

Prepared Statement of the Federal Trade Commission  
on

**"Health Fraud and the Elderly: A Continuing Health Epidemic"**

Before the  
U.S. Senate Special Committee on Aging

Washington, D.C.

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**I. Introduction**

Mr. Chairman and members of the Committee, I am Howard Beales, Director of the Bureau of Consumer Protection, of the Federal Trade Commission. I am pleased to have this opportunity to provide information concerning the Commission's efforts to ensure the truthfulness and accuracy of marketing for health products and services. My comments will focus in particular on our work to combat fraudulent claims for products marketed as treatments or cures for serious diseases, many of which are particularly prevalent among elder citizens, including cancer, heart disease, and arthritis.<sup>(1)</sup>

The mission of the Federal Trade Commission is to prevent unfair competition and to protect consumers from unfair or deceptive acts or practices in the marketplace. As part of this mission, the Commission has a longstanding and active program to combat fraudulent and deceptive advertising claims for health products.<sup>(2)</sup> Since the fall of 1997, the Commission has filed twenty-seven cases against companies using false or deceptive claims to market unproven products that allegedly cure such ailments as cancer, arthritis, sleep apnea, impotence, osteoporosis, or circulatory diseases.

Despite these efforts, unfounded or exaggerated health claims remain common in the marketplace, and combating health fraud remains one of the Commission's top priorities. Cooperative law enforcement that focuses on marketers who promote products that jeopardize the health of users as well as those who make unfounded therapeutic claims for serious diseases is a keystone of that effort. Although aggressive law enforcement is crucial, the best consumer protection comes from preventing consumers from being deceived in the first instance.

Thus, the Commission emphasizes consumer education to help consumers spot and avoid health fraud. Finally, we also work to provide businesses with the guidance necessary to avoid violating the law.

We believe these efforts are important because health fraud often targets a very vulnerable segment of our population -- those suffering from serious or incurable health conditions and diseases. The victims are often fearful and desperate. As one commentator observed, "[I]t is difficult to explain, and often impossible to comprehend, the degree of suffering seen in some cancerous conditions, cases of arthritis, and certain nervous disorders."<sup>(3)</sup> In such circumstances, therapeutic claims, even outrageous claims that ordinary consumers would dismiss as fraudulent, can be and are convincing enough to persuade consumers to purchase these products.

In other circumstances, a number of factors, including lack of information and false beliefs about health and the causes of disease, may also contribute to a particular consumer's susceptibility to

health fraud.<sup>(4)</sup>

## II. Consumer Injury

At the consumer level, the costs of these products and services range from a few dollars to tens of thousands of dollars for cancer treatments offered in foreign "clinics." In most cases, these products and services are not covered by insurance.

In addition to economic injury, some products and services can pose a serious health threat. The promise of worthless or unproven remedies can deter victims from seeking the best available treatments. In some instances, particularly in the area of cancer, marketers have even told victims that it is not necessary for them to seek conventional treatment. For example, one website for an unproven treatment told consumers:

Does this mean you can cancel your date for surgery, radiation and chemotherapy? YES! After curing your cancer with this recipe it cannot come back. THIS IS NOT A TREATMENT FOR CANCER: IT IS A CURE! But if you do not wish to make your doctor angry, you could follow her or his wishes, too. Be careful not to lose ANY VITAL ANATOMICAL PARTS in surgery though, because you may need them later when you are healthy!<sup>(5)</sup>

In some patients, delaying treatment may worsen the condition.

