

**“THE COMMISSION’S ROLE IN POLICING DECEPTIVE MARKETING OF  
DIETARY SUPPLEMENTS”**

**Prepared Statement of the Federal Trade Commission**

**Before the**

**Committee on Commerce, Science and Transportation**

**United States Senate**

**Washington, D.C.**

**October 28, 2003**

Mr. Chairman and members of the Committee, I am Howard Beales, Director of the Bureau of Consumer Protection (“BCP”) of the Federal Trade Commission (“FTC” or “Commission”).<sup>1</sup> The Commission is pleased to have this opportunity to testify about our efforts to ensure the truthfulness and accuracy of marketing for dietary supplements. I will discuss the Commission’s mission and our latest activities in this area, including recent coordinated enforcement with the Food and Drug Administration (“FDA”) and our efforts to address the problem of deceptive weight loss advertising.

The mission of the FTC 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 about the benefits or safety of health-related products, including dietary supplements.<sup>2</sup> The dietary supplement industry encompasses a broad range of products, from vitamins and minerals to herbals and hormones, and represents a substantial segment of the consumer healthcare market. Industry sales for 2001 were estimated to be \$17.7 billion.<sup>3</sup>

Some dietary supplement products offer the potential for real health benefits to consumers. Scientific research is increasingly showing that better diets and better nutrition, including consumption of specific nutrients, can improve consumers’ health. At a time when

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<sup>1</sup> The written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any individual Commissioner.

<sup>2</sup> Our authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits “unfair or deceptive acts and practices in or affecting commerce,” and Section 12, which prohibits the false advertisement of “food, drugs, devices, services or cosmetics.” 15 U.S.C. §§ 45, 52.

<sup>3</sup> *Supplement Business Report 2002*, NUTRITION BUS. J., § 2 (2002)

individual consumers are asked to make more decisions about their health care, access to truthful information about health-related products is more important than ever. Consumers, however, will have greater difficulty making good nutrition choices if the marketplace contains bad information.

Unfortunately, unfounded or exaggerated claims for dietary supplements have proliferated. My testimony today will describe the Commission's efforts to deal with the serious threat to consumer health that such fraud presents. I will focus on some areas of particular concern, including deceptive weight loss advertising and Internet health scams that prey on consumer fears about the latest health scare, whether anthrax or Severe Acute Respiratory Syndrome ("SARS"). I will also describe our recent efforts to step up coordination with FDA.

#### **The FTC's Law Enforcement Efforts**

Challenging deceptive claims in the advertising of health care products, and particularly dietary supplements, has long been a priority of the FTC's consumer protection agenda. The Commission has filed more than one hundred law enforcement actions over the past decade challenging false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements.<sup>4</sup> In recent years, we have increased our commitment of resources to combat deception and fraud in health-related industries and it is currently one of our top consumer protection priorities. Since last December, the FTC has challenged deceptive advertising for health care products with a total of more than \$1 billion in sales, most of that for dietary

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<sup>4</sup> A complete list of the Commission's dietary supplement cases is available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietadvertisingcases.pdf>.

supplements.<sup>5</sup>

The Commission focuses its enforcement priorities on products that present significant safety concerns for consumers, on advertising making unfounded claims of treatment for serious diseases, and on large national advertising campaigns for products for which the supporting science is nonexistent or clearly inadequate. Many of our recent actions have focused on specific media where fraudulent claims appear to be more prevalent, such as nationally aired infomercials and the Internet. In the past year, the Commission has filed or settled cases challenging claims for supplements marketed for almost every imaginable health problem: to treat serious diseases like cancer, multiple sclerosis, heart disease, emphysema, diabetes, and Alzheimer's; or to cause effortless, substantial and immediate weight loss; or to stop snoring; or even to increase bust size.<sup>6</sup> We continue to pursue aggressive enforcement and currently have approximately forty active investigations involving other cases of deceptive supplement marketing.

