Prepared Statement of the Federal Trade Commission

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Mr. Chairman and members of the Subcommittee, I am J. 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 the marketing of dietary supplements for children.[1]

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 the health benefits and safety of dietary supplements, especially those products marketed to or for children.[2]

The dietary supplement industry represents a substantial and growing segment of the consumer healthcare market with industry sales for 2002 estimated to be $18.8 billion.[3] A recent survey of complementary and alternative medicine use in the United States shows that more than one-third of U.S. adults age 18 and over are turning to alternative medicine, including

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[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] The Commission's 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 2003.

herbal products, enzymes and other dietary supplements.[4] The market for children's supplements has also been growing. Industry analysts estimate annual sales of children's supplements reached $510 million as of July 2002 and represented one of the top niche markets in the supplement industry.[5]

The supplement category encompasses a broad range of products, from vitamins and minerals to herbals and hormones. Products promoted specifically for children extend beyond traditional multivitamins to include preventives and cures for a variety of childhood ailments ranging from colds to more serious conditions like attention deficit/hyperactivity disorder (AD/HD). Most recently, the Commission has seen the appearance of a few children's products promoted for weight loss.

Certainly, some supplements offer the potential for real health benefits to consumers. The scientific research on the associations between supplements and health is accumulating rapidly. A 2001 NIH conference on Dietary Supplement Use in Children, however, found that little is known about the evidence base to support appropriate indications for use in children or about the safety of children's supplements.[6]

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[4] Barnes, P. et al., *CDC Advance Data Report #343. Complementary and Alternative Medicine Use Among Adults: United States, 2002* (May 27, 2004). Reprint *available at* http://www.nccam.nih.gov. The study found that 36% reported using some form of complementary and alternative medicine, and that 19% specifically used natural products such as herbs, other botanicals and enzymes, most without consulting a healthcare practitioner.

[5] Source: *Nutrition Business Journal* (July 2002).

[6] The conference was sponsored by the National Institute of Child Health and Human Development and the Office of Dietary Supplements of NIH. *See Dietary Supplement*

Commission law requires that claims about the safety and efficacy of any health-related product, including dietary supplements, be substantiated by competent and reliable scientific evidence before the claims are made. The Commission seeks to ensure that consumers get accurate information so that they can make informed decisions about how to manage their own healthcare. Bad information can pose a threat to the health and well-being of consumers. In recent years the Commission has brought several actions against deceptive promotions of supplements to children as part of its broader supplement law enforcement program. The agency also has made an effort to educate parents about the appropriate and safe use of children's supplements. The Commission's testimony today will highlight some of those enforcement and education efforts.

The FTC's Dietary Supplement Advertising Program

The agency has committed a significant portion of its consumer protection resources to combating false, misleading, or unsubstantiated claims in advertising for healthcare products, including dietary supplements. Over the past decade the Commission has filed or settled more than 100 law enforcement actions challenging allegedly false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements. The Commission has focused its 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 products that may present significant safety concerns to consumers.

Use in Children: Who, What, Why, and Where Do We Go From Here (Feb. 2001). Executive Summary *available at*: <http://www.nichid.nih.gov/about/od/prip/pastevents/executive_summary.htm.>

As in all its advertising programs, the Commission works to make sure its enforcement actions have a strong impact, for example, by holding accountable not just the supplement manufacturer but other parties that play a role in deceptive marketing, such as ad agencies, infomercial producers, distributors, and catalog companies.[7] The Commission has sought to obtain 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.[8] Finally, when the marketing of a supplement raises safety concerns, the Commission has required that strong warning statements be placed in labeling and advertising and, in certain cases, has imposed limits on how and to whom the product can be marketed.[9]

The Commission coordinates all of its enforcement efforts closely with the Food and Drug Administration (FDA). As you know, the two agencies have overlapping authority over

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[7] *See, e.g., Vital Basics, Inc. et al.*, Dkt. No. C-4107 (2004) (consent); *Creative Health Institute, Inc. and Kyl L. Smith,* Dkt. No. C-4108 (2004) (consent) (Respondents included the marketer, the individual who developed the product and others); *see also The Quigley Corp.,* Dkt. No. C-3926 (2000) (consent); *QVC, Inc.,* Dkt. No. C-3955 (2000) (consent) (Respondents included the products' manufacturer and marketer as well as the home shopping channel on which the products were advertised). The Commission's cases generally are *available at* www.ftc.gov.

