PREPARED STATEMENT OF
THE FEDERAL TRADE COMMISSION

on

DECEPTIVE MARKETING OF DIETARY SUPPLEMENTS
FTC ENFORCEMENT ACTIVITIES

Before the

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

Washington, D.C.

May 26, 2010
I. Introduction

The Federal Trade Commission (“FTC” or “Commission”) submits this statement to Chairman Kohl, Ranking Member Corker, and Members of the Special Committee on Aging. The statement details recent FTC enforcement efforts to protect consumers from false or misleading claims about dietary supplement products. The Commission appreciates the opportunity to submit this statement for the record.

The Federal Trade Commission works to prevent unfair competition and protect consumers, including older Americans, from unfair or deceptive practices in the marketplace. As part of its antitrust efforts, the Commission has made it a priority to lower prescription drug costs for seniors by stopping pay-for-delay deals in the pharmaceutical industry.\(^1\) In addition, many of the FTC’s consumer protection efforts have sought to address marketing scams that prey disproportionately on seniors.\(^2\) Marketing of unproven cures or treatments for various health conditions is a prime example of fraud impacting older Americans, and is a priority for FTC enforcement. This statement focuses specifically on the Commission’s active law

\(^1\)In these pay-for-delay patent settlements, also known as exclusion or reverse-payment settlements, the brand-name drug firm pays its potential generic drug competitor to abandon a patent challenge and delay entering the market with a lower-cost generic product. The FTC estimates that such deals, by denying consumers access to lower-priced, generic drugs, cost Americans $3.5 billion a year.

\(^2\)The FTC has brought cases, for example, against fake charities that take advantage of seniors’ generosity and against companies that offer worthless medical discount cards. See, e.g., *FTC v. Marleau*, No. C09-5289BHS (W.D. Wash. final order June 18, 2009) (for-profit company soliciting for sham police, fire and veterans non-profit charitable organizations); *FTC v. 6554962 Canada Inc.*, No. 08-C-2309 (N.D. Ill. default judgment and order Aug. 19, 2009) (bogus medical or drug discount plans offered by defendants pretending to be calling from the Social Security Administration, Medicare, or a consumer’s bank). The FTC also seeks to address fraud against seniors through education and outreach, in partnership with the AARP.
enforcement program to combat such fraud in the dietary supplement marketplace. The agency coordinates these efforts closely with the Food and Drug Administration (“FDA”), and draws on the expertise of other government authorities, including the Office of Dietary Supplements of the National Institutes of Health (“NIH/ODS”).

The dietary supplement industry continues to represent a substantial and growing segment of the consumer healthcare market. U.S. sales were an estimated $25 billion last year, a six percent increase over the previous year. In fact, market analysts suggest that the downturn in the economy has actually led to increased spending on supplements as consumers attempt to manage their own healthcare and avoid expensive doctor visits and prescription medications. Given this trend, it is more critical than ever that the Commission work to ensure that consumers are getting truthful and accurate information, backed by solid scientific evidence, about dietary supplements.

This statement will explain how the FTC coordinates with the FDA, describe how the FTC identifies targets and brings enforcement actions, and also highlight recent FTC enforcement and consumer outreach efforts.

II. Coordination with FDA

The FTC and FDA have concurrent jurisdiction over dietary supplements and other

3The Commission’s authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits “unfair or deceptive acts or 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.


5Id.
health and nutrition products. The two agencies work closely to police the marketplace for false or unsubstantiated claims and for products or marketing practices that present safety concerns. Under a longstanding liaison agreement,\(^6\) the FTC has primary authority over the advertising of foods, including dietary supplements, while FDA has primary responsibility for the labeling of those products. Despite differences in statutory authority, the two agencies have successfully coordinated enforcement policy.\(^7\)


\(^8\)As part of the exchange of information, FDA compliance and law enforcement personnel have access to the FTC’s secure, online complaint database, Consumer Sentinel, which received over one million consumer complaints in 2009. The FTC staff obtains information from FDA records on adverse events reported for the dietary supplement industry and on labeling notifications filed with FDA by supplement manufacturers.

