

**Prepared Statement of the Federal Trade Commission**

**J. Howard Beales, III**

**Director, Bureau of Consumer Protection**

**Before the**

**Committee on Governmental Affairs**

**Subcommittee on Oversight of Government Management,**

**Restructuring and the District of Columbia**

**United States Senate**

**Washington, D.C.**

**October 8, 2002**

Mr. Chairman and members of the Subcommittee, I am Howard Beales, Director of the Bureau of Consumer Protection, Federal Trade Commission ("FTC" or "Commission"). The Commission is pleased to have this opportunity to provide information concerning our efforts to ensure the truthfulness and accuracy of marketing for dietary supplements, including weight loss products and other supplements containing the herbal ingredient, ephedra.<sup>(1)</sup> I will discuss the Commission's mission, our latest activities in the weight-loss area, and then address the specific questions you raised.

The mission of the Federal Trade Commission is to prevent unfair competition and to protect consumers from unfair or deceptive 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 either the health benefits or safety of dietary supplements.<sup>(2)</sup> The dietary supplement industry represents a substantial and growing segment of the consumer healthcare market. Industry sales for 2001 were estimated to be \$17.7 billion.<sup>(3)</sup> The supplement category encompasses a broad range of products, from vitamins and minerals to herbals and hormones.

There is no question that some of these products offer the potential for real health benefits to consumers. The scientific research on the associations between supplements and health is accumulating rapidly. Unfortunately, unfounded or exaggerated claims in the marketplace have also proliferated. The role of the Federal Trade Commission is to ensure that products are marketed in a manner that is truthful and not misleading, and that consumers have adequate information about the efficacy and safety of dietary supplements to make well-informed decisions. The Commission attempts to accomplish this goal through its law enforcement efforts and consumer and business education.

Today the Commission's testimony will provide an overview of our enforcement efforts and other activities to combat deception in the supplement marketplace. The Commission's testimony will focus on our activities to combat the false and unsubstantiated claims being made in the weight loss product category.

**The FTC's Dietary Supplement Advertising Program**

Challenging misleading or unsubstantiated claims in the advertisement of dietary supplements is a priority of the FTC's consumer protection agenda. The Commission has filed more than 80 law enforcement actions over the past decade challenging false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements. The Commission focuses our enforcement priorities on national advertising claims for products with unproven benefits, products promoted via the Internet and elsewhere to treat or cure serious diseases, and claims for products that present significant safety concerns to consumers.

As in all our advertising programs, we work to make sure our enforcement actions have a strong impact. For example, the Commission holds accountable not just the supplement manufacturer but other parties that play a role in deceptive marketing, like ad agencies, infomercial producers, distributors, retailers, catalog companies, and celebrity endorsers.<sup>(4)</sup> In addition, we have sought to obtain more meaningful relief for consumers, going beyond the basic cease and desist orders in many cases, to require substantial monetary relief for consumer redress or disgorgement of profits.<sup>(5)</sup> Finally, when the marketing of a supplement raises safety concerns, the Commission has required that strong warning statements be placed in labeling and advertising.<sup>(6)</sup>

### **Weight Loss Advertising Report**

As the Subcommittee is aware, ephedra is often marketed as a weight-loss product. Last month, the staff of the Federal Trade Commission released a "Report on Weight-Loss Advertising: An Analysis of Current Trends."<sup>(7)</sup> The report was initiated as a response to increasing recognition of the detrimental effects of obesity and to the serious challenges facing law enforcement agencies in their efforts to stop deceptive advertising for weight loss products and services. Consumers spend billions of dollars on products that purport to promote weight loss. A majority of these products appear to fall into the dietary supplement category.<sup>(8)</sup>

The FTC staff's Weight Loss Advertising Report analyzed claims from a nonrandom sample of 300 advertisements disseminated during the first half of 2001, including ads in all major forms of media. With the assistance of members of the Partnership for Healthy Weight Management, the staff collected ads from television, direct mail, and the Internet. Staff also obtained a sample of ads from newspapers and conducted a more systematic review of ads appearing in selected magazines. By comparing a sample of ads disseminated in 1992 and 2001 in eight national magazines, the Commission staff looked at trends in the frequency of ads, the types of products marketed, and the most common advertising techniques. The analysis showed that more than half (55%) of the ads collected contained at least one representation that was very likely to be false or to lack substantiation. The historical comparison of magazine ads also revealed a much higher frequency of questionable claims and marketing techniques in 2001 compared to a decade ago. For example, ads in the 2001 magazine sample were much more likely to use dramatic before-and-after photos and other consumer testimonials, to promise substantial, rapid and permanent

weight loss, often without any diet or exercise, and to promise "guaranteed" and "scientifically proven" results.

