losses of more than $100,000. The defendants claim that their proper classification is under category 4, applicable to losses between $20,000 and $100,000, because the kickbacks they received totalled $77,350.

The district court correctly declined to resolve this issue on the ground that it had no power to order redesignation of the severity category. "The proper vehicle for attacking the execution of sentence, including the application of the Parole Board's Guidelines, is 28 U.S.C. § 2241." *Thompson v. United States*, 536 F.2d 459, 460 (1st Cir.1976). Motions under that provision must be brought before a district court that has jurisdiction over the prisoner or his custodian. *Id.* at 460–61. These defendants are incarcerated in Pennsylvania and Connecticut. The district court for the District of Rhode Island therefore had no jurisdiction over the defendants' motion, even if it were treated as a petition under 28 U.S.C. § 2241.

The denial of the motion to redesignate the defendants' severity rating is *affirmed.*

REMOVATRON INTERNATIONAL CORPORATION and Frederick E. Goodman, Petitioners,

v.

FEDERAL TRADE COMMISSION, Respondent.

No. 88–2245.

United States Court of Appeals, First Circuit.

Heard Aug. 4, 1989.

Decided Sept. 11, 1989.

Advertisers petitioned for review of Federal Trade Commission's cease and desist order which found advertising of their hair removal machine to be deceptive and FTC moved for injunction pendente lite. The Court of Appeals, Bownes, Circuit Judge, held that: (1) documents relating to machine allegedly similar to advertisers' machine were properly excluded as irrelevant; (2) evidence was sufficient to support finding that advertisements were deceptive; (3) FTC did not abuse its discretion by requiring advertisers to obtain scientific support before making further claims of permanent hair removal; and (4) requirement that advertisers insert specific language in future advertisements did not constitute corrective advertising requirement.

Petition denied; motion for injunction pendente lite granted.

1. Trade Regulation ⇐763

If establishment claim is specific, stating specific type of substantiation for product, advertiser must possess specific substantiation claimed and, if nonspecific, Federal Trade Commission decides what type of support is necessary, which is usually two well-controlled scientific studies; "establishment claims" are statements to effect that scientific tests establish that product works, while "non-establishment claims" are statements to effect that product works.

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

2. Administrative Law and Procedure ⇐669

Trade Regulation ⇐832

Contention that Federal Trade Commission found advertisers liable on theory not advanced by FTC in its complaint was not properly preserved for review in light of advertisers' failure to complain that their right to fair notice had been violated or to request reconsideration following FTC's decision and order.

3. Administrative Law and Procedure ⇐764

Trade Regulation ⇐842

Any error in admission of documents only for limited purpose of showing postclaim substantiation of advertisers' prod-

uct was harmless in light of ALJ's examination of documents and subsequent finding that none constituted requisite well-controlled study supporting advertisers' claims.

4. Trade Regulation ⇐798

Documents relating to machine advertisers contended was similar to their hair removal machine were properly excluded as irrelevant in light of undisputed evidence that advertisers did not know of documents, which arguably supported claim that their machine permanently removed hair, when they made their permanency claims.

5. Trade Regulation ⇐798

Document evidencing Food and Drug Administration's objection to advertisers' claims that their machine permanently removed hair was properly admitted to rebut advertisers' assertion that their actions, which allegedly violated statute requiring reasonable basis for advertising claims, were in good faith and not deliberate; while Federal Trade Commission was not required to prove willful, knowing or deliberate act in order to prove violation of statute, such showing did have bearing on scope of remedy. Federal Trade Commission Act, § 5, as amended, 15 U.S.C.A. § 45.

6. Administrative Law and Procedure ⇐764

Trade Regulation ⇐842

Any error in excluding testimony of Federal Trade Commission's consumer protection specialist, who advertisers wished to use to show that proceeding in which they were alleged to have no reasonable basis for their advertising claims concerning hair removal machine was not in public interest, but was private controversy brought about by electrologists' fear of competition posed by advertisers' product, was harmless in light of evidence which would have rendered any testimony by specialist on origins of complaints, documents in his possession, and his relationship with electrolysis industry repetitious. Federal Trade Commission Act, § 5, as amended, 15 U.S.C.A. § 45.

7. Trade Regulation ⇐763

Violation may occur with respect to deceptive advertisements, even if other advertisements contain accurate, nondeceptive claims. Federal Trade Commission Act, § 5, as amended, 15 U.S.C.A. § 45.

8. Trade Regulation ⇐763

Disclaimers or qualifications in any particular advertisement are not adequate to avoid liability for deceptive advertising unless they are sufficiently prominent and unambiguous to change apparent meaning of claims and to leave accurate impression. Federal Trade Commission Act, § 5, as amended, 15 U.S.C.A. § 45.

9. Trade Regulation ⇐763

Commonsense net impression of advertisers' claims was that their machine could remove hair permanently and that this claim was supported by scientific evidence and, accordingly, advertisements were deceptive and in violation of statute requiring reasonable basis for establishment claims, absent well-controlled scientific study to support permanency claim; "reasonable basis," for purposes of establishment claims, meant well-controlled scientific studies. Federal Trade Commission Act, § 5(a), as amended, 15 U.S.C.A. § 45(a).

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

10. Trade Regulation ⇐763

Federal Trade Commission did not abuse its discretion by requiring advertisers to obtain scientific support before making further claims that their product could permanently remove hair following finding that advertisers' permanency claims and claims of scientific supporting evidence constituted deceptive advertising. Federal Trade Commission Act, § 5(a), as amended, 15 U.S.C.A. § 45(a).

