

PREPARED STATEMENT OF

THE FEDERAL TRADE COMMISSION

on

ALTERNATIVE HORMONE REPLACEMENT THERAPY PRODUCTS

Before the

SENATE SPECIAL COMMITTEE ON AGING

Washington, DC

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I. Introduction

Chairman Kohl, Ranking Member Smith, and Members of the Committee, I am Eileen Harrington, Deputy Director of the Bureau of Consumer Protection of the Federal Trade Commission (“FTC” or “Commission”).¹ I appreciate the opportunity to discuss the Commission’s efforts to address the misleading online advertising of “alternatives” to hormone replacement therapy as well as its work to combat all types of Internet fraud.

Among its many benefits, the Internet provides consumers with access to a vast array of information and products, including health-related items. Unfortunately, the online medium also provides an opportunity for irresponsible marketers to prey on consumers with false or misleading claims that can cause economic injury and have potentially serious consequences for consumers’ health. Therefore, pursuant to its broad authority to prevent “unfair or deceptive acts or practices,”² the FTC has a longstanding and active program to protect consumers in the online environment.

This testimony provides an overview of the FTC’s efforts with respect to health-related fraud, including an explanation of its jurisdiction over health products and a discussion of the FTC/FDA project to address the misleading marketing of hormone replacement therapy alternatives. Pursuant to the Committee’s request, the testimony then discusses the FTC’s broader program to combat online scams in general.

¹ This written statement presents the views of the Commission. My oral testimony and responses to questions reflect my views and do not necessarily represent the views of the Commission or any individual Commissioner.

² Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45(a). In addition, Section 12 of the Federal Trade Commission Act prohibits the false advertisement of “food, drugs, devices, services, and cosmetics.” 15 U.S.C. § 52.

II. Health-Related Fraud

A. Overview

The Commission employs a three-pronged strategy to protect consumers from deceptive claims for health-related products: (1) law enforcement; (2) consumer education; and (3) business outreach. In each of these areas, the FTC works closely with its state, federal, and international partners, including state attorneys general, the Food and Drug Administration (“FDA”), and members of the Mexico, United States, and Canada Health Fraud Working Group.

On the law enforcement front, over the past decade the FTC has initiated 229 enforcement actions challenging false and misleading health and safety claims for products ranging from weight-loss pills to cancer cures. Of particular note, the Commission successfully challenged deceptive “fountain of youth” claims used to advertise purported human growth hormone (“HGH”) products in a number of cases.³ Additionally, in November the FTC obtained a federal court order requiring the purveyors of the Q-Ray bracelet to refund up to \$87 million to consumers who had purchased the product based on the defendants’ false representation that the bracelets significantly alleviated pain.⁴

On the consumer education front, the Commission has released a host of materials on how to avoid being victimized by false claims for everything from cure-alls, to indoor tanning, to

³ E.g., *FTC v. Pacific Herbal Servs.*, No. CV05-7247 (C.D. Cal.) (Prelim. Inj. Oct. 19, 2005), www.ftc.gov/os/caselist/pacificherbal/pacificherbal.shtml; *FTC v. Global Web Promotions*, No.04C3022 (N.D. Ill.) (Final Order June 16, 2005); www.ftc.gov/os/caselist/0423086/0423086.shtml; *FTC v. Great American Prods.*, No. 3:05CV170 (N.D. Fla.) (Final Order May 20, 2005), www.ftc.gov/os/caselist/0323247/0323247.shtml; *FTC v. Creaghan Harry*, No. 04C4790 (N.D. Ill.) (Final Order May 5, 2005), www.ftc.gov/os/caselist/0423085/0423085.shtml.

⁴ *FTC v. QT Inc.*, No. 03C 3578 (N.D. Ill.) (Final Order Nov. 13, 2006), www.ftc.gov/opa/2006/09/qray.htm.

diet and fitness products.⁵ For example, the FTC issued a Consumer Alert on HGH pills and sprays.⁶ Most recently, the Commission released its “Glucobate” teaser website advertising a phony miracle product to help consumers avoid deceptive diabetes claims.⁷

On the business outreach front, the Commission has created numerous materials geared toward helping businesses avoid making deceptive claims. For example, the FTC’s publication “Dietary Supplements: An Advertising Guide for Industry,” provides easy-to-understand explanations of advertising standards for the marketing of health products, along with many useful examples.⁸ Additionally, the Commission conducts advertising “surfs” looking for potentially violative claims, and then follows up with warning letters, which can ultimately lead to law enforcement action. For example, the FTC sent warning letters to more than 90 Internet marketers promoting purported HGH products for “anti-aging” benefits.⁹ Finally, the Commission has worked with industry trade associations to implement effective self-regulation procedures.