Deferred treatment is not the only risk, however; some products and services are themselves dangerous. This is a concern the Commission takes very seriously. Safety is a primary criterion the Commission uses in its case selection process, as illustrated by our recent cases against marketers of products containing comfrey, an herbal product that, when taken internally, can lead to serious liver damage.<sup>(6)</sup>

## III. Law Enforcement

The Federal Trade Commission, Food and Drug Administration, U.S. Postal Service, and state law enforcement and regulatory agencies all play a role in protecting consumers, especially seniors, from health fraud. Over the years, there has been a high degree of cooperation among these agencies, including the sharing of information and technical and scientific expertise as well as the coordination of law enforcement efforts. For example, to combat health fraud on the Internet, the Commission initiated *Operation Cure.All*,<sup>(7)</sup> a comprehensive consumer and business education and law enforcement and regulatory initiative targeting deceptive and misleading Internet promotion of products and services as cures or treatments for serious diseases. In addition to the FTC, participants in *Operation Cure.All* include the Food and Drug Administration,<sup>(8)</sup> several state attorneys general, and Health Canada.

The initial phase of *Operation Cure.All* consisted of two Internet surfs<sup>(9)</sup> conducted in 1997 and 1998. As a result of these surfs we found over 1600 sites world-wide making questionable claims for products marketed as treatments for heart disease, cancer, HIV/AIDS, diabetes, arthritis, and multiple sclerosis. Of these, over 800 were located in North America, with the vast majority in the United States. To put these numbers in perspective, it took surfers only about 3 hours each to find these sites, which we believe represent only the tip of the iceberg. The results from these surfs were used to identify areas for targeted law enforcement, e.g., magnetic therapies, and, as discussed below, in our industry education efforts.

This year, the Commission has filed eight cases as part of *Operation Cure.All*, targeting companies that market a variety of devices, herbal products, and other dietary supplements to treat or cure cancer, arthritis, Alzheimer's, diabetes and many other diseases. Among the products for which

marketers made unsubstantiated health benefit claims were a DHEA hormonal supplement, St. John's Wort, various multi-herbal supplements, colloidal silver, comfrey, and a variety of electrical therapy devices.<sup>(10)</sup>

The following are illustrative of the kinds of claims that the Commission challenged in its *Operation Cure.All* cases this year:

THIS IS NOT A TREATMENT FOR CANCER: IT IS A CURE! . . . It takes 5 days to kill the parasites that cause intestinal cancer. The cancer is then killed . . . . (*herbal product*)

We cannot list all 650 diseases that colloidal silver is effective against but here is a list of some of the common ones: Common cold, stomach ulcers, acne, burns, shingles, arthritis, strep, tuberculosis . . . (*colloidal silver*)

[T]here are . . . literally hundreds of scientific studies supporting the components of this breakthrough formula. Here are some of the most dramatic new findings. . . . And finally, a breakthrough study on nearly 1,000 subjects published in the prestigious journal of epidemiology showing a significant reduction in the risk for atherosclerosis. . . . the leading cause of death in Western nations. (*anti-aging DHEA product*)

Herb Veil 8 has been used in the successful removal of carcinoma, adenocarcinoma, and melanoma. (*botanical product*)

This formula is a "power house" and has been used on (and restored to health), cancer of the spine, arthritis, and polio, and has helped rebuild torn cartilage and sinews, fractures, etc. etc..." (*product containing comfrey*)

Prior to this year, the FTC had filed eight *Operation Cure.All* cases. The challenged products include Cat's Claw,<sup>(11)</sup> shark cartilage,<sup>(12)</sup> cetylmyristoleate (CMO),<sup>(13)</sup> Essiac Tea,<sup>(14)</sup> and magnetic therapies.<sup>(15)</sup> In all these cases the companies made strong claims about treatments or cures for serious diseases with little or no evidence to support the claims.<sup>(16)</sup>

Other Commission initiatives include conducting Internet investigation training courses for more than 2000 individual law enforcement staff, including representatives of 20 countries, 30 states, and 22 federal agencies. The Commission also maintains a comprehensive consumer complaint data base, Consumer Sentinel. Complaints come into the system through telephone and mail inquiries to our Consumer Response Center as well as through our online complaint form at [www.ftc.gov](http://www.ftc.gov). Complaints are also forwarded to the system from many public and private partners. Complaint information in the system is available to over 300 law enforcement agencies.