11. Trade Regulation ⇐821

Federal Trade Commission's requirements that advertisers include in any advertisement which claimed their machine could remove hair a disclaimer stating that such removal was only temporary, and that they send copy of order and a notice to all

past purchasers of their machine, did not constitute corrective advertising requirements; requirement that notice be sent merely insured full compliance with spirit of FTC's order and modified materials advertisers had already disseminated, and advertisers were only required to include disclaimer when they also claimed their machine was able to remove hair.

12. Trade Regulation ⇐795

Injunction pendente lite enjoining advertisers from violating terms of Federal Trade Commission's cease and desist order was warranted to prevent future economic harm to potential purchasers and clients who would not buy or receive treatments from advertisers' hair removal machines were it not for their deceptive advertising.

David M. Lipton, with whom David Hayes Erickson, Lipton & Pemstein and Judith Ashton, Davis, Malm and D'Agostine, Boston, Mass., were on brief for petitioners.

Melvin H. Orlans, Atty., F.T.C. with whom Kevin J. Arquit, Gen. Counsel, New York City, Jay C. Shaffer, Deputy Gen. Counsel, Cincinnati, Ohio, and Ernest J. Isenstadt, were on brief for respondent.

Before BOWNES, TORRUELLA and SELYA, Circuit Judges.

BOWNES, Circuit Judge.

Petitioners, Removatron International Corporation (Removatron) and Frederick E. Goodman, seek review of the Federal Trade Commission's [1] cease and desist order and decision which found the advertising of Removatron's epilator machine to be deceptive. The FTC defends the Commission's decision and order and requests that we issue an injunction *pendente lite*. For the reasons set forth below, we deny the petition for review and issue the injunction.

I. FACTS

Hirsutism is perceived as a problem by some people, particularly women. Many products are marketed to reduce or eliminate excessive hair. To remove hair permanently, the dermal papilla must be completely destroyed. The dermal papilla is a group of cells that forms a portion of the hair follicle. Most remedies offer only temporary relief. Electrolysis permanently removes hair but the process can be painful and may leave scars and pits in the skin.

Petitioners market a product that they claim can remove unwanted hair permanently without the side effects associated with electrolysis. Their product uses a pair of tweezers to remove the hair; while the tweezers grasp the hair but before it is removed, the machine emits radio frequency energy (RFE) that travels down the tweezers and along the hair. Petitioners claim that the RFE causes tissue damage and destruction of the dermal papilla by heating the tissue in much the same way a microwave heats food. Petitioners' product is approved by the Federal Communications Commission (FCC) to emit radio waves at a particular frequency.

Petitioners advertise their product mainly in the beauty industry trade magazines. Sales are made after a series of telephone calls, mailings of literature, and meetings. The machine costs about $4,000. During the sales process, the purchasers are told that the machine will not work for everyone and that permanent removal will only be obtained after several treatments. Women who wish to be treated by the machine are given much the same information in written or oral form by the machine owner or operator. The written information is provided by petitioners who also provide purchasers with advertisements to place in local print media. Treatments cost approximately $35 per hour.

Rather than rehash all the evidence anent petitioners' advertising, we present only a few typical samples of the types of claims made by petitioners. The petitioners stated that with Removatron treatments, hair removal can be "permanent" and unwanted hair will no longer be a

1. For clarity, we will refer to the Federal Trade Commission *qua* prosecutor as FTC; we will refer to the Federal Trade Commission *qua* adjudicator as the Commission.

problem; the ads also stated the machine is "effective" and an "alternative to electrolysis." The advertising also included statements that the machine has been "clinically tested and endorsed" and "clinically tested and shown superior." The ads also claimed that the FCC approved petitioners' product.

[1] The FTC filed a complaint against petitioners alleging that they did not have a reasonable basis for their advertising claims and thus, their ads were in violation of § 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.[2] The complaint alleged that petitioners did not have a reasonable basis for their claims. It did not allege that petitioners had made "establishment" claims, which would require scientific evidence in support of the claims made.[3]

After a lengthy trial, the administrative law judge (ALJ) agreed with the FTC and issued a cease and desist order. The ALJ found that the petitioners made both express and implied claims that their machine could remove hair permanently and that any disclaimers were ineffective and ambiguous. He also found that these claims were establishment claims, *i.e.* they purported to be supported by scientific evidence. He further found that the ads expressly claimed FCC approval and that these claims implied government approval of the entire product, not just the approval to emit radio waves at a certain frequency.[4]

The ALJ then turned to the question of whether the petitioners had a reasonable basis for their claims. After an exhaustive discussion of hair growth and biology, he determined that, because the ads claimed scientific support for the claims made, two well-controlled scientific studies[5] were needed to show a reasonable basis for those claims. *See Thompson Medical Co., Inc. v. FTC*, 791 F.2d 189, 194–96 (D.C.Cir. 1986), *cert. denied*, 479 U.S. 1086, 107 S.Ct. 1289, 94 L.Ed.2d 146 (1987). The ALJ analyzed the voluminous experimental, theoretical, and testimonial evidence, as well as the evidence relating to comparable products, presented by petitioners and found all of it lacking when compared to the rigors of well-controlled studies. The ALJ, therefore, held that petitioners had violated 15 U.S.C. § 45. The ALJ found that petitioners' claims caused substantial financial and emotional consumer injury. Based on these findings and holdings, he entered an order, which in pertinent part required the petitioners: (1) to cease and desist from advertising their machine as a method of permanent hair removal unless they first possessed two well-controlled scientific studies supporting those claims; (2) to in-

2. 15 U.S.C. § 45(a)(1) states that "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful."

