FTP v. Pantron I Corp., 33 F.3d 1088 (1994)

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Jeffrey A. Babener, principal attorney in the Portland, Oregon, law firm Babener & Associates, and editor of www.mlmlegal.com, represents many of the leading direct selling companies in the United States and abroad.

FTC v. Pantron I Corp., 33 F.3d 1088 (1994)

Case: FTC v. Pantron I Corp. (1994)

Subject Category: Marketing

Agency Involved: FTC

Court: Court of Appeals, Ninth Circuit (C.D. California)

Case Synopsis: The Ninth Circuit was asked to determine if a seller of a hair loss product can be held liable for misrepresentation if the product's effectiveness can only be attributed to the placebo effect.

Legal Issue: Is an advertisement a misrepresentation if it the effectiveness of the product can only be attributed to the placebo effect?

Court Ruling: The Ninth Circuit held that a seller is liable for misrepresentation of its product's effectiveness if it can only be attributed to the placebo effect using acceptable standards of scientific research. Pantron claimed that it's product reduced hair loss, and cited two European studies to confirm its claim. The FTC claimed that the studies were not held to acceptable scientific research standards, and cited multiple US based studies that held to the contrary using double blind and placebo controlled process that was published in peer reviewed journals.

Practical Importance to Business of MLM/Direct Sales/Direct Selling/Network Marketing/Party Plan/Multilevel Marketing: Many MLM and Direct Sales companies market health care products, and any effectiveness claims need to comply with appropriate laws and be backed up by reliable and reputable scientific research.

FTC v. Pantron I Corp., 33 F.3d 1088 (1994): The Ninth Circuit held that a seller is liable for misrepresentation of its product's effectiveness if it can only be attributed to the placebo effect using acceptable standards of scientific research. Pantron claimed that it's product reduced hair loss, and cited two European studies to confirm its claim. The FTC claimed that the studies were not held to acceptable scientific research standards, and cited multiple US based studies that held to the contrary using double blind and placebo controlled process that was published in peer reviewed journals.

33 F.3d 1088

63 USLW 2145, 1994-2 Trade Cases P 70,694

FEDERAL TRADE COMMISSION, Plaintiff-Appellant-Cross-Appellee,

v.

PANTRON I CORPORATION, et al., Defendants-Appellees-Cross-Appellants.

Nos. 92-56228, 92-56292.

United States Court of Appeals,

Ninth Circuit.

Argued and Submitted Feb. 3, 1994.

Decided Aug. 25, 1994.

Before: D.W. NELSON, REINHARDT, and BRUNETTI, Circuit Judges.

REINHARDT, Circuit Judge:

These consolidated appeals require us to decide a previously unresolved question of federal consumer protection law: Whether it is lawful for a seller to represent a product as "effective" when its efficacy results solely from a "placebo effect." [FN1] We conclude that the answer is no and that the representation constitutes a "false advertisement" under the Federal Trade Commission Act.

FN1. The term "placebo effect" refers to the fact that even a product of no inherent merit whatsoever will often have some degree of effectiveness in treating the condition for which it is employed, for psychological or other reasons. For example, a patient who ingests sugar pills while believing that they are strong pain relievers may well experience some pain relief, even though sugar pills are themselves inherently worthless in treating pain. In this example, the sugar pill is a "placebo" and the relief experienced by the patient is the "placebo effect."

The Federal Trade Commission, Pantron I Corporation, and Hal Z. Lederman appeal separate parts of the district court's order which enjoined Pantron and Lederman (Pantron's president and sole owner) from making certain advertising representations regarding the effectiveness of a purported baldness cure which Pantron markets as "The Helsinki Formula." In its appeal, the F.T.C. claims that the district court erred by not also enjoining Pantron and Lederman from representing that: (1) the Formula "was the subject of medical investigative work by responsible European physicians," and (2) the Formula "*1091 is effective to some extent for some people in dealing with male pattern baldness." The F.T.C. also argues that the district court erred in refusing to grant monetary equitable relief. In their cross-appeal, Pantron and Lederman argue that the district court erred in concluding that the Formula is a "drug" under 15 U.S.C. § 55(c). They also ask for sanctions. We reverse the district court's judgment to the extent that the F.T.C.'s appeal challenges it. However, we affirm the district court on the issues raised in the cross- appeal.

I.

Pantron I Corporation and Hal Z. Lederman market a product known as the Helsinki Formula. [FN2] This product supposedly arrests hair loss and stimulates hair regrowth in baldness sufferers. The Formula consists of a conditioner and a shampoo, and it sells at a list price of $49.95 for a three- month supply. The ingredients which allegedly cause the advertised effects are polysorbate 60 and polysorbate 80. [FN3] Pantron offers a full money-back guarantee for those who are not satisfied with the product.

FN2. Except where there is a special reason to differentiate the two, the remainder of our opinion will refer to Pantron and Lederman collectively as "Pantron."

FN3. The complete ingredient listing for the shampoo is: purified water, olefinsulfate, cocamidopropyl betaine, amino oxide, glycerine, chamomile extract, aloe vera gel, allatonin, D-panthenol, propylene glycol, jojoba oil, wheat germ oil, PABA, Vitamins A, D, and E, biotin, polysorbate 80, nucleic acids (RNA-DNA), folic acid, keratin protein, polyquaterium 10, citric acid, imidozolidinyl urea, and fragrance.

The complete ingredient listing for the conditioner is: water, polysorbate 80, polysorbate 60, biotin, propylene glycol, imidozolidinyl urea, niacin, and fragrance.

This case involves the F.T.C.'s challenge to Pantron's advertisements promoting the Helsinki Formula. These advertisements (including late-night infomercials hosted by the "Man from U.N.C.L.E.," Robert Vaughn) feature both the hair loss claim and the claim that the Formula promotes growth of new hair in

baldness sufferers. They also represent that recognized scientific studies support these claims. As occasionally occurs in our administrative state, Pantron's advertising claims came under rather intense scrutiny from a variety of regulatory entities. After the United States Postal Service, [FN4] the Food and Drug Administration, [FN5] the Los Angeles County District Attorney, [FN6] and even the Council of Better Business Bureaus [FN7] took varying degrees of action against Pantron's advertising and marketing of the Formula, the Federal Trade Commission filed the instant suit on November 18, 1988. The F.T.C.'s complaint directed itself to the advertisements which represented that the Helsinki Formula was effective and that there was scientific support for this conclusion. The complaint alleged that the representations were false and constituted an unfair or deceptive trade practice in violation of sections 5 and 12 of the Federal Trade Commission Act. See 15 U.S.C. §§ 45, 52. The Commission sought a permanent injunction and monetary equitable relief.

FN4. The Postal Service filed an administrative complaint against Pantron in February of 1987, which alleged that Pantron was making false claims regarding the Formula's effectiveness in preventing hair loss and promoting hair regrowth. As a result of this action, Pantron and the Postal Service entered into a consent order that prohibited Pantron from making such claims when selling their products through the mail unless the claims were supported by reliable scientific evidence.

FN5. An F.D.A. agent inspected Pantron's facilities in June of 1987. Two months later, the F.D.A. sent Pantron a "Notice of Adverse Findings," which stated that the agency was unaware of competent scientific evidence to support the efficacy claims made on the Helsinki Formula's labels.

FN6. In July of 1987, the D.A.'s office executed a search warrant on Pantron's facilities and alleged, in the probable cause affidavit, that Pantron's claims that the Helsinki Formula would promote hair growth were false.

