

**Prepared Statement of the Federal Trade Commission on
"Agency Lockout on the Off-Label Use of EDTA Chelation Therapy"**

**Presented by Jodie Bernstein,
Director, Bureau of Consumer Protection,**

**Before the
Committee on Government Reform,
United States House of Representatives**

Mr. Chairman and members of the Committee, I am Jodie Bernstein, Director of the Bureau of Consumer Protection, Federal Trade Commission ("FTC" or "Commission"). I am pleased to have this opportunity to provide information concerning the Commission's investigation and settlement with the American College for the Advancement of Medicine.⁽¹⁾

At the outset, I would like to note that the Commission's testimony concerns a pending law enforcement matter. Therefore, much of the information relating to this matter is protected from public disclosure under the Federal Trade Commission Act and the agency's rules and policies concerning the confidentiality of investigative information. The Commission's statement provides information concerning the investigation consistent with these statutory and policy constraints.

I. Introduction

The mission of the Federal Trade Commission is to prevent unfair competition, and to protect consumers from unfair or deceptive practices in the marketplace. In particular, the Commission enforces Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts and practices in or affecting commerce,"⁽²⁾ and Section 12, which prohibits the false advertisement of "food, drugs, devices, services, or cosmetics."⁽³⁾ To advance its mission, the Commission has long sought to prevent the dissemination of false and misleading advertising. The Commission recognizes that advertising provides many important benefits to consumers and to competition. For example, the Commission has opposed bans on advertising by doctors and other professionals as anticompetitive restraints of trade. *American Medical Association*, 94 F.T.C. 701, 987 (1979), *aff'd*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982). But, these benefits from advertising may be thwarted when the information disseminated is false or misleading.

Accurate information about health care choices is vital to consumers. Each year, consumers spend hundreds of billions of dollars on health care products and services. Advertising plays an important role in informing consumers about the availability, cost, and other features of these products and services.

Unfortunately, in the health care field, as is true in almost all industries, some of the

information provided to consumers can be false or misleading. When that happens, the consequences of deception can be especially serious, causing not only economic injury by undermining consumers' ability to make informed choices, but creating risks to consumer health and safety. For this reason, the Commission has paid close attention to deceptive advertising claims for health care products and services.⁽⁴⁾

II. History of the ACAM Investigation

The ACAM investigation was opened in January, 1996.⁽⁵⁾ At the time of our investigation, the association promoted EDTA chelation therapy⁽⁶⁾ (herein "chelation therapy") as an effective treatment for atherosclerosis. The Commission has alleged that ACAM promoted this therapy directly to the public through an Internet Website and through brochures it distributed to consumers who contacted ACAM. The Commission's action challenges only ACAM's promotional activities.

In its investigation, Commission staff sought and received from ACAM materials it uses to promote chelation therapy, as well as material that the association has relied upon to support its claims relating to the efficacy of EDTA chelation therapy. For example, ACAM promotional materials stated that "*Chelation therapy is a safe, effective and relatively inexpensive treatment to restore blood flow in victims of atherosclerosis,*" and "*Chelation therapy is used to reverse symptoms of hardening of the arteries, also known as atherosclerosis or arteriosclerosis.*" Staff also conducted an independent literature search and contacted third party resources to collect materials on chelation therapy. Staff reviewed all of this material and submitted key papers and studies to experts familiar with research methodologies or the etiology and treatment of atherosclerosis.⁽⁷⁾ In addition, staff consulted with other government agencies and health organizations to ascertain their views.

Attorneys for ACAM met numerous times with Commission staff and provided their views relating to this case. Based on its investigation, staff was concerned that ACAM's supporting evidence was inadequate to support ACAM's claim that EDTA chelation therapy is effective in the treatment of atherosclerosis and ACAM's implied claim that scientific studies proved that the treatment was effective was false. Thereafter, consistent with normal Commission practice, ACAM representatives met with me, and each of the Commissioners to present their arguments against Commission action. Following these meetings, ACAM decided to enter into a settlement of the allegations against it.