\(^9\)Staff of the FTC’s Bureau of Consumer Protection (including the Division of Advertising Practices and the Division of Enforcement), FDA’s Center for Food Safety and Applied Nutrition (“CFSAN”) and Center for Drug Evaluation Research (“CDER”), as well as the Department of Justice’s Office of Consumer Litigation, participate on these calls.
to stop fraud and deception, using the strongest tools available to each agency. The FTC, for example, has the power to compel supplement companies to provide documents relating to the substantiation of claims. When appropriate, the FTC can also take quick action in federal court to obtain a temporary restraining order, appointment of a receiver to take control of a fraudulent business, and an asset freeze. The FDA has the power to conduct seizures and order the destruction of misbranded product.\(^\text{10}\)

III. FTC Enforcement Program

Over the past decade, the Commission has filed well over 100 law enforcement actions challenging claims about the efficacy or safety of a wide variety of supplements. The Commission has focused its enforcement on national advertising campaigns for products with unproven benefits, products promoted to treat or cure serious diseases, products that may present significant safety concerns to consumers, and products that are deceptively marketed to vulnerable populations, such as children or the elderly.

A. Case Selection, Enforcement Process, and Remedies

Potential cases come to the FTC’s attention from a number of different sources, including complaints from consumers (through the Consumer Sentinel Network), competitors, consumer health advocates, industry self-regulatory groups (such as the National Advertising Division of the Council of Better Business Bureaus), agencies (e.g., FDA, NIH/ODS, and state attorneys

\(^{10}\)One example of a coordinated effort using all of these tools is the action against Seasilver USA, Inc. for the marketing of a supplement purported to treat or cure cancer, AIDS, diabetes, and 650 other diseases. *FTC v. Seasilver USA, Inc.*, No. CV-S-0676-RHL-LRL (D. Nev. final order Mar. 4, 2004). After the FTC obtained a temporary restraining order and asset freeze and the FDA seized the defendants’ product, the FTC reached a settlement with the defendants that included $4.5 million in consumer redress. The FDA’s companion settlement included the destruction of $5.3 million worth of misbranded supplements.
general), and Congress. In addition, the FTC staff routinely monitors major television and print media, as well as newer forms of marketing like digital and viral marketing, to identify national advertising campaigns that are likely to have the most substantial consumer impact. The staff also watches for new trends by reading the trade press, attending industry trade shows, and checking consumer complaint databases. This allows the staff to quickly identify the latest fad weight loss ingredient or spot a surge in products to treat specific diseases. Finally, the Commission works with FDA and foreign law enforcement partners to identify specific health problems that may be the subject of particularly widespread fraud by unscrupulous online marketers and then identifies specific targets by conducting coordinated Internet surfs.

Once the staff has identified a target that appears to be making unfounded claims, it opens an investigation and issues civil investigative demands ("CIDs") to compel the production of documents and information by the supplement marketer and others with relevant information. The staff uses this powerful investigative tool to obtain marketing and labeling materials, sales information, and relevant substantiation materials. Dietary supplement investigations often involve an assessment of the scientific evidence related to a claimed health benefit. In many instances, the staff will contract with a scientific expert in the relevant field to

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11Section 20 of the FTC Act provides the Commission with the authority to issue a CID to compel the production of records, answers to interrogatories, or the taking of testimony whenever the agency “has reason to believe that any person may be in possession, custody, or control of any documentary material or tangible things, or may have any information, relevant to unfair or deceptive acts or practices.” 15 U.S.C. § 57b-1(c)(1). The FTC may bring an action in federal court to compel a CID recipient’s compliance with a CID.

12The staff has the option initially to request documents and information through the use of a voluntary “access letter” in the place of a CID.
help assess the adequacy of the substantiation for the claim.\textsuperscript{13}

If formal action is warranted, the FTC can proceed either administratively or in federal court.\textsuperscript{14} Administrative orders typically include cease-and-desist provisions covering the specific challenged claims, along with broader “fencing-in” requirements that other claims be truthful and adequately substantiated. Violations of an administrative order can result in civil penalties that accrue at the rate of $16,000 per violation,\textsuperscript{15} and can reach $1 million and higher.\textsuperscript{16} They are thus a strong deterrent against future deceptive advertising.

The majority of the Commission’s cases against deceptive supplement marketing in recent years, however, have been brought in federal district court pursuant to Section 13(b) of the FTC Act.\textsuperscript{17} This option allows the Commission to obtain both preliminary and permanent injunctive relief as well as other equitable remedies, such as consumer redress or disgorgement.

\textsuperscript{13} In addition, the FTC staff routinely consults with FDA in assessing the scientific validity of a claimed supplement benefit.