⁵ See, respectively, www.ftc.gov/bcp/online/edcams/cureall/coninfo.htm; www.ftc.gov/bcp/online/pubs/health/indootan.htm; and www.ftc.gov/bcp/online/edcams/fitness/index.html.

⁶ www.ftc.gov/bcp/online/pubs/alerts/hghalrt.pdf.

⁷ Teaser sites mimic real web pages, using common buzz words and making exaggerated claims like those found on many deceptive websites. At first glance, the teaser site appears to advertise a miracle cure. When consumers click for more information, they learn the ad is actually a consumer education piece posted by the FTC to warn consumers about rip-offs. See www.wemarket4u.net/glucobate.

⁸ www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm. This publication was accessed over 25,000 times last year.

⁹ www.ftc.gov/opa/2005/06/greatamerican.shtm.

On all three fronts, the FTC frequently collaborates with the FDA on health issues.

Although the FTC and the FDA both have jurisdiction over health-related products, the agencies coordinate closely pursuant to a longstanding agreement.¹⁰ Under this agreement, the FTC has primary responsibility to regulate the advertising of over-the-counter drugs, food, cosmetics, and devices, while the FDA regulates the labeling of these products. The FDA also has primary responsibility to regulate claims made in both the advertising and labeling of prescription drugs. In many cases, however, the agencies work together to leverage resources and have a greater effect on the marketplace. The agencies' project to address misleading claims for alternative hormone replacement therapy products sold on the Internet is a good example of these joint efforts.

B. Targeting Deceptive Claims for Hormone Replacement Therapy Alternatives

Hormone replacement therapy is medication containing female hormones that doctors prescribe to treat symptoms of menopause as well as other conditions. In 2002, the Women's Health Initiative (sponsored by the National Institutes of Health) terminated a clinical trial of hormone replacement therapy because the overall health risks (e.g., of heart disease and breast cancer) outweighed the benefits of the therapy.¹¹ This stunning news fueled the growth of a market promoting "natural alternatives" to hormone replacement therapy. These products

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

¹¹ National Institutes of Health News Release, July 9, 2002, www.nhlbi.nih.gov/new/press/02-07-09.htm. Since that time, researchers further analyzed the trial data and one recent review suggests that the heart risks may have been overstated. Jacques E. Rossouw, MD, *Postmenopausal Hormone Therapy and Risk of Cardiovascular Disease by Age and Years Since Menopause*, 297 JAMA 1465-1477 (2007).

include “natural” progesterone creams and sprays.¹² Some of the marketers claim that their “natural” progesterone products are safe and effectively prevent, treat, or cure serious diseases, such as cancer, heart disease, and osteoporosis. However, the FTC is not aware of competent and reliable scientific evidence to substantiate these claims.¹³

Therefore, working in conjunction with the FDA, FTC staff surfed the Internet for websites claiming that their progesterone products were safe or could prevent, treat, or cure serious diseases. The staff used search engines to identify relevant websites and then examined the sites to determine whether they made potentially deceptive claims. The FDA staff conducted its own surf to identify websites. The FTC and FDA staff coordinated efforts and compared surf results so that each agency would send letters to different targets and therefore have a greater impact. The FTC found 34 websites making questionable safety and disease prevention claims and sent warning letters to each. The FDA staff sent letters to an additional 16 websites.

The FTC staff’s emails explained that the marketers must have competent and reliable scientific evidence to substantiate any health claim they make about their products. The emails urged the marketers to review their product claims to make sure they complied with the law. In addition, the FTC’s emails provided information about FDA law, as well as links to resources the

¹² In addition, some online pharmacies offer compounded hormones which they claim are customized to an individual’s needs based on an analysis of a saliva sample.

¹³ FTC law requires that marketers possess competent and reliable scientific evidence to substantiate claims about the safety and efficacy of health-related products, including dietary supplements. FTC Policy Statement Regarding Advertising Substantiation, *appended to Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984), www.ftc.gov/bcp/guides/ad3subst.htm.

marketers could consult for guidance.¹⁴ Likewise, FDA warning letters provided information about FTC law.

The FTC staff recently conducted a follow-up review of the websites to determine if the sites removed or modified the safety or disease prevention claims. Although many sites revised their claims, unfortunately, slightly more than half of the websites, 19 of 34, continue to sell “natural” progesterone creams and sprays by making unsubstantiated claims that they are safe or can treat or prevent cancer, heart disease, or osteoporosis. The FTC staff now is following up with the companies and will make enforcement recommendations.