### **Public Workshop on Weight Loss Products**

In light of the findings of the Weight Loss Advertising Report the Commission will explore other strategies, beyond traditional law enforcement efforts, to curb deception in the weight loss industry. Even with an increase in enforcement actions by the FTC and other agencies in the past decade, deceptive claims continue to rise.<sup>(9)</sup> Aggressive law enforcement will always remain a critical component of an effective program to combat weight loss scams, but it is clear that we must also pursue other approaches. The Commission will continue to engage in consumer education efforts to increase awareness of weight loss scams and will work with industry toward better self-regulatory programs.

Toward that end, the Commission is holding a public workshop on Advertising of Weight Loss Products on November 19.<sup>(10)</sup>

The purpose of the workshop is to explore both the impact of deceptive ads on the public health and new approaches to fighting the proliferation of misleading claims. A wide variety of stakeholders, including government officials, scientists, public health groups, marketers of weight loss products, advertising professionals, and representatives of media have been invited to participate.

With that background about the FTC's dietary supplement program and our activities relating to weight loss advertising, the testimony will now focus on the specific questions posed by the Subcommittee.

#### **1. Please discuss the enforcement actions that FTC has taken against companies that have marketed ephedra-containing products as safe and without side effects.**

The FTC has brought four enforcement actions challenging unqualified safety/no side effects claims for supplements containing ephedra.<sup>(11)</sup>

These actions have included products marketed as alternatives to street drugs such as Ecstasy as well as body-building supplements and energy supplements. FTC staff also has additional non-public investigations pending that include safety claims for ephedra products. Although we recognize that the Department of Health and Human Services (HHS) is awaiting the completion

of a review of the scientific evidence on ephedra safety, under the FTC Act an advertiser is required to have competent and reliable scientific evidence supporting claims made in advertising before they are made. Under that standard, the FTC has alleged that unqualified safety claims in advertising for ephedra products are deceptive.

In each of the four ephedra cases, the Commission has imposed orders that both prohibit unsubstantiated safety claims and require a strong disclosure warning about safety risks in all future advertising and labeling by the respondent.<sup>(12)</sup> In addition, the order against Global World Media Corp., for its marketing of ephedra as a street drug alternative, includes a prohibition against marketing in media targeted at young audiences.<sup>(13)</sup>

**2. Does the FTC believe that ephedra-containing products are safe? Would such a claim be substantiated by current science? What percentage of advertisements for ephedra products claimed that they were safe? What percentage of ephedra ads included warnings about the health risks associated with the use of the product?**

The FTC act requires that objective claims about products and services be substantiated *before* the ad is disseminated. The substantiation standard required for safety claims is one of "competent and reliable scientific evidence." As discussed in response to Question 1, the FTC has brought four cases alleging that unqualified safety claims for ephedra are not substantiated by this level of evidence and thus violate Section 5 of the FTC Act.<sup>(14)</sup>

Twenty-three ads, or about 8%, of the 300 sampled for the Weight Loss Advertising Report identified ephedra, ephedrine or Ma Huang as an ingredient.<sup>(15)</sup> Of these:

- 11, or 48%, made safety claims.<sup>(16)</sup>
- 7, or 30%, included a specific health warning about ephedra's potential adverse effects.

**3. The FTC's recent report about the increased number of deceptive advertisements for weight loss products compared advertisements in 1992 and 2001. Please explain the rationale for choosing the year 1992 for this analysis.**

The year 1992 was selected for comparison because it allowed staff to compare ads that appeared after the FDA promulgated its final rule on weight loss products with ads appearing after the 1994 passage of the Dietary Supplement Health and Education Act (DSHEA).<sup>(17)</sup>

**4. Certain products require pre-market approval prior to sale in the United States. Dietary supplements do not require such pre-market approval. Therefore, the public may experience considerable exposure to an unsafe dietary supplement before any government action ensues. Is the FTC the most appropriate agency to be policing the safety of dietary supplements?**

The Food and Drug Administration has both the expertise and the principal statutory authority to oversee the safety of dietary supplements. The Federal Trade Commission also gives enforcement priority to cases involving false or unsubstantiated safety claims in supplement advertising and by engaging in education efforts to alert consumers to potential safety risks. Our efforts are coordinated closely with FDA staff and we rely heavily on FDA and other scientific agencies for advice on the health effects of supplements. We view our activities on supplement safety as playing an important supporting role to FDA's more comprehensive efforts to ensure the safety of dietary supplements.

