Prepared Statement of

the Federal Trade Commission on

"The Internet Sale of Prescription Drugs From Domestic Websites"

Before the

Committee on Government Reform

United States House of Representatives

Washington, D.C.

March 27, 2003

Mr. Chairman and members of the Committee, I am Howard Beales, Director of the Bureau of Consumer Protection of the Federal Trade Commission. I am pleased to have this opportunity to discuss the Commission's consumer protection activities relating to the online marketing of health products and specifically prescription drugs.[1]

The Commission is charged by Congress with preventing deceptive or unfair acts or practices

[1] This written statement presents the views of the Federal Trade Commission. Responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

[2] 15 U.S.C. § 45(a). In addition, Section 12 of the FTC Act prohibits the false advertisement of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52.

adult users in 1998[3] to over 70 million by October 2002.[4] Moreover, it is clear that consumers are turning to the Internet not just for health information but to purchase health care products as well. Unfortunately, the online medium also provides an easy opportunity for irresponsible marketers to prey on sick or vulnerable consumers with false or deceptive claims that can cause potentially serious consequences to consumers' pocketbooks and, potentially, their health.

Pursuant to its broad authority to prevent unfair and deceptive practices, the Commission actively monitors Internet commerce. In health care, as in many other areas, the Commission takes a lead in enforcing existing laws to ensure that advertising claims are not misleading or deceptive. Moreover, in the area of Internet commerce, the Commission has been sensitive to concerns that Internet advertising be treated the same as advertising in other media.

Operation Cure.All is an integral part of the Commission's campaign against the marketing of fraudulent health-related products on the Internet. The initiative began in 1997 in response to rising concerns about the proliferation of questionable marketing claims for health products on the Internet. *Operation Cure.All* is an on-going, coordinated law enforcement and consumer/business education initiative targeting deceptive and misleading Internet promotion of products and services that promise to cure or treat serious diseases or conditions such as cancer, HIV/AIDS, arthritis, diabetes, multiple sclerosis, and heart disease. The FTC works with numerous law enforcement partners including the Food and Drug Administration ("FDA"), Health Canada, the Competition Bureau of Industry Canada,

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[3] Cyberdialogue, Inc. (June 1999).

[4] Pew Internet & American Life Project, *Counting on the Internet: Most Expect to Find Key Information Online, Most Find the Information They Seek, Many Now Turn to The Internet First* (Dec. 29, 2002).

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[7] *Western Botanicals, Inc., et al*., Civ. Action No. CIV.S-01-1332 DFL GGH, (E. D. Cal., filed July 13, 2001) (Stipulated Final Order) and *Christopher Enterprises, Inc., et al*., Civ. Action

devices,[17] magnetic therapies,[18] and unproven cancer therapies delivered in Mexico.[19] Copies of all *Operation Cure.All* cases are available on the Commission's website at www.ftc.gov. Overall, the Commission has brought 105 cases in the last five years challenging deceptive and misleading health-related claims in advertising.

Consumer education is the third critical component of *Operation Cure.All*. The FTC uses each case as another opportunity to get consumers the information they need to protect themselves. For example, the Commission, in conjunction with the FDA, published a consumer education brochure, *Miracle Health Claims: Add a Dose of Skepticism*, and an online consumer feature, *Health Claims*

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[17] *Western Dietary Products Co., et al.*, Civ. Action No. CO1-0818R (W.D. Wash., filed Dec. 26, 2001) (Stipulated Final Order) and *Dr. Clark Research Assoc., et al., d/b/a Dr. Clark Zentrum*, Civ. Action No. l:03CV0054, (N.D. Ohio, filed Jan. 8, 2002) (complaint for permanent injunction and other equitable relief). Among other products, the defendants sold an electrical unit called the "Zapper" for the treatment and cure of cancer, Alzheimer's, diabetes, arthritis, and HIV/AIDS. Another device case was *Michael Forrest, d/b/a Jaguar Enterprises of Santa Ana, a/k/a Jaguar Enters.*, Dkt. No. C-4020 (July 30, 2001) (consent). The respondents claimed that their electronic therapy devices known as, among others, the "Black Box," "Magnetic Pulser," "Beck-Rife unit," and "Portable Rife Frequency Generator," would cure or prevent cancer and other serious diseases. The defendants also sold a number of "Miracle Herbs," for the treatment of cancer, AIDS, and bacterial and viral infections.

