Prepared Statement of the Federal Trade Commission on

"Agency Lockout on the Off-Label Use of EDTA Chelation Therapy"

Presented by Jodie Bernstein,
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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 connthe 10( )]TJ 51(t)-2(ha)4(t)-dt(on)-D(f)3Bgr[(i)-2(hi)-2(i)-1(l)-2(2(on, t)-2(h

information provided to consumers can be false or misleading. When that happens, t 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, 1998.[5] At the time of our investigation, the association promoted EDTA chelation therapy (hereinafter "chelation therapy")[6] 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 support 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

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.

existing standard for substantiation developed by a government agency or other

State Medical Boards, as well as the Board's Ad Hoc Committee on Health Fraud. Th
Federation also jointly sponsored with the Federal Trade Commission and the National

coronary artery disease is unproven, unsafe, or both include: The National Institutes of Health, The Na
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