[8] *See, e.g., Vital Basics, Inc. et al.,* Dkt. No. C-4107 (2004) (consent) ($1 million in consumer redress)*; FTC v. Seasilver USA, Inc., et al.,* Civil Action No. CV-5-0676-RHL-LRL (D. Nev. Mar. 4, 2004) (final stipulated order) ($4.5 million in redress). The Seasilver defendants also agreed in a separate settlement with FDA to destroy $5.3 million in misbranded products.

[9] *See, e.g., Global World Media Corp.,* Dkt. No. C-3772 (1997) (consent) (warning on ephedra risks and ban on marketing of certain products in media with majority youth audience); *Christopher Enterprises, Inc., et al.,* Civil Action No. 2:01 CV-0505 ST (D. Utah 2001) (final stipulated order) (ban on marketing of comfrey products for internal use and application on external wounds).

the marketing of dietary supplements and operate under a longstanding liaison agreement whereby the FTC has primary responsibility for claims made in advertising and the FDA for claims made in labeling.[10] Since December 2002, the FTC and FDA have intensified the level of this cooperation with stepped-up enforcement against deceptive supplement marketing. The staff of the two agencies have formed a joint enforcement task force that has led to improved information sharing and more effective joint actions that make the best use of the unique enforcement tools available to each agency. Both agencies have benefitted. For the FTC's part, the joint effort has helped us to bring more than 40 actions targeting fraudulently marketed supplements and other health products in the 18 months since the inception of the task force.[11]

Actions Involving Children's Supplements

The agency's efforts to police the supplement marketplace include especially close scrutiny of products marketed for use in children or otherwise targeted to appeal to young consumers. In the last ten years, thirteen of the Commission's actions against deceptive supplement advertising have addressed children's products, including three actions to date in 2004.[12] These actions have involved products making allegedly unfounded promises to prevent

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

[11] *See Federal Trade Commission Attacks $1 Billion in Deceptive Health Marketing Since December*, FTC Press Release (July 10, 2003), *available at* <http://www.ftc.gov/opa/2003/07/diethealth.htm>.

[12] A complete list of FTC cases involving children's supplements, including citations, is attached as Attachment A. The Commission files a complaint in a case when 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.

colds, products allegedly deceptively touted as safe and natural alternatives for the treatment of attention deficit/hyperactivity disorder (AD/HD), and, most recently, products promoted to help children lose weight. Some of the challenged products have contained stimulants or hormones that raise safety concerns or herbs with known toxicity.

1. Substantiation of Claims for Children's Dietary Supplements

The Commission has made it clear to the supplement industry that it will carefully evaluate the research for supplements marketed to children or to any other specific population, to make sure that the evidence supports safety and efficacy for the population to whom the product is marketed.[13] In some instances, research that has been conducted on children has failed to find the same effect as research conducted for the same product using an adult population.[14]

For example, the Commission's 1999 action against **Quigley Corporation** focused, in part, on claims made about the benefits of the company's "Cold-Eeze" zinc lozenges and "Kids-Eeze" zinc bubble gum for reducing the severity of cold symptoms and even preventing colds in children. In fact, although there was some limited evidence at the time on the effect of zinc on

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[13] *See, e.g., Dietary Supplements: An Advertising Guide For Industry*, Part B.5., *available at* <http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>.