On December 8, 1998, the Commission accepted, subject to public comment, an Agreement containing a Consent Order executed by ACAM. ACAM, while not admitting the Commission's allegations, waived its right to contest the issues in a trial on the merits. The Commission's complaint accompanying the consent agreement alleges that ACAM made: (1) unsubstantiated claims that EDTA chelation therapy is effective in treating atherosclerosis (blocked arteries); and (2) false claims that scientific studies prove that EDTA chelation therapy is an effective treatment for atherosclerosis.⁽⁸⁾ The proposed consent order would prohibit ACAM in the future from making unsubstantiated claims concerning the effectiveness of chelation therapy in the treatment of circulatory diseases, and would prohibit ACAM from misrepresenting scientific evidence in connection with its

advertising for chelation therapy.

It is important to understand what the proposed order does not do. It does not restrict any ACAM member from offering or performing chelation therapy. It does not prohibit ACAM or any chelationist from promoting or advertising chelation therapy.⁽⁹⁾ It does not restrict communications between doctors and patients about course of treatment decisions. Rather, the order would simply require that advertising claims be truthful and substantiated.

On December 16, 1998, the Commission placed the complaint and agreement on the FTC's public record for sixty days for comment. The comment period expired on February 16, 1999. The Commission has now reopened and extended the comment period until March 31, 1999.⁽¹⁰⁾

III. Legal Principles

In considering the advertising claims by ACAM, the Commission applied the same legal principles it has developed and applied over decades of reviewing health claims for products or services. They are well established principles articulated in Commission case law and explained in our policy statements, and they are designed to ensure that consumers are given truthful and nonmisleading information so that they can make decisions about their health and safety.

These principles are:

- Objective claims that a product or service is effective must be supported by a reasonable basis.⁽¹¹⁾
- What constitutes a reasonable basis depends on the nature of the claims and the context in which they are presented in the ad.
- If an advertiser states or implies a level of support for a claim, the advertiser must in fact have that level of substantiation.
- If the advertiser is silent on the level of support, the level of substantiation is determined on the basis of a number of factors, such as the type of product, type of claim, benefits of a truthful claim, the cost and feasibility of developing substantiation for the claim, the consequences of a false claim, and the amount of substantiation that experts in the field believe is reasonable.⁽¹²⁾
- Scientific evidence is required to support claims when an advertisement states or implies that claims are supported by scientific evidence, or when unqualified claims concern the efficacy or safety of a drug.⁽¹³⁾

In assessing the amount of substantiation experts in a field believe is reasonable, the Commission gives great weight to the generally accepted standards in the relevant fields of research and consults with experts from a wide variety of disciplines. Where there is an

existing standard for substantiation developed by a government agency or other authoritative body, the FTC accords substantial deference to that standard.⁽¹⁴⁾

The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented in advertising.

In past cases, the Commission has often required well-controlled clinical studies to substantiate drug and medical device efficacy claims.⁽¹⁵⁾ When considering whether a claim is substantiated, all available evidence is evaluated, including contrary evidence. Commission staff evaluated the evidence relating to the effectiveness of EDTA chelation therapy in a manner consistent with these principles.

IV. Access to Medical Treatment

I have been asked to comment on whether the Commission's action restricts patient access to medical treatment. It does not. The proposed order does not pertain to a physician's use of chelation therapy. Also, as mentioned above, the proposed order does not apply to doctors acting in their individual capacities giving advice to their patients and it does not regulate how individual doctors use or prescribe drugs in the course of treating or advising their patients or other choice of therapy issues. The proposed order applies only to representations made in advertising and promotional material by ACAM, a trade association, *i.e.*, commercial speech, disseminated to consumers.

