UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

April 1, 2004

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Re: Petition for Rulemaking from the First Amendment Health Freedom Association
FTC File No. P034515

Dear Mr. Emord:

On April 16, 2003, you submitted a rulemaking petition to the Federal Trade Commission on behalf of the First Amendment Health Freedom Association ("Petition").[1] The Petition asserts that the Commission's rules of practice and procedure for investigating false or misleading health-related claims in food, drug, and dietary supplement advertising violate the First Amendment and the Administrative Procedure Act ("APA"). To remedy these alleged legal infirmities, the Petition requests that the FTC commence a rulemaking to make four specific changes to its rules of practice and procedure.[2] Specifically, the Petition requests that, when investigating health-related advertising, the FTC staff be required to: (1) evaluate the scientific evidence before initiating an investigation; (2) identify the specific advertising content that the staff considers to be misleading and the basis for that belief in the initial access letter or civil investigative demand ("CID"); (3) identify, at the earliest possible point in the investigation, the

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[1] The Petition includes a discussion of Petitioner's "standing to pursue legal redress" against the FTC in federal court, Petition at 9-10. We do not find it necessary to address this issue.

[2] The Petition was filed pursuant to Section 18(a)(1)(B) of the Federal Trade Commission Act, 15 U.S.C. § 57(a)(1)(B), and Commission Rule 1.9, 16 C.F.R. § 1.9. Petition at 1. These provisions allow any "interested person" to petition the agency to commence a trade regulation rulemaking to "define with specificity acts or practices which are unfair or deceptive in or affecting commerce." The Petition, however, does not request that the Commission change its rules to declare an act or practice unfair or deceptive. Rather, it seeks changes in the FTC's rules of practice and procedure relating to the investigation of health-related advertising claims. The Commission, therefore, has determined to consider the Petition as a request that it commence a non-trade regulation rulemaking proceeding. *See* 16 C.F.R. §§ 1.21 and 1.25.

specific grounds for the staff's belief that the substantiation is inadequate; and (4) issue warning letters to advertisers as a primary enforcement mechanism, rather than initiating formal investigations by access letter or CID.

After careful consideration of the arguments raised in the Petition and the relevant facts, law, and policy, the Commission finds that the FTC's current rules of practice and procedure for investigating health-related claims are fully consistent with the First Amendment and the APA. The Petition seeks to require the FTC staff, in essence, to determine that a violation of the FTC Act has occurred prior to conducting an investigation and obtaining the very information necessary for making such a determination. The Federal Trade Commission Act ("FTC Act") and implementing rules already provide adequate procedural safeguards, including judicial review, to protect advertisers from overly broad or arbitrary investigations and enforcement. Beyond those formal procedures, the FTC staff conducts investigations that are tailored to address the specific law violations at issue and to minimize the burden on advertisers. For these reasons, and as more fully discussed below, the Commission denies the Petition.

FTC Authority and Investigative Procedures

The FTC's authority over advertising for drugs, devices, and foods, including dietary supplements, derives from Sections 5 and 12 of the FTC Act.[3] Advertisers are prohibited from making false or misleading claims for these products[4] and also must have adequate substantiation for objective product claims before the claims are disseminated.[5] In enforcing Sections 5 and 12, the Federal Trade Commission does not review and approve advertising or advertising claims prior to dissemination. Instead, it is the advertiser's obligation in the first instance to ensure compliance with the law. After dissemination of an ad, the Commission staff might commence a law enforcement investigation to determine whether specific claims in the ad may be false or unsubstantiated.

The Commission's practices and procedures for investigating deceptive claims are the same whether an advertiser is making a health-related claim or some other type of claim. Section 3 of the FTC Act authorizes the Commission to "prosecute any inquiry necessary to its duties."[6]

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[3] Section 5 of the FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce, including deceptive advertising. 15 U.S.C. § 45. In addition, Sections 12 and 15 of the FTC Act prohibit the dissemination of false advertisements, defined as advertisements that are misleading in a material respect, for foods (including dietary supplements), drugs, and devices. 15 U.S.C. §§ 52, 55.

[4] *See* FTC Policy Statement on Deception, *appended to Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984).

[5] *See* FTC Policy Statement on Advertising Substantiation, *appended to Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984).

[6] 15 U.S.C. § 43.

