Federal Trade Commission

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Priorities for Dietary Supplement Advertising Enforcement

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I. Introduction

I appreciate the opportunity to be here today to discuss my priorities for advertising enforcement in the dietary supplement area. I want to thank the Council for Responsible Nutrition for inviting me to speak.

We live in a time where medical advances and research breakthroughs are reported in the news on a daily basis, and science appears to be on the brink of providing us with a solution to every problem. Meanwhile, consumers are becoming more health conscious and they are pro-actively seeking out both information and products to address their health concerns and improve the quality of life for themselves and their families. The FTC wants consumers to have truthful information so they can make well-informed decisions for themselves, but we also want to

[1] The views expressed here are my own and do not necessarily represent the views of the Federal Trade Commission or any Commissioner.

ensure that advertisers don't make promises that aren't backed by solid science.

As science advances, so does the nature of advertising substantiation. Advertising substantiation itself has become an industry, with experts, labs, and consultants for hire – some legitimate, some less so – offering substantiation services to advertisers. For the FTC, having to keep up with current research and cutting-edge science can make analysis of substantiation a more complex task, sometimes requiring the assistance of multiple experts.

Nonetheless, while science evolves, one thing stays the same. There have always been – and there will always be – marketers who advertise pills that claim to be able to provide us with health, beauty, longevity, and a cure for whatever ails us. Investigations of unsubstantiated efficacy claims for health products and dietary supplements will continue to be an active area for enforcement.

Today, I want to highlight a few areas of our enforcement agenda for dietary supplements: products posing safety concerns, actions involving retailers, suppliers and manufacturers, and our collaborative enforcement efforts with the FDA. I also want to talk about our recently revised endorsement guides, and an effort to clarify the substantiation requirement in our orders.

II. Products posing safety concerns

The FTC makes it a priority to investigate products that pose serious health concerns for consumers, either because they promise a cure for a serious disease that requires medical treatment, or because the product itself may present undisclosed risks to some consumers.

Some marketers of dietary supplements make disease treatment and prevention claims that far exceed the bounds of the structure/function claims that are permitted under the 1994 Dietary Supplement Health and Education Act (DSHEA). Such disease claims may deter

consumers from seeking necessary medical treatment for serious conditions such as cancer, diabetes, and HIV.

In a major law enforcement initiative targeting bogus cancer cures, the FTC announced 11 actions last year charging a number of companies and individuals with making false or unsubstantiated claims that their products – including laetrile, black salve, essiac tea and other herbal mixtures, coral calcium, and shark cartilage – cure or treat cancer, and, in some cases, that clinical or scientific evidence proves the products work.[2] One seller also was charged with deceptive use of a consumer testimonial about the product's efficacy because the ad failed to disclose the connection between the endorser and the company: the "consumer" endorser was, in fact, the owner of the company.[3] Most of these actions have been resolved through settlements that bar future false or unsubstantiated claims and require notification to purchasers that little or no scientific evidence exists to demonstrate product effectiveness and urging them to consult with their doctors. Four of the settlements also required a monetary payment. As of this date, one case remains, which is currently pending on appeal to Commission after the ALJ found that the respondents cancer-related claims violated the FTC Act. The cancer cure cases were the result of an Internet surf coordinated among the FTC, the U.S. Food and Drug Administration (FDA), and the Canadian Competition Bureau. The FTC and the FDA also issued a significant number of warning letters in connection with the surf.

As an important adjunct to the cancer sweep law enforcement initiative, the Commission launched *Cure-ious? Ask*, a consumer education campaign to raise awareness about bogus cancer

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[2] *See* Press release, FTC Sweep Stops Peddlers of Bogus Cancer Cures (Sept. 18, 2008), available at http://www2.ftc.gov/opa/2008/09/boguscures.shtm.

[3] *Holly A. Bacon d/b/a Cleansing Time Pro.*, Docket No. C-4238 (Oct. 22, 2008).

treatment claims and to encourage consumers to discuss treatment options with their doctors. The Commission's partners in this effort were the American Society of Clinical Oncology, the Cleveland Clinic, and the National Association of Free Clinics, all of whom are disseminating campaign information to both patients and medical care practitioners.

