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COMMENT

SELF-PRESCRIBING MEDICATION: REGULATING PRESCRIPTION DRUG SALES ON THE INTERNET

INTRODUCTION

In today’s rapidly developing world of e-commerce, almost anything can be obtained over the Internet and delivered right to your front door.¹ Every day there is news of yet another company selling some type of product online.² Like every other consumer good, prescription drugs are conveniently available on the Internet.³ Online pharmacies allow consumers to purchase prescription drugs over the Internet without face-to-face consultations with a licensed physician.⁴ Many Internet sites are

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¹ See generally Steve Lohr, In E-Commerce Frenzy, Brave New World Meets Old, N.Y Times G3 (Oct. 10, 1999) (explaining that although traditional retail shopping is still dominant, online retail sales are expected to grow from an estimated $20 billion this year to $185 billion by the year 2004).

² See generally id.


⁴ Fischman, supra n. 3, at ¶ 2. U.S. News & World Report conducted an investigation and successfully purchased several different prescription drugs, including controlled substances such as Phentermine, a weight-loss drug. Id. at ¶ 10. U.S. News & World Report sent for a range of prescription drugs from heart medications to steroids to painkillers by answering medical questionnaires and submitting credit card numbers and received almost all prescription drug on their list. Id. at ¶ 4; see generally e.g. Drug Quest.com <http://foreignpharmacies.com> (accessed Mar. 27, 2002) (selling a publication on how consumers can purchase prescription medication legally without a prescription from foreign countries for a fee); Yahoo.com <http://www.yahoo.com> (accessed Mar. 3, 2002) (netting fifty-five results in search for “buying prescription drugs without a prescription”); ePrescribe.com

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designed to mimic an office visit. Patients send medical information via the Web to an online doctor who reviews the information from a brief questionnaire and ships the pharmaceuticals directly to the consumer’s residence. Thus, online pharmacies allow consumers to obtain prescription drugs without a physical examination from a doctor.

The sale of prescription drugs from foreign countries is of particular concern to the Food and Drug Administration (“FDA”). Some medications sold on the Internet may be legal in foreign countries but not approved for use in the U.S. In addition, products not approved for sale in

<http://www.ePrescribe.com> (accessed Sept. 20, 2000) (selling “embarrassment” drugs without a valid prescription and claiming that thousands of psychiatrists and practitioners are prescribing certain medications after reviewing the patient’s medical history and without a physical examination). Medical factors that would prohibit a physician from prescribing these medications are discoverable through a review of patient’s medical history. Id. at ¶ 2. The proprietor of this Web site believes that there is no reason to suggest that an in-person review of this history is any more relevant than an online consultation. Id. The author was personally able to purchase ten Viagra 100 mg tablets for $158, consultation and shipping included, within minutes of entering ePrescribe.com. As an ePrescribe.com patient, you are able to:

1. Enjoy complete privacy, discretion, and dignity while addressing your condition;
2. Play an active role and participate more fully in your process of care; and
3. Enjoy your health care in an enlightened manner and maintain better health; and
4. Enjoy a professional consultation at an affordable cost.

Id.


(1) Do you have any of the following conditions: Leukemia, Multiple Myeloma, Sickle Cell Disease, Peptic Ulcers, or Retinitis pigmentosa (an eye disorder)?; (2) Do you take any form of nitroglycerine?; (3) Have you previously been treated for sexual dysfunction?; (4) Please list all medications that you are currently taking; (5) Please list all allergies (including medications); (6) Please list any surgeries; (7) Do you have any medical conditions for which you are currently being treated?; (8) Is there anything in your medical history that you deem relevant?; (9) Are you currently or have you ever been treated for any heart problems?

Id.

6. See generally id. It is no longer necessary to make an appointment to see a doctor who examines you, discusses treatment options, then writes a prescription for a drug approved by the Food and Drug Administration. See generally id. The prescription from the doctor was taken to the local pharmacy, where a registered pharmacist filled it and cautioned the patient not to take aspirin or drink alcohol while on the medication. Id. That is how it used to be. See generally id.