3. "Establishment" claims are statements to the effect that scientific tests establish that a product works. "Non-establishment" claims are statements to the effect that a product works. *See Thompson Medical Co., Inc. v. FTC*, 791 F.2d 189, 194 (D.C.Cir.1986), *cert. denied*, 479 U.S. 1086, 107 S.Ct. 1289, 94 L.Ed.2d 146 (1987). An establishment claim may be either specific, one which states a specific type of substantiation, or non-specific, one which does not. *Id.* If an establishment claim is specific, the advertiser must possess the specific substantiation claimed; if it is non-specific, the Commission decides what type of support is necessary, which is usually two well-controlled scientific studies. *Id.*

4. Petitioners did not appeal the findings with respect to the FCC claims to the Commission, nor did they raise any issue involving those claims in their petition for review in this court. We, therefore, need not discuss further this aspect of the case.

5. The Commission defines a valid scientific test as "one in which persons with skill and expertise in the field conduct the test and evaluate its results in a disinterested manner using testing procedures generally accepted in the profession which best insure accurate results." *In re Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 463 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112, 94 S.Ct. 841, 38 L.Ed.2d 739 (1973). The FTC's expert, Dr. Van Scott, testified that, in this field, at least one well-controlled test would be needed to be accepted as establishing permanency claims. He testified at length about the method for such a test: the experiment would have to include a control in which the machine was used but no RFE was emitted and it would have to be a double-blind experiment in which neither the patient nor the person determining hair loss knew whether the patient received the RFE treatment. He also testified that such an experiment would probably cost about $40,000.

clude in future advertising claiming that their product will remove hair, a disclaimer that the machine can only remove hair temporarily; (3) to send each purchaser a copy of the order; and (4) to provide future purchasers with a copy of the order. Petitioners appealed to the Commission.

The Commission adopted most of the ALJ's findings and conclusions and affirmed the order in large part. The Commission rejected petitioners' arguments that the ALJ erred in various evidentiary rulings. The Commission rejected the ALJ's finding that petitioners' claims had caused emotional injury to any purchaser or woman who had used the machine. The Commission agreed with the ALJ's findings that petitioners had made "establishment" claims and thus needed to have scientific support for those claims. It found, however, that petitioners needed one well-controlled scientific study in order to have a reasonable basis for their claims, not two, as the ALJ had found. In a footnote, the Commission analyzed the factors for non-establishment claims, *see In re Pfizer, Inc.*, 81 F.T.C. 23 (1972), and held that, even when viewed in this light, petitioners needed at least one study in order to have a reasonable basis for their claims.[6] Because petitioners lacked any such studies, the Commission affirmed the finding of a violation of 15 U.S.C. § 45. By an evenly divided vote, the Commission modified the order to require that petitioners cease their permanency claims until they possessed one well-controlled scientific study supporting that claim; two Commissioners would have upheld the ALJ's determination that two such studies were needed. The Commission also modified the ALJ's order by deleting the requirement of providing future purchasers with a copy of the order because it felt the rest of the order was comprehensive enough to make this requirement unnecessary; one Commissioner would have retained this provision but only for five years.

Petitioners filed a petition for review in this court. The issues are: (1) whether there was a violation of petitioners' right to due process; (2) various evidentiary rulings by the ALJ; (3) the sufficiency of the evidence; (4) the requirement that petitioners possess one well-controlled study before making permanency claims; and (5) the requirement that petitioners insert specific language in future ads. We address each issue seriatim, stating, as necessary, additional facts.

II. DUE PROCESS

[2] Petitioners argue that their fifth amendment right to due process was violated because the ALJ and Commission found them liable on a theory not alleged by the FTC in its complaint. They contend that the complaint alleges only that they made non-establishment claims but that the ALJ and Commission analyzed their substantiation in light of an establishment theory. Because they were not on notice as to the theory of liability, they say they were not given a full and fair opportunity to defend themselves. We need not decide whether the FTC's complaint was insufficient to provide petitioners with sufficient notice because we reject this contention as not being properly preserved for review.

The general rule is that " '[i]n the absence of extraordinary circumstances, none of which are apparent here, we have regularly declined to consider points which were not seasonably advanced below.' *Clauson v. Smith*, 823 F.2d 660, 666 (1st Cir.1987) (collecting cases)." *United States v. Lott*, 870 F.2d 778, 781 (1st Cir.1989). This general rule applies with equal force to arguments not presented to the Commission in the first instance. *See, e.g., Litton Indus., Inc. v. FTC*, 676 F.2d 364, 369 (9th Cir. 1982); *Cotherman v. FTC*, 417 F.2d 587, 590–94 (5th Cir.1969) (waiver of subject matter jurisdiction by failure to appeal that issue to the Commission). In *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37, 73 S.Ct. 67, 69, 97 L.Ed. 54 (1952), the Court said:

> Simple fairness to those who are engaged in the tasks of administration, and to the litigants, requires as a general

6. Our review focusses on the "establishment" claims finding.

rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice.