FN7. In October of 1988, the National Advertising Division of the Council of Better Business Bureaus sent Pantron a letter stating that the studies on which the company relied for its efficacy claims had not been properly conducted. It requested that Pantron cease claiming that the Helsinki Formula is effective in preventing hair loss and promoting hair regrowth.

The district court conducted a 5-day bench trial in November of 1989. The F.T.C. presented *1092 a variety of evidence which tended to show that the Helsinki Formula had no effectiveness (other than its placebo effect) in arresting hair loss or promoting hair regrowth. The Commission introduced the expert testimony of Dr. Karl Kramer, a dermatologist who stated that, based on his knowledge and review of the medical literature, there was "no reason to believe" that the Helsinki Formula would be in any way useful in treating hair loss. He also stated that his opinion was in accord with the consensus view of the medical community.

Dr. Kramer's testimony was corroborated by two other experts, Drs. Elaine Orenberg and Theodore Ganiats. Dr. Orenberg stated that the studies on which Pantron relied--by Dr. Schreck-Purola and Dr. Pons--failed to satisfy the generally-accepted scientific standards of being randomized, double-blinded,

and placebo controlled. Dr. Ganiats, who had conducted a study of another polysorbate-60-based baldness treatment, expressed his opinion that neither polysorbate-60 nor polysorbate-80--the two allegedly result-producing ingredients in the Helsinki Formula--was effective in reducing hair loss or promoting hair regrowth. [FN8] The court also took judicial notice that the Food and Drug Administration had issued a rule that prohibited marketers of over-the-counter baldness treatments from labelling their products as effective. See 21 C.F.R. § 310.527. The F.D.A.'s final rule, which applies to all over-the-counter hair growth products, specifically identifies polysorbate 60 and several other ingredients which are found in the Helsinki Formula. See id. § 310.527(a). The F.D.A. rule concludes that "[b]ased on evidence currently available, all labeling claims for OTC hair grower and hair loss prevention drug products for external use are either false, misleading, or unsupported by scientific data." Id. [FN9]

FN8. He explained his conclusion with the following statement:

When you start with the fact there's no reason to believe that either drug would work, and you add to that the fact that one drug has been shown not to work, it's very damning evidence for the whole family.

He further elaborated: We have a condition before the study that it is unlikely that polysorbates were effective. It's unlikely because we can't imagine a reasonable mechanism of action. If we would have had a positive study, it would have had to have been confirmed, because it still would have been unlikely. But a negative study, given the pre-study possibility of it being effective was very low, coupled that with a negative study makes it incredibl[y] unlikely.

FN9. The F.T.C. also brought to the district court's attention two other district court cases and a U.S. Postal Service decision which had all determined that polysorbate-based products produced by other manufacturers were ineffective in reducing hair loss and promoting hair regrowth. See F.T.C. v. California Pacific Research, 1991-2 Trade Cas. (CCH) ¶ 69,564, 1991 WL 208470 (D.Nev.1991); F.T.C. v. Intra-Medic Formulations, No. 85-2819 (S.D.Fla. Feb. 25, 1986); In re New Generation, U.S.P.S. Dkt. No. 11/152 (May 13, 1983), vacated sub nom. California Pacific Research v. United States Postal Serv., Civ. No. R-83-172 (BRT) (D.Nev. Jan. 10, 1985), rev'd, 794 F.2d 682 (table) (9th Cir.1986), cert. denied, 479 U.S. 986, 107 S.Ct. 577, 93 L.Ed.2d 580 (1986). These decisions had reviewed essentially the same studies as were introduced into evidence in the present case, but Pantron was not a party to any of them.

Finally, the F.T.C. introduced evidence of two studies which had determined that polysorbate-based products were ineffective in stopping hair loss and promoting hair regrowth. The more important study, known as the Groveman study, was a placebo-controlled, double-blinded, randomized study which was published in the Archives of Internal Medicine, a peer-reviewed journal. See Howard D. Groveman, et al., Lack of Efficacy of Polysorbate 60 in the Treatment of Male Pattern Baldness, 145 Archives of Internal Medicine 1454 (1985). This study found "[n]o statistically significant difference" between the control and treatment groups, and that nearly a quarter of the participants in each group reported new hair growth. The authors concluded that "polysorbate 60 is not an effective remedy for MPB [male pattern baldness]," and that hair regrowth products possess a very strong placebo effect. [FN10] In

addition, the F.T.C. introduced *1093 the so-called Shuster study, an unpublished study which compared a polysorbate-based product to Pantene, a hair product that was presumed to have no inherent curative or restorative qualities. This study also concluded that polysorbate-based products were ineffective, although the F.T.C. acknowledges that "the failure to include a clearcut placebo somewhat reduces [its] value." [FN11]

FN10. Dr. Kramer stated that the Groveman study was "corroborating evidence" for his conclusion that the Helsinki Formula was not effective. Dr. Orenberg stated that the Groveman study (along with the Shuster study) was conducted according to the most scientifically appropriate criteria of any of the clinical studies on polysorbate-based products she had reviewed (including the Pons and Schreck-Purola studies). Dr. Ganiats, one of the doctors who conducted the Groveman study, testified that it was validly designed and performed for its objective. Finally, Dr. Donald Guthrie, the F.T.C.'s statistician, testified that the Groveman study "was a well- designed and well-executed study, generally following scientific principles you find in a good scientific study." He further stated that "the methodology of the study was quite good," and that "from the statistical standpoint it seems quite competently done."

FN11. Notwithstanding the lack of a clear placebo, Dr. Kramer testified that the Shuster study was a "well-designed scientifically-controlled study" and that, if one accepts the inference that Pantene is without inherent curative or restorative qualities, the study "lends some support to the proposition that the polysorbates do not work in male pattern baldness." Dr. Orenberg testified that the Shuster study closely approximated the proper scientific standards.

In response, Pantron introduced evidence that users of the Helsinki Formula were satisfied that it was effective. It offered the live and deposition testimony of 18 users who had experienced hair regrowth or a reduction in hair loss after using the Formula. It also introduced evidence of a "consumer satisfaction survey" it conducted in late 1988. In this "survey," which occurred during routine sales follow-up calls, a representative of Pantron interviewed a cross-section of 579 Helsinki Formula customers. Although the Pantron official who conducted the survey could not remember the questions he asked, and the company did not keep a record of these questions, Pantron introduced the results of its "survey" into evidence. The survey data showed positive results in a significant percentage of users, ranging from 29.4% of those who had used the product less than 2 months, to 70% of those who had used it for 6 months or more. Pantron also introduced evidence that over half of its orders come from repeat purchasers, that it had received very few written complaints, and that very few of Pantron's customers (less than 3%) had exercised their rights under the money-back guarantee.

Pantron also introduced several clinical studies of its own. First, it offered the results of Finnish studies, for which the Helsinki Formula was named, performed by Dr. Ilona Schreck-Purola. Her uncontrolled, unblinded, unrandomized, un-peer-reviewed study concluded that a polysorbate-based product was effective in arresting excessive hair loss within two to four weeks, and that it led to new hair growth in 60% of the subjects within four months. Although Dr. Schreck-Purola acknowledged that "the medical community remains of the opinion that polysorbates are not effective in treating male pattern

baldness," [FN12] she nonetheless stated that, in her opinion, polysorbates help alleviate baldness by destroying the cholesterol in the testosterone that destroys hair follicles.