[14] Last December the NIH's National Center for Complementary and Alternative Medicine (NCCAM) announced the results of research it had funded on echinacea, an herb popularly used to treat colds and other upper respiratory infections. The placebo-controlled study involved 534 children ages 2 to 11 and found no benefit in children, either for shortening the duration or lessening the symptoms of colds. Further, the study found that echinacea use was associated with an increased risk of rash. James A. Taylor *et al.*, EFFICACY AND SAFETY OF ECHINACEA IN TREATING UPPER RESPIRATORY TRACT INFECTIONS IN CHILDREN, 290 J. OF THE AM. MED. ASS'N 2824 (Dec. 3, 2003).

cold symptoms in adults, there was no evidence on cold prevention, and the one zinc study using a children's population failed to find any benefit in reducing cold symptoms in children.[15]

2. Purported AD/HD Treatments

It has been estimated that AD/HD affects 3 to 5 percent of school-aged children in the United States.[16] A variety of supplement products and ingredients on the market are promoted with claims ranging from increasing concentration, improving behavior, or enhancing school performance, to promises of complete cures for AD/HD. Due to the prevalence of these promotions and the serious nature of the health condition at issue, the Commission has focused much of its enforcement efforts on this category of children's supplements. To date, the Commission has settled six actions against companies marketing a variety of supplements for the treatment of AD/HD or its symptoms, focusing on the most widely promoted products and those making claims that allegedly far exceed any scientific evidence of a benefit.[17]

The first two actions involved a multi-level marketer, **New Vision International, Inc.,** and **Max F. James,** a high level distributor for New Vision, both charged with making

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[15] The Commission also challenged other claims as unsubstantiated and beyond the existing science, including claims, not specific to children, that the products would relieve allergies and reduce the risk of contracting pneumonia.

[16] Attention Deficit-Hyperactivity Disorder Information Page, NIH National Institute of Neurological Disorders (Mar. 21, 2003), *available at* <http://www.ninds.nih.gov/health_and_medical/ disorders/adhd.htm>.

[17] Although not directly marketed for AD/HD, an earlier Commission case, **Zygon International, Inc.**, challenged, as unsubstantiated, claims that the company's "SuperBrain Nutrient Program" would enhance intelligence and memory. Marketing for the product included claims that pregnant women taking the product would enhance the intelligence of their children.

unsubstantiated claims for a combination of dietary supplements called "God's Recipe" that included an herbal drink containing grape seed extract, a mineral capsule, and a multi-enzyme tablet containing alfalfa and barley sprouts. The package was promoted through compelling testimonials as a cure for AD/HD and a natural alternative to Ritalin. Subsequent actions included a consent order with **J&R Research** settling charges that the company made unsubstantiated claims that its pycnogenol supplement was effective in treating not only AD/HD, but also cancer, heart disease, arthritis, diabetes, and multiple sclerosis; a consent order with **Efamol Nutraceuticals, Inc.** settling charges of unsubstantiated claims that two essential fatty acid supplements, "Efalex" and "Efalex Focus," could treat or cure AD/HD; and a consent order with **Natural Organics, Inc.** challenging the deceptive marketing of a multi-ingredient supplement called "Pedi-Active A.D.D."

Most recently, the Commission settled charges against **Vital Basics, Inc.** relating to the marketing of "Focus Factor," a multi-ingredient supplement purported to improve focus, memory, concentration, and academic performance in children, teenagers, adults, and senior citizens alike. The campaign for Focus Factor involved widely disseminated television and radio infomercials and Internet marketing. The Commission's consent order included a $1 million consumer redress payment.[18] The Commission also obtained a consent order against **Kyl Smith**, the developer of Focus Factor, and his company **Creative Health Institute**, along with an additional $60,000 payment for consumer redress.

[18] The Vital Basics case also challenged safety and efficacy claims for "V-Factor," a supplement marketed as a male sexual performance enhancer.

3. Bodybuilding Supplements Appealing to Young Athletes

Dietary supplements marketed to increase athletic performance and strength may be particularly attractive to young athletes and bodybuilders. For that reason, in 1999 the Federal Trade Commission challenged ads promoting a category of body-building supplements that raised safety concerns and were popular among teenage athletes. The Commission brought action against two marketers of supplements containing androstenedione and other steroid hormones, **MET-Rx USA, Inc.** and **AST Nutritional Concepts**. Both companies were charged with making unsupported safety claims for their products, and were required to place strong warnings in future advertising and labeling warning against the potential risks of using steroid hormones, including potential unwanted changes in male and female sexual characteristics and increased danger for persons at risk of prostate or breast cancer.[19] The orders in both of these cases also required an additional warning for certain products that contained the powerful cardiovascular and central nervous system stimulant, ephedra, which has since been banned by the Food and Drug Administration.