Section 6 of the FTC Act, in particular, gives the agency the authority to "gather and compile information concerning, and . . . investigate . . . the . . . business, conduct, [or] practices . . . of any person, partnership, or corporation . . . ."[7]

The Commission has the authority to issue civil investigative demands to investigate whether claims made in advertising are false or unsubstantiated. Specifically, Section 20 of the FTC Act allows the agency to issue a CID whenever it "has reason to believe that any person may be in possession, custody, or control of any documentary material or tangible things, or may have any information, relevant to unfair or deceptive acts or practices."[8] The recipient of a CID has a legal obligation to comply, and the Commission may bring an action in federal court to compel the production of documents and other information specified in a CID. The Commission staff may use an "access letter" rather than a CID to investigate whether claims made in advertising are deceptive. The staff uses such letters to request that advertisers and others produce specific documents and other information to assist in the agency's investigation.

After its investigation is completed, the FTC staff will decide whether to close the matter or to recommend that the Commission initiate a law enforcement action. The Commission may commence a law enforcement action if it finds "reason to believe" that the advertising claims are unfair or deceptive and that such action would be in the public interest. The agency can issue an administrative complaint under Section 5(b) of the FTC Act, or it can file a complaint in federal district court seeking injunctive relief under Section 13(b) of the FTC Act.[9]

An advertiser is not compelled to modify or discontinue advertising merely because the staff has initiated an investigation of the claims.[10] Nor is the advertiser compelled to change or cease advertising during the pendency of litigation.[11] The Commission can order an advertiser to cease and desist making claims only after the agency has proven that the claims are deceptive and an adjudicator has issued a final order limiting future claims.[12]

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[7] 15 U.S.C. § 46(a).

[8] 15 U.S.C. § 57b-1(c)(1).

[9] 15 U.S.C. §§ 45(b); 53(b).

[10] Of course, deceptive advertising is a violation of the FTC Act whether it occurs before, during, or after the investigation. An advertiser who continues to make deceptive claims during the course of an investigation thus may be subject to larger financial remedies (such as greater consumer redress or disgorgement) based on sales due to ongoing deception during the investigation.

[11] However, a federal district court in a Section 13(b) action may issue preliminary injunctive relief ordering that an advertiser cease or modify its marketing claims.

[12] As an alternative to litigation, an advertiser may elect to settle the charges against it by entering into a consent agreement (without admitting liability) by which it consents to entry

The Petition argues that certain of these investigative practices and procedures, as applied to health-related advertising claims, violate both the First Amendment and the Administrative Procedure Act and must be modified. For the reasons set forth below, we conclude that these arguments are without merit.

Request for Rule Requiring that the Staff Evaluate the Science Before Initiating Investigation

The Petition seeks the adoption of a rule requiring Commission staff to "ascertain from scientific experts the competence and reliability" of the advertised health benefit before it commences a law enforcement investigation. The FTC staff, according to the Petition, often initiates investigations based on supposition rather than after consulting with scientific experts. The Petition contends that this practice imposes on advertisers the high costs of responding to a CID or access letter in an investigation that may be without scientific merit. Neither the law nor the facts support the Petitioner's argument.

Both practically and conceptually, assessing the state of the relevant science before obtaining documents from the advertiser through a CID or an access letter may be difficult, if not impossible. For example, the formulation of a dietary supplement, including the active ingredients and the amounts of those ingredients, is critical to determining which scientific studies are relevant. The advertiser itself is the most reliable source of this information and may be the only source. In other instances, the relevant scientific research may include proprietary studies that the advertiser has funded or conducted and that are not in the public domain.[13] Consequently, even though the Commission staff typically does conduct some initial assessment into the scientific basis for claims before sending a CID or access letter to an advertiser, imposing such a requirement in all cases could prevent or limit investigations of some false or unsubstantiated health-related claims.[14]

Well-established case law holds that the Commission is not required to compile evidence, including scientific evidence, of a possible law violation before it may investigate. The Supreme Court has said that the FTC, like other administrative agencies with law enforcement responsibilities, has the legal authority to investigate "merely on suspicion that the law is being

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of a final order and waives all right to judicial review.

[13] Given that advertisers have a right to make truthful and non-misleading claims based even on unpublished data, the advertiser stands to benefit from providing such data to the staff before, rather than after, the staff conducts its review of the adequacy of the science.