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<sup>5</sup> This represents the total sales for products the Commission challenged in seventeen actions from December 2002 through July 2003.

<sup>6</sup> *FTC v. Seasilver USA, Inc.*, No. CV-S-03-0676-RLH-LRL (D. Nev. filed June 12, 2003) (complaint for injunctive and other equitable relief involving Internet and infomercial marketing for multi-ingredient supplement for 650 diseases); *FTC v. Kevin Trudeau*, 03 C 904 (N.D. Ill. filed June 9, 2003) (complaint for permanent injunction and other equitable relief involving infomercial marketing of "Coral Calcium Supreme" supplement for several diseases); *Wellquest Int'l, Inc.*, No. CV-03-5002 PA (RNBx) (C.D. Cal. filed July 10, 2003) (complaint and final stipulated orders including \$3.2 million in consumer redress for marketing of "Bloussant" herbal supplement to increase bust size and other products); *FTC v. Health Lab. of N. Am.*, No. 031457 (D.D.C. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); *FTC v. USA Pharmacal Sales, Inc.*, No. 8:03-CV-1366-T-23EAJ (M.D. Fla. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); *U.S. v. Michael S. Levey*, No. CV-02-4670 GAF (AJWx) (C.D. Cal. June 30, 2002) (complaint challenging no side effects and weight loss claims for a supplement containing ephedra).

We recognize that an effective enforcement program requires more than just a volume of cases. It also requires strong remedies. In the past year, we have increased our use of the federal courts in cases of egregious health fraud. The FTC has filed fourteen of the last seventeen actions against supplement and other health product marketers in federal court which enables us to obtain, when appropriate, immediate injunctions, asset freezes and, in many cases, large judgements for disgorgement of profits or consumer redress. When necessary and appropriate, we have moved to obtain an *ex parte* temporary restraining order. Two recent examples involve allegedly fraudulent multi-million dollar marketing campaigns using the Internet and heavily-aired national infomercials. In our action against *Seasilver USA* for its sale of a concoction of multiple minerals, herbs and other ingredients to treat 650 diseases, the District Court in Nevada immediately placed the defendants under a restraining order, receivership and asset freeze.<sup>7</sup> We obtained similar relief in our action against Kevin Trudeau, Robert Barefoot, and related parties for their allegedly fraudulent marketing of “Coral Calcium,” a purported cure for cancer, multiple sclerosis, and other diseases or conditions.<sup>8</sup>

Our remedies seek to address not just economic injury to consumers but also potential injury to health. When the marketing of a supplement presents a health risk to consumers

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<sup>7</sup> *FTC v. Seasilver USA, Inc.*, No. CV-S-03-0676-RLH-LRL (D. Nev. filed June 12, 2003).

<sup>8</sup> *FTC v. Kevin Trudeau*, No. 03C904 (N.D. Ill. filed June 9, 2003). The FTC has also obtained significant funds for consumer redress in several cases. *See, e.g., FTC v. Rexall Sundown, Inc.*, No. 00-7016-CIV-Martinez (S.D. Fla. March 11, 2003) (stipulated final order including redress fund of up to \$12 million); *FTC v. Enforma Natural Prods., Inc.*, No. 04376JSL (CWx) (C.D. Cal. Apr. 25, 2000) (stipulated final order including \$10 million in consumer redress); *FTC v. Slim America, Inc.*, No. 97-6072-CIV-Ferguson (S.D. Fla. June 30, 1999) (final judgment for permanent injunction and damages, including \$8.3 million in consumer redress).

through misleading or unsubstantiated safety claims, the Commission has imposed strong warning remedies in labeling and advertising, and sometimes restrictions on specific claims or methods of marketing.<sup>9</sup>