\textsuperscript{14} In both administrative cases and federal court cases, the advertiser frequently elects to settle the charges by entering into a consent agreement or stipulated order without admitting liability. In some instances, where the deceptive practice is limited in scope, duration, or severity and quickly corrected, the FTC staff may issue a public closing letter instead. The letter typically outlines the nature of the FTC’s concerns and explains why formal action was not taken. See, e.g., Pharmavite LLC (FTC staff closing letter addressing overstated cholesterol reduction claims for NatureMade CholestOff) (Apr. 16, 2009), http://www.ftc.gov/os/closings/090416cholestoffclosingletter.pdf.


\textsuperscript{17} 15 U.S.C. § 53(b).
of ill-gotten gains.\textsuperscript{18} In cases of outright fraud or repeated law violations, the Commission has sought bans on marketing of certain categories of products and the posting of performance bonds.\textsuperscript{19}

The Commission works to make sure its enforcement actions hold accountable not just the supplement manufacturer but also other parties involved in the creation or dissemination of the deceptive claims, including company owners and key officers, ad agencies, infomercial producers, distributors, and retailers.

\section*{B. Recent Examples of Enforcement Efforts}

In the past two years alone, the FTC has filed or settled 30 cases involving supplements promoted with false or unsubstantiated claims for everything from the common cold to cancer. The Commission has also worked with FDA and foreign authorities to conduct Internet sweeps targeting especially pervasive or pernicious trends. Recent sweeps have resulted in more than 130 warning letters by the FTC, followed by targeted law enforcement against those failing to stop or modify claims.

\subsection*{1. Representative Cases}

\textit{Airborne Health, Inc. and Other Cold and Flu Products:} In 2008, the Commission settled charges of false and unsubstantiated claims for Airborne effervescent tablets.\textsuperscript{20} The marketers of Airborne engaged in a nationwide television and print campaign promoting

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\textsuperscript{18}See, e.g., \textit{FTC v. Airborne Health, Inc.}, No. CV-08-05300 (C.D. Cal. final order Sept. 5, 2008) (up to $30 million for consumer redress program in connection with deceptive cold prevention and treatment claims).
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\textsuperscript{19}See, e.g., \textit{FTC v. 7 Day Mktg., Inc.}, No. CV08-01094-ER-FFM (C.D. Cal. final order Feb. 17, 2008) (banning marketers of herbal colon cleanse to cure cancer from involvement in any infomercial marketing).
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\textsuperscript{20}\textit{FTC v. Airborne Health, Inc.}, No. CV-08-05300 (C.D. Cal. final order Sept. 5, 2008).
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Airborne as clinically proven to prevent colds and flu and protect against exposure to germs in crowded environments, like airplanes. The FTC lawsuit named not only the company, but also the inventor of the product and her husband. The settlement required that the defendants contribute up to an additional $6.5 million to a private class-action settlement, resulting in a total of $30 million available for consumer redress.

Airborne conducted such a successful marketing campaign that it spurred several private label copycat cold remedy products. National retail chains replicated the supplement using similar package claims and placing their products next to Airborne on the shelf. In response, the Commission brought parallel cases in 2009 against three major retail chains, Rite Aid, CVS, and Walgreen, as well as Improvita Health Products, a contract manufacturer and distributor that sold the copycat supplement to several retail chains. Each of these additional cases has settled with orders that include permanent injunctions and funds for consumer redress.

**Direct Marketing Concepts, Inc.:** An FTC lawsuit in federal district court against the marketer of two dietary supplements, “Coral Calcium” and “Supreme Greens,” culminated in court orders in 2009 against various defendants that included monetary judgments totaling nearly


22 *FTC v. CVS Pharmacy, Inc.*, No. CA09-420 (D.R.I. final order Sept. 9, 2009) ($2.8 million for consumer redress).


$70 million. Infomercials for the products claimed they would cure many serious diseases, including cancer, Parkinson’s, heart disease, and autoimmune disease. The order also addressed the defendants’ failure to disclose that the promotional programming was, in fact, paid advertising, and their practice of charging consumers on an ongoing basis without their consent.

**Roex, Inc.:** This Commission action involved an unusual marketing technique, with products sold by means of a nationally broadcast, live call-in radio program titled “The Truth About Nutrition.” The Commission settled charges against the company, its principal, and one of the radio show hosts, for allegedly deceptive claims that an infrared sauna device would treat cancer, and that various supplements would treat cancer, AIDS, diabetes, Alzheimer’s, Parkinson’s, and other diseases. The order required the defendants to pay $3 million for consumer redress. In March 2010, the Commission distributed refunds to more than 5,700 consumers with the average check totaling approximately $500.

