tion allowed the jury to find copying without also finding substantial similarity between Aldon's and Spiegel's statuettes. However, we do not think this is so. The judge had just said that "overwhelming" similarity where "the similar elements are of such an unusual or distinct nature that it is unlikely that someone else would have dreamed them up on his own or arrived at them in any way other than by copying" permitted an inference of copying "without very convincing proof" of access. The next sentence, here challenged by Spiegel, simply advised the jury that such an "overwhelming" degree of similarity was not required where proof of access was present. See 3 Nimmer on Copyright, supra, § 13.03[D] at 13-39. In any event, even if the sentence is interpreted to communicate the meaning attributed by Spiegel, the error was harmless, in view of the statement of Spiegel's counsel to the jury that "I won't tell you that [Aldon's and Spiegel's] products aren't virtually the same." Moreover, a reading of the entire eight-page charge on copying leaves no doubt that the judge properly charged the jury on similarity.

[4] The judgment of the district court is affirmed. The parties' respective requests for award of attorneys' fees are denied.[5]

elements than the plaintiff's work, a strong case of copying would be made by reason of those similarities, even without very convincing proof of the defendant's access to the plaintiff's work.

On the other hand, the more convincing the proof of access by the copier, the assumed copier [of] the plaintiff's work, the less impressive the similarities have to be to support a conclusion of copying. You should consider these and all other logically relevant circumstances in deciding whether you find that the defendant copied the plaintiff's work. [Emphasis added.]

BRISTOL-MYERS COMPANY,
Petitioner,

v.

FEDERAL TRADE COMMISSION,
Respondent.

No. 1053, Docket 83-4167.

United States Court of Appeals,
Second Circuit.

Argued April 2, 1984.

Decided June 25, 1984.

Drug manufacturer sought review of an order of the Federal Trade Commission made in respect to advertising by the plaintiff of its well-known analgesics. The Court of Appeals, Oakes, Circuit Judge, held that: (1) portion of order of the Commission was premised upon Commission's factual determination, which was supported by substantial evidence, that only two well-controlled clinical studies could establish plaintiff drug manufacturer's superior freedom-from-side-effects claim for its analgesic; (2) generally, Food and Drug Administration is concerned only with evaluating absolute safety and efficacy, and not with questions of comparative safety and efficacy that arise in over-the-counter drug advertising, but with simply providing low threshold for withdrawal of drug on safety grounds, and thus FDA requirements and regulations did not govern resolution of issue as to whether order of FTC was supported by substantial evidence or was overly broad; and (3) the FTC order was not overly broad, vague, or unreasonable.

Petition denied, and order enforced.

5. Aldon challenges the granting of the $20,000 remittitur and requests that the full jury verdict be restored. Aldon accepted the remittitur, and under established law in this circuit could not raise the issue even if it had cross-appealed, which it has not. *Akermanis v. Sea-Land Service, Inc.*, 688 F.2d 898, 903 (2d Cir.1982), cert. denied, — U.S. —, 103 S.Ct. 2087, 77 L.Ed.2d 298 (1983) and — U.S. —, 104 S.Ct. 700, 79 L.Ed.2d 165 (1984).

1. Drugs and Narcotics ⇐5

Portion of order of Federal Trade Commission was premised upon Commission's factual determination, which was supported by substantial evidence, that only two well-controlled clinical studies could establish plaintiff drug manufacturer's superior freedom-from-side-effects claim for its analgesic. Federal Food, Drug, and Cosmetic Act, § 505(d), as amended, 21 U.S.C.A. § 355(d).

2. Drugs and Narcotics ⇐5

Generally, Food and Drug Administration is concerned only with evaluating absolute safety and efficacy, and not with questions of comparative safety and efficacy that arise in over-the-counter drug advertising, but with providing low threshold for withdrawal of drug on safety grounds, and thus FDA requirements and regulations did not govern resolution of issue as to whether order of Federal Trade Commission was supported by substantial evidence or was overly broad. Federal Trade Commission Act, §§ 5, 12, as amended, 15 U.S.C.A. §§ 45, 52; Federal Food, Drug, and Cosmetic Act, § 505(d), (e)(1), as amended, 21 U.S.C.A. § 355(d), (e)(1).

3. Drugs and Narcotics ⇐10

Contentions of drug manufacturer on challenge to order of the Federal Trade Commission could be rejected by Court of Appeals on ground that they had not previously been raised before the Commission.

4. Drugs and Narcotics ⇐5

Absolute precision is not possible in certain orders of the Federal Trade Commission, and order prohibiting drug manufacturer from making any therapeutic performance or freedom-from-side-effects claim for any over-the-counter analgesic without reasonable basis consisting of competent and reliable scientific evidence supporting claim was not shown to be unduly vague. Federal Trade Commission Act, §§ 5, 12, as amended, 15 U.S.C.A. §§ 45, 52; Federal Food, Drug, and Cosmetic Act, § 505(d), (e)(1), as amended, 21 U.S.C.A. § 355(d), (e)(1).