### **Coordination with FDA**

The FTC and FDA have concurrent jurisdiction over dietary supplements and other health and nutrition products and work closely to challenge deceptive and unsubstantiated claims. Under a longstanding liaison agreement,<sup>10</sup> the FTC has primary responsibility for the advertising of foods, cosmetics, devices, and over-the-counter drugs, while FDA has primary responsibility for the labeling of those products and advertising of prescription drugs. In many of our investigations of dietary supplement advertising claims, the FDA staff provided scientific expertise and technical assistance. The staff of the two agencies have always coordinated closely on enforcement matters. In the past year, however, the level of cooperation and the

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<sup>9</sup> See, e.g., *FTC v. Health Lab. of N. Am.*, No. 031457 (D.D.C. July 1, 2003) (stipulated final order requiring warning statement for weight loss product containing ephedra); *AST Nutritional Concepts & Research, Inc.*, No. 99-WY-2197 (D. Colo. May 4, 2000) (stipulated final order requiring warnings about the risks of androstenedione, a steroid hormone, and about the risks of ephedra contained in a body-building supplement); *Mex-RX US, Inc.*, No. SACV99-1407-DOC (ANX)(C.D. Cal. Nov. 24, 1999) (stipulated final order requiring warnings about both androstenedione and ephedra); *Panda Herbal Int'l, Inc.*, FTC Dkt. No. C-4018 (July 30, 2001) (consent order requiring warning about interaction of St. John's wort, a botanical ingredient, with certain HIV/AIDS medications); *Global World Media Corp.*, FTC Dkt. No. C-3772 (Oct. 9, 1997) (consent order requiring warning about "Herbal Ecstasy" [sic], a street drug alternative containing ephedra and prohibiting ads for Herbal Ecstasy and similar products containing ephedra in any media where more than 50% of the audience is under twenty-one years of age); *Christopher Enter., Inc., et al.*, 2:01 CV-0505 ST (C.D. Utah Nov. 29, 2001) (stipulated final order prohibiting marketing of comfrey, a botanical ingredient associated with severe liver toxicity, for internal consumption or application to open wounds, and requiring warning for other uses).

<sup>10</sup> See Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶ 9,859.01 (1971).

volume of coordinated law enforcement has been unprecedented.

In December 2002, FDA Commissioner Mark McClellan announced a significant initiative to improve consumer access to timely and accurate information about nutrition and health in both the dietary supplement and the food marketplaces. The dual goals of this Consumer Health Information for Better Nutrition Initiative are to provide more flexibility for food marketers to convey information about emerging nutrition science and to improve the accuracy of health information for dietary supplements by stepping up enforcement against deceptive claims.

To implement the enforcement component of the initiative, the FTC and FDA staff formed a joint task force on dietary supplement marketing. Through that joint enforcement task force, the two agencies have been able to identify more efficiently the worst offenders, to share more easily information about the marketers and their products, to assess more thoroughly the safety and efficacy data, and to formulate a more effective plan to stop fraud and deception, using the strongest tools available to each agency.

The FTC and FDA announced the results of the first six months of coordinated enforcement efforts on July 10, 2003. For the FTC's part, this coordination resulted in seventeen actions that were filed or settled against supplement advertisers claiming cures for a wide variety of serious diseases and representing deceptive product sales of more than \$1 billion. These efforts include joint FTC federal court actions and FDA product seizures in the *Seasilver USA* and *Kevin Trudeau/Robert Barefoot* cases. In addition to these two formal joint actions, the FDA also provided technical assistance to the FTC in its investigation and recent action against

Glenn Braswell and his company, Gero Vita.<sup>11</sup> Glenn Braswell was the principal behind a massive direct marketing campaign involving a myriad of supplements sold through glossy, magazine-like publications including the “*Journal of Longevity*.” The products touted by Gero Vita, under names such as “Lung Support Formula,” “Antibetic Pancreas Tonic,” and “Theraceutical GH3 Romanian Youth Formula” purported to treat everything from asthma, emphysema, diabetes, and Alzheimer’s, to weight loss and aging.