III. Internet Fraud

The Commission’s efforts to halt deceptive, online, health-related claims are part of a larger, aggressive program to combat Internet fraud. For over a decade, the FTC has employed the same three-pronged strategy discussed above – law enforcement, consumer education, and business outreach – to address a wide array of online consumer protection problems, including data security, pretexting, identity theft, children’s online privacy, spam, and spyware.

Online fraud generally falls into two categories: (1) old-fashioned schemes that have simply moved online, such as pyramid schemes, deceptive work-at-home opportunities, and false product claims;¹⁵ and (2) Internet trickery and other scams that exploit new technology and are

¹⁴ See FTC Press Release and Sample Warning Letter, www.ftc.gov/opa/2005/11/hormone.htm.

¹⁵ See, e.g., *FTC v. SkyBiz.com, Inc.*, No. 01-CV-396-EA (N.D. Okla.) (Stipulated Final Order Jan. 28, 2003), www.ftc.gov/opa/2003/03/skybiz.htm (pyramid); *FTC v. Stuffingforcash.com*, No. 02C 5022 (N.D. Ill.) (Stipulated Final Order Jan. 30, 2003), www.ftc.gov/opa/2003/07/spammers.htm (work at home); *FTC v. Phoenix Avatar, LLC*, No. 04C 2897 (N.D. Ill.) (Stipulated Final Order Mar. 29, 2005), www.ftc.gov/opa/2005/03/phoenix.htm (diet patches).

unique to the computer age, such as pagejacking, phishing, and modem hijacking.¹⁶ Since 1994, the FTC has filed 538 actions against individuals and corporations that have used the Internet to unleash a wide variety of deceptive and unfair practices on American consumers. The Commission's efforts to address deceptive spam and spyware illustrate this broader Internet fraud program and the tools the FTC employs to combat online scams.

Since 1997, the Commission has filed 89 actions against 241 defendants in which spam was an integral element of a scheme that harmed consumers.¹⁷ Twenty-six of these cases were filed after Congress enacted the CAN-SPAM Act,¹⁸ which, among other things, prohibits email senders from using deceptive message headers and subject lines. In many instances, scam artists use unsolicited commercial email to put a new twist on schemes that previously could be conducted in the offline world. For example, last year the FTC alleged that Internet marketer Jumpstart Technologies disguised commercial email messages to appear as personal messages from friends and misled consumers as to the terms and conditions of its "free" movie ticket promotions. To resolve those allegations, the company paid \$900,000, the largest civil penalty obtained under the CAN-SPAM Act.¹⁹ Deceptive spam also can be part of a scheme that is

¹⁶ See, e.g., *FTC v. Carlos Pereira*, No. 99 Civ. 562 (E.D.N.Y.) (Final Order Jan. 24, 2005), www.ftc.gov/opa/1999/09/atariz.htm (pagejacking); *FTC v. Hill*, No. H 03-5537 (S.D. Tex.) (Stipulated Final Order May 24, 2004), www.ftc.gov/opa/2004/03/phishinghilljoint.htm (phishing); and *FTC v. Sheinkin*, No. 2-00-3636-18 (D.S.C.) (Stipulated Final Order Aug. 15, 2001), www.ftc.gov/opa/2001/08/sheinkin.htm (modem hijacking).

¹⁷ Two of these cases addressed the deceptive sale of human growth hormone. *Supra* note 3.

¹⁸ Controlling the Assault of Non-Solicited Pornography and Marketing Act, 15 U.S.C §§ 7701-7713.

¹⁹ *United States v. Jumpstart Techs., LLC*, No. C-06-2079 (N.D. Cal.) (Stipulated Final Order Mar. 22, 2006), www.ftc.gov/opa/2006/03/freeluxtix.htm.

unique to the Internet. For example, in one case the FTC alleged that a defendant's email messages claimed that consumers won a Sony PlayStation in order to lure consumers to an adult website and surreptitiously redirect their Internet connections through a 900-number that charged them up to \$3.99 a minute for the new connection.²⁰