5. Drugs and Narcotics ⇐5

It was necessary that every provision of order of Federal Trade Commission bear "reasonable relation" to conduct of drug manufacturer that was found unlawful, but portion of Commission's order prohibiting unsubstantiated claims by drug manufacturer concerning effectiveness and freedom-from-side-effects was not objectionable as overbroad or as not bearing reasonable relation to violation. Federal Trade Commission Act, §§ 5, 5(b), 12, as amended, 15 U.S.C.A. §§ 45, 45(b), 52; Federal Food, Drug, and Cosmetic Act, §§ 1-902(b, c), as amended, 21 U.S.C.A. §§ 301-392.

6. Drugs and Narcotics ⇐10

Under "fencing-in" doctrine, Federal Trade Commission may frame remedy which extends beyond precise illegal conduct found, and factors to be taken into consideration included nature and extent of violation, adaptability or transferability of practice to other products and past record of performance. Federal Trade Commission Act, §§ 5, 5(b), 12, as amended, 15 U.S.C.A. §§ 45, 45(b), 52; Federal Food, Drug, and Cosmetic Act, §§ 1-902(b, c), as amended, 21 U.S.C.A. §§ 301-392.

7. Constitutional Law ⇐90.3

Deceptive advertising enjoys no constitutional protection, and may be regulated, and even in absence of finding of actual deception, agencies may properly regulate speech that is merely potentially deceptive. Federal Trade Commission Act, §§ 5, 12, as amended, 15 U.S.C.A. §§ 45, 52; U.S.C.A. Const.Amend. 1; Federal Food, Drug, and Cosmetic Act, § 505(d), as amended, 21 U.S.C.A. § 355(d).

8. Drugs and Narcotics ⇐10

Federal Trade Commission's factual finding, based on its investigation of drug manufacturer's ads, that consumers viewing ads would believe them to be making claims supported by reasonable basis and that, lacking such basis, the ads were deceptive constituted conclusion which was entitled to "great weight" from reviewing court, as against contention that Commission was not entitled to presume that con-

sumers expect all supportable product claims to possess reasonable basis to support the claims. Federal Trade Commission Act, §§ 5, 12, as amended, 15 U.S.C.A. §§ 45, 52; U.S.C.A. Const.Amend. 1; Federal Food, Drug, and Cosmetic Act, § 505(d), as amended, 21 U.S.C.A. § 355(d).

9. Drugs and Narcotics ⇐5

Federal Trade Commission order purporting to remedy wrongs which Commission has found not to have been committed should be set aside, but portion of its order applying to "unusual or special ingredient representations" for all of plaintiff's over-the-counter drugs was reasonably related to violation made by misrepresenting that plaintiff's analgesics did not contain aspirin. Federal Trade Commission Act, § 5, 12, as amended, 15 U.S.C.A. §§ 45, 52; Federal Food, Drug, and Cosmetic Act, § 505(d), (e)(1), as amended, 21 U.S.C.A. § 355(d), (e)(1).

10. Drugs and Narcotics ⇐5

In interpreting advertisements, Federal Trade Commission may rely on its own expertise in such area and need not resort to surveys and consumer testimony, and Commission's finding that ads indicated that doctors recommended plaintiff's analgesic product more than any other over-the-counter internal analgesic was supported by substantial evidence on the record. Federal Trade Commission Act, §§ 5, 12, as amended, 15 U.S.C.A. §§ 45, 52; Federal Food, Drug, and Cosmetic Act, § 505(d), (e)(1), as amended, 21 U.S.C.A. § 355(d), (e)(1).

11. Drugs and Narcotics ⇐5

Fact that audio portion of television advertisement was qualified by reference to "all leading brands of pain reliever" did not take effect on consumer of full ad into account and did not preclude finding by the Federal Trade Commission that message conveyed by ads was false and misleading. Federal Trade Commission Act, §§ 5, 5(b), 12, as amended, 15 U.S.C.A. §§ 45, 45(b), 52; Federal Food, Drug, and Cosmetic Act, §§ 1–902(b, c), as amended, 21 U.S.C.A. §§ 301–392.

12. Drugs and Narcotics ⇐5

In view of fact that coverage of Federal Trade Commission's order to drug manufacturer was otherwise quite narrow, being limited, in one portion, to false claims that an ingredient is unusual or special, and, in another portion, to unsubstantiated claims regarding recommendations or endorsements, order was not unreasonable in applying to all nonprescription drugs manufactured by plaintiff as against contention that false advertising was shown only with respect to certain products. Federal Trade Commission Act, §§ 5, 5(b), 12, as amended, 15 U.S.C.A. §§ 45, 45(b), 52; Federal Food, Drug, and Cosmetic Act, §§ 1–902(b, c), as amended, 21 U.S.C.A. §§ 301–392.

Kenneth A. Plevan, New York City (Miriam L. Siroky, Elaine D. Ziff, Skadden, Arps, Slate, Meagher & Flom, New York City, Gilbert H. Weil, Gerald Guttman, Jay S. Davis, Weil, Guttman, Davis & Malkin, New York City, of counsel), for petitioner.

Melvin H. Orlans, Atty., F.T.C., Washington, D.C. (John H. Carley, Gen. Counsel, Howard E. Shapiro, Deputy Gen. Counsel, Ernest J. Isenstadt, Asst. Gen. Counsel, F.T.C., Washington, D.C., of counsel), for respondent.

Before FEINBERG, Chief Judge, and FRIENDLY and OAKES, Circuit Judges.

