



Federal Trade Commission

**Remarks of Lydia B. Parnes
Director, Bureau of Consumer Protection
Federal Trade Commission
51st Annual FDLI & FDA Conference
Washington, D.C.
March 26, 2008**

**“Anticipating New Consumer Protection Challenges in the
Food and Drug Marketplace”**

I. Introduction¹

I would like to thank the Food and Drug Law Institute for inviting me to be part of their annual conference. I would also like to extend my congratulations to this year's FDA Alumni Association Wiley Award winner, John Villforth. I know that everyone who has participated in FDLI's programs has benefitted from the wisdom and insight that John brought to FDLI following his long and distinguished career at FDA.

I understand that one of the themes of this year's conference is the challenge that government faces in keeping up with the rapidly evolving food and drug marketplace. Science and technology is driving innovations in all areas, including nutrition and health-related fields. New foods, drugs, and dietary supplements hit the marketplace every day. In 2006, for example, over 20,000 new products were introduced, just in the food and beverage industry.² Some of these offered fewer calories and better nutrition to improve overall health. Some of them contained functional ingredients proven to deliver very specific health benefits, like lower cholesterol.

As long as new products are grounded in sound nutrition and medical science, that's great news for consumers. If products reach the market with claims that are still unproven, however, that's bad, both for consumer health and for a healthy and competitive industry. Government must find the right balance between giving consumers timely access to products that can improve their lives, while still protecting them from products that are ineffective or may

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

²See "The U.S. Food Marketing System: Recent Developments 1997-2006," USDA, Economic Research Service (May 2007), available at, www.ers.usda.gov/publications/err42/.

even harm them.

II. Working with FDA

Earlier this morning, you heard from Commissioner Eschenbach about recent FDA initiatives. Relative to the FDA, the Federal Trade Commission is quite small. We are an independent agency with nearly 1100 employees and a budget of just over \$240 million. Our staff consists primarily of lawyers and economists. Although we do not have the scientific and technical expertise of the FDA, our staff has developed a keen understanding of marketplace forces and consumer behavior. Our expertise in the workings of the market is a valuable complement to FDA's oversight of the food and drug industry. That is why we frequently partner with the FDA on health issues. The two agencies share jurisdiction over foods, drugs, devices, dietary supplements and other health-related products pursuant to a longstanding agreement.³ Under this agreement, the FTC has primary responsibility to oversee the advertising of over-the-counter drugs, food, cosmetics, and devices, while the FDA regulates the labeling of these products. It is an arrangement that draws on the strengths of both agencies and has served consumers well for over 35 years.

Both the FDA and FTC are committed to protecting consumer welfare and promoting competition in the food and drug industries. The Commission's legal framework, however, is quite different from that of FDA. We are primarily a law enforcement agency, not a regulatory body. The FTC Act directs the agency to stop unfair and deceptive practices in commerce. Period.⁴ The mandate is broad. It encompasses nearly every product and service sector of the

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

⁴Federal Trade Commission Act, 45 U.S.C. § 45.

economy. It gives the Commission both a clear direction and leaves us with the flexibility to adapt quickly to the emerging marketplace. It is that flexibility that I would like to focus on this morning.

III. The Little Agency That Could

I am proud of the Commission's record of anticipating and responding quickly to new consumer protection challenges. Our uniquely simple legislative framework makes that possible. I think our small size benefits us too. The Commission is "The Little Agency that Could." Our limited numbers mean that our staff must be agile. We must move easily back and forth from high tech issues like spyware and identity theft, to environmental trends like the marketing of carbon offsets, to public health crises like childhood obesity. More importantly, our small size forces us to be creative in how we address problems in the market. We must draw on resources outside our agency. For that reason, we frequently call on private companies and industry groups to apply their technical know-how and creativity to consumer problems. Some may be skeptical, but I have seen industry create strong self-regulatory solutions in a shorter time, with tougher standards, and better enforcement than any federal agency could hope to implement.

We also rely on consumers themselves. The FTC is always finding new ways to reach consumers, alerting them to scams, and teaching them to be more savvy shoppers. Our teaser Web sites promoting the weight loss miracle – "Fat Foe Eggplant Extract" – and the diabetes cure – "Glucobate, Elixir of Muskmelon" – are just two examples.⁵ These teaser sites entice consumers to click to purchase our fictitious products, and then warn them against Internet fraud

⁵See Fat Foe teaser site, available at <http://wemarket4u.net/fatfoe/>, and Glucobate teaser site, available at <http://wemarket4u.net/glucobate/index.html>.

and direct them to more reputable sources of health information, like the CDC.