Since December, the two agencies have also issued a combined total of more than 200 warning letters, cyber letters, and e-mail advisories to various companies marketing dangerous or fraudulent health products over the Internet. The cyber letter or e-mail warning has proven to be a very effective tool to address the proliferation of health scams on the Internet.<sup>12</sup>

The Internet can be a convenient medium for unscrupulous marketers who hope to profit from consumer fears about the latest public health scare. Many of the e-mail warning letters issued by the Commission in the past year have involved the marketing of dietary supplements and other products to treat or prevent SARS, anthrax infections, and various agents of biological, chemical or nuclear terrorism.<sup>13</sup> Although it would not be feasible to develop a formal case and file an action against each of the many health scams that pervade the Internet, the Commission has achieved voluntary compliance by most of the web marketers contacted in our recent e-mail

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<sup>11</sup> *FTC v. A. Glenn Braswell*, No. CV 03-3700 DT (PJWx) (C.D. Cal. filed May 27, 2003) (complaint for permanent injunction and other equitable relief).

<sup>12</sup> The FTC has worked to combat Internet health fraud for many years, initiating the “Operation Cure.All” project begun in 1997, that includes the FDA and many other state, federal, and international authorities. Since 1997, the Commission has issued more than 1000 advisory and warning letters as part of this project.

<sup>13</sup> The texts of sample FTC warning letters are posted on the FTC web site. *See, e.g.*, <<http://www3.ftc.gov/opa/2002/01/warnair.htm>>.



sweeps. The dietary supplement industry response to the Commission's efforts contributed to the high compliance rate. All of the principal trade associations representing supplement marketers have twice backed the FTC's efforts with strong public pronouncements against unfounded claims – first in the case of anthrax treatments, and more recently in the case of SARS-related promotions.<sup>14</sup>

### **Weight Loss Advertising**

In some segments of the health products industry, even the most active enforcement program and toughest remedies cannot completely clean up the deception. The rapidly growing, multi-billion dollar weight loss industry appears to be one area for which the Commission must consider other approaches, and enlist new partners, to augment traditional law enforcement.

The high rate of obesity in the United States has become a significant health problem. More Americans, including children, are overweight or obese than ever before. As a result, diabetes and many other weight-related illnesses are also increasing. Many federal agencies, scientific organizations, health professionals, and consumer groups are trying to better understand the complex causes of obesity and how it can be reversed. The Commission can address one aspect of the problem by stopping the companies that pitch ineffective products promising quick, easy, and dramatic weight loss. Such products not only are a waste of money, but also lure consumers away from more difficult but successful weight loss strategies.

It is no surprise that many marketers have been tempted to profit from the growing obesity problem with outrageous but highly appealing claims for dietary supplements and other

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<sup>14</sup> See <<http://www.ftc.gov/opa/2001/11/webwarnltr.htm>> (FTC warning letter describing joint industry statement of support).

products and programs. The U.S. market for weight loss products reached \$37.1 billion in 2001 and has been growing at a rate of 6 to 7% a year.<sup>15</sup> Few things sell better than a magic bullet for weight loss and it is precisely that quick and easy weight loss pill that we saw dominating the market in our 2001 review of weight loss advertising.

In September 2002, the staff of the Federal Trade Commission released the *Report on Weight-Loss Advertising: An Analysis of Current Trends* (“Weight Loss Advertising Report”).<sup>16</sup> The Report analyzed claims from 300 advertisements disseminated during 2001 and concluded that the use of false or misleading claims in weight-loss advertising is widespread. More than half (55%) of the 300 ads made claims that were almost certainly false or at the very least likely to lack substantiation. A comparison of these ads with a sample from 1992 revealed a much higher frequency of questionable claims and marketing techniques in 2001 compared to a decade ago. For example, ads in the 2001 sample were much more likely to promise substantial, rapid and permanent weight loss, often without any diet or exercise. Furthermore, two-thirds of the products promoted in 2001 were dietary supplements, representing a major shift from 1992 when meal replacement products were the most promoted category.<sup>17</sup>

As with any instance of deceptive advertising, the Commission has responded with tough enforcement. The agency has taken action against nearly one hundred deceptively marketed weight loss products, most of them supplements, since 1990. Despite such constant

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<sup>15</sup> MARKETDATA ENTERPRISES, INC., THE U.S. WEIGHT LOSS & DIET CONTROL MARKET 6 (2002).