OAKES, Circuit Judge:

Bristol-Myers Company (Bristol) petitions for review of an order of the Federal Trade Commission (the Commission or FTC) made in respect to the advertising by Bristol of its well-known analgesics, Bufferin and Excedrin. The order represents over ten years of agency work formally commencing with the filing of complaints on February 23, 1973 by the Commission against Bristol and its advertising agencies, Ted Bates & Co., Inc. and Young & Rubicam, Inc., concerning alleged violations of sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52 (1982). On the same day the Commission also filed complaints challeng-

ing the advertising of certain competing non-prescription internal analgesic products, including Anacin (*In re American Home Products Corp.*, 98 F.T.C. 136, 362 (1981), *enforced as modified, American Home Products Corp. v. FTC*, 695 F.2d 681 (3d Cir.1983) (*AHP*) [1]), and Bayer Aspirin (*In re Sterling Drug, Inc.*, No. 8919 (July 5, 1983), *appeal pending*, No. 83-7700 (9th Cir. filed Jan. 30, 1984)). We have considered each of Bristol's claims as to the remedial order and deny the petition for review and grant enforcement.

The Commission Decision and Order

The Commission's decision upheld findings by its Administrative Law Judge (ALJ) that Bristol had engaged in a variety of deceptive practices in advertising Excedrin and Bufferin from 1960 to 1973, but dismissed the complaint allegations concerning Excedrin PM because it found that Bristol had not made the challenged claims as to that product. In concluding that Bristol and its advertising agencies had deceptively advertised Excedrin and Bufferin, the Commission found that Bristol had misrepresented that the analgesic superiority of Excedrin and Bufferin over competing products was scientifically proved, or "established," by the artful use of certain phrases such as "scientific tests" and "medically endorsed," as well as by the use of visual images. Bristol was found to have made seven false and deceptive claims of this nature, concerning both the efficacy and the freedom-from-side-effects of its non-prescription internal analgesic products.[2] Part I of the Order prohibits Bristol from making comparative establishment claims asserting the superior effectiveness or freedom-from-side-effects of its OTC internal analgesics without proof consisting of "two or more adequate and well-controlled clinical investigations" conducted in accordance with procedures set forth in detail in the Order.

In addition the Commission found that Bristol had claimed, without a reasonable basis, that both Bufferin, which is a form of buffered asprin, and Excedrin, a combination of aspirin, salicylamide, acetaminophen and caffeine, relieved tension and that physicians recommend Bufferin more frequently than they recommend any other OTC internal analgesic. Finding that such unsubstantiated claims were deceptive, the Commission in Part II of its Order requires Bristol not to make "any therapeutic performance or freedom-from-side-effects claim" for any OTC internal analgesic unless it has a "reasonable basis for making that claim [consisting of] competent and reliable scientific evidence supporting that claim." Part II, then, requires that all claims of this type be reasonable, while Part I imposes more rigorous requirements on similar comparative establishment claims.

The Commission also found that Bristol deceptively advertised that its products contained "unusual" or "special" ingredients even though the very same ingredi-

1. Following the Third Circuit's decision in *AHP*, the FTC reopened its proceedings against AHP and subsequently modified the order to make it similar in scope to the orders in *Bristol* and in *Sterling Drug*. *See In re American Home Products Corp.*, No. 8918, June 7, 1984.

2. Such claims that the efficacy or safety of a product is scientifically established will be referred to as "establishment claims," and the non-prescription internal analgesics at issue here will be referred to as "OTC" (over the counter) internal analgesics. Further, we adopt the Commission's use of the term "comparative claim" to mean a claim which compares one drug with another, with "noncomparative claim" being a claim made uniquely about one product.

Bristol misrepresented that it had been established that: (1) Bufferin relieves pain faster than aspirin; (2) Bufferin relieves pain twice as fast as aspirin; (3) Bufferin will upset a person's stomach less frequently than aspirin; (4) a dose of Excedrin relieves more pain than a dose of aspirin; (5) a dose of Excedrin relieves twice as much pain as a dose of aspirin; (6) Excedrin is a more effective pain reliever than aspirin or any other OTC analgesic; and (7) Excedrin is more effective than any other OTC analgesic because it has four ingredients. Charges that Bristol had made eight other establishment claims were dismissed, because the claims were found not to have been made.

ents are commonly used in other OTC drug products intended for the same use or uses as the product advertised. These "special ingredient" claims were also found to have been made so as to conceal the fact that Bufferin and Excedrin were aspirin based, the deception operating by way of emphasis upon the unspecified analgesic ingredient. Part IIIA of the Order prohibits special ingredient advertising when the ingredient referred to is commonly used in other products for the same purpose. Noting that Bristol had previously signed stipulations in respect to special ingredient claims for a cold remedy and a facial cream, this part of the Order was applied across the board to all Bristol OTC products and not merely to OTC internal analgesics.

The Commission further found that Bristol falsely represented that doctors recommend Bufferin more than any other OTC internal analgesic. Part IIIB of the Order prohibits Bristol from representing "that any group, body or organization endorses or recommends [the use of a Bristol OTC drug] unless at the time such statement or representation is made, respondent has a reasonable basis for such statement or representation." This part of the Order was applied to all Bristol OTC drug products in the light of an earlier history of similar "doctors recommend" claims made by Bristol in connection with other products. *See In re Bristol-Myers Co.*, 46 F.T.C. 162, 170 (1949) (order), *aff'd*, 185 F.2d 58 (4th Cir. 1950); 24 F.T.C. 1554 (1937) (stipulation).