8. Id. § Test. of Ivan Fong (noting that foreign online pharmacies may be based in countries where quality standards or manufacturing practices do not approach what the
the U.S. generally do not conform to specified manufacturing practices and quality assurance procedures required by U.S. laws and regulations.\(^9\) It is illegal for a foreign pharmacy to ship prescription drugs into the U.S.\(^10\) However, foreign online pharmacies pose a difficult challenge for the U.S. to enforce laws against them because the seller is not within U.S. jurisdiction.\(^11\)

Although online prescription drug sales are currently unmonitored and unregulated, the practice of pharmacology is currently regulated by the states.\(^12\) All states have enacted laws regulating the practice of pharmacology and medicine.\(^13\) State regulations of pharmacology serve to protect patients from harm resulting from the use of unsafe drugs and counterfeit drugs.\(^14\) More importantly, state regulations prevent the improper practice of medicine and pharmacology.\(^15\)

According to the National Association of Boards of Pharmacy ("NABP"),\(^16\) requirements for practicing pharmacists are strict and heav-

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9. Id. (noting that prescription drugs available from a foreign pharmacy are either products for which there is no U.S. approved counterpart or foreign versions of drugs approved by the FDA).

10. Id. (stating that prohibiting foreign firms from selling prescription drugs in the U.S. would also be complicated if the activity in question is legal in the country where it is originating); see Requirements of Laws & Regulations Enforced by the U.S. Food & Drug Administration § II <http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm> (accessed Oct. 5, 2000) [hereinafter FDA, Requirements of Laws] (noting that drugs are restricted from importation unless they are covered under an Investigational New Drug Application or by an approved New Drug Application which can be obtained from the FDA).


12. Sen. Comm. on Health, Education, Labor & Pensions, Hearings on E-Drugs § Test. of Jane E. Henney ¶ 9 (Mar. 21, 2000) [hereinafter Senate Hearing] (noting that all states have a board of pharmacy that requires pharmacists to be licensed or registered to the practice of pharmacy).

13. House Hearing, supra n. 7, § Test. of Janet Woodcock ¶ 17 (explaining the process of obtaining a prescription drug). Receiving prescription drugs for the first time requires that a patient to be physically examined by a licensed health care practitioner. Id. The practitioner then determines appropriate treatment and issues a prescription for an FDA-approved drug. Id. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets the state practice standards. Id.

14. Id.

15. Id.

16. See generally National Association of Boards of Pharmacy Online <http://www.nabp.net> (accessed Sept. 10, 2000) [hereinafter Boards of Pharmacy Online]. The NABP was established in 1904 to assist state licensing boards in developing, implementing, and enforcing uniform standards to protect the public health. Id. § Preamble; Mission Statement. Pharmacy boards from the fifty states, the District of Columbia, three U.S. territories, nine Canadian provinces, and four Australian states make up the association membership. Id. § Who we are.
ily regulated. However, in addition to magnifying existing problems by reaching potentially millions of consumers worldwide, online drug sales create unique issues for regulatory and law enforcement bodies at the state, federal, and international level. Internet technology can obscure the source of the product as well as provide some degree of anonymity to persons responsible for making and shipping the product. Thus, the regulatory issues cross the traditional regulatory boundaries as well as federal and state jurisdictional lines.

Presently, there are no laws that require an Internet pharmacy to disclose whether its online doctors or pharmacists are licensed to dispense drugs to its consumers. Moreover, there are no licensing requirements for opening an online pharmacy. As the confusion over online pharmacies mounts, one thing is clear, online dispensing medicine is growing at a substantial rate. If this trend continues, problems will arise where patients in the U.S. would easily be able to obtain drugs that have not been approved by the FDA. Consumers will receive drugs that have not tested in rigorous clinical trials, without the advice of a physician.

There is virtually no accountability for online pharmacies that dispense drugs inconsistent with state policies. Moreover, there are no safeguards that address drugs obtained from foreign online pharmacies. Accordingly, government agencies must emphasize the importance of ensuring that minimum standards of proper medical care are met with respect to Internet prescribing. Therefore, U.S. government

17. See generally id.; House Hearings, supra n. 7, § Test. of Jodie Bernstein (arguing for legislation would require Web sites offering prescription drugs to disclose certain information).

18. Senate Hearings, supra n. 12, § Test. of Jane E. Henney.

19. Id. (noting that participants in a transaction can be widely dispersed geographically in different states or countries and may never meet).

20. Id. (regulating the activity is further complicated if one or more participants in the transaction are located outside the U.S.).