FN12. Both Drs. Kramer and Orenberg testified that the Schreck-Purola study (as well as the Pons study; see infra) was scientifically invalid because it lacked a placebo control and was not reproducible because it lacked a standardized way of measuring the hair. They testified that the studies did not provide a proper basis to conclude that polysorbate-based products would be effective in alleviating male pattern baldness.

Pantron also introduced the testimony of Dr. Annik Pons, a French dermatologist who conducted an uncontrolled, unblinded study of a polysorbate product's effectiveness. This study relied on two measures of hair loss. First, participants were to count the number of hairs which fell in their sink or on their pillow each day. Second, the participants received three examinations by physicians who, applying the same amount of pressure each time, pulled a tuft of hair from the participant's scalp and counted the number of hairs pulled out. [FN13] Employing this method, the doctors found an 82-87% decrease in the rate of hair loss in eleven months. The physicians sought to measure new hair growth as well; using a magnifying device to count new hairs, they found new hair growth *1094 in up to 35% of the participants within three months. Based on these results, Dr. Pons testified that a polysorbate- based product was effective. [FN14]

FN13. Dr. Kramer testified that these measurements were "sort of haphazardly done," and therefore the study was not reproducible.

FN14. Pantron also introduced evidence of an uncontrolled, unblinded study by a Dr. Marie, which was conducted in France on 46 male subjects at about the same time Dr. Pons conducted her study. This study, which used substantially the same methodology as the Pons study, found a substantial decrease in hair loss, as well as new hair in 30 of the 46 subjects.

Finally, Pantron introduced the testimony of Dr. Paul Williams. Dr. Williams, a statistician, testified that the Groveman study was invalid because its sample size (68 men received polysorbate 60 and 73 men received a placebo) was inadequate. He stated that there was a 40% chance that the Groveman experiment would falsely conclude that an effective product is ineffective. He estimated that a minimum of 151 subjects in each group would be necessary for the study's conclusions to be reliable. [FN15]

FN15. As noted above, the F.T.C. offered the testimony of its own statistician, Dr. Guthrie, to rebut Dr. Williams's testimony.

On September 24, 1991, the district court issued findings of fact and conclusions of law. It found that Pantron had made the representations of efficacy and scientific support that the F.T.C. had alleged. Turning to the question whether these representations were false, the district court determined that "[t]here is no evidence in the record to support a contention that the Helsinki Formula is wholly ineffective." The district court found that the studies and anecdotal evidence offered by Pantron

"support[ed] the proposition that the compound works for some people some of the time." [FN16] Thus, it concluded that the F.T.C. had failed to carry its burden of showing that Pantron made a false claim when it represented that the Helsinki Formula was effective.

FN16. In another part of its decision, the district court phrased its finding as follows: "the Helsinki Formula most probably works some of the time for a lot of people." With respect to the issues raised on this appeal, there is no significant difference between these two statements, and we treat them interchangeably.

However, the district court found "no scientifically valid evidence that polysorbate 60 is effective for treatment of hair loss or for inducing growth." Thus, the district court concluded that the F.T.C. had "marginally carried its burden on the charge of falsity in defendant's claims of scientific proof." Accordingly, it entered an injunction, which barred Pantron and Lederman from making any express or explicit representations that scientific evidence establishes that the Helsinki Formula "is effective in any way in the treatment of baldness or hair loss." However, the order specifically allowed the defendants to

state that the Helsinki Formula (or a product similar thereto) was the subject of medical investigative work by responsible European physicians, if such statement is accompanied by clear and conspicuous disclosure that the work did not conform to recognized standards in the United States for medical/scientific studies.

Another provision of the injunction prohibited "any misrepresentation ... regarding the effectiveness of such product or program in the treatment of baldness," but it allowed Pantron and Lederman to

state that the Helsinki Formula is effective to some extent for some people in dealing with male pattern baldness, if such statement is accompanied by clear and conspicuous disclosure that the product's effectiveness (1) is more likely to involve arrest of hair loss than growth of new hair, and (2) is not explained or supported by scientific studies recognized under standards in use in the United States.

The court refused to order monetary equitable relief, because it concluded that "[t]he F.T.C. has not established that defendants' conduct caused actual deception and injury to consumers, nor that defendant Lederman knew or should have known such conduct was fraudulent." [FN17]

FN17. In its order for judgment, the district court added an additional conclusion of law: "The Helsinki Formula is a drug within the meaning of 15 U.S.C. Section 55(c)."

The F.T.C. appeals from the district court's refusal to award broader injunctive relief and any monetary equitable relief. *1095 Pantron cross- appeals from the district court's conclusion that the Helsinki Formula is a "drug" for purposes of 15 U.S.C. § 55(c).

II.

The F.T.C. challenges the portions of the injunction which allow Pantron and Lederman to make representations regarding the effectiveness of and support among responsible European physicians for the Helsinki Formula. [FN18] It argues that the district court clearly erred in finding that there was "no evidence ... to support a contention that the Helsinki Formula is wholly ineffective," and in finding that "the Helsinki Formula most probably works some of the time for a lot of people." The Commission also claims that the district court applied an incorrect legal standard in evaluating the evidence of effectiveness. We agree that the district court used an erroneous legal standard and hold that the parts of the order challenged by the F.T.C. must be modified.

FN18. In their cross-appeal, Pantron and Lederman do not challenge any part of the district court's injunction.

A.

The Federal Trade Commission brought this suit pursuant to sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52. Section 5(a) of the Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce" and empowers the Commission to prevent such acts or practices. 15 U.S.C. § 45(a)(1) & (2). Section 12 of the Act is specifically directed to false advertising. That section prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, or cosmetics." 15 U.S.C. § 52(a)(2). It also provides that the dissemination of any such false advertisement is an "unfair or deceptive act or practice in or affecting commerce" within the meaning of section 5. 15 U.S.C. § 52(b). The Act defines "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect." 15 U.S.C. § 55.

[1] In its own adjudications, the F.T.C. has to some extent clarified the legal standards which apply in section 12 cases. In Cliffdale Assocs., 103 F.T.C. 110 (1984), the Commission announced a three-part test for determining whether an advertisement is misleading and deceptive in violation of section 12. Under this test,

the Commission will find an act or practice deceptive if, first, there is a representation, omission, or practice that, second, is likely to mislead consumers acting reasonably under the circumstances, and third, the representation, omission, or practice is material.

Id. at 164-65. The Commission has consistently adhered to the Cliffdale Associates standard. See, e.g., Figgie Int'l, 107 F.T.C. 313 (1986); Thompson Medical Co., 104 F.T.C. 648 (1984). Although we have not heretofore explicitly adopted the test, we have stated that "[t]he new standard became binding on the F.T.C. when it was adopted in Cliffdale Associates." Southwest Sunsites, Inc., v. F.T.C., 785 F.2d 1431, 1435 n. 2 (9th Cir.), cert. denied, 479 U.S. 828, 107 S.Ct. 109, 93 L.Ed.2d 58 (1986). See also Kraft, Inc. v. F.T.C., 970 F.2d 311, 314 (7th Cir.1992) (setting forth the Cliffdale Associates test in slightly edited form), cert. denied, --- U.S. ----, 113 S.Ct. 1254, 122 L.Ed.2d 652 (1993). As we previously suggested in Southwest Sunsites, we believe that the general outlines of the Cliffdale Associates test set forth the

appropriate general principles for determining whether advertising is deceptive. Except as noted below, see infra nn. 20-21, we adopt that standard.