On the other hand, the Commission declined to accept complaint counsel's recommendation that Bristol be required to run corrective advertising. *See Warner-Lambert Co. v. FTC*, 562 F.2d 749, 756–59 (D.C. Cir.1977), *cert. denied*, 435 U.S. 950, 98 S.Ct. 1576, 55 L.Ed.2d 800 (1978). It also declined to uphold the ALJ insofar as his order would have applied to the labelling of Bristol products as well as to Bristol's advertising, in the light of the FTC's liaison agreement with the FDA as set forth in *AHP*, 98 F.T.C. at 411.

Discussion

Bristol makes a variety of objections to all three parts of the Order. As to Part I, Bristol contends that it should apply only to effectiveness claims, and that it should permit reliance on FDA studies. Part II is alleged to be unduly and unconstitutionally vague and overbroad, and is also said to rely on an "advertising substantiation" doctrine which violates the First Amendment. Part III is also allegedly overbroad. Moreover Part IIIA is said not to be reasonably related to any violation actually found by the FTC, and Part IIIB based upon fact-finding which is clearly erroneous.[3]

A. *Part I's applicability to freedom-from-side-effects claims.* Bristol argues that the FTC had no basis for requiring two adequate, well-controlled clinical studies for freedom-from-side-effects comparative claims, so that Part I of the Order should be modified to apply solely to effectiveness claims. The Commission is said to have relied in formulating the two studies requirement upon FDA regulations which themselves distinguish between effectiveness claims, the validity of which should be proved by "controlled clinical investigations," and safety claims, proof of which "shall consist of adequate tests by methods reasonably applicable...." 21 C.F.R. § 330.10(a)(4)(i) (safety), (ii) (effectiveness) (1983). The Commission is also said to have erred in stating that its clinical study requirement is consistent with the 1962 amendments to the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 355(d) (1982). Under that statute, Bristol states, the "substantial evidence standard" applies only to product effectiveness claims and

3. On appeal Bristol argued that Part II's reasonable basis requirement for noncomparative claims put it at a disadvantage in relation to AHP, since the Third Circuit deleted the reasonable basis provision from the FTC's order in *AHP*. However, when the Commission modified the order in *AHP* in light of the Third Circuit's opinion, it included a new reasonable basis provision analogous to the one we are addressing here designed to meet the objections of the Third Circuit in *AHP*. Thus Bristol's competitive disadvantage argument has been mooted by the modified order in *AHP*.

does not apply to safety claims. *See E.R. Squibb & Sons, Inc. v. Weinberger*, 483 F.2d 1382, 1385 (3d Cir.1973). And pointing to the Commission's own opinion in *AHP*, Bristol notes that no freedom-from-side-effects claims were held subject to the two well-controlled clinical studies requirement in *AHP*. This is so because the only freedom-from-side-effects establishment allegation made in that case was dismissed because AHP was found not to have made the claim. 98 F.T.C. at 374 n. 21. Bristol proposes that the correct test should be that product safety may be evaluated by "clinical or other experience, tests, or other scientific data." *See E.R. Squibb & Sons*, 483 F.2d at 1385 nn. 18, 19. Under that standard Bristol states that it submitted four studies to support its claim that Bufferin upsets the stomach less frequently than aspirin.

[1] We agree with the Commission, however, that the side-effects portion of Part I is premised on the Commission's factual determination supported by substantial evidence, that only two well-controlled clinical studies could establish Bristol's superior freedom-from-side-effects claim for Bufferin. Even assuming that Bristol is entitled to raise this question here for the first time, *United States v. L.A. Tucker Trucklines, Inc.*, 344 U.S. 33, 36–37, 73 S.Ct. 67, 68–69, 97 L.Ed. 54 (1952), the Commission found that Bristol claimed that Bufferin was proven to cause less stomach upset than aspirin without adequate substantiation. Dr. Grossman, an expert in the field of gastroenterology and gastrointestinal side-effects of aspirin, testified that only well-controlled clinical studies could establish that Bufferin causes less stomach upset than aspirin. His testimony amounts to substantial evidence on the record, which the Commission was entitled to rely upon in setting its standard. It should also be noted that the Third Circuit, in the context of reviewing the "substantial question" doctrine in that case,[4] concluded that both comparative safety (freedom-from-side-effects) and comparative effectiveness claims could appropriately be subjected to the two clinical test standard. *See* 695 F.2d at 695–98. Here as there the Order is upheld as supported by substantial evidence.

[2] Insofar as FDA requirements and regulations are concerned, they simply do not govern this case. Not only is a different regulatory scheme involved, but generally speaking the FDA is concerned only with evaluating absolute safety and efficacy, and not with the questions of comparative safety and efficacy that arise in OTC drug advertising. Moreover, *E.R. Squibb & Sons*, 483 F.2d 1382, is wholly inapposite. That case involved withdrawal, not approval of a new drug application, and in providing that withdrawal may take place where "clinical or other experience, tests, or other scientific data show that such drug is unsafe," 21 U.S.C. § 355(e)(1) (1982), the FDA regulatory scheme simply provides a low threshold for withdrawal of a drug on safety grounds.