In the present case, the petitioners knew, at the latest when the ALJ issued his opinion and order, that an establishment theory was the basis for finding them liable. Yet, they did not complain to the Commission that their right to fair notice had been violated. Under Commission rules, they, therefore, waived any such argument. 16 C.F.R. § 3.51(b). Furthermore, once the Commission issued its decision and order, which relied mainly upon an establishment analysis, the petitioners neither requested reconsideration, 16 C.F.R. § 3.55, nor sought a reopening of the proceedings, 16 C.F.R. §§ 3.71, 3.72. The petitioners have not taken the appropriate steps to preserve this issue. We, therefore, do not consider it.

III. EVIDENTIARY RULINGS

A. *Rulings Concerning Substantiation*

Petitioners challenge four evidentiary rulings of the ALJ, all of which were upheld by the Commission, regarding information relating to the substantiation of their advertising claims: (1) the admission of a number of documents only for the limited purpose of showing post-claim substantiation;[7] (2) the exclusion of page 59 of a book on hair and hair removal; (3) the exclusion of the so-called "Mehl" documents;[8] and (4) the admission of a Notice of Adverse Findings sent by the Food & Drug Administration (FDA) to Removatron.

(1) The admission of documents for a limited purpose

[3] With respect to the first ruling, if there was error at all—which we doubt—it was harmless. As we discuss *infra*, petitioners needed to possess a well-controlled study supporting their claims. The ALJ examined each of these documents and found that none reached this level of support. Thus, even if they had been admitted without limitation, petitioners would have fared no better in the final analysis.

(2) The exclusion of page 59 of a book

With respect to the second ruling, the petitioners' claim of error is factually inaccurate. Page 59 of the book was admitted as both an exhibit for the FTC, CX–178, and an exhibit for petitioners, RX–92.

(3) The exclusion of the Mehl documents

[4] As to the third ruling, the ALJ excluded a series of documents relating to a machine petitioners contended was similar to their machine. A valid efficacy test substantiating a competing product may be used if the product has a "similar composition" and the test "was known to and verified by" the person seeking to use it as substantiation for their own claims. *Pfizer*, 81 F.T.C. at 68. We need not decide whether the Mehl device is indeed similar to the petitioners' machine since the undisputed evidence is that petitioners did not know of the documents when they made their permanency claims. Petitioners admit that they did not learn of the existence of these documents until the FTC produced them as part of pre-trial discovery. Thus, it was impossible for petitioners to show either knowledge or verification prior to making their claims. The documents were properly excluded as irrelevant.

(4) The admission of a notice of adverse findings by the FDA

[5] In regard to the fourth ruling, the FDA's notice shows that, since at least 1982, the FDA objected to petitioner's claims of permanency because the FDA's Bureau of Medical Devices did not believe RFE-tweezer epilators could remove hair permanently. While this document could not be used to prove that petitioners' claims were false, its relevancy lay in another area—it put petitioners on notice that at least one arm of the executive branch

7. These documents are denoted in the record as RXS–1, 3, 4, 13, 14, 15, 16, 17, 19, 24 and 29.

8. These documents are denoted in the record as RXS–2, 4, 5, 45, 46, 56, 58, 60, 61 and 97.

found their claims suspect. The FTC need not prove a willful, knowing or deliberate act in order to prove a violation of 15 U.S.C. § 45. *Chrysler Corp. v. FTC*, 561 F.2d 357, 363 (D.C.Cir.1977) ("intent to deceive is not a required element for a section 5 violation"). But, such a showing does have a bearing on the scope of the remedy, *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1155 (9th Cir.1984), *cert. denied*, 470 U.S. 1084, 105 S.Ct. 1843, 85 L.Ed.2d 143 (1985). The Commission used this document to rebut an assertion that petitioners' actions were in good faith and not deliberate. We agree with the Commission finding: "Thus, [petitioners'] reliance on their substantiation cannot be considered reasonable or in good faith given what they learned from the FDA." [9]

B. *Exclusion of McDonough's Testimony*

[6] Petitioners complain that the ALJ improperly refused to allow them to call Francis X. McDonough, an FTC Consumer Protection Specialist. McDonough was primarily responsible for investigating the present case and assisted in its prosecution. Petitioners wished to use McDonough to show that the present proceeding was not in the public interest, but rather that it was merely a private controversy brought about because electrologists feared competition from petitioners and other manufacturers of RFE epilators.[10] A proceeding is not in the public interest if it is merely a private controversy. *See FTC v. Klesner*, 280 U.S. 19, 28–30, 50 S.Ct. 1, 4, 74 L.Ed. 138 (1929). This does not mean, however, that a controversy which begins as a private matter can never be or become a matter of public interest. *See International Parts Corp. v. FTC*, 133 F.2d 883, 885 (7th Cir.1943). We need not delve into whether the present case was indeed in the public interest since petitioners have not raised that issue on appeal and since, if there was an error in excluding McDonough's testimony, it was harmless.

As a part of pre-trial discovery, the FTC provided petitioners with all documents received by McDonough in the course of his investigation. Furthermore, the ALJ accorded petitioners wide latitude in presenting evidence of the electrologists' role in this case. They were allowed to call Fino Gior,[11] founder of the International Guild of Electrologists, and to introduce documentary evidence on this point. Gior testified at length to the steps his organization took in gathering complaints and in providing them to McDonough. Thus, any testimony by McDonough on the origins of complaints, the documents in his possession, and his relationship with the electrolysis industry would have been repetitious at best. Any testimony concerning McDonough's method, lack of expertise or bias when examining the information in his possession would have been irrelevant to the public interest inquiry since such information concerns the substantiation of petitioners' claims. Furthermore, there is no claim that McDonough was an expert in evaluating scientific data nor did the ALJ or Commission rely on McDonough's evaluations—they each made independent inquiries into the validity of the substantiation petitioners offered for their claims.