In this case, there is no question that Pantron represented that the Helsinki Formula was effective. The district court found that the advertisements "contain claims (a) that the Helsinki Formula is effective to arrest hair loss and promote regrowth, and (b) that the product's efficacy is demonstrated by responsible and recognized scientific studies." Pantron does not challenge this finding on appeal. There is also no question that these claims are material. Express *1096 product claims are presumed to be material, [FN19] and Pantron does not assert that its representations were immaterial. [FN20] Therefore, the only question before us is whether Pantron's representations regarding the product's effectiveness were likely to deceive or mislead consumers. [FN21]

FN19. See Thompson Medical Co., 104 F.T.C. at 816; F.T.C. Policy Statement on Deception, Oct. 14, 1983 (hereinafter "Policy Statement "), reprinted in Cliffdale Associates, 103 F.T.C. at 174, 182.

FN20. Accordingly, we need not decide whether a representation must be "likely to affect [consumers'] choice of, or conduct regarding, a product" in order to be "material" under section 15, Cliffdale, 103 F.T.C. at 165, or whether the statute encompasses the misrepresentation of "any fact that is important to consumers." Id. at 188 (Pertschuk, Commissioner, concurring in part and dissenting in part).

FN21. In addition, because this case involves express objective product claims, we do not consider whether these claims are "so far-fetched that reasonable consumers would not believe [them]." Thompson Medical, 104 F.T.C. at 788-89 n. 6. Thus, we do not decide whether section 12 requires "that an act or practice be considered from the perspective of a 'consumer acting reasonably under the circumstances,' " Cliffdale, 103 F.T.C. at 165, or whether it "requires only that a substantial number of consumers could be misled." Id. at 187 (Pertschuk, Commissioner, concurring in part and dissenting in part).

[2][3] There are a number of ways in which a representation, omission, or practice can mislead consumers within the meaning of section 12. [FN22] In particular, the Commission has identified two theories on which the government can and often does rely in section 12 cases involving objective product claims. First, the government can assert a so-called "falsity" theory. To prevail on such a theory, the government must "carry the burden of proving that the express or implied message conveyed by the ad is false." Thompson Medical, 104 F.T.C. at 818-19. Alternatively, the government can rely on a so-called "reasonable basis" theory. To prevail on this theory, the government must "show that the advertiser lacked a reasonable basis for asserting that the message was true." Id. at 819. In determining whether an advertiser has satisfied the reasonable basis requirement, the Commission or court must first determine what level of substantiation the advertiser is required to have for his advertising claims. Then, the adjudicator must determine whether the advertiser possessed that level of substantiation.

FN22. The Policy Statement provides the following non-exclusive list:

Practices that have been found misleading or deceptive in specific cases include false oral or written representations, misleading price claims, sales of hazardous or systematically defective products or services without adequate disclosures, failure to disclose information regarding pyramid sales, use of bait and switch techniques, failure to perform promised services, and failure to meet warranty obligations.

Reprinted in Cliffdale, 103 F.T.C. 174, 175. In addition, the Policy Statement noted that "[a]dvertising that lacks a reasonable basis is also deceptive." Id. n. 5.

Although the district court conducted both a "falsity" and a "reasonable basis" analysis, the F.T.C clearly and expressly abandoned the reasonable basis theory, both in the district court and in this court. [FN23] Accordingly, we discuss only the falsity theory.

FN23. This abandonment is puzzling, to say the least, because it is difficult to imagine how the Commission could fail to prevail on a reasonable basis theory. Application of the factors set forth in Thompson Medical, 104 F.T.C. at 821, would appear to compel the conclusion that Pantron should be required to possess some controlled clinical evidence that the Helsinki Formula is effective. This conclusion stems from the nature of the product claims, see Porter & Dietsch, Inc., 90 F.T.C. 770, 885 (1977) (stating that claims that any food, drug, or device can help a user achieve any result, such as weight loss, require "competent scientific or medical tests or studies"), aff'd, 605 F.2d 294 (7th Cir.1979), cert. denied, 445 U.S. 950, 100 S.Ct. 1597, 63 L.Ed.2d 784 (1980), the fact that the placebo effect makes it "difficult or impossible for consumers to evaluate by themselves" the truth of these claims, Thompson Medical, 104 F.T.C. at 822, the economic harm consumers suffer if the advertisement is false, see id. at 824-25 (requiring two controlled clinical tests because a false claim would be "economically harmful to consumers," despite its finding that any health risk was "minimal"), and the fact that "experts in the field would agree" that it is reasonable to require at least one (and possibly more than one) controlled clinical test. Id. at 821. As we explain infra, the record appears to make it clear that Pantron cannot meet even that minimal requirement. However, in view of the F.T.C.'s representations at trial and on appeal, we do not base our decision in whole or in part on a failure to meet the reasonable basis requirement.

*1097 B.

[4] The district court concluded that the F.T.C. failed to carry its burden of proving that Pantron's efficacy representations were false. It held that "[t]o prevail on its charge that defendant has misrepresented the efficacy of the 'Helsinki Formula,' the F.T.C. must prove that the product is wholly ineffective; i.e., that it does not work at all." The district court held that the F.T.C. had not satisfied its burden of proof. It concluded that, although Pantron's clinical studies did not conform to contemporary American scientific standards, they nevertheless showed that the Formula is effective in reducing hair loss in many people.

We hold that the district court erred in concluding that Pantron's representations regarding the Helsinki Formula's efficacy did not amount to false advertising. Although there was sufficient evidence in the record to support the district court's finding that use of the Helsinki Formula might arrest hair loss in some of the people some of the time, the overwhelming weight of the proof at trial made clear that any effectiveness is due solely to the product's placebo effect. As we explain infra, we conclude that a claim of product effectiveness is "false" for purposes of section 12 of the Federal Trade Commission Act if evidence developed under accepted standards of scientific research demonstrates that the product has no force beyond its placebo effect.

As Drs. Kramer, Orenberg, and Ganiats testified, the consensus of the medical and scientific community is that polysorbate-based products have no effectiveness beyond their placebo effect in combatting male pattern baldness. See supra pages 1091-92. Even Dr. Schreck-Purola acknowledged that the medical community had reached such a conclusion. It has done so because it has found no credible theory explaining how these products work. As Dr. Ganiats explained, when, as in the case of the Helsinki Formula, "we can't imagine a reasonable mechanism of action," responsible scientists cannot conclude that the product is effective absent very strong evidence coming from well-designed studies. See supra note 8. [FN24] Dr. Kramer echoed this view, stating that "the standards to which you are held when one is testing an unorthodox theory really have to be quite rigid." [FN25]

FN24. Drs. Kramer, Orenberg, and Ganiats all implicitly or explicitly rejected Dr. Schreck-Purola's theory that the Helsinki Formula works by destroying the cholesterol in the testosterone which kills hair follicles. Dr. Kramer came the closest to accepting this theory when, under cross- examination, he stated that Dr. Schreck-Purola's proposed mechanism was "an interesting theory" which might conceivably affect the progress of male pattern baldness. Yet Dr. Kramer clearly found this theory unworthy of reliance--based on his knowledge and review of the literature, he saw "no reason to believe" that the Helsinki Formula would be effective in any way. See supra page 1092.