[18] *Magnetic Therapeutic Techs., Inc.* Dkt. No. C-3897 (Sept. 7, 1999) (consent) and *Pain Stops Here! Inc.* Dkt. No. C-3898 (Sept. 7, 1999) (consent). The respondents marketed magnetic devices to treat or alleviate numerous medical problems and diseases, including cancer, liver disease, arthritis, and high blood pressure.

[19] *Biopulse International, Inc., et al.*, Civ. Action No. C023511 (N.D. Cal., July 23, 2002) (Stipulated Final Order). Biopulse was a U.S.-based company offering its purported treatments in a clinic in Tijuana, Mexico. The defendants used two "therapies" in this clinic: (1) the so-called "insulin-induced hypoglycemic sleep therapy" which involved injecting insulin into cancer patients to "starve" cancer tumors, among other things, and which typically cost up to $39,900; and (2) the so-called "Acoustic Lightwave Therapy" which was based on the so-called "Rife machine" technology (allegedly worked by emitting frequencies that purportedly destroyed cells or organisms that caused arthritis, candida yeast, diabetes, flu, headaches, parasites, lyme disease, pneumonia, and some cancers).

on the Internet: Buyer Beware. These publications have been widely disseminated.[20] In addition to reaching consumers through these materials, the agency also has set up a "teaser" site which mimics a website selling a product to treat arthritis.[21] Teaser sites attract and then educate consumers who may be lured by questionable claims on commercial sites.

In addition to *Operation Cure.All*, the Commission also has conducted an initiative targeted at the marketing of bioterrorism-related products on the Internet. Shortly after the tragedy of September 11 and subsequent events, the FTC executed this initiative with the assistance of the FDA, several State Attorney General offices,[22] and the California Department of Health Services. As a result of the project, the FTC sent fifty warning letters to website operators marketing health-related products, such as dietary supplements, advising them to stop making unsubstantiated bioterrorism representations. All but three of these sites are now in compliance, or under investigation by other agencies. Prompt FTC enforcement action also prevented the marketing of a home test kit for anthrax that did not work, and stopped a seller

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[20] Nearly fifty thousand copies of the *Miracle Health Claims* brochure were distributed in FY02. The online English version of this brochure was accessed 28,366 times during FY02, and the Spanish version has been accessed 1,305 times since May 2002. The *Buyer Beware* online consumer feature was accessed 3,526 times during FY02. In May 2002, the FTC also launched a special website for this initiative, called *Operation Cure.All*. Between October 2002 and March 2003, the website was accessed 26,920 times, and between May and September 2002, 9,515 times.

[21] This teaser site was visited 1,112 times in FY02.

[22] The Attorney General offices of Alaska, Arizona, Arkansas, California, Connecticut, Florida, Illinois, Iowa, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, Wyoming, and the District of Columbia Office of the Corporation Counsel, participated in this project.

[23] Robust competition between emerging Internet firms and incumbent "brick and mortar" firms

[24](...continued)
professional conduct." Federation of State Medical Boards, *Report of the Special Committee on Professional Conduct and Ethics*, Section IV (April 15, 2000).

[25] *See, e.g., State ex rel. and Kansas B. of Pharmacy v. Focus Med. Group, Inc.*, Civ. Action No. 99C749 (Shawnee Cty. Dist. Ct., filed June 9, 1999).

[26] Testimony of Kansas Attorney General Carla J. Stovall before the Health, Education, Labor, & Pensions Committee, Hearing on E-Drugs: Who Regulates Internet Pharmacies, March 21, 2000.