9. This was not the only evidence of petitioner's lack of good faith: they failed to follow their own expert's advice that they conduct an appropriate scientific study.

10. Petitioners claim that their inability to call McDonough led to the exclusion of

> the following evidence: (1) most of the evidence Mr. McDonough had in his possession showed that [RFE] epilators are effective; (2) Mr. McDonough assumed as valid information showing ineffectiveness and assumed as invalid information showing effectiveness; (3) virtually all of the information he gathered showing ineffectiveness was gathered by electrologists who were direct competitors of Removatron; (4) such information was known to Mr. McDonough to be biased; (5) Mr. McDonough established a close working relationship with the electrologists and encouraged the production of complaints; (6) out of 134 complaints, all but 12 were gathered by these competitors; [and] (7) Mr. McDonough did not communicate his bias and the unevaluated nature of the adverse information to the Commission.

Brief for Petitioner at 56.

11. His legal name is Serafino Giordano but most the documents sent by him and introduced at trial are signed Fino Gior.

We find no reason to overturn any of the evidentiary rulings.

IV. SUFFICIENCY OF THE EVIDENCE

In reviewing the Commission's determinations, "[t]he findings of the Commission as to the facts, if supported by the evidence, shall be conclusive." 15 U.S.C. § 45(c); *see also FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 454, 106 S.Ct. 2009, 2015, 90 L.Ed.2d 445 (1986); *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 73, 54 S.Ct. 315, 318, 78 L.Ed. 655 (1934). In fleshing out this provision, the Supreme Court has stated:

> The statute forbids a court to "make its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences." *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 73 [54 S.Ct. 315, 318, 78 L.Ed. 655] (1934). Rather, as under the essentially identical "substantial evidence" standard for review of agency factfinding, the court must accept the Commission's findings of fact if they are supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 [71 S.Ct. 456, 459, 95 L.Ed. 456] (1951); see also *Beneficial Corp. v. FTC*, 542 F.2d 611, 616 (CA3 1976), cert. denied, 430 U.S. 983 [97 S.Ct. 1679, 52 L.Ed.2d 377] (1977).

Indiana Federation, 476 U.S. at 454, 106 S.Ct. at 2015–16. "[S]ubstantial evidence to support an agency finding may exist 'even though suggested alternative conclusions may be equally or even more reasonable and persuasive.'" *Montgomery Ward & Co., Inc. v. FTC*, 691 F.2d 1322, 1327 (9th Cir.1982) (quoting *Colonial Stores, Inc. v. FTC*, 450 F.2d 733, 739 (5th Cir.1971)).

The guidelines for appellate review of the legal aspects of the Commission's decision have been charted by the Court:

> Th[e] statutory scheme necessarily gives the Commission an influential role in interpreting § 5 [15 U.S.C. 45] and in applying it to the facts of particular cases arising out of unprecedented situations. Moreover, as an administrative agency which deals continually with cases in the area, the Commission is often in a better position than are courts to determine when a practice is "deceptive" within the meaning of the Act. This Court has frequently stated that the Commission's judgment is to be given great weight by reviewing courts. This admonition is especially true with respect to allegedly deceptive advertising since the finding of a § 5 violation in this field rests so heavily on inference and pragmatic judgment. Nevertheless, while informed judicial determination is dependent upon enlightenment gained from administrative experience, in the last analysis the words "deceptive practices" set forth a legal standard and they must get their final meaning from judicial construction.

FTC v. Colgate-Palmolive Co., 380 U.S. 374, 385, 85 S.Ct. 1035, 1042–43, 13 L.Ed.2d 904 (1965) (footnote omitted). *See also Indiana Federation*, 476 U.S. at 454, 106 S.Ct. at 2015–16 (legal issues are for the courts to determine, but we "are to give some deference to the Commission's informed judgment"); *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 686 (3d Cir.1982) (*AHP*).

[7, 8] The Commission's findings with respect to what representations are made in advertisements are factual. *See, e.g., Thompson Medical*, 791 F.2d at 197 (quoting from the FTC's brief); *AHP*, 695 F.2d at 686; *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3d Cir.1976), *cert. denied*, 430 U.S. 983, 97 S.Ct. 1679, 52 L.Ed.2d 377 (1977). In making such findings,

> "The tendency of the advertising to deceive must be judged by viewing it as a whole, without emphasizing isolated words or phrases apart from their context," *Beneficial, supra*, 542 F.2d at 617. The impression created by the advertising, not its literal truth or falsity, is the desideratum....

AHP, 695 F.2d at 687. Each advertisement must stand on its own merits; even if other advertisements contain accurate, non-de-

ceptive claims, a violation may occur with respect to the deceptive ads. *See Chrysler Corp.*, 561 F.2d at 363. Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression. Anything less is only likely to cause confusion by creating contradictory double meanings. *See Giant Food, Inc. v. FTC*, 322 F.2d 977, 986 (D.C.Cir.1963), *cert. dismissed*, 376 U.S. 967, 84 S.Ct. 1121, 12 L.Ed.2d 82 (1964).