While the Internet Training Course and Consumer Sentinel cover many more areas than health fraud, these initiatives have contributed significantly to law enforcement efforts in the health area as well. For example, the Internet training we provide to health fraud investigators at federal and state agencies improves efficiency in conducting investigations of Internet companies marketing questionable products. In addition, Consumer Sentinel has become a valuable source of leads and other information about companies that may be engaged in deceptive marketing of health products.

The FTC is committed to obtaining strong remedies that will adequately protect consumers against health fraud. As already noted, the provisions of the Federal Trade Commission Act empower the Commission to prevent unfair or deceptive acts or practices in or affecting commerce<sup>(17)</sup> and false advertisements for foods, drugs, devices, cosmetics and services.<sup>(18)</sup> In addition to prohibiting false claims, these provisions require, in most cases, that marketing claims about the efficacy or safety of a health-related product or service must be supported by competent and reliable scientific

evidence.<sup>(19)</sup> In general, competent and reliable scientific evidence consists of tests, studies, or other scientific evidence that has been conducted and evaluated according to standards that experts in the field accept as accurate and reliable.<sup>(20)</sup>

Given the number of companies marketing health products and our limited resources, we cannot investigate and prosecute every possible case. Factors that are considered in case selection include (1) the safety of the product or service, (2) whether the product or service is being marketed as a treatment or cure for a serious disease or health condition, (3) the egregiousness of the claims, (4) the scope of the marketing and sales, and (5) the extent to which bringing a particular case will serve the Commission's industry compliance and consumer education mission.

Enforcement actions can take one of two forms. The Commission can file an administrative action or it can file its action directly in federal district court. Federal district court actions are particularly appropriate where the case involves a potentially unsafe product, or when immediate injunctive relief is necessary to stop an ongoing deceptive advertising campaign or to preserve assets for consumer redress. In either case, the Commission may seek broad remedial relief.<sup>(21)</sup>

In addition to prohibiting specific deceptive product claims, Commission orders in the health area typically prohibit unsubstantiated claims for other foods, drugs, dietary supplements, devices or services. In cases where a company utilizes third party distributors, Commission orders often require the company to notify its distributors of the Commission's action and to monitor future advertising. Where appropriate, the Commission attempts to obtain the payment of consumer redress or, where redress is impractical, disgorgement of ill-gotten gains to the U.S. Treasury. Also, in appropriate cases, the Commission may order a company to undertake a specific consumer education program. For example, in the Commission's action against a company marketing a product known as Essiac Tea<sup>(22)</sup> as a scientifically proven cancer cure, the Commission's consent order required that the company send notices to past purchasers advising them that there is no reliable evidence that Essiac Tea is effective against cancer.<sup>(23)</sup>

#### **IV. Consumer and Business Education**

The Commission recognizes that the primary goal of consumer protection is to prevent consumers from being injured. For that reason, the Commission maintains a comprehensive consumer education program. Today we are releasing a publication produced with the FDA, called "Miracle Health Claims: Add a Dose of Skepticism." This brochure provides specific information about the efficacy and safety of popular products as well as information about spotting and avoiding health fraud. Another brochure, "Who Cares: Sources of Information About Health Care Products and Services," published jointly with the National Association of Attorneys General, informs consumers about where they can go for information about arthritis cures, alternative medicine, and other health issues, and where they can file complaints about health fraud. The Commission also works with other federal agencies, like the Administration on Aging, and organizations like the AARP, to get our health fraud messages to older audiences.

The Commission also uses the Internet to distribute its consumer education messages. The Commission's Website, [www.ftc.gov](http://www.ftc.gov), provides links to reliable sources of health information, including [www.healthfinder.gov](http://www.healthfinder.gov), developed by the Department of Health and Human Services, and consumer education tips such as those found in "Virtual Health Treatments Can Be Real World Deceptions."<sup>(24)</sup> Our web-based consumer education material has received nearly 80,000 accesses since October 1, 2000. These materials are also available in printed form. In addition, the Commission maintains a number of "teaser" sites like "Arthriticure," "Virility Plus," and "Nordicalite," which can be found using common search engines and are set up to mimic health fraud sites. When consumers attempt to order the products, however, they get a message that if the site were real, they could have been scammed. Then, most importantly, consumers are advised of the tip-offs that the site was a scam and where to turn for reliable information. The Commission's three health-

related teaser sites have received over 20,000 accesses from October 1999 through August 2001.