[27] *See, e.g., Illinois v. Express Today, Inc.*, Civil Action No. 99 CH 0452 (D. Ill., Sangamon Co.), filed Oct. 21, 1999.

[28] U.S. GENERAL ACCOUNTING OFFICE, INTERNET PHARMACIESel Civil A246 Tf (I)bs Twa.07w (HA-S 0 ap92

As the Committee is aware, the rapid growth in online sales of prescription drugs and the increase in the practice of online prescribing, both of which are taking place across state and even international borders, present significant technological and logistical challenges to the traditional regulatory framework.[30] In the past, state medical and pharmacy boards have expressed concerns that their existing enforcement tools are not adequate to police the online medium.[31] In many cases it can be inc8latory frorcrcensintoo statelicensed ,boards hrci23cy bwebsr isoof ewors2hei Uses othumstanf onlines. Ev-

[30] *The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet: A Report of the President's Working Group on Unlawful Conduct on the Internet*; Appendix D Internet Sale of Prescription Drugs and Controlled Substances (Mar. 2000) <http://www.usdoj.gov/criminal/cybercrime/append.htm>.

[31] *See, e.g.*, Letters from the Connecticut Medical Examining Board, dated March 19, 1999 ("the difficulties of exercising jurisdiction over an out-of-state physician who does not have a Connecticut license in these circumstances are substantial"); Louisiana State Board of Medical Examiners, dated January 29, 1999 ("Regrettably, our investigations have revealed that those individuals who have advertised and dispensed Viagra® without physical examination, have been physicians licensed in states other than Louisiana and located beyond our jurisdictional reach."); Board of Medical Licensure & Supervision of the State of Oklahoma, dated February 19, 1999 ("Oklahoma law does require establishment of valid doctor/patient relationship and proof of medical necessity for any type of treatment but obviously this Board has no jurisdiction across state lines."); Tennessee Board of Osteopathic Examination, dated March 10, 1999 ("Having jurisdiction over the issue is one thing; practically enforcing the situation is quite another issue."); and State of Wisconsin Department of Regulation & Licensing, dated February 12, 1999 ("Wisconsin does not have the ability to police this kind of activity all around the country.").

The principal federal agency with authority in this area is the FDA. The FDA has primary jurisdiction to regulate labeling and advertising claims made by the manufacturer, distributor or packer of prescription drugs.[32] In addition, the FDA has the authority to take action against the dispensing of a prescription drug without a valid prescription.[33]

In contrast to the states and the FDA, the Commission's role in this area is limited to protecting consumers from unfair or deceptive practices by online pharmacies. The FTC Act prohibits deceptive or unfair acts or practices in commerce. The marketing of prescription drugs online is deceptive in violation of FTC law if it involves a material misrepresentation or omission likely to mislead consumers acting reasonably under the circumstances to their detriment. Thus, the Commission has authority to bring an enforcement action where an online pharmacy makes false or misleading claims about the products or services it provides.[34] The online prescribing and dispensing of prescription drugs that does not involve a deceptive or unfair practice, however, does not fall within the agency's scope of authority.[35]

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[32]*See* 21 U.S.C. § 351 *et seq.*

[33]*See* 21 U.S.C. §§ 353(b)(1); 331(a), and 333.

[34]*See* Deception Policy Statement, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984). The Commission also has authority under its unfairness jurisdiction to regulate marketing practices that cause or are likely to cause substantial consumer injury, which is not reasonably avoidable by consumers, and not outweighed by countervailing benefits to consumers or to competition. *See* Unfairness Policy Statement, appended to *International Harvester Co.*, 104 F.T.C 949, 1070 (1984); 15 U.S.C. § 45 (n).

[35] The Commission, however, can address situations where medical professionals have made false or misleading claims in advertising or other promotional literature distributed to potential consumers about the efficacy, safety, cost or other benefits of the services or products they provide.

