptive claims, something the industry itself proclaims as a

147. 695 F.2d at 693-95, 712-14.
148. See, e.g., National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157 (7th Cir. 1977) cert. denied, 439 U.S. 821 (1978) (first amendment does not preclude state from ensuring that commercial speech is free from deception). See also Staff Report, supra note 146, at 267-85 (discussing the impact of first amendment issues on deceptive advertising regulations); NADER REPORT, supra note 127, at xiii (some corporate lawyers prefer irregularities in formal administrative procedures so that agency decisions will be overruled in court on due process grounds); Developments in the Law-Deceptive Advertising, supra note 122, at 1027-29 (courts consistently hold that deceptive advertising proscriptions do not violate first amendment provisions).
149. Brief of Petitioner American Home Products Corporation at 20, American Home Products Corp. v. FTC, 695 F.2d 681 (the substantial question theory looks to the scientific and medical community and proof acceptable to its majority while the reasonable basis standard looks at the reliability of evidence possessed by the advertiser who makes the claim).
150. Pfizer, Inc., 81 F.T.C. 23, 62 (1972) (the reasonable basis doctrine requires advertisers to possess the level of substantiation for advertising claims which is fair to consumers and is based on the type of claim, the extent of consumer reliance on it, and the feasibility of obtaining support for it). Id.
151. See NLRB v. Bell Aerospace Co., 416 U.S. 267 (1974); SEC v. Chenery Corp., 332 U.S. 194 (1947); Golden Grain Macaroni Co. v. FTC, 472 F.2d 882 (9th Cir. 1972), cert denied, 412 U.S. 918 (1973). Agencies have discretion to choose the setting for announcing new rules and standards; Judge Adams focused on the requirements of notice and whether or not AHP had the opportunity to argue its position fully under the controlling theory. 695 F.2d at 693-95. See supra notes 55-61 and accompanying text. Cf. Ford Motor Co. v. FTC, 673 F.2d 1008 (9th Cir. 1982), cert. denied, 103 S. Ct. 358 (1982) (FTC abused its discretion by changing the law with widespread application in an adjudicative setting).
152. See L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 564 (1965) ("a de facto rule-making power is recognized when a court approves (as it often does) a policy or interpretation").
goal,\textsuperscript{153} although the present system does not seem to have achieved such a result.\textsuperscript{154}

It could be argued that consumers should be aware that vendors will make any claim to sell their products, but because of the unique nature of over-the-counter drugs and the state of advertising in modern America, with its impact on those subjected to its unrelenting presence in all forms of the media,\textsuperscript{155} caveat emptor has given way to caveat venditor.\textsuperscript{156} Thus, the most ignorant consumer is protected and under no duty to act wisely in the face of false advertisements which induce a purchase.\textsuperscript{157}

Such a theory is so integral to this area of law, that Judge Adams took no notice of it. He did state categorically, citing no authority, that over-the-counter drugs are susceptible to objective comparison testing.\textsuperscript{158} Counsel for the FTC indicated that there can be no “absolute proof” of comparative claims even though certain procedures can be employed when testing analgesic products

\textsuperscript{153} See J. BACKMAN, ADVERTISING AND COMPETITION 159 (1967) (this work, funded by a grant from the Association of National Advertisers, generally lauded advertising’s benefits to a capitalist society, but cautioned that “[e]very piece of advertising does not lead to . . . benefits. Certainly there is wide agreement that misleading advertising must be proscribed.”); 1 R. CALLMAN, supra note 126, at § 19.2(b)(3) (indicating that medicine ads with scientific explanations and claims insufficiently supported by accepted authority are “unfair to the public” and tend to “discredit advertising.”) (quoting the Association of National Advertisers and the American Association of Advertising Agencies appearing at Handler, The Control of False Advertising Under the Wheeler-Lea Act, 6 LAW & CONTEMP. PROBS. 91, 101 (1939)).

\textsuperscript{154} See R. NADER, M. GREEN & J. SELIGMAN, TAMING THE GIANT CORPORATION 25, 152 (1976) (reporting a study conducted by a public interest law firm affiliated with Georgetown University which found 60% of ads by television manufacturers were inadequately substantiated; an ad substantiation program initiated by the FTC in 1971, turned up a 30% rate of questionable claims).

\textsuperscript{155} See 695 F.2d at 708, n.43; supra note 102. See also R. NADER, supra note 154, at 24 (the average adult views 40,000 commercials a year on television and the leading 100 national advertisers spent $3.6 billion in 1974 to influence purchasing decisions); Staff Report, supra note 146, at 66-73 (analyzing what experts have found is “low-involvement” on the part of viewers of advertisements, characterized by a lack of perceptual defenses to the repetitive messages conveyed); id. at 55 (a study of 1321 people showed 43% got their information on over-the-counter drugs from advertising).

