## **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.<sup>1</sup>

The Commission is charged by Congress with preventing deceptive or unfair acts or practices in commerce, pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act").<sup>2</sup> This morning I will describe some of the Commission's enforcement efforts and other activities to protect the online consumer from the deceptive marketing of health care products generally, and outline how the FTC's role relates to that of other federal and state authorities with respect to online prescription drugs specifically. As I will explain, there are significant limitations on the Commission's ability to address the online prescribing and sale of prescription drugs over the Internet.

#### I. Protecting Consumers Against Deceptive Online Marketing of Health Products.

The Internet offers significant consumer benefits in the form of greater and easier access to detailed health information, as well as more convenient access to health care products and services.

Use of the Internet to obtain health information has grown dramatically, from approximately 22.3 million

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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<sup>3</sup> to over 70 million by October 2002.<sup>4</sup> 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,

<sup>&</sup>lt;sup>3</sup> Cyberdialogue, Inc. (June 1999).

<sup>&</sup>lt;sup>4</sup> 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).

Procuraduria Federal del Consumidor of Mexico, the Secretaria de Salud of Mexico, several state Attorney General offices, and several state health departments.

As part of the agencies' effort to identify appropriate law enforcement targets, *Operation*Cure.All partners periodically conduct Internet surfs.<sup>5</sup> To date, the FTC and partners have conducted three international surfs, in 1997, 1998 and 2002,<sup>6</sup> and a number of narrowly targeted surfs focused on specific types of diseases or products such as anthrax. The three international surfs identified thousands of sites making questionable treatment claims for serious diseases. Although some of these questionable sites marketed therapies and devices, most sold dietary supplements.

After each surf, the FTC sends email alerts to those websites that make questionable claims and for which email addresses could be obtained, warning them that any health claims they make must be substantiated by competent and reliable scientific evidence. The Commission urges the websites to review their claims to make sure that they complied with the law. In addition, the Commission provides the sites with a list of resources they could consult for additional guidance. Websites that fail to take corrective action may then become targets for law enforcement actions.

<sup>&</sup>lt;sup>5</sup> In an Internet surf, participants use search engines to find relevant Internet sites based on a set of predetermined search terms, for example, "cancer cure." Once a site is identified it is forwarded to a central collection center, where the site is reviewed again to ascertain that it satisfies the selection criteria. In the three health claims surfs the FTC organized, the selection criteria were whether the site appeared to be making questionable claims that the product or service being offered was effective in the treatment, prevention, or cure of cancer, arthritis, heart disease, HIV/AIDS, diabetes, or multiple sclerosis.

<sup>&</sup>lt;sup>6</sup> FTC and FDA led the 2002 surf. In addition to the numerous government agencies and private organizations in the United States, three foreign countries also participated in the surf – Canada, Ireland, and Mexico. This surf focused specifically on sites that sold products and services that promised to cure, treat, or prevent cancer, HIV/AIDS, or arthritis.

Efforts to achieve industry compliance are most effective when they are backed up by traditional law enforcement. The FTC has filed 18 *Operation Cure.All* cases since June 1999. The challenged products include comfrey, <sup>7</sup> cat's claw, <sup>8</sup> shark cartilage, <sup>9</sup> cetylmyristoleate (CMO), <sup>10</sup> Essiac

<sup>&</sup>lt;sup>7</sup> 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 No. 2:01 CV-0505 ST (D. Utah, filed Nov. 29, 2001) (Stipulated Final Order). In both matters, the orders prohibit the defendants from, among other things, marketing any comfrey product for ingestion, for use as a suppository, or for external use on open wounds, unless they have evidence that the product is free of pyrrolizidine alkaloids and that it is safe. The defendants also are required to place a warning disclosure in any ad, promotional material, or product label for any comfrey products intended for topical use.

<sup>&</sup>lt;sup>8</sup>Body Systems Tech., Inc., Dkt. No C-3895 (Sept. 7, 1999) (consent). Cat's claw was promoted primarily as an effective treatment for cancer, HIV/AIDS, and arthritis.

<sup>&</sup>lt;sup>9</sup>Lane Labs-USA, Inc., Civ. Action No. CV-00-3174 (D. N.J, filed Jun. 28, 2000) (Stipulated Final Order); Cartilage Consultants, Inc., Civ. Action No. CV-00-3174 (D. N.J, filed Jun. 28, 2000) (Stipulated Final Order); Body Systems Tech., Inc., Dkt. No. C-3895 (Sept. 7, 1999) (consent).