The Commission is mindful of the development of alternative modes of treatment and, as an agency charged with enforcing competition laws, is sensitive to the competitive impact of its enforcement actions. Indeed, the FTC has a lengthy history of taking actions that prevent anticompetitive conduct in health care and other industries.⁽¹⁶⁾ The Commission believes that careful, consistent enforcement of the standard for advertising claims, *i.e.*, that claims in advertising not be misleading and be adequately substantiated, will enable consumers to receive useful information about their options in the health care marketplace.

Consistent with this policy, the Commission's Analysis for Public Comment issued in conjunction with the consent agreement in this case states that the "Commission's action should not be construed to regulate how doctors use or prescribe drugs in the course of treating their patients or other choice of therapy issues." This message is clearly stated in the letter ACAM would be required to send to doctors under the consent agreement. *See* Attachment A to the Consent Agreement.

V. Coordination with other Regulatory Agencies.

The Commission has been asked to discuss the FTC's interactions with the Federation of State Medical Boards, individual state medical boards, and other Federal regulatory or enforcement agencies in regard to physicians who incorporate the use of EDTA chelation into their practice of medicine. Commission staff has attended meetings of the Federation of

State Medical Boards, as well as the Board's Ad Hoc Committee on Health Fraud. The Federation also jointly sponsored with the Federal Trade Commission and the National Association of Attorneys General a law enforcement conference on June 26-27, 1997 in Dallas, Texas in which EDTA chelation therapy was discussed by some participants. Generally, these meetings involved the informal exchange of information, including the identification of current areas of interest; discussions of how to coordinate law enforcement activity, *e.g.*, identifying appropriate contacts in other agencies on particular matters; presentations by experts on various types of products or services; and descriptions of each participating agency's law enforcement authority, priorities, and procedures. FTC staff also has contacted staff of the California State Medical Board and other boards in order to collect information concerning chelation therapy. In addition, in at least one instance, our staff was contacted by a state medical board concerning physician advertising for chelation therapy.

FTC staff has contacted staff at other federal agencies as well, including the Public Health Service, National Institute of Health's Heart, Blood and Lung Institute, the Food and Drug Administration, and the National Center for Complementary and Alternative Medicine concerning either specific scientific questions or to obtain information concerning the agency's position, if any, on the effectiveness of EDTA chelation therapy. Commission staff regularly consults with other regulatory agencies on advertising issues. Through these contacts, Commission staff has developed a good working relationship with state and federal regulatory agencies and keeps them advised of Commission actions in related areas.

VII. Conclusion

The Commission has received a substantial number of comments on the proposed settlement with ACAM. When the comment period is closed, staff will review the comments and make its recommendation to the Commission. The Commission will then consider whether to adopt the order as final or direct such further action as it may consider appropriate.

Appendix

Pacific Medical Clinics Management, Inc., No. CV-901277 GT (CM) (S.D. Cal. filed Sept. 17, 1990) (misrepresentation of safety and efficacy of treatment for obesity).

Reproductive Genetics In Vitro, P.C., 114 F.T.C. 802 (1991) (false and unsubstantiated success rate claims for IVF infertility treatment).

Dr. Scott M. Ross, 115 F.T.C. 54 (1992) (misrepresentation of safety, recovery period, discomfort of liposuction).

NME Hospitals, Inc., 115 F.T.C. 798 (1992) (false claims success rate and superiority of Bowel-Disorder surgery).

Belage Plastic Surgery Center, 115 F.T.C. 871 (1992) (misrepresentation of safety, lack of risks, recovery period, painlessness of breast implants).

Medical Marketing Services, Inc., 116 F.T.C. 35 (1993) (misrepresentation of risks, pain, recovery period and results of chemical face-peels).

David Green, M.D., 119 F.T.C. 930 (1995) (misrepresentation of pain, permanence and success rate of non-surgical vein treatment).

Stillman Dyslexia Center and Transformational Training Center, Inc., No. CV-95-0685-ER (Shx) (C.D. Cal. filed Feb. 2, 1995) (false and unsubstantiated efficacy claims for dyslexia treatment device).

