

**Prepared Statement of
the Federal Trade Commission on**

"Drugstores on the Net: The Benefits and Risks of Online Pharmacies"

**Before the
Subcommittee on Oversight and Investigations
of the
Committee on Commerce
United States House of Representatives**

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Mr. Chairman and members of the Subcommittee, I am Jodie Bernstein, Director of the Bureau of Consumer Protection of the Federal Trade Commission ("FTC" or "Commission"). I am pleased to have this opportunity to review with you the Commission's consumer protection activities relating to the practices of online pharmacies.⁽¹⁾

I. Introduction

The Commission is well aware of the rapid growth of the marketing of health care products and services via the Internet and has been actively monitoring and pursuing law enforcement in this area for some time. The agency, for instance, has conducted enforcement and consumer education initiatives to combat health fraud on the Internet; has been a leader in protecting consumer privacy in the online medium; and is now monitoring online pharmacy websites, conducting investigations, and making referrals to other federal and state authorities as appropriate. This morning I will discuss our authority in this area, how the FTC's role relates to that of other federal and state authorities, and describe some of our enforcement efforts and other activities to protect the online consumer from the deceptive marketing of health care products generally, and prescription drugs specifically. I would also like to identify what the Commission believes are the most significant challenges facing federal and state authorities with enforcement authority over online pharmacies and suggest possible solutions.

The Internet offers significant consumer benefits in the form of greater and easier access to detailed health information, as well as more convenient, and often cheaper, access to health care products and services. In 1998, 22.3 million adults in this country sought health and medical information online, nearly 70% before visiting a doctor's office.⁽²⁾ The number is predicted to increase to 30 million by the year 2001.⁽³⁾ More and more often, consumers are turning to the Internet not just for health information but to purchase health care products. Unfortunately, the online medium also provides an easy opportunity for irresponsible marketers to prey on sick or vulnerable consumers with potentially serious consequences to

consumers' health and pocketbooks.

Like other health care promotions on the Internet, the availability of prescription drugs via online pharmacies offers potential benefits to consumers, including convenience and value. Many online pharmacies appear to operate in essentially the same manner as mail order pharmacies and in keeping with standards of state licensing authorities. Nevertheless, our review of the current practices of some online pharmacies and of some physicians that provide online prescription services indicates the potential for serious consumer injury. 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. The Commission has limited anecdotal evidence of specific occasions where consumers have, in fact, received a prescription drug via the Internet that would be clearly inappropriate or even dangerous because of the age, health, or other drug use of the consumer.⁽⁴⁾

As the Subcommittee is aware, the rapid growth in online sales of prescription drugs and the increase in the practice of online prescribing, both of which are occurring across state and even international borders, present significant technological and logistical challenges to the traditional regulatory framework. State medical boards and state pharmacy boards have both expressed concerns that their existing enforcement tools are not adequate to police the online medium.⁽⁵⁾ 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. Our review of almost 100 sites provided by Subcommittee staff found that very few provided adequate identifying information. 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 against an out-of-state physician or pharmacy prescribing or dispensing prescription drugs inappropriately via the Internet.

The Commission can play a role in protecting consumers who use online pharmacies by bringing cases against specific deceptive practices. The agency can also assist other federal and state authorities in their investigatory work. The FTC's authority, however, is limited and may not fully address the important consumer protection issues raised here. To a large extent, the practices that present the greatest concerns involve issues relating to the appropriate standards for prescribing and dispensing drugs, both of which have been traditionally regulated by the states. The Commission suggests that the Subcommittee consider whether additional legislative measures are necessary to address the unique characteristics of this medium and ensure greater protections for consumers. Specifically, requirements for clear and prominent disclosure of identifying information for the online prescribing physician, the online pharmacy and the website owner, if different, as well as the states where prescriptions will be dispensed, would greatly assist state law enforcement efforts. We also recommend that additional consideration be given to assisting states with extraterritorial jurisdiction issues.

II. Scope of Commission Authority

The Commission's authority derives from the agency's mandate to prevent deceptive or unfair acts or practices in commerce, pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act").⁽⁶⁾ The marketing of prescription drugs online would be deceptive in violation of FTC law if it involved a 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.⁽⁷⁾ For example, the Commission would have authority to take action if an online pharmacy or website operator made false or misleading claims about the safety or efficacy of the drug it was offering.⁽⁸⁾ Another example of a deceptive practice within the Commission's jurisdiction would be the misrepresentation by an online pharmacy of its privacy practices, for instance, false statements about how the site collects and uses medical information about the consumer.⁽⁹⁾

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.⁽¹⁰⁾ Although some parties have suggested that certain online prescribing practices by physicians may be so inadequate as to be unfair, these practices raise difficult issues involving physician practices that the Commission has traditionally refrained from regulating.