B. *Part I and FDA approval as establishment evidence.* Bristol seeks to modify Part I of the Commission Order to permit it to rely upon FDA regulations or other definitive FDA action approving claims for OTC internal analgesics as "establishing" such claims. Since the FDA is responsible under its Act, 21 U.S.C. §§ 301–392 (1982), to ensure that all OTC drugs are safe, effective and not misbranded, *see* 21 C.F.R. § 330.10 (1983), Bristol argues that the FTC should be satisfied by FDA approval. In this connection we note the existence of a liaison agreement between the two agencies, 36 Fed.Reg. 18,539 (1971), whereby the FTC defers to the FDA when allegedly deceptive claims appear on labelling for food, drugs or cosmetics.

4. In *AHP*, Part I–B of the Commission Order provided that whenever AHP's advertisements claim superior effectiveness or freedom-from-side-effects, even when those advertisements do not overtly claim that this superiority has been established or proven, AHP must provide two or more well-controlled clinical studies to support the superiority claims or disclose that the superiority is open to "substantial question." *See* 695 F.2d at 684, 693–702. The "substantial question" provision of the *AHP* order was subsequently dropped from the modified order.

And we also note that the FDA has instituted an OTC Drug Review Program. *See* 21 C.F.R. § 330.1 (1983); *see generally Cutler v. Kennedy*, 475 F.Supp. 838, 844–45 (D.D.C.1979).

[3] Here too Bristol's contentions could be rejected on the ground that they were not previously raised before the Commission. Even on the merits, however, the modifications Bristol requests are unnecessary, if not undesirable. As we have indicated, the FDA's regulations are concerned almost exclusively with absolute claims. Part I of the Commission's Order here deals solely with comparative establishment claims. Therefore almost nothing would be gained by allowing the FDA's regulations to be used as requested by Bristol. Moreover FDA determinations are usually complex and subject to varying interpretations. To allow Bristol to rely on its evaluation of these determinations could conceivably lead to more deceptive advertisements and to more disputes with the FTC. The Commission is entitled to fashion its order to avoid such problems. There is nothing, however, to prevent Bristol from seeking modification from the Commission under section 5(b) of the Act, 15 U.S.C. § 45(b) (1982), and Commission regulations, 16 C.F.R. § 3.72 (1984) in the unlikely event that the FDA has occasion to consider a particular relevant comparative establishment claim and approves it without clinical testing.

[4] C. *Part II's alleged vagueness.* Citing *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392, 85 S.Ct. 1035, 1046, 13 L.Ed.2d 904 (1965), Bristol argues that Part II of the Order is unduly vague insofar as it declines to specify "the amount and kinds of evidence necessary to constitute a reasonable basis for Bristol-Myers' future claims." The Commission has allegedly improperly left the determination of what constitutes a reasonable basis to case-by-case analysis. This is especially unfair, Bristol argues, because the only reasonable basis violation found in this case relates to a discontinued claim by Bristol that Excedrin, a drug containing caffein as one ingredient, is a "tension reliever." Finally, Bristol points to the Third Circuit's statement in *AHP* that "[b]ecause the Commission has chosen not to bind itself in advance to rules as to the interpretation of the phrase 'reasonable basis,' any order which essentially relies upon 'reasonable basis' language will be imprecise, although not necessarily so." 695 F.2d at 710.

But absolute precision is not possible in certain FTC orders, and we have upheld reasonable basis provisions formulated in substantially identical terms. *E.g., Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1245–46, 1250–51 (2d Cir.), *cert. denied*, 444 U.S. 980, 100 S.Ct. 481, 62 L.Ed.2d 406 (1979); *see also* our decision enforcing the FTC's order in *In re Fedders Corp.*, 85 F.T.C. 38, 69 (1975) (performance claims for airconditioners must be substantiated by "competent scientific, engineering or other similar objective material"), *order enforced, Fedders Corp. v. FTC*, 529 F.2d 1398 (2d Cir.), *cert. denied*, 429 U.S. 818, 97 S.Ct. 63, 50 L.Ed.2d 79 (1976). We note also that Part II of the Order is limited in scope to performance and side-effects claims for OTC internal analgesics and that it defines reasonable basis to consist of "competent and reliable scientific evidence." Moreover, the Commission has issued some 21 litigated orders and 126 consent orders involving advertising substantiation using equivalent language. If the Third Circuit decision in *AHP* may be read as holding that the reasonable basis standard of "competent and reliable scientific evidence" is excessively vague, with respect we decline to follow it since our own decisions require that we uphold the Order. But we note that the *AHP* court recognized that while reasonable basis language is "imprecise," it was careful to add the clause, "although not necessarily fatally so." 695 F.2d at 710. The part of the Order in that case was in fact vacated for the combined problems of overbreadth and vagueness.