21. House Hearings, supra n. 7, § Test. of Janet Woodcock (noting that consumers usually do not know if a Web site is licensed or if it uses licensed doctors or pharmacists); Id. § Test. of Jodie Bernstein (arguing for legislation that would require Web sites offering prescription drugs to disclose certain information).

22. Id.

23. Carol Smith, Virtual Pharmacies Hope to Tap Health Care Market, Seattle Post Intelligencer D1 ¶ 9, 10 (Feb. 1, 1999) (indicating that total prescription drug sales expected rise from $100 billion plus last year to $150 billion over the next four years).

24. House Hearings, supra n. 7, § Test. of Herman I. Abromowitz (explaining the problems with online pharmacies).

25. Id.


27. Id.

28. Id.
agencies must work with foreign governments to share information on the drug approval process in order to develop specific regulations for Internet pharmacies.\footnote{29}

This comment will analyze the unique problems associated with the sale of prescription drugs over the Internet. In addition, this comment will analyze the current developments of online pharmacies and the FDA's regulatory responses to these issues. This comment will also examine current state and federal laws and explain why these laws do not adequately address the unique problems associated with Internet pharmacies. Finally, this comment will propose a new solution that will preserve the benefits of, while reducing the risks involved with the use of, online pharmacies.

BACKGROUND

BENEFITS AND RISKS OF ONLINE PHARMACIES

The growth of Internet prescription drug sales undoubtedly has the potential to provide significant societal benefits.\footnote{30} For consumers, the idea of dealing with online pharmacies is appealing because it offers convenience, privacy, and often saves money.\footnote{31} Individuals who might otherwise have difficulty going to a pharmacy to obtain needed medications such as shut-ins, the elderly, and those in rural communities will surely benefit from the convenience of being able to order and obtain their prescription drugs online.\footnote{32} Online drug sales are also likely to foster price competition for prescription drugs among licensed sellers.\footnote{33} Moreover, online pharmacies are able to provide consumers with written product information and references to other sources of information often more easily than in the traditional storefront.\footnote{34} As doctors begin to use com-

\footnote{29. Id.}  
\footnote{30. House Hearing, supra n. 7, § Test. of Jane Henney.}  
\footnote{31. Id. (noting that the chief attractions to purchasing goods online are the speed and ease of choosing and ordering products from the privacy of their home); John Henkel, Buying Drugs Online: It's Convenient & Private, But Beware of 'Rogue Sites', 34 FDA Consumer 24, 25 ¶¶ 9, 10 (Jan. 1, 2000) (citing a survey in the fall of 1999 by Consumer Reports that showed that buyers could save as much as twenty-nine percent by obtaining certain drugs online). Another study, conducted in 1999 by the University of Pennsylvania and published in the Annals of Internal Medicine, tracked Internet sales of Viagra and Propecia and found that the two drugs were an average of ten percent more expensive online than at local Philadelphia-area pharmacies. Id.; Mark Grossman, E-Pharmacies Give Regulators Headaches, Broward Daily Bus. Rev. A1 ¶ 1 (May 23, 2000) (explaining that there are "silent sufferers" who would rather not discuss conditions of baldness, impotence, or venereal disease with their health care providers, and instead, turn to the Internet for treatment).}  
\footnote{32. Henkel, supra n. 31, at ¶ 9.}  
\footnote{33. Id.}  
\footnote{34. Id.}
puter technology to transmit prescriptions, a reduction in prescription error is also possible because handwritten prescriptions can often be misunderstood.\textsuperscript{35}

While legitimate prescription drug sales over the Internet can provide tremendous benefits to consumers, the benefits may come at the expense of safety.\textsuperscript{36} Some online pharmacies sell prescription\textsuperscript{37} drugs without a prescription.\textsuperscript{38} Also, drugs that patients receive could be new drugs unapproved by the FDA, improperly manufactured to be sub- or super-potent, contaminated or outdated, marketed with fraudulent health claims, or a counterfeit drug\textsuperscript{39} with inert ingredients.\textsuperscript{40} The online pharmacist often does not know contraindications\textsuperscript{41} for a prescribed drug without a complete patient medical history.\textsuperscript{42} Of course, the consumer can deliberately lie on the pharmacy's online questionnaire in order to obtain the medication.\textsuperscript{43} Furthermore, the consumer can answer inaccurately from a failure to understand the questions on the question-

\textsuperscript{35} House Hearing, supra n. 7, § Test. of Herman I. Abromowitz (explaining that after a physician sees a patient and performs an adequate medical history and physical, computer order and online transmission of prescriptions to a pharmacy provides an alternative mechanism for prescription transmission and reduces error that can occur from failure to understand handwritten prescriptions).