The Commission engages in an extensive industry education campaign. For example, in 1998 the Commission published "Dietary Supplements: An Advertising Guide for Industry."<sup>(25)</sup> This publication provides easy-to-understand explanations of advertising standards for the marketing of health products, along with many useful examples. In addition, Commission staff has sent more than a thousand email advisories to websites that are making questionable therapeutic claims. These emails alert website operators to the questionable nature of their claims and provide links to resources to help them determine whether they are in compliance with applicable law. Based on our random sampling of sites that have received these advisories, approximately 25% take some form of remedial action, either taking the website down or removing the questionable claims.

## V. Conclusion

Health fraud poses a direct and immediate threat of both economic and physical injury to persons already suffering from serious conditions and diseases. The elderly are particularly vulnerable because of the high incidence of health-related problems in this age group. With thousands of marketers pushing worthless or unproven remedies, and limited enforcement resources, there is reason for concern.

On the positive side, consumers now have more accurate, reliable health information available to them, through the Internet and other sources, than ever before, and consumer surveys show that consumers are using these resources in record numbers.<sup>(26)</sup> Federal and state agencies, as well as many of our foreign counterparts, recognize the need to coordinate and share scarce resources in the battle against health fraud. As our past experience demonstrates, this cooperation is an absolutely essential ingredient of success. The Commission will continue its aggressive law enforcement and consumer and industry education program to combat health fraud, and to the extent possible, increase its efforts in this critical area of consumer protection.

### Endnotes

1. The written statement presents the views of the Federal Trade Commission. My oral statement and responses to questions are my own and are not necessarily those of the Commission or any individual Commissioner.
2. Our authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts and practices" in commerce and Section 12, which prohibits the "false advertisement" of foods, drugs, devices, services, and cosmetics. 15 U.S.C. §§ 45, 52.
3. Warren E. Schaller & Charles R. Carroll, *Health Quackery & the Consumer* 28 (1976).
4. Schaller & Carroll at 26-7.
5. *FTC v. Western Dietary Products Co. (Skookum)*, C01-0818R (W.D. Wash., filed June 6, 2001).
6. *FTC v. Western Botanicals, Inc.*, S-01-1332 DFL GGH (E.D. Cal., filed July 25, 2001) (Stipulated Permanent Injunction); *FTC v. Christopher Enterprises, Inc.*, 2:01CV-0505 ST (C.D. Utah, filed July 6, 2001) (Stipulated Preliminary Injunction).
7. "Operation Cure.All" Targets Internet Health Fraud: FTC Law Enforcement and Consumer Education Campaign Focuses on Stopping the Quacks and Supplying Consumers with Quality Information, June 24, 1999, available at <http://www.ftc.gov/opa/1999/9906/opcureall.htm>.
8. As part of the *Operation Cure.All* initiative, FDA filed an action seeking a permanent injunction against a website operator selling products containing shark cartilage, a glycoalkaloid, and arabinoxylana as treatments for cancer and other serious diseases; sent 48 *Cyber Letters*, untitled letters sent via electronic mail, to sites making drug claims for colloidal silver; issued warning letters to several firms marketing devices that purportedly send electrical energy into the body to destroy parasites and/or shatter cells to cure serious diseases, such as cancer; and issued public warnings about products containing aristolochic acid, a toxic contaminant, and comfrey.

9. In an Internet surf, participants use common search engines to find relevant Internet sites based on a set of predetermined search terms, for example, "cancer therapy." Once a site is identified, it is forwarded to a collection center, where the site is reviewed again to verify that it satisfies the selection criteria. In the two health claims surfs the FTC organized, the selection criteria were whether the site appeared to be making questionable claims that the product or service being offered was effective in the treatment, prevention or cure of cancer, arthritis, heart disease, HIV/AIDS, diabetes, or multiple sclerosis.