III. Interaction with Federal and State Regulatory Authorities

As we have noted, many aspects of the online prescribing and dispensing of prescription drugs do not fall clearly within the agency's traditional scope of authority or expertise and have been the primary responsibility of other federal and state agencies.

The other principal federal agency with authority in this area is the Food and Drug Administration ("FDA"). The FDA has primary jurisdiction to regulate labeling and advertising claims made by the manufacturer, distributor or packer of prescription drugs.⁽¹¹⁾ In addition, the FDA has the authority to take action against the dispensing of a prescription drug without a valid prescription.⁽¹²⁾ Because the FTC and the FDA have such closely related and overlapping authority over a number of products, including prescription drugs, the two agencies coordinate closely pursuant to a longstanding liaison agreement.⁽¹³⁾ In fact, the Commission recently referred to the FDA's Office of Criminal Investigation two matters involving U.S. websites that were offering prescription drugs without requiring prescriptions.

Many of the concerns expressed about online pharmacies relate to the practice of physicians engaging in online medical consultations with consumers and issuing prescriptions without any pre-existing doctor-patient relationship. The question of when and under what circumstances, if at all, it is safe and appropriate to prescribe medications without actually seeing a patient is difficult and raises issues that fall beyond this agency's traditional expertise.

The Commission has long refrained from challenging practices that fall within the doctor-

patient relationship, including communications between doctors and patients about course of treatment decisions.⁽¹⁴⁾ The FTC does not have the authority to revoke an individual physician's license or to enforce state licensing requirements. The agency believes that judgments about the practice of medicine are better left to the individual state medical boards, which establish standards of practice and oversee the licensing of individual physicians. It is our understanding that many states currently prohibit the issuing of prescriptions based solely on a consumer's answers to an online questionnaire.⁽¹⁵⁾

Similarly, the licensing and regulation of pharmacies, like the licensing of physicians, has traditionally taken place at the state level by state pharmacy boards. The Commission does not have authority to revoke a pharmacy's license or to enforce regulations relating to licensing of pharmacies. Again, issues about what constitute appropriate practices by an online pharmacy are better left to the state authorities with the relevant expertise.

While the Commission believes that state authorities should continue to have responsibility for enforcement of licensing requirements for physicians and pharmacies, the FTC has and will continue to provide assistance to those authorities in individual investigations.

IV. Specific Commission Activities Relating to Online Pharmacies

The Commission believes its role with regard to online pharmacies is limited under the current legal framework and that the primary responsibility should remain with the states and FDA. Within the scope of our authority, we have taken a number of actions in this area: monitoring websites; conducting investigations; and making referrals to other federal and state authorities. In addition, we coordinate many of our activities through an interagency working group.

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. On April 26, 1999, an interagency working group, comprised of the FTC, FDA, the Department of Justice (DOJ), the Drug Enforcement Agency (DEA), and other federal and state agencies, met to consider the regulation of online pharmacies and other issues relating to the sale of drugs over the Internet. One of the group's tasks is to explore enforcement issues and potential jurisdictional gaps. One follow-up meeting has been held and an additional meeting is scheduled for September 1999. The FTC will continue to participate in the meetings of this group and to consult informally with appropriate authorities as specific issues arise.

Another important function of the Commission is that of monitoring the practices of online pharmacy sites and using our Internet expertise to assist other state and federal authorities in their enforcement efforts. The FTC has the technical capacity to monitor and investigate Internet marketing and is continuing to upgrade our current technology. For example, our computer equipment permits staff to locate and preserve websites for evidentiary purposes.

The Commission's monitoring activities have led to a few preliminary investigations. In one situation, staff completed two mock online consultations in order to obtain the prescription

drug Viagra®. For one of these consultations, staff described a number of factors in the "patient's" medical history that should have raised serious concerns about the appropriateness of issuing a prescription for Viagra®, such as bypass surgery, obesity, family history of heart disease and the absence of any information about other medications. In both cases, staff was issued a prescription without question and was able to purchase the Viagra® online. This investigation led to referrals to the relevant state medical and pharmacy boards. To the extent possible, Commission staff have also assisted state authorities in identifying and locating specific online pharmacies and physicians.