<sup>&</sup>lt;sup>10</sup>John Sneed and Melinda Sneed d/b/a Arthritis Pain Care Center, Dkt. No. C-3896 (Sept. 7, 1999) (consent); *CMO Distribution Centers of America*, Dkt. No. C-3942 (May 16, 2000) (consent); *EHP Prods.*, *Inc.*, Dkt. No. C-3940 (May 16, 2000) (consent). These products were marketed for the treatment and cure of arthritis.

tea, 11 colloidal silver, 12 Chitosan, 13 ephedra, 14 St. John's Wort, 15 anti-aging supplements, 16 electronic

 $<sup>^{11}</sup>$ Michael D. Miller, d/b/a Natural Heritage Enters., Dkt. No. C-3941 (May 16, 2000) (consent). This product was promoted for the treatment of cancer.

<sup>&</sup>lt;sup>12</sup> Robert C. and Lisa M. Spencer, d/b/a Aaron Co., Dkt. No. C-4019 (July 30, 2001) (consent). The respondent made false and unsubstantiated safety and efficacy claims for Colloidal Silver, and Chitosan, with Vitamin C; and unsubstantiated claims that "Ultimate Energizer," a product containing ephedra (ma huang), was safe and had no side effects. The Order required warning labels on products containing ephedra.

<sup>&</sup>lt;sup>13</sup> *Id*.

<sup>&</sup>lt;sup>14</sup> *Id*.

<sup>&</sup>lt;sup>15</sup> The two matters in this area are *Panda Herbal International, Inc., et al.*, Dkt. No. C-4018 (July 30, 2001) (consent) and *ForMor, Inc., et al.*, Dkt. No. C-4021 (July 30, 2001) (consent). These respondents sold numerous products to treat a number of serious diseases. Among other claims, they claimed that those with HIV or AIDS could use St. John's Wort as a safe treatment for the disease. Not only were these claims unsubstantiated, St. John's Wort is known to interfere with proven HIV/AIDS medications. The orders, among other prohibitions, require that the respondents place a disclosure warning in advertisements, promotional materials, or product labels regarding the potential dangerous interactions between St. John's Wort and some prescription drugs.

<sup>&</sup>lt;sup>16</sup> MaxCell BioScience, Inc., et al., d/b/a Oasis Wellness Network, Dkt. No. C-4017 (July 30, 2001) (consent). This case involved an anti-aging product containing, among other ingredients, the hormone DHEA, and an at-home urine test to gauge overall health and youthfulness.

devices,<sup>17</sup> magnetic therapies,<sup>18</sup> and unproven cancer therapies delivered in Mexico.<sup>19</sup> Copies of all *Operation Cure.All* cases are available on the Commission's website at <a href="www.ftc.gov">www.ftc.gov</a>. 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* 

<sup>17</sup> 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. 1:03CV0054, (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.

<sup>&</sup>lt;sup>18</sup>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.

<sup>&</sup>lt;sup>19</sup> *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 "insulininduced 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.<sup>20</sup> 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.<sup>21</sup> 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,<sup>22</sup> 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 of colloidal silver products from claiming that it cured 650 diseases, including anthrax and ebola.

<sup>&</sup>lt;sup>20</sup> 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.

<sup>&</sup>lt;sup>21</sup> This teaser site was visited 1,112 times in FY02.

<sup>&</sup>lt;sup>22</sup> 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.

### II. The Benefits, Risks, and Challenges Presented by Online Pharmacies

Like other health care promotions on the Internet, the availability of prescription drugs via online pharmacies can offer benefits to consumers, including convenience and value. Many online pharmacies appear to operate like, and compete with, traditional "brick and mortar" or mail order pharmacies. Some online pharmacies and some physicians who provide online prescription services, however, are not so scrupulous. As documented by prior Congressional hearings and State and Federal enforcement actions, consumers can easily obtain online access to prescription drugs, often by completing a basic online questionnaire that receives cursory, if any, review before the drugs are dispensed. Significant potential for injury exists when prescriptions are issued without adequate review of the consumer's medical history or when unapproved drugs are sold to consumers over the Internet by overseas pharmacies. As a consumer of the consumer of the consumer's pharmacies.

Robust competition between emerging Internet firms and incumbent "brick and mortar" firms offers many potential benefits to consumers. In October 2002, the Commission hosted a three day public workshop to examine effective strategies for balancing competition and regulatory priorities in the e-commerce context. *See* Federal Trade Commission, Public Workshop, *Possible Anticompetitive Efforts to Restrict Competition on the Internet* (Oct. 8-10, 2002), *available at* <a href="http://www.ftc.gov/opp/">http://www.ftc.gov/opp/</a> ecommerce/anticompetitive/index.htm>.

