"ISSUES RELATING TO EPHEDRA-CONTAINING DIETARY SUPPLEMENTS"

Prepared Statement of the Federal Trade Commission

J. Howard Beales, III
Director, Bureau of Consumer Protection

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and

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Mr. Chairman and members of the Subcommittees, I am Howard Beales, Director of the Bureau of Consumer Protection, Federal Trade Commission ("FTC" or "Commission").[1] The Commission is pleased to have this opportunity to testify about 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. I will discuss the Commission's mission and our latest activities in this area.

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 about the benefits or safety of health-related products, including dietary supplements.[2] 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.[3]

Some dietary supplement products offer the potential for real health benefits to consumers. Unfortunately, unfounded or exaggerated claims in the marketplace are proliferating. As the level of deceptive claims has expanded, however, so too have our enforcement actions. Since December 2002, the Commission has targeted deceptive claims for more than $1 billion[4] in health care products, a majority of which were dietary supplements.

This testimony will provide an overview of our enforcement efforts and other activities to combat deception in the supplement marketplace, including our efforts in the weight loss area. It then will focus on our specific efforts to challenge deceptive safety and efficacy claims in the marketing of supplements containing ephedra.

The FTC's Law Enforcement Actions Against Misleading Dietary Supplement Ads

Challenging misleading or unsubstantiated claims in the advertising of health care products, and particularly dietary supplements, is a priority of the FTC's consumer protection agenda. The Commission has filed more than ninety law enforcement actions over the past decade challenging false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements.[5] In this year alone, the Commission has filed or settled fifteen cases challenging claims for various supplement products, including three cases that specifically challenged safety and efficacy claims for ephedra.[6] The Commission focuses its enforcement priorities on claims for products with unproven benefits or that present significant safety concerns for consumers, and on false and unsubstantiated claims for products purported to treat or cure serious diseases.

The Commission's enforcement actions seek to stop deceptive advertising and obtain meaningful relief for consumers. In addition to obtaining cease and desist orders, in appropriate cases, the Commission secures substantial monetary relief for consumer redress or disgorgement of profits.[7] Further, when the marketing of a supplement involves misleading or unsubstantiated safety claims, the Commission requires that strong warning statements be placed in labeling and advertising.[8]

Weight Loss Advertising Report

As the Subcommittees are aware, ephedra often has been marketed as an aid to weight loss. Consumers spend billions of dollars on products that purport to promote weight loss.[9] 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").[10] 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. Nearly 40% of the 300 ads made at least one representation that was almost certainly false. An additional 15% of the ads made at least one representation that was very likely to be false, or, at the very least, 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.[11]

Of the 300 advertisements sampled for the Weight Loss Advertising Report, twenty-three, or about 8%, identified ephedra, ephedrine or Ma Huang as an ingredient. Of these, eleven made safety claims, and seven included a specific health warning about ephedra's potential adverse effects. Given that 60% of the sampled ads that made safety claims did not identify ingredients at all, these numbers almost certainly understate the prevalence of ephedra product advertising.

Public Workshop on Weight Loss Products

In light of the Weight Loss Advertising Report's findings, the Commission held a public workshop in November 2002 to explore the impact of deceptive weight loss product ads on the public health and identify new approaches to fighting the proliferation of misleading claims.[12] 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 later this year.

In addition, our staff has been meeting with members of the media, and other interested parties to encourage them to weed out facially false weight loss advertising before it runs.[13] We are exploring what assistance the Commission can provide to the media in this effort.

Coordination with the Food and Drug Administration

Under a longstanding liaison agreement,[14] the FTC has primary responsibility for the advertising of foods, cosmetics, devices, and over-the-counter drugs while the Food and Drug Administration ("FDA") has primary responsibility for the labeling of those products and advertising of prescription drugs. Our dietary supplement activities follow the same model. We coordinate our enforcement efforts closely with the FDA. Our enforcement actions targeting false or unsubstantiated supplement safety claims play an important supporting role to the FDA's more comprehensive efforts to ensure the safety of supplement products.[15]

Since December 2002, the FTC and FDA have intensified the level of their cooperation. The Commission staff actively participated in the work of the FDA's Consumer Health Information for Better Nutrition Initiative to better provide reliable information to consumers about important developments in nutrition and health, and to step up enforcement actions against deceptive claims for dietary supplements and other health products. On July 10, 2003, the FTC and the FDA announced the results of the first six months of coordinated enforcement efforts, including joint actions against widely advertised supplements claiming cures for serious diseases.[16]