FN25. By contrast, a study can corroborate an accepted scientific theory without being held to the strictest standards. Thus, the Groveman study, which was placebo-controlled, double-blinded, randomized, and published in a peer-reviewed journal, corroborates the consensus of medical opinion as described by the F.T.C.'s experts, even if it was not perfect in its design. The district court gave two significant reasons for disregarding this study: that it did not test "the precise formula marketed as the Helsinki Formula" and that it "probably did not involve a sufficient number of subjects." As to the first criticism, it applies as well to Pantron's studies on which the district court relied. The Pons study, like the Groveman study, involved polysorbate 60 but not polysorbate 80, and Dr. Schreck-Purola had previously stated in court documents that the Helsinki Formula did not contain the formula she studied. As for the second criticism, it is inconsistent with the district court's treatment of Pantron's studies. The district court found that Pantron's studies "solidly supported" the conclusion that the Formula is effective for some people "irrespective of certain 'state-of-the-art' scientific deficiencies in that work." Yet the court heard unrebutted testimony that whatever the flaws of the Groveman study, it was far more reliable and consistent with scientific standards than Pantron's French and Finnish studies.

Yet Pantron did not present any evidence which rebutted the consensus of the medical community that polysorbate-based products such as the Helsinki Formula are inherently ineffective. All of the evidence of effectiveness adduced by Pantron can be explained by the placebo effect. Dr. Kramer offered uncontradicted testimony that hair growth studies reflect the existence of a very high *1098 placebo effect, as high as 41% in one study. [FN26] Moreover, this placebo effect has an objective as well as a subjective component: not only do parties to the study misperceive hair growth, but patients will on occasion experience actual, measurable hair growth despite the fact that they have used a product of no intrinsic worth. Although the reasons for this objective placebo effect are unclear, the testimony presented in the district court indicated that a likely explanation is the stimulation of the scalp which comes from massaging any product, including plain water, into the head on a regular basis.

FN26. Drs. Pons, Schreck-Purola, and Williams all agreed that there is a substantial placebo effect.

None of Pantron's evidence of effectiveness takes the placebo effect into account. Pantron's evidence of consumer satisfaction is the most obviously flawed. The substantial placebo effect indicates that consumers simply cannot tell whether over-the-counter baldness cures are effective, inherently or otherwise. This is especially true in light of the irregular procession of hair loss--what an individual reports as the product's effectiveness in arresting hair loss may simply be the natural course of baldness. Much of Pantron's "consumer satisfaction" evidence is suspect on other grounds as well. Pantron's so-called "consumer satisfaction survey" was conducted by its own sales staff "as we did our follow ups to offer additional product." No record of the questions was kept. In addition, Pantron's low refund rate may not represent satisfaction. As Dr. Andreasen testified, even dissatisfied consumers may fail to exercise their right to a refund, because they think it not worth the trouble, because they feel guilty for having been deceived, because they credit the product's ineffectiveness to their own failure to follow instructions, or for any one of a number of other reasons.

Similarly, Pantron's clinical studies--and the expert testimony which relied solely on these studies--simply failed to account for the placebo effect. It is undisputed that these studies were not placebo-controlled. Pantron argues, however, that despite the lack of placebo controls, these studies were valid measures of the Helsinki Formula's effectiveness. First, it argues that Dr. Schreck-Purola's tests involved scalp biopsies which eliminated all subjectivity in the measurement of hair loss. Yet, because the study was neither controlled nor blinded, it could not account for the naturally irregular course of hair loss, nor for biased observation. Most significantly, it could not account for the objective aspect of the placebo effect.

Pantron also argues that "the French and Finnish studies were controlled by 'historical controls.' " The company contends that, because the participants in the study had previously tried many other remedies without success, the lack of results the participants had achieved in the past served as a control. Yet the designs of these studies never explicitly incorporated "historical controls," and they did not make a detailed comparison of the polysorbate-based products's results with the results the participants had achieved previously. [FN27] Finally, Dr. Kramer offered unrefuted testimony that historical controls are

especially poorly suited for hair loss studies because of the irregular progression of male pattern baldness.

FN27. The one exception is the Pons study, which did collect some data on the products previously used by the participants and the results previously obtained. However, as Dr. Kramer testified, this study suffered from significant flaws in its research design, such as heavy reliance on self- reporting, division of the study subjects among too many investigating physicians, and lack of reproducibility.

Finally, Pantron relies on Dr. Schreck-Purola's testimony that the success rate in the Schreck-Purola and Pons studies was too high to be explained by the placebo effect. Although the Rogaine studies showed a placebo effect of only 30-40%, the Schreck-Purola study showed hair growth in 60% of the subjects, and the Pons study showed hair growth in 80% of the subjects. Yet as Pantron's statistical expert conceded, it is improper to compare placebo rates across different studies, because "the placebo effect ... is entirely dependent upon the experimental design and the people doing the evaluation and the protocol that's been established." Absent a true control, Pantron's studies simply do not rebut the clinical and *1099 other scientific evidence presented by the F.T.C., which clearly demonstrates that any effectiveness of the Helsinki Formula arises solely from the placebo effect. [FN28]

FN28. Because of the strong placebo effect, and the fact that it has an objective component, absent a controlled study design a physician who actually tests a product such as the Helsinki Formula will be in no better position to determine whether the product is effective than one who merely reviews the studies. Thus, the district court should not have discounted the F.T.C.'s expert testimony on the ground that the Commission's experts had not personally tested the Helsinki Formula. In any event, none of Pantron's experts had tested the precise formula the company sells, either. See supra note 25.

C.

Assessing this evidence, the district court concluded that the F.T.C. had failed to carry its burden of showing that the Helsinki Formula is "wholly ineffective." In essence, the district court held that, as a matter of law, a seller can represent that its product is effective even when this effectiveness is based solely on the placebo effect. We believe that the district court misapprehended the law.

As an initial matter, we should explain that we reject the argument vigorously urged by the F.T.C., that the district court clearly erred as a factual matter in determining that "the Helsinki Formula most probably works some of the time for a lot of people." The Commission argues that this finding is inconsistent with another finding made by the district court, that there was "no scientifically valid evidence that polysorbate 60 is effective for treatment of hair loss or for inducing growth." [FN29] In essence, the F.T.C. urges that we should hold that contemporary standards of scientific evaluation--which preclude the consideration of the placebo effect--are the determinants of what is "true" and what is "false." In its view, when the application of these contemporary scientific standards would lead to the conclusion that a product is ineffective, any claim that the product is effective is "false" in an intrinsic, absolute sense. We disagree. Contemporary scientific standards obviously are not the definitive or sole

measure of what is "true" or "false." Galileo's theories were contrary to then-contemporary scientific standards, but we treat as a given that these theories were as essentially "true" when he explained them as they surely are today. Moreover, depending on our terms of reference, it may well not be incorrect to say that an efficacy representation is "true" when the product's effectiveness results solely from the placebo effect: for, in a certain sense, it would be "true" for a seller of sugar pills to represent that they relieve pain for some of the people some of the time, just as it would be "true" for Pantron to state that the Helsinki Formula sometimes arrests hair loss. Whether because of psychological factors or because of the physiological effects of regularly massaging any product into the scalp, the evidence makes clear that the Helsinki Formula does work to some extent to combat baldness in some people some of the time.