<sup>16</sup> Copies of the Weight Loss Advertising Report can be found at <http://www3.ftc.gov/bcp/reports/weightloss.pdf>.

<sup>17</sup> Weight Loss Advertising Report at 21.

and vigorous law enforcement actions, deceptive weight loss advertising has increased over the same period.

Traditional law enforcement alone is not an adequate solution to weight loss scams. The Commission is working actively on other approaches to augment its traditional enforcement and is reaching out to new partners in this effort. The Commission held a public workshop in November 2002 to identify new approaches to fighting the proliferation of misleading claims.<sup>18</sup> Government officials, scientists, public health groups, marketers of weight loss products, advertising professionals, and representatives of the media participated in the day-long event. A report on the results of the workshop will be released in the next few months.

One encouraging outcome of the FTC's report and workshop has been a renewed interest by responsible members of the weight loss and dietary supplement industries to partner with government and other groups in meaningful self-regulatory efforts. Just two weeks ago, the FTC and the Partnership for Healthy Weight Management, a broad coalition that includes the FTC, public health groups, scientists and industry representatives, hosted a meeting of trade associations representing the dietary supplement industry and private companies engaged in the marketing of weight loss products and services. The purpose of the meeting was to consider the development of self-regulatory guidelines for weight loss advertisers. There are many challenges to developing a successful self-regulatory program, but the individual companies and associations that attended this meeting demonstrated a real commitment to the effort.

In addition, subsequent to the weight loss report, the FTC staff met with members of the media and other interested parties to encourage them to weed out facially false weight loss

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<sup>18</sup> Advertising of Weight Loss Products, 67 Fed. Reg. 59,289 (2002).

advertising claims before they are disseminated.<sup>19</sup> We believe that the media can play a significant role here in cleaning up the weight loss market and we hope to minimize the burden on those that are willing to take on this responsibility. A significant focus of the Commission's 2002 workshop was on identifying claims that are not scientifically feasible for any weight loss product, such as "eat all you want and still lose weight." Based on the testimony from the workshop, other comments received, and the agency's experience in policing weight loss advertising, the Commission staff has distilled, and will shortly publish, a brief checklist to aid media screening of weight loss ads.

### **Conclusion**

The FTC will work closely with FDA to continue to reach out to marketers, the media, and other interested parties to combat deception in dietary supplement marketing. We will maintain our high level of traditional enforcement activities while exploring other approaches to enhance those efforts. The Commission thanks the Committee for focusing attention on this important consumer issue and for giving the Federal Trade Commission an opportunity to discuss its role. The Commission looks forward to working with the Committee on our initiatives involving the marketing of dietary supplements.

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<sup>19</sup> See, e.g., Remarks of FTC Chairman Timothy J. Muris to the Cable Television Advertising Bureau (Feb. 11, 2003), DO THE RIGHT THING (APOLOGIES TO SPIKE LEE), <<http://www.ftc.gov/speeches/muris/030211rightthing.htm>>; Remarks By Commissioner Sheila F. Anthony Before The Food and Drug Law Institute 45<sup>th</sup> Annual Educational Conference (Apr. 16, 2002), COMBATING DECEPTION IN DIETARY SUPPLEMENT ADVERTISING, <<http://www.ftc.gov/speeches/anthony/dssp2.htm>>; Remarks of Commissioner Orson Swindle to the Aggressive Advertising and the Law Conference (Apr. 28, 2003), COMBATING DECEPTIVE ADVERTISING - THE ROLE OF ADVERTISERS, THE MEDIA, AND THE FTC , <<http://www.ftc.gov/speeches/swindle/030428aggressive.htm>>.