10. Press releases for *Operation Cure*. All cases filed this year are available at <http://www.ftc.gov/opa/2001/06/cureall.htm> and <http://www.ftc.gov/opa/2001/07/chrisenter.htm>. Cases filed this year include *Panda Herbal Int'l, Inc.*, No. C-4018 (Aug. 8, 2001) (consent) (St. John's Wort and Herb Veil 8 marketed as treatment for HIV/AIDS and skin cancer, respectively); *ForMor, Inc.*, No. C-4021 (Aug. 8, 2001) (consent) (St. John's Wort marketed as treatment for HIV/AIDS; and colloidal silver and shark cartilage marketed as treatments for cancer and arthritis, among many other diseases); *MaxCell Bioscience, Inc.*, No. C-4017 (Aug. 8, 2001) (consent) (multi-ingredient product containing DHEA marketed to reverse aging and prevent age-related diseases); *Michael Forrest d/b/a Jaguar Enterprises of Santa Ana*, No. C-4020 (Aug. 8, 2001) (consent) (miracle herbs and black box, magnetic pulser, and Beck-Rife units marketed as treatments for cancer and arthritis); *Robert C. Spencer d/b/a Aaron Company*, No. C-4019 (Aug. 8, 2001) (consent) (colloidal silver marketed as treatment for cancer and many other diseases); *FTC v. Western Dietary Prods. Co. (Skookum)*, C01-0818R, *supra*, note 5 (herbal cure packages and "zappers" marketed as treatments for cancer); *FTC v. Western Botanicals, Inc.*, *supra*, note 6 (comfrey); *FTC v. Christopher Enterprises, Inc.*, *supra*, note 6 (comfrey).

11. *Body Systems Technology, Inc.*, No. C-3895 (Sept. 7, 1999) (consent). Cat's Claw was promoted primarily as an effective treatment for cancer, HIV/AIDS, and arthritis. Copies of all *Operation Cure*. All cases are available at the FTC's Website, [www.ftc.gov](http://www.ftc.gov).

12. *Lane Labs-USA, Inc.*, No. 00W3174 (D.N.J.; filed Jun. 28, 2000) (Stipulated Final Order); *Body Systems Technology, supra*, note 11. Shark cartilage was promoted to treat or cure cancer.

13. *John Sneed and Melinda Sneed d/b/a Arthritis Pain Care Center*, No. C-3896 (Sept. 7, 1999) (consent); *CMO Distribution Centers of America*, No. C-3942 (May 16, 2000) (consent); *EHP Products, Inc.*, No. C-3940 (May 16, 2000) (consent). CMO was marketed to treat arthritis.

14. *Michael D. Miller, d/b/a Natural Heritage Enterprises*, No. C-3941 (May 16, 2000) (consent). Essiac Tea was promoted as a treatment for cancer.

15. *Magnetic Therapeutic Technologies, Inc.*, No. C-3897 (Sept. 7, 1999) (consent); *Pain Stops Here! Inc.*, No. C-3898 (Sept. 7, 1999) (consent). Magnetic Therapeutic Technologies and Pain Stops Here marketed magnetic devices to treat or alleviate numerous medical problems and diseases, including cancer, liver disease, arthritis and high blood pressure.