In bringing these actions, the Commission coordinated closely with the Food and Drug Administration, as well as the Department of Justice's Drug Enforcement Agency and the White House Office of National Drug Control Policy, to better understand the risks these products

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[19] Specifically the consent orders required that the following statement be displayed prominently in advertising and labeling: **"WARNING:** This product contains steroid hormones and may cause breast enlargement, testicle shrinkage, and infertility in males, and increased facial and body hair, voice deepening, and clitoral enlargement in females. Higher doses increase these risks. <u>If you are at risk for prostate or breast cancer you should not use this product.</u>"

posed and how young athletes used them. The agency also worked with the National Federation of State High School Associations to help raise awareness among student athletes about the dangers of using any performance-enhancing substances. In addition, earlier this year, the FDA sent 23 companies warning letters indicating that the agency considers the marketing of products containing androstenedione to be prohibited. Specifically, the FDA warning letters indicated that such products are adulterated under the Federal Food, Drug, and Cosmetic Act because androstenedione is a new dietary ingredient for which there is not adequate evidence of safety.

4. Other Cases Raising Safety Concerns

When necessary, the Commission will impose additional remedies, beyond warning requirements, to ensure that potentially dangerous supplements do not harm young consumers. In the Commission's 1997 action against **Global World Media Corp.**, for example, the agency challenged the marketing of a supplement named "Herbal Ecstacy," a product containing a high dosage of ephedra, that was promoted as an "absolutely safe" natural alternative to street drugs to get "high." The product was advertised with psychedelic print and television ads in media with large youth audiences, including even MTV and Nickelodeon in some markets. The Commission's order required strong warning statements in advertising and labeling.[20] And, to further protect young consumers to whom the marketing had been targeted, the order also prohibited any future advertising of Herbal Ecstacy and similar ephedra products in media with a

[20] The specific warning for the 1997 order was: "**WARNING:** This product contains ephedrine which can have dangerous effects on the central nervous system and heart and could result in serious injury. Risk of injury increases with dose.**"**

predominantly young audience.[21] Since that time, FDA has banned ephedra products because of serious safety risks.

In another matter, the Commission addressed the marketing of several products containing comfrey, an herb associated with severe liver toxicity. **Christopher Enterprises, Inc.** used the Internet and other media to market various cure-all remedies containing comfrey. Some of these comfrey products were promoted for use in young children as a cough and cold remedy and even for use in babies and pregnant women for treatment of a variety of infections. The Commission alleged that the company's safety claims were false. Because of the severe risks associated with this herb, the Commission's 2001 consent order banned the company from marketing any comfrey product either for internal use or for application to open wounds. The consent order further required that products sold for external use were required to be labeled and advertised with warning statements making it clear that comfrey can cause serious liver damage and even death.[22]

Most recently, the Commission charged **Direct Marketing Concepts, Inc.** with making

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[21] The consent order prohibited dissemination of 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.

[22] The warning reads: "**Warning:** External Use Only. Consuming this product can cause serious liver damage. This product contains comfrey. Comfrey contains pyrrolizidine alkaloids, which may cause serious illness or death. This product should not be taken orally, used as a suppository, or applied to broken skin. For further information contact the Food and Drug Administration: http://vm/cfsan.fda.gov." The final stipulated order also included a $1.4 million judgment that was suspended provided defendants paid $100,000 in consumer redress).

several false and unsubstantiated claims about the safety and efficacy of two dietary supplements marketed through widely-aired infomercials. In addition to challenging claims that the products could prevent or cure cancer and other diseases and cause substantial weight loss, the Commission also challenged a claim relating to the safety of one product for children and pregnant women. Specifically, the Commission complaint charged the marketers with making unfounded claims that "Supreme Greens," a combination of numerous plant and herbal ingredients, was safe for everyone, including pregnant women, children, and persons on medication.