[5] D. *Part II's alleged overbreadth and unreasonable relation to the violation.* Every provision of the Order must bear a "reasonable relation" to the conduct

of Bristol that was found unlawful. *See ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 220–21 (2d Cir.1976). Part II of the Order prohibits unsubstantiated claims concerning effectiveness and freedom-from-side-effects. Bristol argues that the only effectiveness claim it made that was found to be without a reasonable basis was the noncomparative claim that Bufferin and Excedrin relieved tension, and that this finding is too narrow a basis to justify Part II of the Order. The Third Circuit, in striking the "reasonable basis" provision in Part II–D of the *AHP* Order as vague and overbroad, did so in part because the only noncomparative advertising claim on which that part of the Order was based was the claim that Anacin relieves tension. 695 F.2d at 711.

But we agree with the Commission that Part II of the Order here is more narrowly drawn than the section struck in *AHP*. The provision is limited to the product category in question, namely OTC internal analgesics, and directly addresses that violation. Moreover, none of the violations covered by Part II are also covered by other parts of the Order. In the original *AHP* order nonestablishment comparative claims were covered by a separate "substantial question" provision. Bristol's advertising of this nature is pervasive, involving two different OTC internal analgesic products and encompassing widely disseminated comparative and noncomparative claims regarding both performance and freedom-from-side-effects.

[6] Under the "fencing-in" doctrine, the Commission may frame a remedy which extends beyond the precise illegal conduct found. *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395, 85 S.Ct. 1035, 1048, 13 L.Ed.2d 904 (1965); *FTC v. National Lead Co.*, 352 U.S. 419, 428–29, 77 S.Ct. 502, 508–09, 1 L.Ed.2d 438 (1957). Considering the nature and extent of the violation, the adaptability or transferability of the practice to other products and the past record of performance, the factors considered by the Ninth Circuit in *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir.1982), the Commission's Order must be supported here. From 1960 to 1973, Bristol spent over two hundred fifty million dollars advertising its products, and in the process it made seven deceptive establishment claims and three deceptive reasonable basis claims. In sum we find it proper for the Commission to rely on false establishment claims as a basis for extending the Order's coverage to deceptive nonestablishment claims. *See Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 305–06 (7th Cir.1979), *cert. denied*, 445 U.S. 950, 100 S.Ct. 1597, 63 L.Ed.2d 784 (1980); *In re Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 441, 462–63 (1973), *order enforced, Firestone Tire & Rubber Co. v. FTC*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112, 94 S.Ct. 841, 38 L.Ed.2d 739 (1973). To rule otherwise would allow Bristol to continue to make the same unsubstantiated and false claims by simply removing the "doctors recommend" language from its advertisements.

Bristol argues, moreover, that the FTC never considered whether Bristol had a reasonable basis for its establishment claims in this case since they were covered by the more rigorous standard of Part I of the Order. But this is beside the point when we consider the number of establishment claims that were in fact proven unsubstantiated. In terms of the history of Bristol's dealings with the Commission,[5] while Bristol prevailed in *In re Bristol-Myers Co.*, 85 F.T.C. 688, 741, 743 (1975), and received only a warning in *In re Bristol-Myers Co.*, 74 F.T.C. 780, 851, 860 (1968) (violation found but no order entered), we note that Bristol has entered into seven stipulations

5. For litigated cases involving Bristol, *see In re Bristol-Myers Co.*, 36 F.T.C. 707, 715 (1943) (false and deceptive advertising claims regarding the laxative "Sal Hepatica"); *In re Bristol-Myers Co.*, 46 F.T.C. 162, 170 (1949) (false therapeutic claim for "Ipana" toothpaste and false claim that dentists recommend it), *aff'd, Bristol-Myers Co. v. FTC*, 185 F.2d 58 (4th Cir.1950); *In re Grove Laboratories*, 71 F.T.C. 822, 830 (1967) (false and deceptive advertisements regarding "Pazo Formula," a hemorrhoid preparation), *enforced in part, Grove Laboratories v. FTC*, 418 F.2d 489 (5th Cir.1969); *In re Bristol-Myers Co.*, 74 F.T.C. 780, 851, 860 (1968).

admitting violations charged which may be introduced into evidence in any subsequent proceeding.[6] Bristol's repeated use of false and misleading advertising amply justifies the scope of Part II of the FTC's remedial order.

[7] E. *The First Amendment Argument.* Bristol argues that Part II violates the First Amendment in the light of the protection due commercial speech. *See Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976). *See also In re RMJ*, 455 U.S. 191, 207, 102 S.Ct. 929, 939, 71 L.Ed.2d 64 (1982). But, as we have pointed out, deceptive advertising enjoys no constitutional protection and it may be regulated, *Jay Norris*, 598 F.2d at 1251–52; *see In re RMJ*, 455 U.S. at 203, 102 S.Ct. at 937. Even in the absence of a finding of actual deception, agencies may properly regulate speech that is merely potentially deceptive. *See Friedman v. Rogers*, 440 U.S. 1, 15, 99 S.Ct. 887, 897, 59 L.Ed.2d 100 (1979). This Order is not as broad as the order we upheld against First Amendment challenge in *Jay Norris*.

Nor is the prior substantiation doctrine as applied here in violation of the First Amendment. Bristol contends that the FTC is not entitled to presume that consumers expect all supportable product claims to possess a reasonable basis to support the claims. It therefore wishes us to reject a whole series of FTC cases allegedly relying on such a presumption. *See, e.g., In re National Commission on Egg Nutrition*, 88 F.T.C. 84, 174, 191 (1976), *enforced as modified, National Commission on Egg Nutrition v. FTC*, 570 F.2d 157 (7th Cir.1977).