Recent Developments Involving the Marketing of Ephedra Products

The FTC has challenged marketers of dietary supplements containing ephedra when they make claims that the products cause substantial weight loss or are safe or have no side effects. The recently released Department of Health and Human Services report, *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects* ("Rand Report"), concluded that the existing scientific evidence on the efficacy for weight loss of ephedra-containing dietary supplements supports only "modest" weight loss of about ½ pound per week for up to four to six months.[17] Furthermore, in contrast to assurances in ads that ephedra is safe or without side effects, the Rand Report concluded that "the use of ephedrine and/or the use of ephedra or ephedrine plus caffeine is associated with two to three times the risk of nausea, vomiting, psychiatric symptoms such as anxiety and change in mood, autonomic hyperactivity, and palpitations."[18] Moreover, the Rand Report noted that adverse event reports for the supplement contain a sufficient number of cases of death, myocardial infarction, cerebrovascular accident, seizure, or serious psychiatric illness in young adults to warrant a case-control study to determine whether ephedra consumption may be causally related to these serious adverse events.[19]

Since 1997, the FTC has brought seven enforcement actions challenging efficacy and safety/no side effects claims for supplements containing ephedra.[20]

These cases have challenged claims for ephedra products marketed for weight loss, body-building and energy supplements, and as alternatives to street drugs such as Ecstasy. In these cases, we have challenged allegedly deceptive efficacy and safety claims as false or unsubstantiated. Our orders have required a strong disclosure warning about safety risks in future advertising and labeling.[21]

For example, the Commission filed two additional settlements with companies that made allegedly deceptive safety and weight loss claims for ephedra supplements. In one case, the Commission's complaint challenged, as false or unsubstantiated, dramatic claims of substantial and safe weight loss for users of a product called Berry Trim Plus.[22] Ads for this product made claims such as "Teacher Loses 70 lbs. In Only 8 Weeks Easily!" and "100% safe!" In the second case, the FTC challenged as false or unsubstantiated claims for an ephedra product called Meta Biological.[23] Ads for this product claimed that "you lose pounds and inches SAFELY. . . without counting calories, without depriving yourself of tasty, delicious foods."

In these two cases, we alleged that there is not sufficient evidence to show that these products work as advertised or are safe for everybody. In both cases, the defendants agreed to an order that bans them from making certain false weight loss claims, requires substantiation for other weight loss claims, prohibits safety claims for ephedra without reliable scientific evidence, and requires the defendants to include a strong warning about safety risks in future advertising and labeling.[24] Both orders also require the defendants to pay consumer redress.

In addition, last month, the U.S. Department of Justice, on the Commission's behalf, sued Michael Levey, Gary Ballen, and their companies.[25] The complaint alleges that these defendants deceptively claim that their ephedra products, "Zymax" and "MillinexES," cause fast, substantial weight loss without dieting or exercise or side effects.[26] The Commission has asked the court to enjoin the defendants from making similar deceptive claims in the future and order the defendants to pay consumer redress. In addition, because the challenged claims violate an earlier Commission order, we have asked the court to award civil penalties. The case remains in litigation.

Deceptive advertising and unsubstantiated claims about the health benefits or safety of dietary supplements put consumers' health at risk. The Commission will continue to take law enforcement action against marketers who make safety and efficacy claims for any product without reliable scientific evidence to back up the claims.

Conclusion

The Commission thanks the Subcommittees 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 Subcommittees on our initiatives involving the marketing of dietary supplements, and, in particular, products containing ephedra.

Endnotes:

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. *Supplement Business Report 2002*, Nutrition Bus. J., § 2 (2002)

4. This represents the total sales for products the Commission challenged in seventeen actions since December 2002.

5. *See, e.g., FTC v. A. Glenn Braswell, et al.*, Civ. Action No. CV 03-3700 DT (PJWx) (C.D. Cal. filed May 27, 2003)(complaint for permanent injunction and other equitable relief)*; FTC v. Enforma Natural Prod., Inc.*, No. 00-4376JSL (Cwx) (C.D. Cal. Apr. 25, 2000) (stipulated final judgment with $10 million in consumer redress); *FTC v. Slim Down Solution, LLC*, No. 03-80051-CIV-PAINE (S.D. Fla. filed Jan. 24, 2003) (complaint for permanent injunction and other equitable relief); *FTC v. KCD Inc*., 123 F.T.C. 1535 (1997) (consent order). A complete list of the Commission's dietary supplement cases is available at <http://www.ftc.gov/bcp/conline/pubs/buspubs/dietadvertisingcases.pdf>.

6. *FTC v. Health Laboratories of North America*, Civ. No. 03 1457 (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.*, Civ. 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*, Civ. 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).

7. *See, e.g., FTC v. Enforma Natural Prods., Inc.,* 04376JSL (CWx) (C.D.Cal. Apr. 25, 2000) (stipulated final order including $10 million in consumer redress); *FTC v. 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).