IV. Responding to New Consumer Health Challenges

A. Childhood Obesity Initiatives

Turning to the theme of this conference, the FTC's consumer protection mission is constantly being reshaped by the dynamics of the marketplace and by consumers' needs. As consumers face new health challenges, we must make sure that the market responds to meet those challenges in a responsible way. For example, when it became clear that childhood obesity was increasing at an alarming rate, the FTC made it a priority to identify actions the food industry could and should take to reverse the trend.

For the past three years, the FTC has advocated for strong self-regulatory programs and other industry solutions. Following a joint FTC/HHS workshop on this issue in 2005, the two agencies issued a joint report. That report laid out a series of recommendations for food and beverage companies and for the media to coordinate reforms in marketing food and nutrition to children. We were asking a lot of industry – joint public service campaigns on diet and health, nutritional guidelines for foods marketed to children, and fundamental changes in a variety of marketing practices, from the licensing of movie characters to in-school promotions.⁶

We have seen major developments since our workshop. The most dramatic was a sweeping collaborative effort by the food industry to change the profile of foods advertised to children. In late 2006, the Council of Better Business Bureaus and the BBB's National Advertising Review Council announced the Children's Food and Beverage Advertising

⁶*Perspectives on Marketing, Self-Regulation, & Childhood Obesity: A Report on a Joint Workshop of the Federal Trade Commission and the Department of Health and Human Services* (April 2006), available at <http://www.ftc.gov/os/2006/05/PerspectivesOnMarketingSelf-Regulation&ChildhoodObesityFTCandHHSReportonJointWorksho.pdf>.

Initiative.⁷ Thirteen major food companies are now participating. Most of these companies have pledged to limit their advertising to children under 12 to only those foods meeting specific calorie or nutritional standards. Three have pledged not to direct any advertising to children under 12. All 13 companies have also agreed to limit the use of licensed characters to healthier products and messages, to end advertising in elementary schools, and not to seek product placement in children's media. I am confident, that as this initiative matures, we will see more companies join. I also hope that industry will expand its programs beyond TV, radio, and print to other forms of children's marketing and promotion, such as product packaging and other in-store point-of-sale advertising.

On the media side, we are seeing entertainment companies like Disney, Nickelodeon, and the Cartoon Network use their considerable appeal to reach children with positive health messages. All three have now adopted policies to limit the licensing of their characters to nutritious foods. You will now see Mickey Mouse and SpongeBob on many products in the produce section of the grocery store. In addition, television networks like Ion Media, which produces children's weekend programming on NBC and Telemundo, are creating story lines that promote healthy eating and exercise.

Reversing childhood obesity trends will likely require years and even decades of concerted effort from all segments of society, not just industry. The FTC will continue to commit substantial resources and attention to this issue. As some of you are well aware, the Commission, acting at Congress's request, is currently conducting a comprehensive study of

⁷"New Food, Beverage Initiative to Focus Kids' Ads on Healthy Choices; Revised Guidelines Strengthen CARU's Guidance to Food Advertisers," (Nov. 14, 2006), *available at* <http://www/bbb.org/Alerts/article.asp?ID=728> .

food marketing to kids. This study will be the first of its kind. It looks beyond measured media, like television and print, to all forms of marketing and promotion. We are looking at how the food industry uses such techniques as product packaging, in-store promotions, character licensing, event sponsorship, and word-of-mouth marketing. No researcher has ever had access to the data we are collecting on many of these marketing techniques. In many cases, even the food companies themselves have never before compiled the data.

It is a massive undertaking for our staff and for the 44 food, beverage, and quick-serve restaurant companies that received our compulsory process orders last August. Submissions came in at the end of last year. I am grateful that the companies contacted were both thorough and conscientious in putting together their responses. Our staff is now analyzing the data and writing a report that we expect to release to Congress and the public this summer. We will report expenditures in aggregated form to protect the confidentiality of the companies. The effort will be well worth it. It will provide the first comprehensive look at the entire landscape of how foods are marketed to children. The report should help inform everyone's efforts to more effectively address childhood obesity.