**David J. Romeo and Stella Labs, LLC:** Deceptive weight loss claims have long plagued the supplement industry. The Commission often sees a flurry of deceptive marketing campaigns with each new weight loss ingredient introduced to the market. In this matter, the Commission challenged claims made by a supplier of *Hoodia gordonii*, derived from a cactus plant native to southern Africa, that the ingredient was a powerful appetite suppressant proven to reduce caloric intake by 1,000 to 2,000 calories per day. The FTC complaint also charged the company with selling fake hoodia to its trade customers who used the ingredient to manufacture weight loss

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supplements. The case is currently in litigation in federal district court.

_Basic Research, LLC_: In another weight loss supplement case, involving a recidivist already under order for the allegedly deceptive marketing of multiple dietary supplements, the FTC has challenged claims for Relacore and Akävar 20/50, supplements that have been promoted in national magazines with claims such as “eat all you want and still lose weight.”\(^{28}\) The Department of Justice, at the FTC’s request, filed suit in federal court last November, charging the company and related parties with violating a 2006 FTC order that involved similar deceptive weight loss marketing and imposed a $3 million judgment. The case is currently in litigation.

2. **Enforcement Sweeps**

While many of the FTC’s enforcement actions target individual supplement manufacturers, the FTC often collaborates with FDA and international authorities to tackle certain categories of health fraud more broadly. The FTC uses enforcement sweeps, for example, to address widespread online marketing of products for serious health ailments, like cancer or diabetes. Such marketing scams are particularly cruel by preying on consumers when they are most vulnerable and desperate, offering false hope and even luring them away from more effective treatments. For every serious disease, especially those with no proven cure, there are hundreds of marketers engaging in such fraud, mostly through Internet marketing.

The FTC also conducts sweeps to stop the fraudulent marketing that often follows any new public health scare. In recent years, the FTC has seen a proliferation of products, including dietary supplements, that purportedly protect against, treat, or cure anthrax, SARS, avian flu, and H1N1 flu. The FTC has found that the best way to quickly shut down such scams is to issue

\(^{28}\textit{FTC v. Basic Research, LLC}, \text{No. 09-CV-972 (D. Utah filed Nov. 2, 2009).}\)
warning letters to as many of these marketers as possible and then follow with targeted cases, as needed.

The FTC has also successfully used smaller scale enforcement sweeps to address exaggerated or unfounded claims for the ingredient du jour in the supplement industry. These might target the latest ingredient promising to cause effortless and dramatic weight loss, or to treat the common cold, or to make children smarter. In such cases, bringing a group of parallel law enforcement actions can be effective in curbing a deceptive marketing trend.

**Operation False Cures - Cancer Sweep:** The most recent of the FTC’s large-scale Internet sweeps was an enforcement effort coordinated with FDA and the Canada Competition Bureau. Initiated with an online surf for fraudulent cancer cure products in June 2007, the FTC sent warning letters via e-mail to 112 Web sites marketing everything from essiac tea and other herbal blends (some containing highly toxic herbs), to laetrile, shark cartilage, coral calcium, mushroom extract, and black salve (a corrosive product that can cause burns and scarring) – all promoted to prevent, cure, or treat cancer. Of the 112 sites contacted by the FTC, nearly 30 percent either shut down their sites or removed the cancer claims. The remainder were reviewed to determine whether law enforcement was appropriate, with some referred to FDA or Canadian authorities. The FTC followed this effort with 11 enforcement actions charging companies and individuals with making false or unsubstantiated cancer claims, and in some cases even misrepresenting that there was scientific proof that their products worked.

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29 In coordination with the FTC, FDA issued warning letters to 28 U.S. companies and two foreign individuals for marketing unapproved drugs, and the Canada Competition Bureau sent warning letters to Canadian companies selling fraudulent cancer cures online.

As of this month, ten of those 11 cases have been successfully settled or litigated, resulting in orders that bar future false or unsubstantiated claims and also require notification to past customers informing them that little or no evidence exists to support the efficacy of the products they purchased and urging them to consult with their doctors.\textsuperscript{31} Four of the settlements also imposed monetary judgments. In addition to aggressively targeting Internet scammers hawking fraudulent cancer cures, the Commission launched an innovative consumer education campaign to teach consumers how to spot and report such scams.\textsuperscript{32}

**H1N1 Flu Sweep:** The rapid spread of the H1N1 flu virus last year and mounting public fears about the epidemic led to a spate of online marketing scams. The FTC worked with members of the International Consumer Protection Enforcement Network (“ICPEN”) to conduct an Internet surf that identified products – including supplements, homeopathic products, air filtration devices, and cleaning agents – for curing, treating, and preventing the spread of the H1N1 virus.\textsuperscript{33} As part of this sweep, the FTC sent warning letters to 20 Web site operators making questionable claims and referred another 13 Web site operators, believed to be located outside the U.S., to foreign law enforcement authorities. In addition, the FTC and FDA sent the first joint warning letter to Weil Lifestyle LLC, regarding a dietary supplement containing the

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\textsuperscript{31}One case was dismissed due to insufficient evidence that the respondents were responsible for the Web site claims at issue.