<sup>&</sup>lt;sup>24</sup> Leading health associations have condemned the practice of online prescribing based solely on answers to online questionnaires. The American Medical Association has taken the position that "Web sites that offer a prescription solely on the basis of a simple questionnaire" do not meet appropriate standards of care for issuing a prescription. *See* Statement of the American Medical Association before the Subcommittee on Oversight and Investigations, Committee on Commerce, U.S. House of Representatives, *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Presented by Herman I. Abromowitz, M.D., July 30, 1999 <a href="https://www.ama-assn.org/ama/basic/article/0,1059,177-486-1,00.html">https://www.ama-assn.org/ama/basic/article/0,1059,177-486-1,00.html</a>; American Medical Association, Report of the Board of Trustees, *Internet Prescribing*, 35-A-99. In addition, the Federation of State Medical Boards believes that the "prescribing of medications by physicians based *solely* on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of (continued...)

#### III. State and Federal Regulation of Online Prescription Drug Practices

Historically, states have regulated pharmacies and the practice of medicine. Accordingly, a number of states have challenged online companies that dispense prescription drugs without a valid prescription. Kansas,<sup>25</sup> Missouri, Illinois, and Michigan have been particularly active.<sup>26</sup> Except where specific statutes permit such practice, a physician engaging in online prescribing for consumers residing in states where the physician is not licensed to practice could be charged with the unlicensed practice of medicine.<sup>27</sup> State enforcement actions have been based on violations of state consumer protection statutes as well as state medical and pharmacy laws. In addition, professional disciplinary actions have been initiated in more than a dozen states.<sup>28</sup> For example, an Oregon physician was sentenced to ten years probation and fined \$5,000 for prescribing drugs online without an examination of the patient.<sup>29</sup>

<sup>&</sup>lt;sup>24</sup>(...continued) professional conduct." Federation of State Medical Boards, *Report of the Special Committee on Professional Conduct and Ethics*, Section IV (April 15, 2000).

<sup>&</sup>lt;sup>25</sup> 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).

<sup>&</sup>lt;sup>26</sup> 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.

<sup>&</sup>lt;sup>27</sup> See, e.g., Illinois v. Express Today, Inc., Civil Action No. 99 CH 0452 (D. Ill., Sangamon Co.), filed Oct. 21, 1999.

<sup>&</sup>lt;sup>28</sup> U.S. General Accounting Office, Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight, GAO-01-69 (2000), Appendix II.

<sup>&</sup>lt;sup>29</sup> *Internet Viagra*, Pittsburgh Post-Gazette, Apr. 2, 2000, at A-12.

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.<sup>30</sup> In the past, state medical and pharmacy boards have expressed concerns that their existing enforcement tools are not adequate to police the online medium.<sup>31</sup> In many cases it can be difficult, without extensive investigation, to identify the name, location, and state of licensure or registration for the physicians, pharmacies, and website operators involved in these practices. Even when parties can be located, it can be difficult and costly for a state medical board or a state pharmacy board to pursue law enforcement action against an out-of-state physician or pharmacy prescribing or dispensing prescription drugs inappropriately via the Internet.

<sup>&</sup>lt;sup>30</sup> 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) <a href="http://www.usdoj.gov/criminal/cybercrime/append.htm">http://www.usdoj.gov/criminal/cybercrime/append.htm</a>.

<sup>&</sup>lt;sup>31</sup> 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.<sup>32</sup> In addition, the FDA has the authority to take action against the dispensing of a prescription drug without a valid prescription.<sup>33</sup>

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.<sup>34</sup> 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.<sup>35</sup>

 $<sup>^{32}</sup>See~21~U.S.C.~\S~351~et~seq.$ 

<sup>&</sup>lt;sup>33</sup>See 21 U.S.C. §§ 353(b)(1); 331(a), and 333.

<sup>&</sup>lt;sup>34</sup>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).

<sup>&</sup>lt;sup>35</sup> 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.

(continued...)

FTC v. Rennert exemplifies the Commission's authority to address deceptive online claims in this arena.<sup>36</sup> 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 each of the first 50 prescriptions he approved per week and \$7.50 for each additional approved prescription request. The stipulated final order enjoined the defendants from misrepresenting their services and required certain disclosures, including the name, address and phone number of the physician and the states where the physician is licensed or authorized to practice and the states from which the entity will accept orders.

<sup>&</sup>lt;sup>35</sup>(...continued)

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

<sup>&</sup>lt;sup>36</sup>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.<sup>37</sup> 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.<sup>38</sup>

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.<sup>39</sup> Also, on April 26, 1999, an interagency working group, comprised of the FTC,

<sup>&</sup>lt;sup>37</sup> "Cipro" is Bayer Corporation's trade name for the drug ciprofloxacin.

<sup>&</sup>lt;sup>38</sup> 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.

<sup>&</sup>lt;sup>39</sup>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, (continued...)

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.<sup>40</sup> 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.

<sup>&</sup>lt;sup>39</sup>(...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.

 $<sup>^{40}</sup>$ These meetings provide a regular forum for exchange of information about ongoing activities and problems.