\textsuperscript{36} Id.; see Drugstore.com, § Your Prescription Information \(<http://www.drugstore.com/cat/11867/tmpl/default.asp?catid=15729>\) (accessed Sept. 20, 2000) (filling prescription drugs using the same three steps as any community or mail service pharmacy: 1) requiring customer to provide valid prescription by a licensed health care provider, 2) requiring each customer to complete an individual patient profile of allergies, current medications, medical conditions, and preferences for generic substitution, and 3) filling and mailing the prescription only after the new prescription is received and verified and the prescription is cross checked for interactions).

\textsuperscript{37} House Hearing, supra n. 7, § Test. of Herman I. Abromowitz; 21 C.F.R. 1306.2 (defining a "prescription" as an order for medication to be dispensed to an ultimate user).


The term "counterfeit drug" means a drug, which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

\textsuperscript{40} Id.

\textsuperscript{41} James Robert Nielsen, Handbook of Federal Drug Law 23 (2d ed., Lea & Febiger 1992) (defining the term "contraindications"). A drug is "contraindicated" when it should not be used, i.e., "where the patient is allergic to the drug or has a hypersensitivity to it."

\textsuperscript{42} See generally id.

\textsuperscript{43} House Hearing, supra n. 7, § Test. of Janet Woodcock.
Most online questionnaires do not meet standards that would be considered "good" medical practice. Moreover, some Web sites make no attempt to explain the potential risks of a drug or follow-up with the patient to determine whether the medication has been effective. In analyzing these and related issues surrounding online pharmacies, it is important to distinguish among the different types of online pharmacies.

B. DIFFERENT TYPES OF ONLINE PHARMACIES

The sale and distribution of pharmaceutical products over the Internet is complex and highly diverse. Online pharmacies can be classified into three basic categories. First, there are the online pharmacies that operate much like the traditional pharmacies. These traditional online pharmacies work the same way as mail order pharmacies that have existed for many years. This type of online pharmacy uses state-licensed pharmacists and requires the consumer to obtain a valid prescription from a licensed physician before ordering the drugs online. Accordingly, consumers must either mail in their prescriptions or have their physicians phone, fax, or mail the prescription to the Internet pharmacy before obtaining the drug. Depending on the Internet pharmacy,
the Web site may contact the physician to verify the prescription in every case or only on an as-determined basis. After a prescription is transmitted to the Internet pharmacy by the methods just described, the Web site dispenses the prescription directly to the patient.

The second category of online pharmacies is the prescribing-based site that offers a two-part service. First, an online doctor offers to diagnose a patient using a medical questionnaire to obtain the patient’s health profile, current medications, and a medical history. Then based on the e-diagnosis, an online doctor determines the cause of illness and prescribes a medication. Next, the patient can purchase the medication on the Web site. Some online pharmacies charge the consumer for both the consultation and the prescription. Other online pharmacies only charge for the consultation if the patient fills a prescription at the Web site based on a doctor’s recommendation. These diagnosing Web sites may appeal to consumers who wish to purchase “lifestyle” drugs but who do not want the inconvenience or embarrassment that might

method you select at checkout. (If we do not receive your prescription within 10 business days, we will contact you for help. If we do not hear from you, your order will be cancelled, and you will be notified via email.) For prescriptions transferred from another pharmacy: 1) You can ask you current pharmacy to phone or fax PlanetRx. 2) PlanetRx can phone the pharmacy currently holding your prescription. Please allow up to five business days for PlanetRx to contact your pharmacy and ship your order. Please allow additional days for shipping, depending on the shipping method you select at checkout. Prescription Verification: PlanetRx will verify prescriptions as we deem necessary according to the law, by contacting your doctor’s office or your current pharmacy.