\textsuperscript{32}See discussion infra, Section IV.

\textsuperscript{33}See Press release, FDA, FTC Warn Public of Fraudulent 2009 H1N1 Influenza Products (May 1, 2009), http://www.ftc.gov/opa/2009/05/swineflu.shtm. The H1N1 Internet sweep was the eleventh joint enforcement effort conducted by members of ICPEN, including both the FTC and FDA.
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herb astragalus that the company claimed could cure H1N1 infections. As with the cancer sweep, the FTC also engaged in consumer outreach in the form of an alert to warn the public of such scams.

**Omega-3 for Children’s Brain and Vision Function:** Most recently, the FTC identified an increase in the number of Omega-3 fatty acid supplements and food products being promoted for school-aged children’s brain and vision function and development. Many of the claims include specific promises of increased intelligence, better focus, mood, memory, concentration, and visual acuity – benefits that lack adequate scientific support. To address this trend, the Commission staff sent letters to 11 companies, advising them to review their labeling and advertising claims. In those letters, the FTC staff described its recent investigation into similar claims by Northwest Natural Products, Inc. (“NNP”), the marketer of “L’il Critters Omega-3 Gummy Fish,” a children’s dietary supplement. The letters advised other marketers that NNP had quickly modified its marketing materials to remove unsubstantiated claims and urged recipients to take the same steps to ensure compliance. The FTC staff is now following up to ensure appropriate responsive actions are taken.

**IV. FTC Consumer Education Efforts**

The Commission complements its law enforcement activities with a variety of innovative

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34See FTC/FDA Joint Warning Letter to Weil Lifestyle LLC (Oct. 15, 2009), www.fda.gov/iceci/enforcementactions/warningletters/ucm186837.htm. In response to the joint warning, Dr. Andrew Weil, the popular integrative medicine physician affiliated with the Web site, agreed to drop or modify all identified claims.


education and outreach efforts for both consumers and industry. The FTC’s consumer outreach has been especially strong on subjects related to health and safety. The agency routinely issues consumer alerts, brochures, and uses other creative approaches, like YouTube videos and Internet microsites, to help consumers safely navigate the supplement marketplace.

For example, as an adjunct to its cancer cure sweep, the Commission launched a campaign, “Cure-ious? Ask,” to alert consumers to cancer scams and encourage them to discuss all treatment options with their doctors. The campaign has its own Web site, featuring a video, with advice on how to spot and report questionable claims and a list of resources on cancer treatments from a variety of government agencies. The Commission’s partners in this effort are 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. The campaign is also mentioned in numerous blogs related to cancer and health.

The Commission also routinely issues consumer alerts, such as its alert in connection with its H1N1 sweep, which warned consumers of deceptive sales pitches for H1N1 treatments, and provided accurate information from the Centers for Disease Control and Prevention about how H1N1 spreads and how to limit exposure to the virus.

Beyond these topic-specific consumer education efforts, the FTC has created several general consumer education brochures related to health, safety, and the efficacy of dietary

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37See http://www.ftc.gov/curious.

supplements. For example, the booklet “Who Cares: Sources of Information About Health Care Products and Services” is aimed at older consumers, their families, and caregivers. It includes information on dietary supplements, weight loss products, miracle cures, and alternative and complementary medicine. These materials are regularly updated and supplemented with assistance from the FDA, NIH/ODS, and other agencies.

V. Conclusion

The Commission will remain vigilant in protecting consumers against fraud and deception in the dietary supplement market. The agency will continue to work closely with FDA and other law enforcement partners to seek strong remedies against unscrupulous marketers. It will also continue to reach out to supplement users to educate them about how to use supplements safely, where to turn for reliable and accurate information about the benefits of supplements, and how to avoid being scammed. The Commission appreciates this opportunity to describe its efforts to the Committee.

39 The booklet is available online at http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea17.pdf. Multiple print copies can be ordered free of charge at http://bulkorder.ftc.gov/.