[14] Commission law requires an advertiser to possess adequate substantiation for a claim prior to the dissemination of the ad. Advertising Substantiation Policy Statement, *appended to Thompson Medical Co.,* 104 F.T.C. at 839. Assuming than an advertiser has complied with this requirement, it should not be unduly burdensome to produce that substantiation to the FTC staff.

violated, or even just because it wants assurances that it is not."[15] The Commission may investigate as long as its inquiry is "within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant."[16]

The FTC's authority to issue CIDs when investigating deceptive or unfair practices, as explained by Congress when it amended the FTC's investigative powers as part of the Federal Trade Commission Improvements Act of 1980,[17] does not require that the Commission compile evidence, including scientific evidence, of a possible law violation prior to commencing a law enforcement investigation. The Senate Report for the legislation stated that there is no minimum quantum of evidence of a possible law violation required before the Commission may use its CID authority to investigate.[18] The Report explained:

> One entirely valid purpose of a CID is to aid Commission investigators in determining whether there exists evidence of a violation. For example, the Commission may avail itself of the CID procedure in aid of an advertising substantiation investigation, in which the Commission seeks to ascertain whether any of a class of advertisers have violated their legal duty to have possessed adequate substantiating information relied upon as a reasonable basis for a product claim, at the time the claim was made.[19]

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[15] *United States v. Morton Salt Co.*, 338 U.S. 632, 642-43 (1950); *id.* at 652 ("[e]ven if . .. the request for information . . . [was] caused by nothing more than official curiosity, nevertheless law-enforcing agencies have a legitimate right to satisfy themselves that corporate behavior is consistent with the law and the public interest"); s*ee also FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1090 (D.C. Cir. 1992), *cert. denied,* 507 U.S. 910 (1993) (district court to enforce subpoena if reasonably relevant to investigation or if "not plainly incompetent or irrelevant to any lawful purpose" and not unduly burdensome); *FTC v. Texaco, Inc.*, 555 F.2d 862, 872-73 (D.C. Cir. 1977); *FTC v. Standard American, Inc.*, 306 F.2d 231, 234 (3rd Cir. 1962).

[16] *FTC v. Texaco Inc.*, 555 F.2d 862, 872 (D.C. Cir. 1977), *quoting U.S. v. Morton Salt*, 338 U.S. at 652.

[17] Prior to the 1980 amendments, the Commission had even broader subpoena power for such investigations. Congress intended the substitution of CID authority for subpoena power to provide parties with greater protection against inquiries that were too vague or too general in subject matter and scope. Federal Trade Commission Improvements Act of 1980, S. Rep. No. 96-500 at 23-24, *reprinted in* 1980 U.S.C.C.A.N. 1102, 1124-25.

[18] Federal Trade Commission Improvements Act of 1980, S. Rep. No. 96-500 at 24 (1979), *reprinted in* 1980 U.S.C.C.A.N. 1102, 1125.

[19] *Id.*

When using CIDs, the staff makes every effort to accommodate legitimate concerns of the advertiser while still obtaining the information needed to conduct a timely evaluation of the advertising in question. An advertiser believing the request is overly burdensome can require review of the CID by the Commission and a federal district court before complying.[20]

Although the Commission is not legally required to consult with scientific experts, the FTC staff, in fact, typically does some initial assessment into the merits of a case before it contacts the advertiser. This assessment often involves an initial consideration of both the claims and the science,[21] especially if the scientific issues are novel.[22] The staff, for instance, usually will examine samples of ads or labeling, and often will purchase the advertised product. In health-related cases, the staff will also typically conduct a search of the scientific literature and consult with Food and Drug Administration, the National Institutes of Health, or independent medical institutions and universities, or others with scientific expertise in the field.

Request for Rule Requiring that the Staff Identify the Specific Advertising Content Considered to Be Misleading and the Basis for that Belief in the Access Letter or CID

The Petition also requests that the Commission promulgate a rule requiring that access letters and CIDs specify precisely the claims that are false or unsubstantiated and provide the basis for that belief. The Petition argues that, without this information, advertisers are forced to engage in broad self-censorship out of fear of increased sanctions, such as increased consumer redress, if a violation is eventually alleged and proven.[23]

Commission statutes and rules require that advertisers receive notice of the nature of the conduct being investigated. Specifically, Section 20(c)(2) of the FTC Act requires that CIDs "state the nature of the conduct constituting the alleged violation which is under investigation

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[20] *See infra* p. 14 for a discussion of the procedural safeguards built into the CID process.