8. *See, e.g.*, *FTC v. Health Laboratories of North America*, Civ. No. 03 1457 (D.D.C. July 1, 2003).

9. Marketdata Enterprises, Inc., The U.S. Weight Loss & Diet Control Market 6 (2002). Marketdata estimated that the total U.S. weight-loss market for 2001 was $37.1 billion and growing at a rate of 6 to 7 % a year.

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

11. Weight Loss Advertising Report at 21.

12. *Advertising of Weight Loss Products*, 67 Fed. Reg. 59,289 (2002).

13. *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 45th 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>.

14. *See* Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶ 9,859.01 (1971).

15. The Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994), requires a manufacturer of a dietary supplement to have substantiation for any structure/function claims it makes so that the claim is truthful and not misleading. DSHEA also authorizes the FDA to proceed against a supplement that presents a significant or unreasonable risk of illness or injury.

16. *See FTC. v. Kevin Trudeau, et al.*, Civ. Action No. 03 C 904 (N.D. Ill. filed June 9, 2003) (complaint for permanent injunction and other equitable relief); *FTC v. Seasilver USA, Inc., et al.*, Civ. Action No. CV-S-03-0676-RLH-LRL (D. Nev. filed June 12, 2003) (complaint for injunctive and other equitable relief).

17. Agency for Healthcare Research and Quality, U.S. Dep't of Health and Human Serv., Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects ("Rand Report") 219 (2003).

18. *Id.* at 9.

19. Rand Report at 223. In addition, at the request of the FDA, researchers conducted an independent review of 140 reports of adverse events related to the use of dietary supplements containing ephedra alkaloids that were submitted to the FDA between June 1, 1997, and March 31, 1999. The results of the review were published in the New England Journal of Medicine in December 2000. The authors found that "thirty-one percent of cases were considered to be definitely or probably related to the use of supplements containing ephedra alkaloids, and thirty-one percent were deemed to be possibly related." The authors also found that, "(o)f the sudden catastrophic cerebrovascular and cardiovascular events, 11 occurred in previously healthy persons." Christine A. Haller & Neal L. Benowitz, *Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids*, 343 New Eng. J. Med. 1833-38 (2000). Other recent studies raise further concerns about the safety of ephedra. *See* Stephen Bent, et al., *The Relative Safety of Ephedra Compared with Other Herbal Products*, 138 Annals of Internal Med. 468-71 (2003) (Although ephedra products make up less than 1% of all dietary supplement sales, they account for 64% of adverse events associated with dietary supplements); L.B. Morgenstern, et al., *Use of Ephedra-Containing Products and Risk for Hemorrhagic Stroke,* 60 Neurology 132-35 (2003) (The rate of hemorrhagic strokes among ephedra users was statistically significantly higher than among non-users for people taking doses above thirty-two milligrams a day).

20. In addition to the three cases listed *supra* note 6, at 3, and discussed in detail below, these actions include *Robert C. and Lisa M. Spencer, dba Aaron Co.,* FTC Docket No. C-4019 (July 30, 2001) (consent order involving safety claims for an energy product containing ephedra); *FTC v. AST Nutritional Concepts and Research, Inc.*, Civ. No. 99-WY-2197 (D. Col. May 4, 2000) (stipulated final order involving safety claims for body-building supplements containing both androstenedione and ephedra); *FTC v. Mex-RX US, Inc.*, 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.,* 124 F.T.C. 426 (1997) (consent order involving street drug alternatives containing ephedra).

21. In addition, the Commission's order against Global World Media for its marketing of ephedra as a street drug alternative includes a prohibition against marketing in media targeted at young audiences. Specifically, the consent order prohibits disseminating any ads for "Herbal Ecstacy" and similar products containing ephedra in any media where more than 50% of the audience is under 21 years of age. *See Global World Media*, 124 F.T.C. at 446.

22. *FTC v. Health Laboratories of North America*, Civ. No. 03 1457 (D.D.C. July 1, 2003).

23. *FTC v. USA Pharmacal Sales, Inc.*, Civ. No. 8:03-CV-1366-T-23EAJ (M.D. Fla. July 1, 2003).

24.For example, the Commission orders in *Health Labs of North America* and *USA Pharmacal Sales* require the following warning in print advertising:

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 care provider tells you to use it. The product may not be safe for your developing baby.

We are carefully reviewing the Rand Report and monitoring the ongoing FDA proposed rulemaking on ephedra to see if their findings would warrant any modification in the safety warnings required by future Commission orders.

25. *U.S. v. Michael S. Levey*, Civ. No. CV-02-4670 GAF (AJWx) (C.D. Cal. June 30, 2002).

26. The Commission also charged the defendants with making similar deceptive weight loss claims for a non-ephedra supplement called "Serotril."