In reviewing whether there is appropriate scientific substantiation for the claims made, "[o]ur task is only to determine if the Commission's finding is supported by substantial evidence on the record as a whole." *Thompson Medical*, 791 F.2d at 196. This is because "[a]ppellate courts have neither the expertise nor the resources to evaluate complex scientific claims." *Id.*

We have read the record in accord with our scope of review and have no trouble finding that there was substantial evidence to support the Commission's findings and conclusions regarding petitioners' advertising.

A. *Petitioners' Claims*

[9] The common-sense net impression of petitioners' advertising claims is that their machine can remove hair permanently and that this claim is supported by scientific evidence. The ads specifically state that the treatments remove hair permanently and are effective. They compare the machine favorably to electrolysis, a method considered effective in removing hair permanently. And the ads claim that the machine has been "clinically tested and shown superior" and "clinically tested and endorsed." Petitioners defend their advertising claims on three grounds.

First, they argue that they never claimed that their machine would produce permanent hair removal for all people all the time. It is irrelevant that petitioners never claimed 100% efficacy; the common-sense reading of the ads is that the machine will permanently remove hair for most people most of the time.

Second, petitioners contend that their ads and sales pitches qualified their permanency claims in two ways: (1) the machine would not work on everyone, and (2) permanent removal could only be obtained after several treatments. As a part of this argument, they assert that the only relevant audience is the beauty industry since that is to whom they advertised and marketed their product. We reject the contention that the relevant audience is only the beauty industry. While it is true that petitioners placed their ads in trade magazines, it is also true that their sales personnel provided brochures and other information to purchasers who were then instructed to provide these materials to potential clients. Furthermore, petitioners provided advertising to purchasers who would then place it in local print media. The relevant audience thus includes potential purchasers and customers of purchasers. The two qualifications made by petitioners are, as the Commission found, ineffective to dispel the overall message that the machine will remove hair permanently. The first qualification merely makes explicit the generally accepted notion that no product works perfectly for everyone. The second does no more than state that permanent hair removal takes more than one treatment. This does not deny the permanency claim; rather, it qualifies when a person can expect permanent results.[12]

12. That this is the message is shown by the following question and answer which are taken from one of petitioners' sales brochures:

DOES REMOVATRON REMOVE HAIR PERMANENTLY?

Yes, but not the first time. Permanent removal of unwanted hair is seldom accomplished in a single treatment. There are a number of reasons why permanent removal may not be achieved with a single treatment. A weak hair may break off below the skin line, or be already detached from the papilla as in the shedding process. Some fair follicles may require more R.F. intensity than can be applied in one treatment due to the variable resistance to the current or even the chemical make-up of a particular body area.

Finally, petitioners argue that the words "clinically tested" do not mean, and would not be taken by a reasonable person as meaning, "supported by rigorous scientific tests." Petitioners claim that "clinical" evidence merely means that a product has been used successfully in a clinical setting, while "scientific" evidence means that actual well-controlled studies had been performed. Regardless of any actual differences there may be between "clinical" and "scientific" evidence, petitioners have offered no basis for us to find that lay people would make such a fine distinction.

B. *The Scientific Evidence*

If one makes a non-specific establishment claim, the Commission determines what evidence would in fact establish such a claim in the relevant scientific community. It then compares the advertisers' substantiation evidence to that required by the scientific community to see if the claims have been established. *See AHP*, 695 F.2d at 691–92. The FTC's expert, Dr. Van Scott, testified that, in this field, at least one well-controlled test would be needed to establish a permanency claim. He also testified that two tests would be better and three superb. The ALJ found that petitioners needed two well-controlled tests in order to establish their claims; the Commission decided one was sufficient. Thus, petitioners needed to present evidence that they possessed at least one well-controlled scientific study that supported their permanency claim. Petitioners do not claim that any of their evidence did in fact reach the level of a well-controlled scientific study. Rather, they argue that the material they possessed showed that they had, as a matter of law, a reasonable basis for their claims. The flaw in this argument is that a "reasonable basis," when one makes establishment claims, means well-controlled scientific studies. Without such a study, petitioners could not, as a matter of law, have a reasonable basis for their establishment claims. Without such a reasonable basis, their ads were deceptive and in violation of 15 U.S.C. § 45(a).

V. REQUIREMENTS OF THE ORDER

A. *One Well-controlled Scientific Study*

[10] The Commission's final order requires that petitioners:

> cease and desist from representing in any manner, directly or by implication, that:
>
> A. Any such hair removal device or other hair removal product, or any such device, will or may achieve permanent hair removal or hair removal on a long-term and not temporary basis, or is otherwise effective, using those words or words of similar import or meaning, unless, at the time of the making of such representation, [they] possess and rely upon competent and reliable scientific evidence that substantiates such representation.

The Order defines " 'competent and reliable scientific evidence' ... as adequate and well-controlled, double-blind clinical testing conforming to acceptable designs and protocols and conducted by a person or persons qualified by training and experience to conduct such testing."

Petitioners correctly note that this requirement prevents them making even a non-establishment permanency claim without scientific support for that claim. They contend that such a requirement is uncalled for under the principles used in determining the scope of non-establishment orders. Petitioners misapprehend, however, the scope of the Commission's power to issue broad orders.

Our role in reviewing a Commission order has been defined by the Supreme Court:

> It has been repeatedly held that the Commission has wide discretion in determining the type of order that is necessary to cope with unfair practices found, and that Congress has placed the primary responsibility for fashioning orders upon the Commission. For these reasons the courts should not "lightly modify" the Commission's orders. *Federal Trade Comm'n v. Cement Institute*, 333 U.S. 683, 726 [68 S.Ct. 793, 815, 92 L.Ed. 1010].