Id. 52. Oliver, supra n. 49, at 98.
53. Id. at 99.
54. Id. at 98; see generally Cyberdocs.com <http://www.cyberdocs.com> (accessed Sept. 20, 2000).
55. See generally id.
56. See generally id.; see also House Hearings, supra n. 7, § Test. of Janet Woodcock (explaining that some prescribing-based sites are comprised exclusively of physicians, who upon issuing a prescription, contract with an online pharmacy to actually dispense the medicine). In some cases, the doctor, pharmacy, and consumer are all located in different states. Id. The strongest criticism of these sites is that an online questionnaire, no matter how detailed, simply cannot substitute for a physical examination. Id. Without an actual face-to-face examination, a patient’s warning signs which might easily be detected by touch could go unnoticed, posing potential risk to the patient. Id.
57. See generally Oliver, supra n. 49.
58. House Hearing, supra n. 7, § Test. of Janet Woodcock; see generally Cyberdocs.com, supra n. 54 (charging a fee for consultation).
60. See generally lifestyledrugs.com <http://www.lifestyledrugs.com> (accessed Sept. 27, 2000) (selling “lifestyle” drugs such as those used for erectile dysfunction, weight loss, or hair loss).
accompany a request to a doctor.\textsuperscript{61}

Finally, the most alarming type of online pharmacy is the online drugstore that allows its consumers to purchase prescription drugs without any type of prescription.\textsuperscript{62} Online pharmacies that sell prescription drugs without a prescription are called "rogue" pharmacies.\textsuperscript{63} A "rogue" pharmacy allows consumers to purchase any prescription drugs after a consumer completes an order form, selecting the desired drug and quantity.\textsuperscript{64} The prescription drug sale is then confirmed with a credit card number.\textsuperscript{65} With rogue pharmacies, no examination is necessary and no medical questionnaire needs to be answered.\textsuperscript{66} These Web sites appeal to consumers who wish to obtain certain medications without first obtaining a prescription.\textsuperscript{67} It is also possible that consumers who have been told by doctors that they should not take certain drugs may try to circumvent the system by going online and buying drugs that their doctors have denied them.\textsuperscript{68} Rogue pharmacies often operate from foreign countries and are usually beyond reach of U.S. authorities because they are not subject to U.S. laws governing the sale of prescription drugs.\textsuperscript{69}

Online pharmacies that dispense prescription drugs based solely on an online questionnaire or without a prescription pose a significant risk to public health.\textsuperscript{70} First, they circumvent the traditional protections built into the doctor-patient relationship.\textsuperscript{71} It is crucial that a doctor require a patient to undergo a physical examination to make a diagnosis and identify all drug allergies or physical ailments that make taking certain drugs dangerous to the patient’s health.\textsuperscript{72} Second, the inability of

\begin{flushleft}
\textsuperscript{61} See generally id.
\textsuperscript{62} House Hearings, supra n. 7, \S Test. of Janet Woodcock.
\textsuperscript{63} Henkel, supra n. 31, at 24.
\textsuperscript{65} See generally ePrescribe.com <http://www.ePrescribe.com/order/confirmorder.asp> (accessed Mar. 29, 2002) (allowing consumer to complete an order for Viagra without a valid credit card). The author was able to complete a sale for ten tablets of Viagra with an invalid credit card number.
\textsuperscript{66} House Hearings, supra n. 7, \S Test. of Janet Woodcock; see generally Foreignpharmacies.com <http://www.foreignpharmacies.com/new_index.htm> (accessed Mar. 29, 2002).
\textsuperscript{68} House Hearing, supra n. 7, \S Test. of Janet Woodcock.
\textsuperscript{69} Id.; see generally David L. Stott, Personal Jurisdiction in Cyberspace: The Constitutional Boundary of Minimum Contacts Limited to a Web Site, 15 John Marshall J. Computer & Info. L. 819 (Summer 1997).
\textsuperscript{70} House Hearing, supra n. 7, \S Test. of Janet Woodcock.
\textsuperscript{71} Id.
\textsuperscript{72} Id. (noting that consumers who buy prescription drugs from rogue Web sites can be harmed from inappropriately prescribed medications, dangerous drug interactions, and contaminated drugs).\
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consumers to confirm the legitimacy of online pharmacies increases the risk that drugs are mislabeled or counterfeit.\textsuperscript{73} In addition, the inability to confirm the authenticity of the doctors associated with online pharmacies offers little comfort regarding the adequacy of medical review.\textsuperscript{74} Finally, because the Internet can be an anonymous medium, some online pharmacies might be nothing more than scams, collecting credit card numbers, but providing no products.\textsuperscript{75} With the traditional pharmacy, consumers have certain protections against the fraudulent sale of prescription drugs;\textsuperscript{76} on the Internet, such protections are not so obviously present.\textsuperscript{77}