**5. Since passage of the Dietary Supplement Health and Education Act, FTC enforcement against deceptive marketing of products has increased significantly, with FTC law enforcement cases involving weight loss products or services in the nineties equaling those filed in the previous seven decades. Does this indicate that the elimination of the requirement for pre-market approval by the FDA has left consumers only protected by the FTC?**

The comparative analysis of magazine advertising from 1992 and 2001 indicates that there has been an increase both in the overall volume of ads for weight loss products and services and in the incidence of deceptive or misleading claims.<sup>(18)</sup> In response, the FTC has stepped up both its own enforcement efforts and its efforts to coordinate with other law enforcement authorities. The Federal Trade Commission is not the only agency to police the dietary supplement industry. DSHEA requires a manufacturer of a dietary supplement to have substantiation for any structure/function claims so that the claim is truthful and not misleading. We, therefore, coordinate our enforcement efforts closely with the Food and Drug Administration. In addition, we work closely with the state Attorneys General, and other state and local law enforcement authorities. We are also increasing our efforts to combat cross border fraud in the weight loss industry and other health-related industries by coordinating with law enforcement agencies in Canada, Mexico and other countries.

**6. Would the FTC agree that it is inefficient to have to screen product marketing once it is on the market rather than before it goes to market? Would the system be more efficient if FDA were allowed to screen the claims made by dietary supplement manufacturers based on current scientific knowledge?**

At this time, the Commission is not aware of any systematic analysis of the relative efficiency of preclearance versus post-claim enforcement in the dietary supplement market. The FTC does not pre-screen advertising claims for dietary supplements or any other product or service within its jurisdiction. Instead, the agency addresses deception in the marketplace largely through post-market enforcement actions targeted against specific false or misleading claims. In applying this approach, the agency seeks to balance the risk of allowing commercial speech that might prove to be false or misleading and the risk of banning or delaying commercial speech that might prove to be true. Considerations like the nature of the claims and the risks that may result from deception are important components of this balancing. Claims about health and safety, in particular, require a rigorous substantiation standard as well as a strong and active enforcement program to back up that standard. The Commission's role in reviewing the truthfulness and accuracy of claims presumes that products are legally in the marketplace and do not pose an unacceptable risk of consumer injury.

**7. Against what percentage of bad actors does FTC have the resources to take enforcement action? Does this leave a large number of bad actors continuing to market to an unsuspecting public because the FTC only has the resources to go after the most prominent and egregious actors?**

Although there is no definitive data to respond to your specific question, the weight loss advertising report strongly suggests that the incidence of false and deceptive claims has increased over the past decade. The Commission has made enforcement against deceptive supplement advertising, including weight loss supplements, a priority of its consumer protection mission and devotes significant resources to investigation and prosecution of cases against false and unsubstantiated advertising in this industry. As in any law enforcement effort, the Commission attempts to direct its resources to the cases involving the greatest amount of harm or otherwise serving an important law enforcement interest. It is important that we continually reassess the efficacy of our enforcement efforts and examine alternative approaches that may increase our effectiveness. These are the questions that we will be examining at our November 19 workshop on weight loss advertising.

Aggressive law enforcement is a critical component of an effective program to combat market deception. At the same time, it seems clear that we should pursue other strategies like consumer

education, better industry self-regulation, and encouraging better media screening of facially false ads. Our workshop will focus on ways to enhance our current approaches to curbing deceptive weight loss advertising and on coming up with creative new strategies to maximize the efficient use of our law enforcement resources.

## Conclusion

The Commission thanks this Subcommittee for focusing attention on this important consumer health issue and for giving the Federal Trade Commission an opportunity to discuss its role. The Commission looks forward to working with the Subcommittee on initiatives concerning our dietary supplement program and our activities involving weight loss marketing.

1. 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 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 or affecting commerce," and Section 12, which prohibits the false advertisement of "food, drugs, devices, services or cosmetics." 15 U.S.C. §§ 45, 52.
3. Source: *Nutrition Business Journal*, Supplement Business Report 2002.
4. See, e.g., *Steven Patrick Garvey, et al.* 00-09358-AHM(AIJx)(C.D. Cal. Nov. 15, 2000) (pending litigation against celebrity endorser for "Fat Trapper" infomercial).
5. See, e.g., *Enforma Natural Prods., Inc.*, 04376JSL (CWx)(C.D. Cal. April 25, 2000) (Stipulated Final Order including \$10 million in consumer redress); *Slim America, Inc.*, 97-6072-CIV-Ferguson (S.D. Fla. June 30 1999) (Final judgment for permanent injunction and damages, including \$8.3 million in consumer redress).
6. See discussion of Question 1 *infra*.
7. "Weight-Loss Advertising: An Analysis of Current Trends" A Federal Trade Commission Staff Report (Sept. 2002) ("Weight Loss Advertising Report"). Copies of the report are available on the Commission's web site, [www.ftc.gov](http://www.ftc.gov).
8. A historical comparison of ads appearing in a sample of eight national magazines in both 1992 and 2001 found that two-thirds of the products promoted in the 2001 sample were for dietary supplements, representing a major shift from 1992 when meal replacement products were the most promoted category. Weight Loss Advertising Report at 21.
9. The FTC has filed more than 80 cases in the past ten years against deceptive weight loss advertising for supplements and other products and services - as many actions as in the prior seven decades combined.