The Commission has also played a role in other closely related areas involving the marketing of health care products on the Internet and the protection of consumer privacy online. For example, the Commission recently announced "Operation Cure.All," a comprehensive consumer education and enforcement initiative to combat health fraud on the Internet. The project was the outcome of two "surf days"⁽¹⁶⁾ in which the FTC and other government and private partner organizations identified nearly 800 websites making questionable claims that a product or treatment could cure or treat diseases like cancer, arthritis, AIDS, multiple sclerosis, diabetes and heart disease. As part of this project, the Commission announced four cases against companies marketing non-prescription health products on the Internet and is currently pursuing additional cases.⁽¹⁷⁾ The Commission has also filed other cases against Internet marketers of health care products in recent years, including a dietary supplement program purported to cure Attention Deficit Disorder and another dietary supplement referred to as "Vitamin O" for the treatment of several diseases including cancer and pulmonary disease.⁽¹⁸⁾

Finally, the Commission has been active in the protection of consumer privacy online, an area that has great relevance to the subject of online pharmacies given that highly sensitive medical information is often collected as part of the online consultation. The Commission, for instance, has engaged in extensive monitoring of the privacy practices of websites, has conducted workshops on the issue, prepared reports to Congress on the self-regulatory efforts of industry on this topic, assisted in the development of legislation to protect children's online privacy, and issued proposed rules to implement that legislation.⁽¹⁹⁾ The Commission has also brought enforcement actions against websites engaged in deceptive practices relating to the collection and use of personal consumer information.⁽²⁰⁾ Online pharmacies that make false or misleading representations about how they collect and use personal information would be subject to similar FTC challenge.

V. 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 professional conduct of individual physicians or issues relating to the licensing of pharmacies and safeguards on the dispensing of prescription drugs that have traditionally been regulated by state authorities. Those state authorities appear to have laws that are substantively adequate to stop irresponsible prescribing and dispensing of drugs via the Internet. The real challenge lies in dealing with the logistical difficulties of identifying

responsible parties and enforcing laws across state boundaries. State authorities and other groups are attempting to address the most troubling practices through issuance of guidelines, certification programs and other non-legislative approaches,⁽²¹⁾ but those efforts, while valuable, still do not provide the tools necessary for effective and meaningful enforcement.

Based on the Commission's experience in this area, we recommend that the Subcommittee consider legislative measures that would assist state authorities in their investigations by mandating that certain identifying information about physicians, pharmacies and website operators be posted. Specifically, we suggest that each website offering prescription drugs for sale be required to disclose the following information clearly and prominently:

- 1) the name, business address, and phone number of the pharmacy that will dispense the prescription and the state or states where such pharmacy is licensed or registered to do business;
- 2) the name, address, and phone number of each physician providing the online prescribing services and the state or states where such physician is licensed or authorized to practice medicine, if such service is offered;
- 3) the name, business address, phone number, and principal officers or owners of the online business offering prescription drugs, if different from the pharmacy or physician; and
- 4) the state or states from which the website will accept orders for prescription drugs.

Finally, the Commission recommends that consideration should be given to determining what other measures are necessary to assist state pharmacy and medical boards with enforcement of state laws against extraterritorial prescribing practices, including possibly granting states the authority to bring actions in federal district court.

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

Endnotes:

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. Cyberdialogue, Inc. (June 1999).
3. *Id.*
4. We have received very few complaints about online pharmacies. In one complaint filed with the FTC, however, a parent reported that her minor son had obtained Viagra® over the Internet. Part of the parent's concern was the fact that her son had bipolar disorder, neurocardiac syncope, and was taking blood pressure

medication at the time, clearly increasing the potential for injury from using this drug.

5. *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.").

6. 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. Under Section 4 of the FTC Act the agency has jurisdiction over marketers based outside the U.S. border selling in the U.S. market that violate Sections 5 and 12. 15 U.S.C. § 44.

7. *See* Deception Policy Statement, appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984).

8. In fact, the Commission has challenged such claims in both the online context and in other media. *See, e.g.*, American College for Advancement in Medicine, Dkt. No. C-3882 (June 22, 1999) (settlement resolving allegations respondent made unsubstantiated claims for effectiveness of therapy using prescription drug for treating heart disease); FTC v. Pacific Medical Clinics, 1992-1 Trade Cas. (CCH) ¶ 69,777 (S.D. Cal. April 8, 1992)(defendants misrepresented effectiveness of prescription drug for treating obesity).