[8] Whatever the merits the argument that the use of such a presumption violates the First Amendment, it is clear that in this case the FTC made a factual finding, based on its investigation of Bristol's ads, that consumers viewing the ads would believe them to be making claims supported by a reasonable basis. It then found that lacking such a basis the ads were deceptive. A conclusion of this nature is "in the very realm of the Commission's greatest expertise—what constitutes deception in advertising.... As such the reviewing court must give the Commission's findings 'great weight.' " *Fedders Corp. v. FTC*, 529 F.2d 1398, 1403 (2d Cir.) (citations omitted), *cert. denied*, 429 U.S. 818, 97 S.Ct. 63, 50 L.Ed.2d 79 (1976). We find the conclusion amply supported in this case.

[9] F. *Part IIIA of the Order and its relation to finding of a violation.* Bristol argues that Part IIIA, which applies to "unusual or special ingredient representations" for all of its OTC drugs, does not relate to any violations found to have been committed by it, since the corresponding allegations in the complaint were resolved in favor of Bristol. A Commission order purporting to "remedy wrongs which the Commission found not to have been committed" should be set aside, *ITT Continental Baking Co. v. FTC*, 532 F.2d at 221. Bristol refers to the fact that the Commission reversed the ALJ's finding that it had represented that Excedrin PM "contains a special sedative or sleep-inducing agent available only in Excedrin PM" whereas that ingredient was available in other OTC drugs as well.

6. The stipulations are as follows:

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

These stipulations, like consent orders, provide that they do not constitute admissions of violations, *see ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 222–23 n. 23 (2d Cir.1976); 3 Trade Reg.Rep. (CCH) ¶ 9593, at 17,095. The stipulations, however, contain a clause authorizing the Commission to use the stipulated facts as evidence in subsequent proceedings against the party. *See, e.g.*, 24 F.T.C. 1405, 1405 n. 2 (stipulation clause).

But we agree with the Commission that Part IIIA is reasonably related to the violation made by misrepresenting that Bufferin and Excedrin do not contain aspirin. The Commission specifically found that one of the ways Bristol had hidden the aspirin content of its products was by "falsely represent[ing] that Bufferin and Excedrin contained special or unusual ingredients." That finding is concededly supported by substantial evidence in that some of Bristol's advertising included the statements that Excedrin contains a pain reliever which works better than "common aspirin" or "plain aspirin" or that it contains "four medically-endorsed ingredients" providing special benefits. We note that AHP has a similar order imposed as proper "fencing-in," *see* 695 F.2d at 702.

[10, 11] G. *The Finding underlying Part IIIB.* Bristol advertised for a time that doctors recommended Bufferin more than any other "leading brand" of OTC internal analgesic. Bristol argues that Part IIIB of the Order, which enjoins Bristol from representing without a reasonable basis that any group endorses or recommends any OTC drug, was based upon a finding that those "doctors recommend" claims for Bufferin were made without appropriate prior substantiation. This finding is said to be without support, Bristol claims, since Bufferin *was* recommended by doctors more often than any other "leading brand" of OTC internal analgesic, a claim which was supported by the National Disease and Therapeutic Index. The FTC agrees that from 1967 through 1971 doctors recommended Bufferin more than Bayer, Excedrin and Anacin. However the Commission found that the ads conveyed the message that physicians recommend Bufferin more than any other OTC internal analgesic, and not just the three other leading brands of aspirin-based products. Since in fact doctors recommend Tylenol, Ascriptin and generic aspirin more often than Bufferin, the FTC found the message conveyed by the ads false and misleading. *See AHP,* 695 F.2d at 687 & n. 10; *FTC v. Sterling Drug, Inc.,* 317 F.2d 669, 674 (2d Cir.1963); *see also Donaldson v. Read Magazine, Inc.,* 333 U.S. 178, 188, 68 S.Ct. 591, 597, 92 L.Ed. 628 (1948).

In interpreting advertisements the Commission may rely on its own expertise in this area and need not resort to surveys and consumer testimony, *J.B. Williams Co. v. FTC,* 381 F.2d 884, 890 (6th Cir.1967). In this case the FTC's finding that the ads indicate that doctors recommend Bufferin more than any other OTC internal analgesic is clearly supported by substantial evidence on the record. The video portion of the Bristol advertisement unqualifiedly and explicitly says "doctors specify Bufferin most," which would plainly be understood to mean that Bufferin was preferred to all other OTC internal analgesics. The fact that the audio was qualified by the reference to "all leading brands of pain reliever" does not take the effect on the consumer of the full ad into account. *See Continental Wax Corp. v. FTC,* 330 F.2d 475, 477 (2d Cir.1964).