FN29. The district court's use of the term "no scientifically valid evidence" referred, essentially, to the lack of properly-conducted, blinded, placebo-controlled clinical studies, as well as the fact that the consensus of scientific opinion holds that polysorbate-based products are ineffective aside from their placebo effect. When the finding of "no scientifically valid evidence" is read in this light, there is no conflict between this finding and the district court's finding that the Helsinki Formula is effective some of the time for some people--presumably because of the placebo effect.

However, neither scientific standards on the one hand, nor the broadest possible definition of "truth" on the other, can determine what constitutes a "false advertisement" under section 12 of the Federal Trade Commission Act. Indeed, a "false advertisement" need not even be "false"; it need only be "misleading in a material respect." 15 U.S.C. § 55. We must read this definition of "false advertis[ing]" in light of the overriding purpose of the F.T.C. Act: "to protect the consumer from being misled by governing the conditions under which goods and services are advertised and sold to individual purchasers." National Petroleum Refiners Assoc. v. F.T.C., 482 F.2d 672, 685 (D.C.Cir.1973), cert. denied, 415 U.S. 951, 94 S.Ct. 1475, 39 L.Ed.2d 567 (1974); see also supra pages 1095-97 (discussing the Cliffdale test). The question we must face, then, is not whether Pantron's claims were "true" in *1100 some abstract epistemological sense, nor even whether they could conceivably be described as "true" in ordinary parlance. Rather, we must determine whether or not efficacy representations based solely on the placebo effect are "misleading in a material respect," and hence prohibited as "false advertis[ing]" under the Act.

[5][6] Taking account of these principles, we hold that the Federal Trade Commission is not required to prove that a product is "wholly ineffective" in order to carry its burden of showing that the seller's representations of product efficacy are "false." Where, as here, a product's effectiveness arises solely as a result of the placebo effect, a representation that the product is effective constitutes a "false advertisement" even though some consumers may experience positive results. In such circumstances, the efficacy claim "is 'misleading' because the [product] is not inherently effective, its results being attributable to the psychosomatic effect produced by the advertising and marketing of the [product]," United States v. An Article ... Acu-Dot ..., 483 F.Supp. 1311, 1315 (N.D.Ohio 1980), as well as (in cases such as this one) the objective effects caused by the use of any product or even non-product in treating the condition in question. The court in Acu-Dot considered a magnetic patch, which the manufacturer had represented as effective in relieving muscle and joint pain. It concluded that "any therapeutic value

of the [patch] is the result of its placebo effect," id. at 1314, and accordingly held that the manufacturer's representations were "misleading" under 21 U.S.C. § 352(a). In reasoning which fully applies to section 12 of the Federal Trade Commission Act, the court noted that "[a] kiss from mother on the affected area would serve just as well to relieve pain, if mother's kisses were marketed as effectively as the Acu-Dot device," id. at 1315, and that a consumer purchasing a pain-reliever would expect it to have more therapeutic value than such a kiss.

The Acu-Dot court's reasoning is persuasive here. Under the evidence in the record before us, it appears that massaging vegetable oil on one's head would likely produce the same positive results as using the Helsinki Formula. All that might be required would be for Wesson Oil to remove Florence Henderson as its flack and substitute infomercials with Mr. Vaughn that promote its product as a baldness cure. As the Commission has explained, the purposes of section 12 of the F.T.C. Act dictate that a court should not allow a seller to rely on such a placebo effect in supporting a claim of effectiveness:

"The Commission cannot accept as proof of a product's efficacy a psychological reaction stemming from a belief which, to a substantial degree, was caused by respondent's deceptions." Indeed, were we to hold otherwise, advertisers would be encouraged to foist unsubstantiated claims on an unsuspecting public in the hope that consumers would believe the ads and the claims would be self-fulfilling.

Bristol-Myers Co., 102 F.T.C. 21, 336 (1983). [FN30] Moreover, allowing advertisers to rely on the placebo effect would not only harm those individuals who were deceived; it would create a substantial economic cost as well, by allowing sellers to fleece large numbers of consumers who, unable to evaluate the efficacy of an inherently useless product, make repeat purchases of that product. See Thompson Medical, 104 F.T.C. at 718 (initial decision). [FN31]

FN30. The F.D.A. has at least implicitly determined that the placebo effect may not be used to support a claim of effectiveness, since it has determined that "all labeling claims for OTC hair grower and hair loss products for external use are either false, misleading, or unsupported by scientific data," 21 C.F.R. § 310.528(a), despite the evident placebo effect of these products.

FN31. Pantron relies on only one case for the proposition that it may advertise a product as effective based only on its placebo effect. Yet this case, F.T.C. v. Simeon Management Corp., 391 F.Supp. 697 (N.D.Cal.1975), aff'd, 532 F.2d 708 (9th Cir.1976), does not stand for this proposition. In Simeon Management, the district court denied a preliminary injunction to prevent a weight loss clinic from advertising that its program included the use of a certain prescription drug which was itself ineffective. The district court concluded that, because the program as a whole had been proven effective through clinical studies, there was no need to enjoin the use of the drug. Here, unlike in Simeon Management, the overwhelming weight of the evidence shows that Pantron's entire hair- growth program is ineffective, and that it consists solely of using the ineffective product.

*1101 The evidence before the district court made clear that there is no reason to believe that the Helsinki Formula is at all effective outside of its placebo effect. Accordingly, it was materially

"misleading" under Cliffdale Associates for Pantron to represent that the Formula is effective in combatting male pattern baldness. We "resist[ ] the impulse to allow [Pantron] to market a product that works only by means of a placebo effect on the basis that it nevertheless often achieves a [result] as claimed." Acu-Dot, 483 F.Supp. at 1315. Rather, we conclude that the district court erred in deciding that the F.T.C. had not shown that Pantron's effectiveness claims were false.

In light of our conclusion, we instruct the district court to remove the portion of its injunction which allowed Pantron to "state that the Helsinki Formula is effective to some extent for some people." Such a representation-- which, on the record before us, rests solely on the placebo effect--is misleading for the reasons set forth above. Moreover, we believe that the misleading nature of this statement is not cured by the district court's requirement that such a representation "be accompanied by clear and conspicuous disclosure that the product's effectiveness (1) is more likely to involve arrest of hair loss than growth of new hair, and (2) is not explained or supported by scientific studies recognized under standards in use in the United States." The first of these limitations does not in any way detract from Pantron's claim--which, on the record before us, is "false" as a matter of law--that the Helsinki Formula is effective. It merely provides a more precise prediction of the manner in which the product will have its purportedly positive effects. As to the second limitation, it fails to provide full and fair information to the consumer and is therefore itself misleading. Scientific studies recognized under standards in use in the United States do not merely fail to explain or support Pantron's effectiveness claims; on the record before us, it is clear that they refute these claims and demonstrate that the Helsinki Formula has no effectiveness aside from its placebo effect. On remand, the district court shall modify its injunction to prohibit the company from making any representations that the Helsinki Formula is effective in arresting hair loss or promoting hair regrowth.