Earlier this year the Commission accepted a settlement that included $3 million in consumer redress to resolve charges of false and deceptive claims that various nutritional supplements could treat, reduce the risk of, or prevent diseases including cancer, HIV/AIDS, diabetes, Alzheimer's disease, Parkinson's disease, strokes and heart attacks, multiple sclerosis, herpes, asthma and glaucoma.[4] The defendants also falsely claimed that one of their products was scientifically proven to be an effective treatment for AIDS. The products were sold on the Internet and through print media, but the primary marketing vehicle was a nationally broadcast, live, hour-long radio call-in program called "The Truth About Nutrition."

Consumers suffering from serious health ailments are particularly vulnerable and sometimes desperate. The marketing of unfounded treatments to such people offers a type of false hope that is particularly cruel. When a seriously ill patient forgoes medically established treatment for an unproven remedy, the damage can be irreparable. Supplements that purport to provide cures or treatments for serious diseases will continue to be a top priority for our enforcement efforts.

The FTC is also concerned about the risks posed by dietary supplements that are intentionally spiked with prescription medications, controlled substances, or other undisclosed

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[4] *See* Press release, Marketers of Dietary Supplements and Devices Agree to Pay $3 Million to Settle FTC Charges of Deceptive Advertising (Mar. 6, 2009), available at http://www.ftc.gov/opa/2009/03/roex.shtm.

ingredients that may be potentially dangerous to some or all users. Despite consumers' growing concerns over the source and purity of supplements and the FDA's establishment of good manufacturing practices (GMP) for dietary supplements, there are still some manufacturers who spike supplements with pharmaceutical ingredients or their chemical analogues. Such adulteration can occur in any type of product but has most commonly been reported in weight loss, athletic performance, and sexual enhancement products.

The danger to consumers is potentially grave. The failure to disclose the presence of such intentionally added ingredients is both deceptive and dangerous. We are currently in discussions with FDA on how the agencies can work together to pursue unscrupulous marketers who sell such products.

III. Cases involving retailers, manufacturers, and ingredient suppliers

We aim to stop deceptive health claims at their source, which is usually the advertiser. But this is not always the case. Sometimes, unsubstantiated claims originate with a retailer, manufacturer, or ingredient supplier. When this occurs, we want to pursue cases against the responsible parties, no matter where they fall in the manufacturing and distribution chain.

Last year, the Commission settled charges that Airborne Health, Inc. disseminated false and unsubstantiated claims that Airborne effervescent tablets prevent or treat colds, protect against exposure to germs in crowded environments, and offer a clinically proven cold remedy.[5] The nation-wide Airborne advertising campaign – and you may recall those ads where the original owner of the company claimed she developed the product because she was sick of

[5] *See* Press release, Makers of Airborne Settle FTC Charges of Deceptive Advertising; Agreement Brings Total Settlement Funds to $30 Million (Aug. 14, 2008), available at www.ftc.gov/opa/2008/08/airborne.shtm.

catching colds from the second-graders she taught – was so successful that national retail chains replicated the supplement, used similar package claims, and placed the product next to Airborne on the shelf. This year, the Commission brought cases against Rite Aid[6] and CVS,[7] with both retailers agreeing to pay consumer redress to settle charges that they made unsubstantiated claims for their Airborne knock-off products.

In a related matter, the Commission also has an action pending against Improvita Health Products, Inc., the contract manufacturer that supplied several retailers with their Airborne knock-off products.[8] The complaint alleges that Improvita provided retailers such as Rite Aid with advertising, packaging, and promotional materials containing unsubstantiated claims.

These cases should send a clear message that the Commission will hold retailers and contract manufacturers accountable for the claims they make – especially the health benefit claims – about their store-brand products. Capitalizing upon another company's successful marketing campaign does not absolve a seller or competing manufacturer from the responsibility to gather its own research and ensure that all of its claims – whether express or implied – are fully substantiated.

This year the Commission also filed a case against an ingredient supplier who sold what was purported to be Hoodia – a substance derived from a rare South African plant that appears to

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[6] *See* Press release, Rite Aid to Pay $500,000 in Consumer Refunds to Settle FTC Charges of False and Deceptive Advertising (July 13, 2009), available at http://www.ftc.gov/opa/2009/07/riteaide.shtm.

[7] *See* Press release, CVS to Pay Nearly $2.8 Million in Consumer Refunds to Settle FTC Charges of Unsubstantiated Advertising of AirShield 'Immune Boosting' Supplement (Sept. 8, 2009), available at http://www.ftc.gov/opa/2009/09/cvs.shtm.