[21] The agency sometimes receives complaints or referrals about deceptive advertising from other government agencies, the medical community, industry groups, individual competitors, public interest groups, or even individual consumers. Often those complaints include information about the nature of the claims and the relevant science.

[22] In many instances, Commission staff already has substantial knowledge of the relevant science from prior investigations of similar products. This is particularly true for dietary supplements, given that over the past decade the agency has brought approximately one hundred dietary supplement advertising actions.

[23] Petitioner's assertion of a "chilling effect" on advertising is addressed in the First Amendment discussion below.

and the provision of law applicable to such violation."[24] The FTC has determined on its own to apply this same requirement to the access letters that the staff sends in lieu of CIDs.[25]

Congress intended Section 20(c)(2) of the FTC Act to require only a general statement of purpose sufficient to verify that the materials and information sought were relevant to the investigation and this requirement "was not intended to be overly strict."[26] The courts have confirmed that the boundaries of an FTC investigation may be drawn "quite generally."[27] Thus, this statutory requirement generally would be satisfied if the Commission stated simply that the purpose of its investigation were to determine whether health-related advertising claims for a particular product are deceptive in violation of Sections 5 and 12 of the FTC Act.

The FTC staff, however, routinely identifies in a CID or an access letter the health-related claims that are the initial focus of the investigation with more specificity than is required under Section 20(c)(2) of the FTC Act or Commission Rule 2.6. In some cases, the staff will identify specific language or other content that may be problematic. In other cases, the staff will attach a copy of the specific ad that is the subject of concern to the CID or access letter. In still other cases, the staff will identify more generally the health benefits that are the focus of the investigation without referring to a specific ad or ad content. As one example, the CID or access letter might request information related to a particular product's purported benefits as a cancer cure.

Nevertheless, requiring that the Commission provide the specific information that the Petition advocates would be difficult or impossible on some occasions. Because the Commission determines the meaning of claims based on its assessment of the net impression of the entire ad,[28] it may not be feasible at the outset of the investigation to list specific statements in isolation or other particular content that is problematic. Moreover, identifying the deceptive elements of an ad often requires access to the very documents and information the staff is seeking in the access letter or CID. For example, the Commission usually seeks copies of other ads as well as copy tests and other consumer research from the advertiser – information that often is instrumental in determining the express and implied claims that the advertiser was communicating. Similarly, information in the possession of the advertiser may also be important for determining the target

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[24] 15 U.S.C. § 57b-1(c)(2).

[25] Commission Rule of Practice 2.6, 16 C.F.R. § 2.6.

[26] S. Rep. No. 96-500 at 23 (1979), *reprinted in* 1980 U.S.C.C.A.N. 1102, 1125.

[27] *FTC v. Invention Submission Corp.*, 965 F.2d at 1090.

[28] *See* Deception Policy Statement, *supra* note 4, 103 F.T.C. at 176 (meaning of claims determined through an examination of the "representation itself, including an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction.").

audience of the ad, another factor in evaluating the express and implied claims conveyed by the ad.[29]

The Petition also requests that Commission staff separately identify those health-related claims that it suspects are "inherently misleading" and those that are only "potentially misleading." The Petition does not explain, however, how these terms are relevant in a post-market investigation of advertising that has already been disseminated.

The Commission investigates health claims in advertising that has already run.[30] The advertising's message has been conveyed to consumers and is either deceptive or not. When the message is deceptive, the advertiser's liability is the same whether the problem was "inherent" or a "potential" problem that was realized in the particular advertisement. An ad with a health claim that has been disseminated without necessary qualification or disclosure is not a "potentially misleading" claim. Instead, it is a completed deceptive act in violation of Section 5 or 12 of the FTC Act. At the end of the investigation, the FTC's complaint will identify the deceptive claims it intends to challenge and the advertiser is given a full range of procedural rights to contest and demand proof of the allegations in an administrative or court proceeding.[31]

Request for Rule Requiring that the Staff Identify, Early in the Investigation, the Specific Grounds for its Belief that the Claimed Health Benefits Are Not Substantiated

The Petition further requests that the Commission staff be required to identify the specific grounds for concluding that the substantiation of a health-related claim falls short of the "competent and reliable scientific evidence" standard. The Petition requests that the staff disclose such information as early as possible during the course of the investigation. It asserts that the FTC staff's failure to explain fully its analysis of the substantiation results in uncertainty about how the FTC will regard future advertising and leads to unnecessary self-censorship by the target of the law enforcement investigation as well as other advertisers.