[12] H. *Part III's application to all nonprescription drugs.* It is argued that Part III of the Order, which limits special ingredients claims and imposes a reasonable basis requirement for "doctors prescribe most" claims made on behalf of *all* of Bristol's OTC drugs, constitutes improper "fencing-in" and so imposes an unreasonable compliance burden on Bristol. Bristol markets sixty categories of OTC products, including antiperspirants, cough and cold remedies, hemorrhoid medication, laxatives, skin protectants, sunburn prevention products, antiseptic lotions and others. *See Standard Oil Co. of California v. FTC,* 577 F.2d 653 (9th Cir.1978) (striking down multi-product order). The Third Circuit rejected, however, a similar argument in *AHP,* 695 F.2d at 704–06, distinguishing *Standard Oil,* where on the strength of just three implicitly misleading advertisements for a single product, a manufacturer and its advertising agency were subjected to an order covering thousands of products, 577 F.2d at 661. Here as in *AHP,* we believe it is appropriate "fencing-

in" to extend the product coverage to other Bristol OTC drugs.

Bristol argues under *Sears, Roebuck*, 676 F.2d at 392, that the extent of the alleged violations, the transferability of the violations to other contexts, its limited past history of deceptive advertising, and other considerations, including vigorous competition from nonaspirin analgesics, all go to make Part III of the Order invalid as constituting too extensive "fencing-in." However, the coverage of Part III is quite narrow, being limited in IIIA to false claims that an ingredient is unusual or special and in IIIB to unsubstantiated claims regarding recommendations or endorsements.

Moreover, most of the facts which we found justified the "fencing-in" in Part II of the Order also justify the "fencing-in" in Part III. To summarize briefly these findings: the violations were extensive; it would be easy to make other similar false special ingredient or unsubstantiated recommendation claims as regards most OTC products; Bristol has a history of similar deceptive practices. *See supra* note 3. We agree with the *AHP* court that false claims which consumers are unable to evaluate for themselves, and which encourage the unnecessary use of a potentially hazardous product, constitute serious violations which help justify the scope of the remedial order. 695 F.2d at 707.

We have considered all of Bristol's claims but find that the Commission quite carefully crafted its remedial order to suit the violations. The Order is broad enough to protect the public while narrow enough to permit compliance without undue burden.

Petition to reverse denied; order enforced.

Appendix: THE COMMISSION'S ORDER

I

IT IS ORDERED that Bristol-Myers Company, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bufferin," "Excedrin," "Excedrin P.M.," or any other nonprescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

Making any representation, directly or by implication, that a claim concerning the superior effectiveness or superior freedom from side effects of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness or comparative freedom from side effects of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness or freedom from side effects that it is represented to have, and (2) that such comparative effectiveness or freedom from side effects is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. The investigations shall be conducted in accordance with the procedures set forth below.

At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be conducted on any disease or condition referred to, directly or by implication, or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

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;

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 organization endorses or recommends such product unless at the time

such statement or representation is made, respondent has a reasonable basis for such statement or representation.

IV

IT IS FURTHER ORDERED that respondent Bristol-Myers Company, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device in connection with the 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 con-

trast 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.

[Parts VII–VIII omitted]

UNITED STATES of America, Plaintiff-Appellant,

v.

Albert P. PACIONE, Jr., Defendant-Appellee.

No. 864, Docket 83–1407.

United States Court of Appeals, Second Circuit.

Argued March 20, 1984.

Decided June 27, 1984.

Five counts of a fifteen-count indictment were dismissed by the United States District Court for the Southern District of New York, Whitman Knapp, J. The United States appealed. The Court of Appeals, George C. Pratt, Circuit Judge, held that in its use of phrase "other criminal means" in extortionate credit transactions statute, Congress was concerned primarily with use of actual and threatened violence by members of organized crime engaged in loan sharking and did not intend to authorize punishment for every creditor violating some other state or federal criminal statute in process of making or collecting usurious loan, and the quoted phrase was meant to supplement the context of "violence" so as to punish those who forced their nonpaying victims into committing crimes, and activities of preparing and threatening to record deed and mortgage that recited false considerations and of actually recording the deed were not within activities Congress meant to proscribe.

Affirmed.

1. Statutes ⇐217.2

Phrase "other criminal means" in extortionate credit transactions statute was sufficiently ambiguous to require examination of legislative history of the statute in order to ascertain its intended scope. 18 U.S.C.A. §§ 891 et seq., 891(6, 7), 892(a), 894(a).

See publication Words and Phrases for other judicial constructions and definitions.

2. Extortion and Threats ⇐25

In its use of phrase "other criminal means" in extortionate credit transactions statute, Congress was concerned primarily with use of actual and threatened violence by members of organized crime engaged in loan sharking and did not intend to authorize punishment for every creditor violating some other state or federal criminal statute in process of making or collecting usurious loan, and the quoted phrase was meant to supplement the context of "violence" so as to punish those who forced their nonpaying victims into committing crimes. 18 U.S.C.A. §§ 891 et seq., 891(6, 7), 1951, 1951(b)(2); N.Y.McKinney's Penal Law § 175.30.

3. Extortion and Threats ⇐25

Activities of preparing and threatening to record deed and mortgage that recited false consideration and of actually recording the deed were not within activities Congress meant to proscribe by its use of "other criminal means" language in extortionate credit transactions statute. 18 U.S.C.A. §§ 891 et seq., 891(6, 7), 1951, 1951(b)(2); N.Y.McKinney's Penal Law § 175.30.

Stephen F. Markstein, Asst. U.S. Atty., S.D. of N.Y., New York City (Rudolph W. Giuliani, U.S. Atty., S.D.N.Y., Martin L.