Genetus Alexandria, Inc., 121 F.T.C. 62 (1996) (false safety and efficacy claims for impotence treatment).

Cancer Treatment Centers of America, 121 F.T.C. 692 (1996) (false and unsubstantiated efficacy claims; unsubstantiated survivorship rate).

American Urological Corporation, No. 1:98-CV-2199 (JOF) (N.D. GA filed Aug. 3, 1998) (false efficacy claims for impotence treatment products).

Endnotes:

1. The written statement presents the views of the Federal Trade Commission. Responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

2. 15 U.S.C. § 45.

3. 15 U.S.C. § 52.

4. *See* Appendix for a list of some recent cases.

5. ACAM is a non-profit corporation under the laws of California composed principally of medical doctors and osteopaths. It is exempt from federal taxation under the Internal Revenue Code, 26 U.S.C. § 501(c)(6), the exemption for "business leagues" and similar organizations that promote members' common business interests. *See* 26 C.F.R. § 1.501(c)(6) -1.

6. Chelation therapy consists of the intravenous injection into the body of a substance which, after bonding with heavy metals in the bloodstream, is expelled through the body's excretory functions. The bonding substance recommended by ACAM, and used generally by practicing chelationists is a man-made amino acid called *ethylene diamine tetraacetic acid* (EDTA).

7. The Commission has provided a list of experts in response to Chairman Burton's request. The list includes highly credentialed scientists and medical professionals in a number of disciplines.

8. Organizations that, at one time or another, have concluded that use of EDTA chelation for the treatment of

coronary artery disease is unproven, unsafe, or both include: The National Institutes of Health, The National Research Council, the California Medical Society, the American Medical Association, the Centers for Disease Control and Prevention, the American Heart Association, the American College of Physicians, the American Academy of Family Practice, the American Society of Clinical Pharmacology Therapeutics, the American College of Cardiology, the American Osteopathic Association, the U.S. Public Health Service, and the U.S. Health Care Finance Administration.

9. Commission staff has engaged in extensive discussions with ACAM's representatives on this point and the staff has provided ACAM with considerable guidance. Moreover, consistent with Commission practice and procedure, if the order is made final, our compliance staff will continue to work with ACAM to provide further guidance concerning compliance with the order. *See Kraft v. FTC*, 970 F.2d 311, 326 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993).

10. The Commission vote to extend the public comment period was 3-1, with Commissioner Sheila Anthony dissenting. Commissioner Anthony and Commissioner Orson Swindle issued separate statements.

11. *See, e.g., Thompson Medical Corp. Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Firestone*, 81 F.T.C. 398, 451-52 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).

12. *Thompson Medical Corp.*, 104 F.T.C. at 821.

13. *Id.* 104 F.T.C. at 822; "FTC Policy Statement Regarding Advertising Substantiation," appended to *Thompson Medical Corp.*, 104 F.T.C. at 839.

14. *See Thompson Medical Corp.*, 104 F.T.C. at 825.

15. *Removatron Int'l Corp.*, 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1998)(requiring "adequate and well-controlled clinical testing" to substantiate claims for hair removal product); *Thompson Medical Corp.*, 104 F.T.C. at 826 (two well-controlled clinical tests required to substantiate arthritis pain relief claim); *See also, Porter & Dietsch, Inc.*, 90 F.T.C. 770, 885 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (claims that any food, drug, or device can help a user achieve any result, such as weight loss, must be substantiated by "competent scientific or medical tests or studies").

16. For example, the Commission has challenged private conspiracies to obstruct nurse midwives and podiatrists from obtaining hospital privileges. *Medical Staff of Memorial Med. Center*, 110 F.T.C. 541 (1988) (consent order); *North Carolina Orthopaedic Ass'n*, 108 F.T.C. (1986) (consent order).