Colgate–Palmolive Co., 380 U.S. at 392, 85 S.Ct. at 1046 (further citations omitted). Courts will interfere with a Commission order only if: (1) " 'the remedy selected bears no reasonable relation to the unlawful practices found to exist,' " *FTC v. National Lead Co.*, 352 U.S. 419, 428, 77 S.Ct. 502, 509, 1 L.Ed.2d 438 (1957) (quoting *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 613, 66 S.Ct. 758, 760, 90 L.Ed. 888 (1946)), or (2) the order's prohibitions are not sufficiently " 'clear and precise in order that they may be understood by those against whom they are directed,' " *Colgate–Palmolive*, 380 U.S. at 392, 85 S.Ct. at 1046 (quoting *FTC v. Cement Institute*, 333 U.S. 683, 726, 68 S.Ct. 793, 815, 92 L.Ed. 1010 (1948)). *See also Sterling Drug*, 741 F.2d at 1155. Petitioners do not challenge the order's clarity or precision, only its scope. In determining whether the scope of an order bears a reasonable relationship to the unlawful practice, we must keep in mind that the Commission is not " 'required to confine its road block to the narrow lane the transgressor has travelled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be bypassed with impunity.' " *National Lead*, 352 U.S. at 429, 77 S.Ct. at 509 (quoting *FTC v. Ruberoid Co.*, 343 U.S. 470, 473, 72 S.Ct. 800, 803, 96 L.Ed. 1081 (1952)). "[T]hose caught violating [15 U.S.C. § 45] must expect some fencing in." 352 U.S. at 431, 77 S.Ct. at 510. The Commission "may fashion its relief to restrain 'other like or related unlawful acts,' " *FTC v. Mandel Bros.*, 359 U.S. 385, 392, 79 S.Ct. 818, 824, 3 L.Ed.2d 893 (1959) (quoting *NLRB v. Express Publishing Co.*, 312 U.S. 426, 436, 61 S.Ct. 693, 699–700, 85 L.Ed. 930 (1941)), because "[t]here is no limit to human inventiveness in [the field of unfair practices]," *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 240, 92 S.Ct. 898, 903, 31 L.Ed.2d 170 (1972) (quoting H.R.Conf.Rep. No. 1142, 63d Cong., 2d Sess., 19 (1914)).

In reviewing the appropriateness of the Commission's "fencing in," courts have examined a number of factors: "(1) the deliberateness of the violation; (2) the violator's past record with respect to advertising practices; ... (3) the adaptability or transferability of the unfair practice to other products," *Sterling Drug*, 741 F.2d at 1155; (4) the seriousness of potential violations, including health hazards, *id.;* (5) the length of time the deceptive ad has been used, *AHP*, 695 F.2d at 699; (6) "the difficulty for the average consumer to evaluate such claims through personal experience," *id.* at 698; and (7) whether the pervasive nature of government regulation of the product at issue is likely to "create a climate in which questionable claims ... have all the more power to mislead," *id.* at 697. In analyzing these factors, "no single factor [is] determinative[;] the 'more egregious the facts with respect to a particular element, the less important it is that another negative factor be present.' " *Sterling Drug*, 741 F.2d at 1155 (quoting *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir.1982)).

Applying the above factors to the present case, we hold that the Commission's requirement is a reasonable fencing in provision. First, the Commission found petitioners' violations to be deliberate and not in good faith. This finding is amply supported by the FDA's Notice to petitioners and the fact they ignored their own expert's advice that they conduct a proper scientific experiment. This factor cuts in favor of a broad remedy. Second, petitioners have not been found liable for any prior violations; this factor cuts in petitioners' favor.[13] Third, the transferability of the unfair practice to other products is irrelevant in deciding whether any such claim, regardless of the product, must be supported by scientific evidence. Fourth, there is no health hazard associated by the product,[14] but there is the possibility of

13. As noted above, and contrary to petitioners' assertion, this factor is not controlling, but merely one of many to be considered. *Sterling Drug*, 741 F.2d at 1155.

14. Petitioners assert that, although the Commission expressly rejected the ALJ's finding that their claims could cause emotional harm to women who did not get permanent removal, the Commission nonetheless affirmed that finding later on in its opinion. This is not so. The Commission stated: "We *generally* affirm the findings and conclusions concerning the appro-

substantial economic harm. Petitioners' machine cost about $4,000. Treatments cost about $35 per hour and clients are told that they will need several treatments in order to obtain permanent removal. This factor points in favor of a broad remedy. Fifth, petitioners have been making permanency claims for years and continue to do so. This factor also points in favor of a broad remedy. Sixth, Dr. Van Scott, the FTC's expert, testified that it would be difficult for the average client to evaluate objectively the efficacy of the treatments because she would want it to work and this would color her perceptions. The same is true for an observer who knew whether a person was receiving RFE or not; this is why double-blind tests are needed. Furthermore, client observations are less likely to be effective since they can only be made after a number of expensive treatments and after any economic harm has already occurred. Seventh, the regulation of medical devices [15] is pervasive. *See, e.g.*, 21 U.S.C. §§ 351–363 (relating to drugs and devices). Thus, a consumer is likely to believe that a questionable claim will have some basis in fact. This factor also points in favor of a broad remedy.