\textsuperscript{156} See 1 R. CALLMAN, supra note 126, at § 19.1(f) (the duty to reveal enough material facts to negate misleading implications is an important exception to the rule of caveat emptor and is triggered when the defendant speaks at all); LeViness, Caveat Eemptor Versus Caveat Venditor, 7 Md. L. Rev. 177 (1943).

\textsuperscript{157} See Charles of the Ritz Dist. Corp. v. FTC, 143 F.2d 676, 680 (2d Cir. 1944) (FTC may insist upon literal truthfulness in advertising); General Motors Corp. v. FTC, 114 F.2d 33, 36 (2d Cir. 1940), cert. denied, 312 U.S. 682 (1940) (FTC can insist advertising is clear enough not to deceive “fools”). See also Staff Report, supra note 146, at 13-15; Millstein supra note 124, at 460.

\textsuperscript{158} 695 F.2d at 697. See supra note 65 and accompanying text.
which reduce the possibility of error to an "acceptable minimum." Given, moreover, the emphasis on placebo effects, the "self-limiting" nature of many kinds of pain for which analgesics are used, and what the FTC has found and described as the subjectivity involved when individuals verbalize their physical condition, it is difficult to understand why Judge Adams believes superiority and freedom from side effects claims are factual and testable, even though he acknowledges the difficulty of verifying these claims. Such a belief merely perpetuates the propensity of advertising copywriters to differentiate products that are identical while adopting "proof" based on threshold levels of substantiation, or encourages advertisers to switch to other equally uninformative forms of advertising because such substantiation can never be achieved. The FTC and the courts would provide better protection for consumers if they took notice of the inutility of any such claims for duplicate over-the-counter internal analgesic preparations.

Further, Judge Adams appears to believe, with the FTC, that the over-the-counter drug industry itself is in the best position to conduct properly controlled clinical studies in an effort to substantiate advertising claims and is capable of doing so. Although there is no way to determine how widespread is the practice of improper clinical investigation and fictitious reporting, the Food and Drug Administration twice reported in 1982 that industry paid investigators were charged, convicted, fined, and imprisoned for not

159. See Brief for Respondent at 6 n.5, American Home Products Corp. v. FTC, 695 F.2d 681 (3d Cir. 1982).

160. 695 F.2d at 698.

161. See Staff Report, supra note 146, at 121-22.

162. See NADER REPORT, supra note 127, at 21 (stating that advertising distinguishes products that are identical and that Americans pay billions every year to be told that these contrived distinctions exist); R. NADER, supra note 154, at 208 (noting the costs of ad campaigns that sell brand name recognition resulting in brand name aspirin costing as much as three times more than store brand versions of the same thing); Developments in the Law-Deceptive Advertising, supra note 122, at 1047.

163. See Brief for Respondent, supra note 159, at 6 n.5 ("[t]wo clinical tests constitute the threshold at which most scientists will consider a comparative drug efficacy claim to be established for working purposes.") (emphasis in original).

164. See 695 F.2d at 714-15. Part I(B) of the Order sets forth the clinical testing requirements with which AHP must comply when making superiority or freedom from side effects claims. Independent experts are supposed to conduct such tests, but if they are not reimbursed for their efforts or directed by the manufacturer seeking to establish support for its product claims, what then is their incentive for undertaking product comparisons and investigations? See generally Pfizer, Inc., 81 F.T.C. 23 (1972) (manufacturer can more easily confirm product claims than individual consumers).
following written protocol and for falsifying data while testing the safety and effectiveness of new drugs. The industry may be in a better position to verify its affirmative product claims vis-a-vis the consumer, but the agencies responsible for overseeing the truthfulness of advertising and labeling claims are further burdened with investigating the professionals who conduct the clinical tests backing those claims.

These assumptions are potentially serious flaws in an otherwise conservative and reasonable outcome for a business at the top of the drug industry with an opportunity to take the lead and ensure that the “stream of commercial information flow[s] cleanly.” AHP either agreed with the outcome or believed that further judicial consideration would be fruitless, because no appeal was taken to the Supreme Court. The disclosure requirements, well supported by holdings in recent cases, and the substantiation requirements produced after ten years of hearings and appeals are still in abeyance as the Commission stayed the Order pending disposition of the petition to reopen filed by AHP. It is almost as if no action had been taken at all and AHP has been free in the intervening years to continue its conduct unfettered.