The district court shall also eliminate that portion of its current injunction which allows Pantron to "state that the Helsinki Formula (or a product similar thereto) was the subject of medical investigative work by responsible European physicians." In the context of an advertisement, such a statement carries the message that responsible scientific studies demonstrate that the Formula is effective. This statement is materially misleading. To be sure, the district court required the statement to be "accompanied by clear and conspicuous disclosure that the work did not conform to recognized standards in the United States for medical/scientific studies." However, we believe that this proviso, like the other proviso added by the district court, does not resolve the problem it seeks to address. A representation that responsible European studies demonstrate the Helsinki Formula's effectiveness is misleading not merely because these studies did not conform to United States scientific standards, but because all available evidence developed under the far higher American standards demonstrates the opposite of the European studies: that the Helsinki Formula is ineffective aside from its placebo effect. Pantron may not rely on the European studies in its advertisements, unless it discloses all facts necessary to ensure that the use of the study results is not misleading. If it wishes to cite the European studies, Pantron must disclose, at a minimum: (1) that recognized standards of medical and scientific experimentation in the United States are stricter than those under which the European studies were performed; (2) that researchers employing recognized American standards have studied the effectiveness of polysorbate-based hair

growth products like the Helsinki Formula; and (3) that the unanimous conclusion of these researchers is that the Helsinki Formula and other similar products have no inherent curative or restorative effect.

III.

[7] The F.T.C. argues that the district court erred in refusing to order Pantron or Lederman to pay restitution to consumers or *1102 disgorge their profits. Because the district court's refusal to award monetary equitable relief was based on the application of erroneous legal principles, we reverse. [FN32] We conclude that an application of the correct legal principles requires the district court to order monetary relief in this case, especially in light of our conclusion, set forth in the previous Part, that the F.T.C. fully proved its falsity case.

FN32. A district court's grant of equitable relief is reviewed for abuse of discretion or the application of erroneous legal principles. See Dexter v. Kirschner, 984 F.2d 979, 982 (9th Cir.1992).

A.

Section 13(b) of the Federal Trade Commission Act provides "[t]hat in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction." 15 U.S.C. § 53(b). This provision gives the federal courts broad authority to fashion appropriate remedies for violations of the Act. As we explained in F.T.C. v. H.N. Singer, Inc., 668 F.2d 1107 (9th Cir.1982), the authority granted by section 13(b) is not limited to the power to issue an injunction; rather, it includes the "authority to grant any ancillary relief necessary to accomplish complete justice." Id. at 1113. This power includes the power to order restitution. See F.T.C. v. Amy Travel Serv., Inc., 875 F.2d 564, 571 (7th Cir.), cert. denied, 493 U.S. 954, 110 S.Ct. 366, 107 L.Ed.2d 352 (1989). A corporation is liable for monetary relief under section 13(b) if the F.T.C. shows that the corporation engaged in misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and that consumer injury resulted. See id. at 573.

Here, the district court concluded that Pantron had falsely claimed that the Helsinki Formula's effectiveness was supported by scientific proof. It also determined that these representations were material to consumers. Thus, the district court found the requisite material misrepresentations. Moreover, as we noted in the previous Part, Pantron's misrepresentations were even more extensive than the district court acknowledged. [FN33] In any event, the district court refused to order the company to pay restitution or disgorge its profits because it concluded that the F.T.C. had not established any actual injury to consumers. In particular, it relied on the fact that "[a]ny individual injuries have been only economic and only in amounts less than $100--for which defendant had offered a reasonably adequate, albeit rarely exercised, remedy."

FN33. Pantron argues that the district court found that the F.T.C. failed to establish the first part of the controlling test, because the district court stated that the F.T.C. had not shown any "actual deception and injury" (emphasis added) and because the district court found that the product was an effective baldness remedy. However, the first part of the standard does not require actual deception but only

misrepresentations of a kind reasonable people rely on. The district court clearly found all facts necessary to this requirement by finding that Pantron made misrepresentations regarding the scientific support for its efficacy claims and that these misrepresentations were material. Moreover, the district court's refusal to find any actual deception cannot stand in light of our conclusion in Part II, supra.

The district court's reasons for denying monetary equitable relief were inadequate as a matter of law. First, the district court erred when it relied on the fact that the consumer injuries have been only economic in nature. It is simply improper to treat this fact as a factor weighing against an award of monetary relief. The remedy of restitution seeks to correct unjust enrichment, and is therefore particularly suited to remedying economic injuries. Moreover, a major purpose of the Federal Trade Commission Act is to protect consumers from economic injuries. It would pervert the purposes of both the restitutionary remedy and the Act to deny monetary relief simply because the injury inflicted by the defendant is only economic in nature.

Second, the district court erred when it concluded that the modest amount of injury suffered by each individual consumer could preclude an order of restitution or disgorgement. Both the Commission and the courts have recognized that consumer injury is substantial when it is the aggregate of many small individual injuries. See Orkin Exterminating Co. v. F.T.C., 849 F.2d 1354, 1365 (11th Cir.1988) ("As the Commission noted, although the actual injury to individual customers *1103 may be small on an annual basis, this does not mean that such injury is not 'substantial.' "), cert. denied, 488 U.S. 1041, 109 S.Ct. 865, 102 L.Ed.2d 989 (1989). As the F.T.C. rightly observes, to allow a district court to deny monetary relief on this basis would preserve the unjust enrichment that a false advertiser has acquired and would do so simply because the advertiser has defrauded a large number of people for small individual amounts. Refusing to order monetary relief on this basis serves no legitimate purpose and is contrary to the purposes of the Act. [FN34]

FN34. Upon remand, the district court has the responsibility for tailoring the appropriate monetary relief. If the court reasonably concludes that it would be impossible or impracticable to locate and reimburse all of the consumers who have been injured by Pantron's misrepresentations, it may order some other remedy which requires Pantron to disgorge its unjust enrichment. Such an alternative remedy should provide direct benefits to consumers to the extent possible, however.

Finally, the existence of a money-back guarantee is insufficient reason as a matter of law to preclude a monetary remedy. As the Seventh Circuit recognized in Montgomery Ward & Co. v. F.T.C., 379 F.2d 666 (7th Cir.1967), allowing a seller to rely on a money-back guarantee as a defense to section 12 charges "would make the false advertising prohibitions of the Act a nullity. Anything might then be advertised as long as unsatisfied customers were returned their money." Id. at 671. For the same reasons, allowing such a guarantee to bar monetary relief would make the broad equitable remedial power in section 13(b) a nullity. Because even many unsatisfied customers will not take advantage of a money-back guarantee, a company which has engaged in consumer fraud would be able to retain a significant portion of the proceeds simply by making a largely illusory money-back offer.

Because the district court's refusal to order monetary relief against the corporation was based on the application of erroneous legal principles, and because an application of the proper principles compels an order of monetary relief, we instruct the district court to order the Pantron Corporation to pay monetary equitable relief to the extent of its unjust enrichment.

B.

[8] We also conclude that the district court abused its discretion in refusing to hold Lederman personally liable for monetary relief. In making this decision, the district court reasoned that the F.T.C. had failed to establish that Lederman knew or should have known that Pantron's conduct was dishonest or fraudulent. The F.T.C., relying on traditional principles of equitable remedies, maintains that knowledge of deceptiveness should not be required for an order of restitution. We have not previously decided this question, and we need not do so here. The evidence is clear that Lederman's state of mind satisfied even the standard employed by those courts which require "knowledge." Those courts require the F.T.C. to show " 'actual knowledge of material misrepresentations, reckless indifference to the truth or falsity of such misrepresentations, or an awareness of a high probability of fraud along with an intentional avoidance of the truth.' " Amy Travel Service, 875 F.2d at 574 (quoting F.T.C. v. Kitco of Nevada, Inc., 612 F.Supp. 1282, 1292 (D.Minn.1985)).