The FTC also has taken law enforcement actions against distributors of spyware – another technology-driven scheme that provides digital data thieves with a back door into consumers' online lives. Spyware is downloaded without authorization and may be used to send high volumes of pop-up ads, redirect computers to unwanted websites, monitor Internet surfing, or record consumers' keystrokes, which, in turn, could lead to identity theft. In the past three years, the Commission has filed 11 cases against purveyors of spyware, disgorging over \$12.9 million of their alleged ill-gotten gains. In the Commission's most recent spyware case, the FTC alleged that Direct Revenue, LLC surreptitiously installed advertising software programs, which monitored Internet use to display targeted pop-up ads on consumers' computers, and deliberately made the programs difficult for consumers to identify and remove. To settle these charges, Direct Revenue agreed to disgorge \$1.5 million and to abide by injunctive provisions that will protect consumers from these practices in the future.²¹

The FTC employs a number of tools to develop its cases targeting online fraud. For example, the Commission identifies potentially violative commercial email through its spam database. Each day, the FTC receives approximately 300,000 pieces of spam – forwarded by

²⁰ *FTC v. BTV Industries*, CV S-03-1306 (D. Nev.) (Stipulated Final Order Nov. 25, 2003), www.ftc.gov/opa/2004/02/playstation2.htm.

²¹ *In re DirectRevenue, LLC*, FTC File No. 052-3131 (Consent Agreement Feb. 16, 2007), www.ftc.gov/opa/2007/02/directrevenue.htm.

computer users to spam@uce.gov – and stores it in a large database, which currently houses more than 400 million pieces of unsolicited commercial email, including emails regarding apparently bogus health claims.

The FTC's Consumer Sentinel database also plays a central role in the agency's law enforcement efforts. The Consumer Sentinel database contains over 3.7 million consumer fraud and identity theft complaints filed with the FTC; other federal, state, and local law enforcement agencies; and private organizations. The FTC, as well as more than 1,600 law enforcement entities worldwide, use the database to identify scams, specific companies generating high levels of complaints, and individual consumers who may have been harmed by illegal activity.²²

In addition, the recently-enacted US SAFE WEB Act²³ provides the Commission with important new tools to fight online fraud that crosses international borders. The Commission's efforts to combat illegal spam, deceptive health-related advertising, and spyware illustrate the need for these tools. Spam is often routed through servers and proxies located overseas and contains links to websites hosted by foreign companies. In addition, sellers of bogus health-related products may be located in foreign countries, but can promote their products to U.S. consumers using the Internet and satellite TV. Spyware distributors also can be located overseas or use foreign ISPs to host their websites. Therefore, in each of these situations, scammers, consumer witnesses, and money derived from scams are located in foreign countries. To help

²² A number of the law enforcement entities that have access to the Consumer Sentinel database investigate health-related matters, including the FDA, state attorneys general, the California Department of Consumer Protection, the Connecticut Department of Consumer Protection, the Montana Department of Administration's Office of Consumer Protection, and the Texas Department of Health.

²³ Undertaking Spam, Spyware, and Fraud Enforcement With Enforcers Beyond Borders Act of 2006, Pub. L. No. 109-455, 120 Stat. 3372 (2006).

overcome the challenges of investigating and prosecuting these types of international fraud, the US SAFE WEB Act strengthens the FTC's ability to cooperate with its foreign counterparts, gather information from international sources, and follow the money trail without tipping off the fraud's perpetrators.

As with health-related fraud, the FTC combines its law enforcement efforts against all types of Internet fraud with consumer education and business outreach campaigns. The FTC has produced a wide array of materials to educate consumers on how to spot and avoid online scams and to increase business awareness on how to comply with the law. For example, the award-winning website, OnGuardOnline.gov, contains tips, articles, videos, and interactive materials to educate consumers on guarding against Internet fraud, filter spam, secure their computers, and protect their personal information. The FTC developed OnGuardOnline in conjunction with industry partners and other agencies, and since its launch in late 2005, the site has attracted more than 3.5 million visits. The FTC also disseminates a variety of business education materials, including materials to inform businesses about complying with the CAN-SPAM Act,²⁴ and publications providing advice on making clear disclosures in online ads.²⁵

IV. Conclusion

The FTC has been involved in policing the Internet for more than a decade and will continue to protect consumers from the various types of online fraud. As technology and scams change, the Commission continues to shift its resources to target those frauds that cause the most harm to consumers. In addition, the FTC will continue its efforts to ensure the truthfulness and

²⁴ See www.ftc.gov/bcp/online/pubs/buspubs/canspam.htm.

²⁵ See www.ftc.gov/bcp/online/pubs/buspubs/dotcom/index.pdf.

accuracy of advertising for health-related products, regardless of the medium in which the ads appear. This includes efforts against deceptive advertising targeted toward older Americans, who are among our most vulnerable populations. Thank you for providing the Commission an opportunity to appear before the Committee.