The Petition's demands regarding the FTC staff's assessment of the substantiation at the start of an investigation are more stringent than the legal requirements for specificity of pleadings at the end of an investigation when a complaint is issued or filed. Commission Rule 3.11(b)(2) requires that an administrative complaint only contain "a clear and concise factual statement sufficient to inform each respondent with reasonable definiteness of the types of acts or practices

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[29] *See* Deception Policy Statement, *supra* note 4, 102 F.T.C. at 179.

[30] Unlike the FDA, the FTC does not require review and approval of health claims before they are made.

[31] Of course, in the interest of preventing further deception, during investigations Commission staff frequently discuss with advertisers the issue of whether future ads would still be deceptive if additional information (such as qualifications or disclosures) were included.

alleged to be in violation of the law."[32] The Federal Rules of Civil Procedure likewise mandate that the allegations in a Section 13(b) complaint need only be "a short and plain statement of the claim showing that the pleader is entitled to relief."[33] To satisfy these requirements, the Commission staff must present allegations sufficiently specific to allow the advertiser to answer them.[34] It would be highly anomalous to require, as the Petition argues, that an agency set forth a clearer or more complete explanation on an issue at the beginning of an investigation than the law requires in a formal complaint resulting from that investigation.

In addition, the FTC staff usually does inform an advertiser during the investigatory phase of a case of the staff's specific concerns about the proffered substantiation. In all health-related advertising investigations, the staff carefully reviews, typically in consultation with one or more scientific experts, the substantiation provided by the advertiser and any other relevant scientific literature. Once this review is completed, and before the staff makes any recommendation to the Commission to initiate a law enforcement action, the staff will normally meet with the advertiser, its counsel, and its experts.[35] The meeting typically is a substantive discussion between the Commission staff and the advertiser, with the FTC staff laying out its assessment of the relevant research and providing the advertiser with an opportunity to respond. The FTC staff, for instance, ordinarily will explain to the advertiser any significant design and implementation flaws in the principal studies on which the advertiser relies; the staff will identify the specific reasons why certain studies may not be relevant to the claimed benefits; and the staff will discuss any conflicting science that appears to negate the claimed benefit.

In addition, the Commission and its staff have provided guidance to industry about how the agency evaluates scientific substantiation for health-related advertising claims. The Commission's 1998 Dietary Supplement Guide, for example, provides a detailed analysis of how the agency evaluates scientific substantiation related to advertising claims for dietary supplements.[36] As noted in the Supplement Guide, the principles for dietary supplement

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[32] 16 C.F.R. § 3.11(b)(2).

[33] Fed. R. Civ. P. 8(a).

[34] *See* Fed. R. Civ. P. 12(e) and FTC Rules of Practice 3.11(c), 16 C.F.R. § 3.11(c).

[35] The staff does not follow this procedure in egregious cases in which the conduct merits seeking an *ex parte* temporary restraining order or other expedited relief.

[36] *Dietary Supplements: An Advertising Guide for Industry*, FTC, Bureau of Consumer Protection (1998). Section II.B. of the guide describes basic principles about the amount and type of evidence required to support a health-related claim; how to evaluate the quality of that evidence; the importance of considering the totality of the evidence rather than individual studies in isolation; and how to evaluate the relevance of the evidence to a specific advertising claim and product.

advertising are equally applicable to any industry making health-related claims.[37] Other sources of industry guidance include: the FTC's Substantiation Policy Statement;[38] the Commission's Enforcement Policy Statement for Food Advertising;[39] and a body of FTC case law, including cases involving dietary supplements.[40]

Request for Rule Requiring that the Staff Issue Warning Letters as its Primary Enforcement Mechanism

Finally, Petitioner requests that, rather than conducting full investigations using compulsory process, with the burden and expense that entails, the staff should instead issue warning letters suggesting how the claims could be modified to cure any potential for a misleading interpretation.[41]

The Petition does not cite any legal basis for its argument. Nor is it clear why issuing a warning letter in lieu of formal enforcement should follow simply because the misleading claims at question could have been rendered non-misleading through the use of appropriate disclosures. The decision whether to pursue a formal law enforcement action or resolve a matter more informally lies at the heart of the Commission's exercise of its prosecutorial discretion. Given the government's substantial interest in preventing harm to consumers from deception, the Commission puts the obligation on the advertiser in the first instance to make truthful and

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37 *Id.* at Section II.B., p.9.