The evidence before the district court clearly established that Lederman acted with at least "reckless indifference to the truth or falsity" of Pantron's representations that scientific support existed for its efficacy claims. In 1982, he wrote to the F.D.A. to inquire about the reliability of the Schreck- Purola studies. The F.D.A. responded with a letter which stated that the agency was unaware of any valid scientific evidence supporting the efficacy of over-the-counter baldness remedies. The agency also sent Lederman an article which related that the F.D.A.'s advisory panel had determined that such hair loss treatments are ineffective. Lederman received similar information from the F.D.A. after he requested assistance from his congressman in 1985. Moreover, even if these communications with the F.D.A. did not make him aware that a high probability existed that Pantron's representations regarding scientific support were false, Lederman certainly gained such an awareness from the *1104 Postal Service Proceedings against him and the company, the FDA's issuance of a "Notice of Adverse Findings," the search by the Los Angeles District Attorney, and the Better Business Bureau's determination that the studies on which Pantron relied were not properly designed or conducted. See supra notes 4-7 and accompanying text. [FN35]

FN35. Lederman responds to these facts by stating that the district court found that he did not act dishonestly because it found that the Helsinki Formula was effective. However, the district court found that Pantron misrepresented the scientific support for its efficacy claims, and the evidence makes it apparent that Lederman had "knowledge" of the misrepresentation. That is all that is necessary for personal liability. Moreover, as we explained supra, the district court erred as a matter of law in concluding that the Helsinki Formula is effective. Accordingly, Lederman cannot rely on this conclusion to avoid personal liability.

There is no doubt from the record that Lederman was aware of a high likelihood that the company's claims of scientific support were false. Given the overwhelming evidence that no scientific support existed for the product's efficacy claims, Lederman could not have failed to know that the scientific support claims were false unless he intentionally avoided the truth. We therefore conclude that the district court erred in refusing to hold Lederman personally liable for monetary relief.

IV.

In its cross-appeal, Pantron argues that the district court's conclusion that the Helsinki Formula is a "drug" within the meaning of 15 U.S.C. § 55(c) should be reversed or stricken. Pantron contends that this conclusion was not necessary to the district court's decision and, in any event, that it was erroneous. We decline to disturb the district court's conclusion.

[9] Pantron raises two arguments in its cross-appeal. First, it contends that we should strike the district court's conclusion that the Helsinki Formula is a "drug," simply because the conclusion was not essential to the outcome of the case. [FN36] Pantron cites no authority for the proposition that an appellate court may strike a district court's conclusion of law merely because it is dictum. [FN37] It simply contends that "[t]he parties did not litigate whether the Helsinki Formula was a 'drug,' " and that it was therefore unfair or improper for the district court to decide the issue. While we might agree that a party could not be bound by a district court's finding on an issue which it did not have notice would be litigated, we conclude that Pantron was adequately informed that the question whether the Helsinki Formula was a "drug" would be contested. The pretrial order clearly identifies this question as one of the issues to be decided at trial. Although Pantron objected on the grounds that the question was unnecessary for decision of the case, it cannot claim that it did not receive notice that the question would be at issue. So long as the district court's conclusion that the Helsinki Formula is a "drug" has sufficient support in the record, therefore, we do not believe it appropriate to strike the conclusion simply because it is unnecessary to the district court's decision.

FN36. Pantron is incorrect when it states that the district court's resolution of this issue was irrelevant to the outcome. Section 12 of the F.T.C. Act, under which this action was brought, only applies to advertisements of "food, drugs, devices, or cosmetics." The district court's finding that the Helsinki Formula is a drug was relevant (although not necessary) to its determination that section 12 applied.

FN37. We do not necessarily accept as correct Pantron's characterization of the district court's conclusion. We do so only ad arguendo. The fact that a conclusion is not necessary does not in and of itself make it dictum. However, this is not the case in which to engage in a jurisprudential discussion of the meaning of the much-debated term "dictum." See, e.g., Charles W. Collier, Precedent and Legal Authority: A Critical History, 1988 Wis.L.Rev. 771.

[10] Pantron's second argument is that the district court erred on the merits in concluding that the product is a drug. We disagree. The company contends that the Helsinki Formula does not fit within the statutory definition of "articles (other than food) intended to affect the structure or any function of the

body of man or other animals." 15 U.S.C. § 55(c)(3). We see no error in the district court's conclusion that the Helsinki Formula is intended to affect the bodily function of hair growth.

*1105 Pantron points to the labels on the Helsinki Formula (which identify the products only as a shampoo and a conditioner) and the television advertisements for the product (which state that it works by cleansing the tissues around the hair follicle and which also state that the Formula is "not a drug"). The company argues that these advertisements make clear that the product is not intended to affect the structure or functions of the human body. Pantron relies on United States v. An Article of Drug, 331 F.Supp. 912 (D.Md.1971), which held that Helene Curtis "Magic Secret" skin lotion, which produced a "temporary wrinkle-smoothing effect," id. at 915, was a cosmetic and not a drug. The "Magic Secret" court reached this conclusion despite the manufacturer's claims that the lotion smoothed away wrinkles and tightened the skin. Pantron seeks to analogize these claims with the representations it made regarding the Helsinki Formula.

However, the rule the "Magic Secret" court set forth supports rather than conflicts with our decision here. Application of the "Magic Secret" analysis dictates the conclusion that, unlike Helene Curtis's skin lotion, the Helsinki Formula is a drug. In holding that "Magic Secret" was a cosmetic and not a drug, the court reasoned that a consumer would interpret the manufacturer's advertisements as representing only that the product would cause a temporary, superficial change in the user's appearance. See, e.g., id. (quoting advertisements which represented that Magic Secret "smooths away wrinkles in minutes, keeps them away for hours"). The claims made by Pantron are far more than assertions that the Helsinki Formula will alter the appearance of the user in a superficial way (such as stretching the skin to smooth away wrinkles) for a short period of time. They are representations that the product will cause the body to generate new hair in parts of the scalp where no hair currently exists. Such a claim is far more likely to be understood as affecting the structure or function of the body, and thus carrying "drug connotations," id., than are Helene Curtis's representations regarding "Magic Secret." The district court did not err in determining that the Helsinki Formula is a "drug."

V.

[11] Finally, Pantron urges that it be awarded double costs and attorneys' fees under F.R.A.P. 38. It claims that the F.T.C.'s appeal is frivolous because it merely seeks to overturn the district court's credibility findings. However, the Commission's position is clearly far from frivolous; as our disposition should suggest, we believe that the F.T.C.'s arguments clearly have merit. We find Pantron's action in seeking sanctions in this case to be wholly inappropriate. As we recently explained, "[s]anctions are an extraordinary remedy," which "will not be granted--nor should they be sought--as a matter of routine." Martel v. County of Los Angeles, 21 F.3d 940, 948 (9th Cir.1994) (emphasis added). Our admonition in Martel bears repeating here: "Parties who improperly seek sanctions, particularly repeat offenders, risk being subjected to sanctions themselves." Id.

VI.

The judgment of the district court is REVERSED in part and AFFIRMED in part. On remand, the district court is directed to modify the injunction as set forth in this opinion, and to order both Pantron and Lederman to pay monetary equitable relief.

http://www.mlmlegal.com/legal-cases/FTC_v_PantronICorp.php