B. Combating Health Fraud

While some health concerns may lend themselves to industry self-regulatory solutions, others respond only to tough law enforcement. We are always on alert for the latest health scams, and we rarely find ourselves lacking for targets. The obesity epidemic continues to fuel the market for weight loss fraud. For example, the marketers of "Slim Coffee" ran ads on several television networks, in magazines, and in Sunday newspaper inserts, promising that this instant coffee drink, containing hoodia, was "clinically proven" to cause weight loss of "up to 5 pounds a week and up to 20 pounds a month" – with no need to change eating habits. I am

pleased to report that the company and its principals settled with the FTC and agreed to a \$923,000 judgment, which has been suspended based on their inability to pay.⁸

Consumers desperate to lose weight easily and effortlessly were also the chosen target for Kevin Trudeau's latest scam. In 2004, the Commission banned Trudeau, author and infomercial host, from marketing any product or service by infomercial and ordered him to pay \$2 million.⁹ The extraordinarily broad ban resulted from his infomercial marketing Coral Calcium as a cure for cancer and other serious diseases. The ban, however, included a narrow exception allowing Trudeau to market books, provided he did not misrepresent their contents. In 2007 Kevin Trudeau published a 255-page hardback book called The Weight Loss Cure "They" Don't Want You to Know About. He promised in infomercials that his book offered a diet that was the "the easiest method known on planet Earth." People could lose weight while eating "whatever they want."

Those who fell for the hype and bought the book learned that they were facing a multitude of restrictions, including a grueling regimen of extreme calorie restrictions, daily injections of a prescription drug difficult to obtain in the U.S., and rules limiting exposure to fluorescent lighting and air conditioning. This was hardly the simple, easy program the infomercial promised. The FTC filed for contempt and the district court judge agreed.¹⁰ The next step will be a hearing to determine an appropriate remedy.

⁸See FTC Press Release, *Sellers of Hoodia Coffee Settle with FTC for Bogus Weight-Loss Claims* (Jan. 15, 2008) available at <http://www.ftc.gov/opa/2008/01/dietcoffee.shtm>.

⁹See FTC Press Release, *Kevin Trudeau Banned from Infomercials* (Sept. 7, 2004) available at <http://www.ftc.gov/opa/2004/09/trudeaucoral.shtm>.

¹⁰See FTC Press Release, *Federal Court Finds Kevin Trudeau in Civil Contempt* (Nov. 21, 2007) available at <http://www.ftc.gov/opa/2007/11/kt.shtm>.

Weight loss scams are a staple of our enforcement program, but there are many other forms of health fraud that the FTC must battle. At the risk of spoiling appetites before the lunch break, let me mention a recent FTC action against the marketer of a colon cleansing program – the “7 Day Miracle Cleanse Program.” Like Trudeau, the defendants chose the infomercial format to promise their program would treat, cure, or prevent AIDS, Alzheimer’s, diabetes, arthritis, and, of course, cause weight loss. One of the defendants appeared on the infomercial as the self-proclaimed “Health Man” and described how he had been diagnosed with both skin cancer and breast cancer. He said he had rejected his doctor’s recommendation to undergo surgery, chemotherapy, and radiation, and instead had been cured within weeks by the 7 Day Miracle Cleanse. As in the Trudeau case, the FTC’s final stipulated order included a broad ban on infomercial marketing. It also included a \$14.5 million dollar monetary judgment, suspended for inability to pay.¹¹ I should note that the case came to our attention as a referral from the Electronic Retailing Self-Regulation Program, a partnership of the Better Business Bureau and the Electronic Retailing Association. The ERSP is an excellent example of industry self-regulation as an effective complement to government.

The FTC also routinely partners with other US and foreign authorities to combat health fraud on the Internet. Over the years we have participated in several Internet surf efforts to identify web sites that are preying on the latest public health scare, from anthrax to SARS. We also target sites offering cures for serious diseases like diabetes and cancer. Our most recent effort was a three-day Internet surf for cancer cures, conducted with the FDA and Canadian authorities. The surf led to advisory emails to 104 websites, and referrals of twelve additional

¹¹See FTC Press Release *Marketers of 7 Day Miracle Cleanse Program Banned from Infomercials* (Feb. 27, 2008) available at <http://www.ftc.gov/opa/2008/02/7day.shtm>.

sites to foreign authorities. We are now following up with targeted enforcement against sites that did not modify or remove their claims.

V. Evolving Marketing Techniques

Just as we shift our resources to respond to shifting consumer protection needs, we must also anticipate and respond to evolving marketing methods. Companies no longer rely just on traditional print or television advertising, or even Web sites, to reach consumers. If we limit our efforts to these old-school media there will be gaping holes in our enforcement program.

In the last few years we have noticed a fundamental shift in the marketing landscape – away from a model where the company controls the message, into a realm where the consumer actively participates in shaping and disseminating information about a product or service. I’m talking about the world of blogs, social networking sites, user-generated content, message board postings, and “buzz” or viral marketing.