[8] *See* Press release, Rite Aid to Pay $500,000 in Consumer Refunds to Settle FTC Charges of False and Deceptive Advertising, *supra* note 6.

be the hot weight-less ingredient of the moment – to trade customers for use in finished diet pills.[9] The complaint alleges false and deceptive claims that were made to trade customers, including that hoodia is scientifically proven to reduce caloric intake by 1,000 to 2,000 calories a day, and representations that the product in question was genuine Hoodia gordonii, when in fact, it was not. Importantly, the complaint alleges that by providing their trade customers with advertising and promotional materials containing false and deceptive claims, the defendants provided the trade customers with the means to deceive consumers.

We want ingredient suppliers to be aware that they are responsible for false and unsubstantiated claims they make to trade customers, not only because they may be deceiving their trade customers, but also because these problematic claims may be passed further on down the line to consumers. We will continue to pursue cases against the parties responsible for making unsubstantiated claims, from wherever they originate.

IV. Collaborative efforts with the FDA

We have renewed efforts to work closely with the Food and Drug Administration by establishing three working groups to share information regarding conventional foods, dietary supplements, and over-the-counter drugs. Staff from the FTC, FDA, and the Office of Consumer Litigation of the Justice Department are conducting regular telephone conferences to increase coordination with respect to strategic planning and case selection. These areas of overlapping jurisdiction include some of the most important FTC advertising program areas. I believe the increased cooperation will enhance the enforcement efforts of both agencies.

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[9] *See* Press release, FTC charges marketers of 'Hoodia' Weight Loss Supplements with Deceptive Advertising (Apr. 27, 2009), available at http://www2.ftc.gov/opa/2009/04/nutraceuticals.shtm.

We are actively seeking out opportunities where it would be appropriate and effective for the FTC and FDA to undertake joint enforcement efforts. Earlier, I mentioned the cancer cures sweep which involved participation from both the FTC and FDA, as well as the anticipated collaboration between the agencies to address the problem of dietary supplements contaminated with prescription drugs and other potentially dangerous pharmaceuticals. In addition, last week the FTC and FDA issued a joint warning letter to a website selling a dietary supplement purporting to protect against cold and flu. We intend to follow-up with additional joint warning letters to other web sites selling products purporting to prevent or treat H1N1 flu virus. These sites were identified earlier in an Internet surf conducted by FTC staff. Unfortunately, whenever a new health concern is in the news headlines – whether it's bird flu, SARS, or swine flu – some marketers rush in to exploit the situation and offer all sorts of cure-all products. We will continue to work with FDA to address these scams.

V. The endorsement guides

I know there has been a lot of press coverage on the revisions to the Commission's Endorsement Guides. The Commission announced several proposed revisions to the Guides in November 2008 and invited public comments on the proposals. The Commission gave careful consideration to all of the comments received during the comment period and announced earlier this month that it had approved final revisions to the Guides.

The Guides define endorsements and testimonials and provide guidelines for consumer and expert endorsements and for the disclosure of material connections.[10] The Commission adopted the Guides in 1980, in an effort to assist advertisers in using this advertising technique

[10] Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 C.F.R. Part 255.

in a lawful and non-misleading way. The basic principles underlying the Guides are unchanged. Endorsements should not contain express or implied representations that would be deceptive, or could not be substantiated, if made directly by the advertiser. Endorsements themselves are not competent and reliable scientific evidence. Experts must have the qualifications they are purported to have, and material connections between endorsers and sellers should be disclosed if they might affect the weight or credibility of the endorsement.

Obviously, the Guides were formulated in a world quite different from the one in which advertisers and marketers promote their goods and services today. This is the first time that the Guides have been revised since their adoption almost 30 years ago. While the basic principles that underlie the Guides remain valid, the specific applications and examples were not developed within a context of program-length infomercials, Internet advertising, word of-mouth or viral marketing, and consumer blogs. In 1980, the advertiser always disseminated the advertisement. With the advent of advertiser-promoted consumer blogging, the advertiser is not always disseminating the endorsement, although it certainly expects to profit from the message.