38 *Advertising Substantiation Policy Statement,* appended to *Thompson Medical Co.*, 104 F.T.C. at 839 (1984).

39 *Enforcement Policy Statement on Food Advertising*, 59 Fed. Reg. 28,388 (June 1, 1994).

40 *See, e.g., Pfizer, Inc.*, 81 F.T.C. 23 (1972) (articulating the factors that determine what level of substantiation is appropriate); *Removatron Int'l Corp.*, 111 F.T.C. 206 (1988), *aff'd* 884 F.2d 1489 (1st Cir. 1989) (assessment of substantiation for hair removal device); *FTC v. Pantron I. Corp.*, 33 F.3d 1088 (9th Cir. 1994), *cert. denied* 514 U.S. 1083 (1995)(assessment of substantiation for Helskini formula baldness treatment); *Schering Corp.*, 118 F.T.C. 1030 (1994) (consent order) (assessment of substantiation for weight loss and appetite suppressant claims for Fibre Trim supplement); *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263 (S.D. Fla. 1999) (assessment of substantiation for weight loss supplements).

41 The Petition suggests the warning letter approach is appropriate when the claims being challenged by the agency are only "potentially misleading," *i.e.*, when the misleading claims are "capable of being rendered non-misleading through the addition of a disclaimer." As already noted, the Commission does not challenge a claim unless and until the claim has been made and consumers are likely to have been misled. *See supra* note 26 and accompanying text.

substantiated claims. Formal enforcement is typically necessary to deter harmful activities in the future and, in appropriate cases, to redress damages caused by the original deception.

Nevertheless, warning letters may be more efficient than formal enforcement action under some circumstances. The Commission staff, for instance, has sent warning letters when it is the most expedient means of reaching a large number of advertisers engaged in similar deceptive advertising practices and individual law enforcement actions against each would be impossible or impracticable.[42] The FTC staff also uses the warning letter approach following formal law enforcement action against large or prominent advertisers, to alert other advertisers making similar claims for similar products that the agency has found reason to believe that the claims are unsubstantiated.[43] The Commission staff issues warning letters when it believes such letters would be more effective than law enforcement action to prevent or deter deceptive claims that would cause consumer injury.

First Amendment and Administrative Procedure Act Challenges

The Petition contends that the practices and procedures that the Commission uses to investigate deceptive health-related claims in advertising are "arbitrary and capricious" in violation of the Administrative Procedure Act, and have an impermissible chilling effect in violation of the First Amendment.

(1) First Amendment

Health-related claims in advertising for foods, dietary supplements, drugs, and devices are commercial speech. The First Amendment limits the government's ability to restrict the free flow of truthful and non-misleading commercial speech, because such speech empowers

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[42] For instance, in the most recent phase of the Commission's Operation Cure.All effort to combat health fraud on the Internet, the agency and its partners identified numerous sites making questionable claims for products and services to treat or cure serious diseases like cancer, AIDS, arthritis, diabetes, multiple sclerosis, and heart disease. The agency sent nearly 200 e-mail advisories to U.S.-based web site operators, informing them of the requirement that they possess adequate substantiation for their claims, and encouraging them to review and modify their sites as appropriate. The agency has used the same e-mail warning approach to address marketing of products for protection against or treatment of anthrax and other threats of biological, chemical, and nuclear terrorism, and most recently for sites marketing SARS treatment and protection products.

[43] Following the Commission's recent filing against the marketers of a coral calcium supplement advertised as a cure for cancer and other serious diseases, for example, the Commission staff sent e-mail warnings to several Internet advertisers making similar claims for other coral calcium products. *FTC v. Kevin Trudeau, Robert Barefoot, et al.*, Civil Action Nos. 98 C 0168; 03 C 904 (Complaint filed June 9, 2003, N.D. Ill.)

consumers to make better-informed purchasing decisions and maximizes consumer welfare.[44] Commercial speech that is false or misleading, however, is not protected by the First Amendment. The government may prohibit deceptive commercial speech entirely.[45]

The Petition challenges the constitutionality of Commission investigative procedures and practices – practices that neither prohibit nor restrict commercial speech in any way.[46] Advertisers who believe their claims are truthful and not misleading are not compelled to cease those claims until after an adjudicator has determined that the claims are deceptive and issued a final order prohibiting the claims. At the point when a final order restricting claims has been issued, an advertiser can appeal on First Amendment grounds.[47]

The Petition contends that, even if the FTC's investigative practices and procedures do not restrict speech, they so discourage advertisers from making health-related advertising claims that there is an impermissible chilling effect in violation of the First Amendment. The Petition

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[44] *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976).