169. See, e.g., Porter & Dietsch, Inc. v. FTC, 605 F.2d 294 (7th Cir. 1979), cert. denied, 445 U.S. 950 (1980).

170. Letter from Benjamin I. Berman, Acting Secretary, FTC, to Samuel W. Murphy, Jr., Esq. (March 18, 1983) (the Commission modified the Order in accordance with the Third Circuit opinion, but stayed its effect until September 30, 1983 or 90 days following disposition of the petition to reopen, whichever is later).

171. Judge Adams noted that tension relief claims ceased in 1973. See 695 F.2d at 703 n.38. During the first half of 1983, Anacin advertising on the major television networks had abandoned comparative claims, relying instead on the endorsement of a renowned actress without disclosing the product’s major ingredient and still referring to that ingredient as “medicine.”
ploying its extraordinary powers, the FTC has had to settle for minor progress with little measurable effect to date.

The FTC long lacked or did not use the power to promulgate rules for regulating the industry practices it is charged with policing.\textsuperscript{172} Hence, it developed its body of unfair trade precepts on a case-by-case basis with a cautious judiciary ever ready and available to approve, limit, modify, or overturn final Commission orders. The result, as illustrated by \textit{American Home Products Corp. v. FTC},\textsuperscript{173} and as noted by commentators,\textsuperscript{174} is a nearly seventy year history of, at best, marginal success in curbing advertising excesses.

Business acts, the FTC reacts, and after years of hearings, testimony from dozens of experts, and a series of appeals, the courts decide whether or not the Commission has exceeded its jurisdiction, has the expertise or evidence to back its findings, or has misapplied the law or acted in an arbitrary and capricious manner. In the meantime, the market changes, advertising campaigns continue to deceive or shift gear, and countless other industries push their puffing beyond the limits of legality in an environment where it may not be profitable to do otherwise.\textsuperscript{175}

The courts have the power to give Commission rulings the force of law, and they have the power to curb forward-looking industry-wide regulatory standards. The court in the instant case has exercised both kinds of power. In the process, it has produced a standard treatise on administrative law and deceptive advertising and continued the judicial trend of pirouetting around a representative of the "fourth branch of government." With its painstaking review, the court has provided an important check on the Commission's effort to advance over-the-counter drug advertising regulation, but


\textsuperscript{173} 695 F.2d 681.

\textsuperscript{174} \textit{See supra} notes 127 and 129.

\textsuperscript{175} \textit{See J. Backman, supra} note 153, at 63-68 (recording the relatively high costs of advertising and promotion of drugs and the intensity of competition among leading manufacturers to remain on top of the industry); Charlton & Fawcett, \textit{The FTC and False Advertising}, 17 KANS. L. REV. 599, 601 (1969) ("[t]he need for deception is an outgrowth of the fierce sales competition by giant companies . . . and its rationale is the protection of millions of promotional dollars that each company stakes on its products.") (quoting \textit{Seldin, The Golden Fleece} 2 (1962)).
at the same time it has guaranteed that a cumbersome and expensive system will remain in a torpid state.

A more liberal use of and judicial support for the temporary preliminary injunction,\textsuperscript{176} more realistic framing of cease and desist orders,\textsuperscript{177} and vigorous Commission adoption of meticulously drafted Trade Regulation Rules\textsuperscript{178} should go a long way toward eliminating advertising practices injurious to competition and consumer health and safety. If this is a goal which advertisers and the public believe is best achieved by government supervision and regulation,\textsuperscript{179} then it should not take ten years of proceedings at taxpayers' and consumers' expense to require a manufacturer to disclose the contents of its product and to prove its claims are substantiated to the satisfaction of the agency with authority to ensure truth in advertising.

\textit{Dale Elizabeth Walker}

\textsuperscript{176} 15 U.S.C. § 53 (1976) (this power is considered to be an extraordinary and drastic measure; it is difficult to find more than a few cases where the FTC has even attempted to use it to regulate advertising). \textit{See} Millstein, \textit{supra} note 124, at 493 (urging strict limitations on its use). If advertisers were subjected to interruptions in their advertising campaigns, it would necessarily be economically prudent for them to be more circumspect with regard to the kinds of claims they make about their products.

\textsuperscript{177} \textit{See} supra note 164 and accompanying text.

\textsuperscript{178} \textit{See} Developments in the Law-Deceptive Advertising, \textit{supra} note 122, at 1091-95.

\textsuperscript{179} \textit{J. Henry, Culture Against Man} 98 (1963) (a critic of the role of advertising in society, Jules Henry recommended that the government treat advertising as a public utility and regulate it as such).