In sum, five factors point toward a broad remedy, one points against and one is irrelevant. Under such circumstances, we hold that the Commission did not abuse its discretion by requiring petitioners to obtain scientific support before making any permanency claims.

B. *Specific Language in Future Advertising*

[11] The Commission's order also requires petitioners to include in any advertisement which claims their machine can remove hair a disclaimer stating that such removal is only temporary,[16] and to send a copy of the order and a notice to all past purchasers of their machine.[17] Petitioners argue that these requirements are corrective advertising requirements and as such, are not warranted under the factors used in determining the need for corrective ads. This argument fails because petitioners misconstrue the nature of these requirements.

The requirement that notice be sent to all past purchasers is not an advertising requirement at all. It merely ensures full compliance with the spirit of the Commission's order and modifies materials petitioners have already disseminated.

The requirement of paragraph I(B) does require petitioners to insert a disclaimer

priate relief." (Emphasis added). We do not read this to alter the Commission's previous express rejection of the ALJ's emotional harm finding.

15. RFE epilators are medical devices. *See* 21 U.S.C. § 321(h)(3) (defining a medical device as anything "intended to affect the structure or function of the body of man or other animal").

16. Under paragraph I(B) of the order, petitioners must cease and desist from representing that

> The Removatron device or any other RFE tweezer-type epilation device or any treatment employing any such device is intended to or is able to remove hair, using those words or words of similar import or meaning, unless the representations clearly and conspicuously disclose the following statement: "IMPORTANT: There is no reliable evidence that [name of the device treatments] provides anything more than *temporary* hair removal"; provided, however, that in any written materials this disclosure shall be in typeface at least as large as the largest typeface in the label, advertising, or any document, and in any multipage documents the disclosure shall appear on the cover or first page, and provided further that this provision shall terminate after five (5) years from the date on which this Order becomes effective.

17. Paragraph III of the order states petitioners must

> Within ninety (90) days after the date of service of this Order, send by first-class mail, a copy of this Order and a notice that the purchaser shall immediately cease using any Removatron advertising or promotional materials containing representations prohibited in parts I and II of this Order, to each purchaser of any of [petitioners'] hair removal devices since January 1, 1976, who is identifiable from [petitioners'] sales records, testimonial letters, mailing lists or other documents containing an address or telephone number for that purchaser. Such advertising and promotional materials include, but are not limited to, any writing, audio tape or other material which employs such words as "permanent," "effective," forever," "long-term," or "works," or which compares the device to electrolysis or distinguishes it from temporary hair removal devices or products.

into any future advertising that claims their machine is able to remove hair. There is, however, a distinction between a corrective advertising requirement and an affirmative advertising requirement. "[A] genuine 'corrective advertising' requirement [is one that] demand[s] disclosure in future advertisements regardless of the content of those advertisements." *AHP*, 695 F.2d at 700. In contrast, an affirmative advertising requirement "requires disclosures only to the extent certain claims are made." *Id.* at 701 n. 33. In the present case, petitioners are only required to include the disclaimer whenever they also claim that their machine is able to remove hair. The Third Circuit's statement in *AHP* is equally relevant here:

> While Part I(B) has a corrective purpose, it is not a corrective advertising requirement in the narrow sense because AHP can escape its strictures by the simple expedient of ceasing to claim superior effectiveness or freedom from side-effects for its non-prescription analgesics.

695 F.2d at 700. Petitioners have not argued that part I(B) would be unwarranted if analyzed as an affirmative advertising requirement.

VI. INJUNCTION PENDENTE LITE

[12] The FTC moved for an injunction *pendente lite;* on April 5, 1989, we issued an order declining to rule on the motion because we did not have pertinent portions of the administrative record before us. In its appellate brief and at oral argument, the FTC renewed its motion. At no point have petitioners argued against the issuance of the injunction if we were to find against them on the other issues.

It is undisputed that petitioners continue to make their deceptive claims in advertisements and that they take in over $500,000 annually in sales of their machines. Under 15 U.S.C. §§ 45(*l*), 45(m), they are not subject to any penalty for violating the Commission's order until that order becomes final. Under the circumstances of this case,

> the Commission's order will not become final until (1) the period allowed for filing a petition for certiorari lapses; (2) a petition for certiorari filed by [Removatron] is denied; or (3) thirty days after the issuance of the Supreme Court's mandate, if the Supreme Court affirms or dismisses the petition for review. *See* 15 U.S.C. § 45(g).

Orkin Exterminating Co., Inc. v. FTC, 849 F.2d 1354, 1369 (11th Cir.1988), *cert. denied*, — U.S. —, 109 S.Ct. 865, 102 L.Ed.2d 989 (1989).

We conclude that an injunction is necessary to prevent future economic harm to those potential purchasers and clients who would not buy or receive treatments from petitioners' machines were it not for their deceptive advertising. *See id.* (granting an injunction *pendente lite* at the same time as a decision on the merits where only economic harm was at issue).

CONCLUSION

The Commission's findings and conclusions were adequately supported on the record. The scope of the order was appropriate under the circumstances of this case. We, therefore, deny the petition for review.

Because of the possibility of economic harm, we grant the FTC's motion for an injunction *pendente lite.* Petitioners are hereby enjoined from violating the terms of the Commission's cease and desist order. This injunction shall remain in effect until the Commission's order becomes "final" under the terms of 15 U.S.C. § 45(g).

SO ORDERED.