Although many consumers do not realize it, rogue pharmacies from foreign countries are illegal.\textsuperscript{78} FDA authorities consider foreign rogue pharmacies to be most dangerous because of their willingness to sell potentially dangerous controlled substances to virtually anyone.\textsuperscript{79} In addition, foreign online pharmacies often sell drugs that are unapproved for medical use in the U.S.\textsuperscript{80} The anonymous nature of the Internet, combined with the fact that many online pharmacies are based in foreign countries, make foreign online pharmacies very difficult to regulate. In fact, the few online pharmacies that are discovered and shut down by the FDA for illegal activity often reappear the next day with a different name or address.\textsuperscript{81}

\textsuperscript{73} \textit{See generally} id.
\textsuperscript{74} \textit{See generally} id.
\textsuperscript{75} \textit{Id.} (noting that consumers may be defrauded by paying money but never receiving the medication they ordered).
\textsuperscript{76} \textit{Id.} (noting that consumers can physically enter a store and see who is selling a drug or can receive approval from their insurance company to use certain mail-order services).
\textsuperscript{77} \textit{Id.}
\textsuperscript{78} \textit{Id.} (explaining that if the drug being sought requires a prescription, that requirement does not go away because it happens to be for sale in a foreign pharmacy without a prescription). Buying the drug is a violation of law, much like it would be if it was bought here in the street. \textit{Id.}; \textit{see} \textit{Federal Food, Drug, & Cosmetic Act}, 21 U.S.C. § 331(a) (2000) (providing exemptions and consideration for certain drugs, devices, and biological products); 21 U.S.C. § 353(b) (2000) (providing prohibitive act under statute).
\textsuperscript{79} \textit{House Hearing, supra} n. 7, § Test. of William K. Hubbard (citing an example of foreign Web site located in Colombia, South America, that was selling drugs in an abortion kit that posed potentially fatal health risks to women when used without a doctor's supervision). There is a growing fear that tragedies may result since some sites offer medications to customers with little or no physician evaluation of a consumer's physical condition, medical history, or age verification. \textit{Id.}; \textit{see} Maria Guzzo, \textit{Possibility of Online Pharmacy Abuse Feared}, 5 Denv. Bus. J. 9B (2000) (available in 2000 WL 16620351) (citing a University of Pennsylvania study that found that of more than 4,000 Internet drug stores in operation, eighty-six were selling Viagra without a prescription or medical evaluation).
\textsuperscript{80} H.R. Subcomm. on Oversight & Investigations Comm., \textit{Gene Therapy}, 106th Cong. § Test. of William K. Hubbard (May 24, 2000).
\textsuperscript{81} \textit{Id.}
C. State Involvement in Regulating Internet Prescribing

State authorities, including state medical and pharmacy boards, have primary jurisdiction in regulating pharmacies and the dispensing of prescription drugs.82 Under existing law in the majority of states, prescribing drugs to a patient outside the state where the physician is licensed is illegal.83 All state medical boards agree that prescribing drugs without physically examining a patient or reviewing a patient’s medical record constitutes practicing medicine at a level far below the acceptable standard of medical care.84 However, there are no state laws or regulations directly addressing the phenomenon of the sale of prescription drugs over the Internet.85

The Federation of State Medical Boards (“FSMB”) has investigated online pharmacies.86 The FSMB Committee on Professional Conduct and Ethics concluded that it is unprofessional conduct for a physician to provide treatment recommendations to a patient without first taking an adequate medical history and conducting a physical examination.87 A

82. House Hearings, supra n. 7, § Test. of Herman I. Abromowitz.
83. Id. (noting that under most state laws, state medical and pharmacy licensure boards have been delegated jurisdiction over medical and pharmaceutical professional practices, respectively).
84. Id.
Before prescribing a medication, a physician must: (1) Ensure that a medical history is obtained and readily available; (2) Provide information to the patient about the benefits and risks of the prescribed medication; (3) Generally perform an examination of the patient to determine a specific diagnosis and whether there actually is a medical problem; and (4) Initiate additional interventions and follow-up care, if necessary, especially when the drug is in question.