Moreover, the Commission's enforcement history with false or deceptive advertising using consumer endorsements, as well as its own research on consumer perception of such ads, has made it increasingly clear that in one key aspect – disclaimers of typicality – the Guides were not working as intended to prevent deception. Such disclaimers simply are not effective. Consumers interpret the results depicted in testimonials to be representative of what consumers can expect to achieve, even where testimonials are accompanied by the statement, "Results not typical." The Commission's consumer research found that even where testimonials were accompanied by the strong statement: "These testimonials are based on the experiences of a few people and you are not likely to have similar results," consumers still believed that the results in

the testimonial were representative of what would generally be achieved.

The misuse of testimonials and endorsements has been particularly prevalent in the promotion of weight-loss products, as described in the FTC staff's 2002 report, *Weight-Loss Advertising: An Analysis of Current Trends*.[11] A review of 300 weight-loss ads revealed that two-thirds used consumer testimonials, and those testimonials rarely described realistic achievements, instead proclaiming extraordinary weight loss results that, in all likelihood, are not achievable. Disclosures regarding atypicality of the advertised results – when they appeared – often were buried in a fine-print footnote or a video superscript flashed too quickly to be read. The typical disclaimers – such as, "results may not be typical" or "results may vary" – did not adequately inform consumers that the reported weight losses were, at best, outliers or extreme cases. Endorsements and testimonials too often convey results that most consumers can never achieve and, in doing so, they make claims that cannot be substantiated.

Clearly, it was time for a change. The Commission has removed the so-called "safe harbor" for disclaimers of typicality from the guidelines. It is no longer a shield from liability to simply use the "Results not typical" language with testimonials. The revised Guides do not bar the use of atypical or best-case testimonials. But where the net impression from an ad is that the experiences of the testimonialists in ad are representative of what consumers can generally expect to achieve, that is, that they are "typical" results, the advertiser should clearly and conspicuously disclose the generally expected result in the depicted circumstances. The Commission's consumer research has found that this is the most effective way to counter the otherwise common consumer perception that testimonials portray typical results. We expect that

[11] The Report is available at http://www.ftc.gov/bcp/reports/weightloss.pdf.

advertisers who have competent and reliable scientific evidence to support a health claim also have reliable information as to what results consumers can generally expect with their products.

While this change in the Guides has garnered quite a bit of attention, the most fundamental principle underlying FTC advertising law remains the same. Advertisers who use testimonials are held to the exact same standard as those who do not. All advertisers are responsible for ensuring that their ads are truthful and not misleading.

We understand that it will require some adjustment for the industry to adopt the new guidelines regarding the use of testimonials. While we will allow a reasonable period of time for people to come into compliance, we want you to know that this change to the Guides is important and we intend to aggressively enforce the revised requirements for testimonials.

VI. Clarifying the substantiation standard in FTC orders

Our experience in bringing enforcement and contempt actions in federal courts suggests that we need to take steps to make our standard injunctive language that prohibits particular kinds of claims unless the defendant "possesses and relies upon competent and reliable scientific evidence that substantiates the representation" more exact. For instance, you may be aware of the recent decision in the *Lane Labs* case, where a district court judge denied the FTC's motion to find the defendants in contempt of a prior FTC order requiring them to have "competent and reliable scientific evidence" substantiating health claims. The Commission is disappointed with this result and intends to appeal.

We will be looking for more precise injunctive language in future orders that will provide clearer guidance to defendants and courts alike as to the amount and type of scientific evidence that will be required in future advertising. In addition to achieving greater precision, we will also seek orders that harmonize with laws and regulations administered by the FDA. A third

goal will be to address those situations where a given piece of research, though it may have been conducted according to established protocols, achieved results inconsistent with the weight of scientific evidence in the relevant field. One outlier study should not be the sole basis of support for a claim that a product will confer a benefit – particularly a health benefit. We need to ensure that our orders are enforceable and do not permit deceptive claims, and I am seeking changes to make that happen.

VII. Conclusions

Before I close, I would like to acknowledge the constructive role that CRN has played in this industry. In particular, CRN's self-regulatory program, which I'm told by my staff that the FTC had a role in fostering, provides an important resource for resolving problematic advertising claims for dietary supplements without the necessity of expending scarce law enforcement resources. We were please to hear that CRN has extended its agreement with NAD to continue this program to 2014.

Consumer protection in the 21st century is a daunting task – confronting challenges that were not imagined even ten years ago. In addition to battling long-standing deceptive practices, the FTC has adapted with the times, and we continue to do so. I look forward to working with you as our regulatory and enforcement programs evolve to meet the challenges.