16. In addition to *Operation Cure*. All, the Commission has filed a number of other cases challenging health product promotions appearing in print, television and direct mail. For example, in *FTC v. Rose Creek Health Products, Inc.*, the Commission challenged claims that *Vitamin O*, which appears to be a saline solution with added oxygen molecules, is effective for the treatment of cancer, heart disease, and joint disintegration. *FTC v. Rose Creek Health Prods. Inc.*, CS-99-0063-EFS (E.D. Wash. 2000) (Stipulated Permanent Injunction). Claims challenged in other cases involve use of yohimbe and other natural ingredients as a treatment for impotence, *American Urological Corp.*, 98-CV-2199 (N.D. Ga. 1999) (Stipulated Permanent Injunction); shark cartilage as a treatment for cancer and arthritis, *Nutrivida, Inc.*, No. C-3826 (Sept. 16, 1998) (consent); a powdered nutritional supplement consisting of wheat germ, wheat bran, soybean extract, and seaweed extract as a treatment for rheumatism and to prevent aging, *Venegas, Inc.*, No. C-3781 (Jan. 27, 1998) (consent); a topical spray consisting of oils, vitamins, and trace ingredients as a treatment for sleep apnea, *Med Gen, Inc.*, File No. 002 3211 (Mar. 29, 2001) (consent subject to final approval); a natural toxic purifier as a treatment for depression and arthritis, *Mega Systems Int'l Inc.*, No. C-3811 (June 8, 1998) (consent); a mixture of vitamins and plant derivatives as a treatment for circulatory problems, hemorrhoids and varicose veins, *Efficient Labs, Inc.*, No. C-3768 (Sept. 19, 1997) (consent); and a mixture of camphor, chondroitin sulfate, and glucosamine sulfate for the treatment of severe pain, *SmartScience*, No. C-3980 (Nov. 2, 2000) (consent). Sales for the challenged products totaled in the tens of millions of dollars.

17. 15 U.S.C. 45(a). A representation, omission, or practice is deceptive if (1) it is likely to mislead consumers acting reasonably under the circumstances; and (2) it is material, that is, likely to affect consumers' conduct or decisions with respect to the product at issue. FTC Deception Policy Statement, *appended to Cliffdale Associates*, 103 F.T.C. 174, 175-76 (1984), available at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>. A practice is unfair if the injury to consumers it causes or is likely to cause (1) is substantial; (2) is not outweighed by countervailing benefits to consumers or to competition; and (3) is not reasonably avoidable by consumers themselves. 15 U.S.C. § 45(n); see also Unfairness Policy Statement, *appended to International Harvester Co.*, 104 F.T.C. 949, 1070 (1984), available at <http://www.ftc.gov/bcp/policystmt/ad-unfair.htm>.

18. 15 U.S.C. § 52. "False advertisement" is defined as "an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual." 15 U.S.C. § 55(a)(1).

19. *Removatron Int'l Corp.*, 111 F.T.C. 206, 297 (1988), *aff'd*, 884 F.2d 1489 (1<sup>st</sup> Cir. 1989); *Thompson Medical Co.*, 104 F.T.C. 648,

821-22 note 59 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

20. See, e.g., *Michael D. Miller*, No. C-3941 (May 16, 2000) (consent), which defines "competent and reliable scientific evidence" as:

tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

21. In order to prevent the responsible individuals from evading a Commission order simply by forming a new corporation, FTC orders frequently cover both the corporation and the individuals in the corporation who controlled or participated in the deceptive or fraudulent practice.

22. Essiac Tea is a mixture of four herbs (burdock root, sheep sorrel, rhubarb root, and slippery elm bark).

23. *Michael D. Miller, d/b/a Natural Heritage Enterprises, supra*, note 14.

24. "Virtual Health Treatments Can Be Real World Deceptions," available at <http://www.ftc.gov/bcp/online/edcams/miracle/index.html>.

25. "Dietary Supplements: An Advertising Guide for Industry," November, 1988, available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>. Since its publication, 11,125 copies of the Guide have been distributed and it has been accessed on our website 91,900 times.

26. According to one survey, almost 100 million Americans have used the Internet to find health information, on average three times per month. Humphrey, T; "Cyberchondriacs Update," Harris Interactive, April 18, 2001, available at [www.harrisinteractive.com/harris\\_poll/index.asp?PID=229](http://www.harrisinteractive.com/harris_poll/index.asp?PID=229). In most instances, users are looking for information about specific conditions or diseases.