[45] *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980); *In re R.M.J.*, 455 U.S. 191, 203 (1982) ("Misleading speech may be prohibited entirely."); *FTC v. Pharmatech Research, Inc.*, 576 F. Supp. 294, 303 (D.D.C. 1983) ("The First Amendment does not prohibit government regulation of false or misleading speech.").

[46] The commercial speech case that the Petition cites as the principal support for its First Amendment challenge involved a broad pre-market prohibition of labeling claims. *Pearson v. Shalala*, 164 F. 3d 650 (D.C. Cir.), *reh'g denied*, 172 F. 3d 72 (D.C. Cir. 1999). The court in *Pearson* rejected FDA's approach to health claims in dietary supplement labeling because the agency had prohibited all claims not supported by significant scientific agreement, including even qualified claims that accurately conveyed the science. The approach prohibited truthful and non-misleading claims from ever reaching consumers. The FTC does not impose any restrictions on advertising claims prior to their dissemination. Advertisers are free to make any claim that can be presented in a truthful and accurate way without any requirement for pre-approval by the FTC. The *Pearson* case is thus inapposite to the FTC investigative practices at issue here.

[47] Commission orders are narrowly tailored to stop deception without imposing restrictions that might chill truthful speech. For a more detailed discussion of the agency's approach to health-related advertising and the specific remedies it imposes in orders involving deceptive advertising claims, see *Comment of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Request for Comment on First Amendment Issues,* FDA Docket No. 02N-0209 (Sept. 13, 2002). The Petition suggests that the FTC should model its approach on the recent initiative of the FDA to allow more leeway for qualified health claims in food labeling. In fact, this FDA initiative was in large part modeled after the FTC's long-standing approach to advertising claims. *See Enforcement Policy Statement of Food Advertising*, 59 Fed. Reg. 28,388 (June 1, 1994).

cites no case law for the proposition that the chilling effect of a law enforcement investigation limits the government's ability to investigate commercial speech to determine whether advertising claims are false or unsubstantiated.[48] Further, the Petition claims that advertisers are impermissibly chilled because they are uncertain of the nature and scope of the Commission staff's investigation of their advertising claims. As described above, advertisers are given adequate notice of the nature and scope of a Commission investigation. The courts have rejected similar arguments of chilling caused by uncertainty.[49]

The petition also claims that advertisers are impermissibly chilled because they bear substantial costs during Commission investigations. The Commission staff makes every effort to conduct its investigations in a timely manner and protect the public. The means used necessarily vary based on a number of factors, including the nature of the potential violations, the size and scope of the advertising, and whether the advertising is ongoing at the time of the inquiry. If an advertiser believes that an investigation is unreasonably burdensome, it has a full set of procedural rights, as discussed above, to ask the Commission or a federal court to limit the extent

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[48] The Petition cites case law addressing the chilling effect of government action on fully protected speech. *See, e.g., City of Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750 (1988) (holding unconstitutional ordinance granting mayor unfettered discretion to deny applications for permits to place news racks on public property); *Cox v. Louisiana*, 379 U.S. 536 (1975) (Court reversed conviction of person picketing against segregation, noting that city's unfettered discretion in regulating peaceful parades and meetings was unconstitutional). The Supreme Court, however, has held that, because it is more hardy, commercial speech is less likely to be chilled than fully protected speech. *Central Hudson,* 447 U.S. at 562-63, *citing Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 456 (1978); *see also Bates v. State Bar of Arizona,* 433 U.S. 350, 383 (1977) ("Since the advertiser knows his product and has a commercial interest in its dissemination, we have little worry that regulation to assure truthfulness will discourage protected speech."); *Kraft, Inc. v. FTC,* 970 F.2d 311, 321 (7th Cir. 1992). The case law involving the chilling effect of government action on fully protected speech thus does not support the arguments advanced in the Petition.