9. The Commission has been very active in the protection of consumer privacy particularly in the online context, as discussed below. The agency has also specifically challenged misrepresentations about the use of a consumer's medical information, although not in the online context. *See, e.g.*, Equifax, Inc., 96 F.T.C. 844 (1980), *rev'd on other grounds*, 678 F.2d 1047 (11th Cir. 1982)(deceptive to represent, inaccurately, that medical information would be released only to specified insurance companies).

10. *See* Unfairness Policy Statement, appended to International Harvester Co., 104 F.T.C 949, 1070 (1984); 15 U.S.C. § 45 (n).

11. *See* 21 U.S.C. §§ 351 *et seq.*

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

13. 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 labeling and advertising of prescription drugs if those claims are made by a manufacturer, packer, or distributor. *See* Working Agreement Between FTC and Food and Drug Administration, 3 Trade Reg. Rep. (CCH) ¶ 9,859.01 (1971). 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.

14. In contrast, the Commission does 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. Dr. Scott M. Ross, 115 F.T.C. 54 (1992) (consent agreement resolving misrepresentations of safety, recovery period, discomfort of

liposuction).

15. *See, e.g.*, attached letters from Alabama State Board of Medical Examiners, dated March 11, 1999; State of Colorado, Department of Regulatory Agencies, dated March 23, 1999; State of Connecticut, Department of Consumer Protection, dated December 17, 1998; Government of the District of Columbia, Department of Health, Office of Professional Licensing, dated March 5, 1999; Kansas Board of Healing Arts, dated January 5, 1999; Louisiana State Board of Medical Examiners, dated January 29, 1999; State of Nevada, Office of the Attorney General, dated March 25, 1999; New Mexico Board of Pharmacy, dated January 19, 1999; State of Oklahoma, Board of Licensure & Supervision, dated February 19, 1999; State of Tennessee, Department of Health, Health Related Boards, dated March 10, 1999; State of Wisconsin, Department of Registration & Licensing, dated February 12, 1999.

16. The FTC has developed a unique concept known as a "surf day." Together with other law enforcement partners, FTC staff use common search engines to surf the Internet for a specified period of time and send business education messages via e-mail to websites making potentially deceptive claims.

17. *See* Arthritis Pain Care Center (APCC) et al., File No. 982 3182 (June 24, 1999)(consent subject to final approval challenging arthritis claims for CMO dietary supplement); Body Systems Technology, Inc., File No. 982 3177 (June 24, 1999)(consent subject to final approval challenging claims for treatment/cure of several diseases including cancer and AIDS for shark cartilage capsules and Cat's Claw herbal supplement); Pain Stops Here! Inc., et al., File No. 982 3175 (June 24, 1999) (consent subject to final approval challenging claims for magnetic therapy to treat cancer, liver disease, arthritis and other conditions); and Magnetic Therapeutic Technologies, Inc. et al., File No. 982 3150 (June 24, 1999)(consent subject to final approval challenging claims for magnetic therapy devices to treat various diseases and conditions including cancer and high blood pressure). Operation Cure. All also included a consumer education campaign that provided links on our website, www.ftc.gov, to sources of reliable health information, gave tips to consumers on how to avoid "virtual health fraud" and set up "teaser" sites to alert Internet users to health scams.

18. New Vision International, FTC Dkt. No. C-3856 (March 3, 1999); FTC v. Rose Creek Health Products, Inc., CS-99-0063-EFS (E.D. Wash.) (case pending).

19. *See, e.g.*, "Self-Regulation and Privacy Online," Prepared Statement of the Federal Trade Commission before the Subcommittee on Telecommunications, Trade, and Consumer Protection of the U.S. House Committee on Commerce (July 13, 1999); *Federal Trade Commission, Self-Regulation and Privacy Online: A Report to Congress* (July 1999).

20. *See, e.g.*, GeoCities, C-3849 (Feb. 12, 1999)(consent order challenging misrepresentations about the website's use of personal information collected from children and adults).

21. Specifically, it is our understanding that the National Association of Boards of Pharmacy is currently developing a certification program for online pharmacies, the "Verification of Internet Pharmacy Practice Sites (VIPPS)." In addition, the Federation of State Medical Boards is currently addressing the issue of online prescribing by physicians and considering a recommendation that prescribing, electronically or otherwise, without an adequate patient evaluation be considered unprofessional conduct under state medical practice. Finally, we understand that the AMA has adopted a resolution on this issue and is developing principles regarding online prescribing services.