5. Weight Loss Supplements

Given the concern about the increasing rate of childhood obesity, marketing of dietary supplements for weight loss in children is another subject of ongoing FTC investigations and law enforcement. With weight loss advertising in general, the Commission is concerned that consumers not be misled by ads promising dramatic, easy, rapid weight loss without diet or exercise.

In one recent case, involving a product called "Skinny Pill for Kids," the FTC challenged advertising by **The Fountain of Youth Group, LLC** and its principal **Edita Kaye**. The company claimed on its web site and in other media that Skinny Pill for Kids was the "First thermic and herbal formula ever developed for weight loss for children 6 to 12." According to the ads, Skinny Pill for Kids would burn fat, block new fat deposits, normalize insulin and blood sugar levels, reduce the risk of obesity-related diseases including heart disease, high blood

pressure and diabetes, and was proven safe by scientific research. The complaint alleged that these claims were unfounded or outright false. Prompt Commission action stopped this marketing campaign before the children's product actually entered the marketplace. Currently, the Commission also is pursuing two other non-public law enforcement matters that include weight loss products marketed specifically for children.

The Commission's efforts to stop the deceptive marketing of weight loss products to children is part of a larger ongoing effort to stop weight loss scams. Going back more than a decade, the agency has maintained an aggressive law enforcement program against weight loss scams, bringing more than 100 cases against false and misleading weight loss claims. In November 2002, the Commission held a public workshop to explore approaches, in addition to traditional law enforcement, to curb ongoing weight loss fraud.[23] Based, in part, on the workshop, the Commission launched a new initiative to enlist the media in screening out facially false weight loss ads before they are run. As part of this effort, the Commission has published, and widely disseminated to television, newspapers and magazine publishers, its *Red Flag: Bogus Weight Loss Claims*[24] brochure, which provides media outlets with easy guidelines for spotting and stopping false claims. Thus far, the response from media has been encouraging.

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[23] The November 2002 workshop brought together government officials, scientists, public health groups, marketers of weight loss products, advertising professionals, and representatives of various media outlets. A report describing the results was issued in December 2003. "Deception in Weight-Loss Advertising Workshop: Seizing Opportunities and Building Partnerships to Stop Weight-Loss Fraud," FTC Staff Report (Dec. 2003). http://www.ftc.gov/reports/index.htm.

[24] *Available at* <http://www.ftc.gov/bcp/conline/pubs/buspubs/redflag.pdf>.

Consumer Education Efforts

As the *Red Flags* brochure exemplifies, the Commission's consumer protection activities are not limited to law enforcement. The agency complements traditional cases with a variety of creative and effective education and outreach for both consumers and industry. In May 2000 the FTC published a feature article on promotions for children's dietary supplements.[25] That article described the FTC's enforcement efforts against various deceptive promotions of children's supplements and detailed some of the concerns surrounding the safety and efficacy of these products. It also provided practical pointers for parents about safe and responsible use of supplements, urging parents to consult with a pediatrician before starting their child on any supplement. The article was reprinted in large and small markets, and was featured in numerous local and regional radio broadcasts, reaching parents throughout the country. The Commission will continue to look for opportunities for consumer education, in partnership with other health and law enforcement authorities. This approach can help parents better protect their children against ineffective and sometimes dangerous health products.

Conclusion

The Commission will continue to have an active program to challenge deceptive marketing of dietary supplements in general and children's supplements specifically. The agency will continue to monitor promotions of children's products, staying alert for new categories of supplements, such as children's weight loss products, and taking action as

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[25] FTC Consumer Feature, *Promotions for Kids' Dietary Supplements Leave Sour Taste*, (May 2000), *available at* <http://www.ftc.gov/bcp/conline/features/kidsupp.htm>.

warranted against unfounded safety and efficacy claims. 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.

ATTACHMENT A