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FTC v. Rennert exemplifies the Commission's authority to address deceptive online claims in this arena.[36] There the Commission alleged that the defendants misrepresented the services they provided. The defendants' website contained statements such as:

> Focus Medical Group is a full service clinic with a full time staff dealing with the treatment of sexual dysfunction. The clinic's licensed medical physicians network with an organization of physicians throughout the United States and Internationally . . . . All of our prescriptions are filled on premises.

Based on these statements, among others, the Commission alleged that the defendants falsely represented that customers were served by a clinic with physicians and an on-site pharmacy. In fact, the defendants' customers were not served by a medical clinic or an on-site pharmacy. The defendants employed one physician in another state to review customers' medical questionnaires. For this service, customers were charged $75.00 if the prescription was approved. The doctor was paid $10.00 for

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See Dr. Scott M. Ross, 115 F.T.C. 54 (1992) (consent agreement resolving misrepresentations of safety, recovery period, discomfort of liposuction).

[36]*FTC v. Rennert* Civ. Action No. CV-S-00-0861 JBR (D. Nev., filed July 6, 2000).

The Commission's most recent intensive look at online prescribing and dispensing practices involved the drug Cipro.[37] In the weeks following press reports of anthrax contamination and related deaths in the fall of 2001, a large number of Internet websites started aggressively marketing Cipro, an antibiotic used in the treatment of anthrax. In an effort to protect consumers from counterfeit Cipro products, the Commission staff, in conjunction with the FDA, reviewed online Cipro sites. In the course of these investigations, the staff ordered product samples from both foreign and domestic websites and had them tested. No counterfeit Cipro was discovered and no actions were filed. The staff forwarded information about foreign sites to the FDA.[38]

Because there are many federal and state authorities with specific roles in the regulation of physicians and pharmacies, it is critical that the various agencies coordinate closely. For example, because the FTC and the FDA have closely related and partially overlapping authority over a number of products, including prescription drugs, the two agencies coordinate closely pursuant to a longstanding liaison agreement.[39] Also, on April 26, 1999, an interagency working group, comprised of the FTC,

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[37] "Cipro" is Bayer Corporation's trade name for the drug ciprofloxacin.

[38] Congress has enacted specific provisions to deal with the distribution of counterfeit drugs. These provisions give the FDA and the Department of Justice a broad panoply of remedial powers, including the power to stop the import of counterfeit products, seize products already in the country, and file injunctive and criminal action in appropriate cases. Moreover, the FDA, which has traditionally dealt with counterfeit drug issues, has the expertise to enforce prohibitions against the marketing of counterfeit drugs. On November 1, 2001, the FDA announced that it had issued warnings to eleven Internet vendors of unapproved foreign ciprofloxacin. One foreign order of ciprofloxacin the FTC received was identified on custom forms as cosmetics.

[39]Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶ 9,859.01 (1971). Under this longstanding formal liaison agreement, the FDA has primary responsibility to regulate claims made in the labeling and advertising of prescription drugs if those claims are made by a manufacturer,

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FDA, the Department of Justice, the Drug Enforcement Agency, and other federal and state agencies, was organized to coordinate enforcement and regulatory activity in this area. The working group meets on roughly a quarterly basis to share information and discuss interagency coordination.[40] In addition, the FTC assists other federal and state authorities in their investigatory work.

VI. Conclusion

The Federal Trade Commission will continue to do its part to combat deceptive practices by online pharmacies and to assist other authorities in their investigative work. For the most part, however, the practices that present the greatest concern and risk of consumer injury are those involving the prescribing and dispensing practices of individual physicians and pharmacies, which are outside of the Commission's traditional authority.

Thank you for this opportunity to present the Commission's views. I will be happy to respond to your questions.

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[39](...continued)
packer, or distributor. The agreement establishes the basic division of responsibilities of the two agencies with respect to the regulation of foods, drugs (both over-the-counter and prescription), cosmetics and devices. With the exception of prescription drugs, the FTC regulates advertising of these products, while the FDA regulates labeling.

[40]These meetings provide a regular forum for exchange of information about ongoing activities and problems.