10. See Public Workshop: Advertising of Weight Loss Products, 67 Fed. Reg. 59,289 (Sept. 20, 2002).

11. *Robert C. and Lisa M. Spencer, dba Aaron Co.*, C-4019 (July 30, 2001)(Consent Order involving safety claims for an energy product containing ephedra); *AST Nutritional Concepts and Research, Inc., et al.*, Civ. No. 99-WY-2197 (D. Co. May 4, 2000)(Stipulated Final Order involving safety claims for body-building supplements containing both androstenedione and ephedra); *Mex-RX US, Inc., et al.*, Civ. No. SACV99-1407-DOC(ANX)(C.D. Cal. Nov. 24, 1999)(Stipulated Final Order involving safety claims for body-building supplements containing both androstenedione and ephedra); *Global World Media Corp.*, C-3772 (Oct. 9, 1997)(Consent Order involving street drug alternatives containing ephedra).

12. For example the consent order in *Robert C. Spencer and Lisa M. Spencer, supra*, n. 11, requires that the following statement be included in all advertising, labeling and other marketing of ephedra products:

**WARNING:** This product contains ephedra or ephedrine alkaloids, which can have dangerous effects on the central nervous system and heart and can result in serious injury. Risk of injury can increase with dose, and may even include heart attack, stroke, seizure or death. Consult a health care provider prior to use if you have high blood pressure, heart or thyroid disease, diabetes, difficulty urinating, prostate enlargement, or glaucoma, or are using any prescription drug. Do not use if you are taking a MAO inhibitor or any allergy, asthma, or cold medication containing ephedrine, pseudoephedrine or phenylpropanolamine. Discontinue use if you experience rapid heart beat, chest pain, severe headache, shortness of breath, dizziness, sleeplessness or nausea. This product is not recommended for use if you are or could be pregnant unless a qualified health provider tells you to use it. The product may not be safe for your developing baby.

A shorter version of this statement is required for television and radio advertisements. The FTC staff coordinated closely with FDA staff in developing this warning to ensure that it was consistent with FDA's current assessment of the safety concerns.

13. Specifically, the consent order prohibits disseminating any ads for Herbal Ecstasy and similar products containing ephedra in any media where more than 50% of the audience is under 21 years of age. *Global World Media Corp., supra*, n.11.

14. In addition to the ephedra cases, the Commission has also challenged, as unsubstantiated or false, safety claims for other dietary supplement ingredients including for: 1) cure-all remedies containing comfrey, a botanical ingredient that has been associated with severe liver toxicity, *see, e.g., Christopher Enterprises, Inc., et al.*, 2:01 CV-0505 ST (C.D. Utah Nov. 29, 2001) (Stipulated Final Order); 2) body-building supplements containing androstenedione, a steroid hormone that is linked to potentially dangerous changes in estrogen and testosterone levels in the body, *see, e.g., Met-RX USA, Inc. and AST Nutritional, supra*, n.11; and 3) HIV/AIDS treatments containing St. John's wort, a botanical that has been found to interfere with certain medications,

including those used to treat HIV/AIDS, *see, e.g., Panda Herbal International, Inc. et al. C-4018* (July 30, 2001)(Consent order).

When the Commission files a complaint, it alleges that it has "reason to believe" that the practices cited in the complaint violate the FTC Act. A consent order that is reached in settlement of such allegations does not constitute an admission by the respondent that a law violation has occurred.

15. There are a number of other ads that did not disclose ephedra as an ingredient but that the Commission knows include the ingredient. In addition, 60% of the sampled ads that made safety claims did not identify ingredients at all, so it is not possible to determine the total percentage of sampled ads making safety claims for ephedra weight loss products.

16. Of the sampled ads containing ephedra that made safety claims, 55% also contained a specific health warning.

17. *See* Weight Loss Advertising Report at 21.

18. *See* Weight Loss Advertising Report at 21-24.