[49] In *Kraft,* for instance, an advertiser contended that the Commission's use of its own expertise rather than extrinsic evidence to determine whether ads made implied claims violated the First Amendment. The advertiser contended that commercial speech was impermissibly chilled because the advertiser was unable to determine whether the FTC would find a particular ad to be misleading. 970 F.2d at 320-21. The Seventh Circuit rejected the First Amendment argument, based both on its finding that the implied claims at issue were sufficiently clear from the face of the ads and on its assessment that commercial speech is less susceptible to chilling than fully protected speech. *Id.* at 321. Similarly, in *Sears, Roebuck*, the Ninth Circuit rejected an advertiser's challenge to an FTC order as impermissibly vague in violation of the First Amendment, noting that an advertiser is familiar with its product and thus in a strong position to be able to verify the accuracy of its claims before disseminating them. *Sears, Roebuck & Co. v. FTC*, 676 F.2d. 385, 400 (9th Cir. 1982), *citing Virginia Bd. of Pharmacy,* 425 U.S. at 777 (concurring opinion of Justice Stewart).

of the investigation. Although there are still some costs associated with being subject to a properly circumscribed investigation of possible advertising violations, the Petition cites no authority for the proposition that these costs have an impermissible chilling effect on commercial speech in violation of the First Amendment.[50]

(2) Administrative Procedure Act

The Petition argues that, because the FTC staff is not required to conduct its own scientific review of health claims before being allowed to initiate an investigation, the staff is left with too much discretion. In using this discretion to send CIDs, Commission staff can impose on advertisers the burden and expense of responding to an FTC investigation. This "unbridled discretion," the Petition charges, is a "clear violation" of law and "arbitrary and capricious" in violation of the Administrative Procedure Act.

For the reasons discussed throughout this response, the arguments in the Petition reflect a misunderstanding of the safeguards available to the recipient of compulsory process. First, the FTC staff does not have the authority to issue CIDs. Instead, the Commission itself must approve a resolution authorizing the use of compulsory process in an investigation and a Commissioner is required to sign each CID prior to its issuance. Second, Section 20 of the FTC Act mandates that each CID "state the nature of the conduct constituting the alleged violation which is under investigation and the provision of law applicable to such violation"; this statement typically includes a clear description of the specific health claims that are the focus of the investigation.[51] Third, the recipient of a CID may file a petition with the Commission to quash the CID if, for instance, that person believes that the CID is overly broad, unduly burdensome, or not related to a legitimate investigative purpose.[52] Finally, to compel a recipient to respond to a CID, the Commission must bring an action in federal district court, thereby providing an additional level of protection against abuse of compulsory process. Given the safeguards built into the issuance and enforcement of CIDs by the Commission and the courts, the Petitioner's charge that the FTC staff has "unbridled discretion" to use CIDs in an arbitrary and capricious manner is baseless.[53]

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50 *See FTC v. Carter,* 464 F. Supp. 633, 642 (D.D.C. 1979), *affirmed,* 636 F.2d 781 (D.C. Cir. 1980) ("[a]t this pre-complaint stage, [the advertiser's] commercial speech is not susceptible to any unconstitutional 'chilling effects' from the current investigation.").

51 FTC Act, Section 20(c)(2), 15 U.S.C. § 57b-1(c)(2).

52 FTC Act, Section 20(f), 15 U.S.C. § 57b-1(f); FTC Rules of Practice, 16 C.F.R. § 2.7(d).

53 The Commission requires that, as with CIDs, access letters to include a clear statement of the purpose of the investigation and the nature of the conduct constituting a law violation. FTC Rules of Practice, 16 C.F.R. § 2.6. The access letter will indicate, for example, that the inquiry is to determine whether an advertiser has engaged in deceptive acts or practices in violation of Sections 5 and 12 of the FTC Act. In addition, as in the case of CIDs, the staff typically identifies with greater specificity the products and advertising claims that are the focus

Conclusion

For all of the foregoing reasons, the Commission denies Petitioner's request for rulemaking.

By direction of the Commission.

C. Landis Plummer
Acting Secretary

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of its investigation. Often an access letter will include quotes of excerpts from an ad or copies of the ad itself. Any party that believes an access letter is inappropriate can refuse to comply, and receive all of the procedural protections that accompany CIDs.