Under the heading of “what’s old is new again” marketers are coming back to that most powerful of selling messages – the word of mouth endorsement by one consumer to another. Genuine consumer promotions and product reviews are essential to a healthy and successful marketplace. And the new technologies that enable consumers to communicate their experiences instantly and electronically on a massive scale can also be positive. However, to the extent companies are involved in shaping or directing these communications, traditional advertising law still applies. Two things are clear. First, marketers should never disguise their own advertising as the personal opinions of consumers. Second, even when the message is genuinely originating from an individual, any relationship between that individual endorser and the marketer needs to be disclosed. Consumers will evaluate an endorsement differently if they are aware it is sponsored in some way.

Some practices clearly violate the FTC Act. Using a fake persona to post messages endorsing your product on an electronic message board, would certainly be considered a deceptive practice. So would creating a corporate blog that gives the false impression of being a personal blog, or commercial email schemes that appear to be sent from friends of the target. The Commission recently took action against Jumpstart Technologies for such a viral email scam. The company offered consumers free movie tickets in exchange for names and email addresses of five or more friends. Jumpstart then sent those friends emails that appeared to come from the initial consumer, with personal subject lines like “Hey” or “Happy Valentines Day.” Our complaint charged Jumpstart with violating the FTC Act and the CAN-SPAM Act, and Jumpstart was required to pay a \$900,000 civil penalty as part of its settlement.¹²

VI. Refining Enforcement Tools

There is one final example I would like to leave you with to illustrate how the Federal Trade Commission is constantly adapting to more effectively protect consumers. That example is our Criminal Liaison Unit. The FTC is a civil law enforcement agency. However, we are committed to protecting consumers from the worst perpetrators of fraud by encouraging their prosecution by criminal law enforcement agencies. We will also assist in those prosecutions when appropriate. In just the past year, federal and state criminal authorities have charged 81 FTC defendants and their associates with crimes arising from acts investigated or prosecuted by the Commission. Forty-seven of those defendants and associates were convicted or pled guilty to sentences totaling 140 years in prison.

As one example, in January 2006, the FTC filed a civil action in federal district court

¹²See FTC Press Release, *FTC Slams Spammer in Pocketbook* (Mar. 23, 2006) available at <http://www.ftc.gov/opa/2006/03/freeflixtix.shtm>.

against Berkeley Premium Nutraceuticals and its founder Steven Warshak.¹³ The defendants had been selling dietary supplements including Rogisen, Avlimil and Enzyte. You may have seen the ads for Enzyte – a purported cure for sexual dysfunction. The ads, featuring the very cheerful “Smiling Bob,” aired on many cable networks and in magazines like Forbes, Playboy, and Cosmopolitan. Consumers who signed up for “free” samples of these products were then enrolled in automatic shipping programs without their authorization. When they tried to cancel, they faced busy phone lines and Web sites that did not work. I am very happy to report that Smiling Bob is probably not smiling anymore. On February 26 of this year, Berkeley executives were convicted in a criminal case stemming from the FTC’s investigation and involving a cooperative effort of the Department of Justice, the FBI, the IRS, the US Postal Inspection Service, and FDA. The jury found several individuals guilty on 93 counts including conspiracy, money laundering, and obstruction of the FTC proceedings. The defendants will forfeit at least \$33 million in assets and are awaiting final sentencing.¹⁴

VII. Conclusion

I am proud of how agile the Federal Trade Commission is in anticipating changes in the marketplace and adapting to better protect consumers and foster healthy competition. We can shift resources quickly and easily to respond to a public health crisis like childhood obesity. We can partner with other authorities to target the latest Internet scams. We can apply the basic tenets of advertising law to new marketing techniques like viral emails. And we can tap into the

¹³See FTC Press Release, *FTC Charges Sellers of Avlimil, Rogisen, and Other Dietary Supplements* (Feb. 2, 2006) available at <http://www.ftc.gov/opa/2006/02/avlimil.shtm>.

¹⁴See Department of Justice Press Release, *Berkeley Executives Convicted of Conspiracy and Fraud in Connection with Sales of Dietary Supplements* (Feb. 26, 2008) available at <http://www.usdoj.gov/usao/ohs/Press/02-26-08.pdf>.

criminal enforcement resources of our sister agencies like the Department of Justice.

I hope that my remarks have given you a good overview of the FTC's efforts. I would be happy to take any questions.