Id.
85. Id. (identifying the state licensing boards of Arizona, Colorado, Connecticut, Illinois, Nevada, New Jersey, Ohio, Texas, Washington, and Wyoming that are continuing or initiating investigations into physicians who participate in Internet prescribing). These state medical licensure boards are acting well within their authority to uphold the standard of medical care when they investigate physicians who participate in Internet prescribing. Id.

On May 3, 1999, the Washington Medical Quality Assurance Commission (“Commission”) initiated a licensure action against a Seattle physician for unprofessional conduct for prescribing Viagra based only on questionnaires completed over an Internet drug-sale site. According to the Commission, the physician was earning $5,000 a month for performing automated online medical reviews. On May 5, 1999, the Illinois Professional Regulation Department suspended the license of a physician who was writing Viagra prescriptions for a pharmacy Web site based on a one-page health form and an $85 consultation charge. There was no examination or discussion with the patient and on May 20, 1999, the physician’s license was reinstated after he agreed to stop prescribing drugs over the Internet or for patients he has not examined. The physician was ordered to pay a $1,000 fine.

Id.
86. House Hearings, supra n. 7, § Test. of Herman I. Abromowitz.
87. Id.
doctor's treatment recommendation includes prescribing medications. Accordingly, if a prescription is not valid, then the online pharmacy may be found to be distributing misbranded medication in violation of the Food, Drug, and Cosmetic Act ("FDCA").

In addition, the NABP has taken the position that any pharmaceutical Web site that uses an online questionnaire without a legitimate patient relationship is illegal. The NABP advocates licensing online pharmacies in every state. Accordingly, the NABP has established a global licensing program, Verification of Internet Pharmacy Practice Sites ("VIPPS"). The VIPPS certifies that an online pharmacy is licensed to dispense pharmaceuticals in all jurisdictions where it transacts business. The VIPPS program acts like a "seal of approval" placed on a Web site. The VIPPS program assures that the online pharmacy has met certain standards and is able to demonstrate compliance with all regulatory, statutory, and licensure requirements of each state in which it intends to dispense prescription drugs. The NABP has organized a list of Internet pharmacies that are in compliance with state laws under the VIPPS program. To date, the NABP has certified fourteen Internet pharmacies.88

88. Id.
89. See infra n. 150 and accompanying (explaining FDCA).
90. See generally Boards of Pharmacy Online, supra n. 16. The NABP represents state pharmaceutical licensing authorities. Id.
91. Id.
92. National Association of Boards of Pharmacy, Verified Internet Pharmacy Practice Sites § VIPPS <http://www.nabp.net/vipps.> (accessed Sept. 20, 2000) (explaining the VIPPS program). "A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria for which VIPPS certified pharmacies follow." Id. Certification under the NABP licensure program requires the pharmacy to meet a seventeen-point practice criteria and undergo a site visit. Id.
93. Id.
94. Id.
95. Id. (stating that "pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient's rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists").
96. Id. (explaining that before VIPPS certification is issued, NABP independently verifies all pharmacy applications, either through on-site inspections or through its computer database of state laws).
97. Id. (explaining that the VIPPS program informs the consumer of the legitimacy of pharmacy Web sites).
98. National Association Boards of Pharmacy, List of Pharmacies <http://www.nabp.net/vipps/consumer/listall.asp> (accessed Apr. 15, 2002) (listing the Internet pharmacies that have received the VIPPS seal of approval). The NABP has awarded the VIPPS certification to accuratepharmacy.com, Caremark Inc., Clickpharmacy.com, CVS Washington Inc., drugstore.com, Eckerd.com, familymeds.com, Merck-Medco Managed Care L.L.C.,
The VIPPS program informs the consumer of the legitimacy of an online pharmacy. The VIPPS program is the first attempt to implement minimum standards on pharmaceutical Web sites. However, the program is voluntary, and many sites continue to operate without any such regulation.

D. FEDERAL INVOLVEMENT IN REGULATING INTERNET PRESCRIBING

1. Food and Drug Administration

The federal government, especially the FDA, the Federal Trade Commission ("FTC"), and the Drug Enforcement Administration ("DEA") have important roles to play in addressing foreign Web sites that are illegally selling prescription drugs in the U.S. The FDA has traditionally regulated prescription drugs, approving drugs to treat various illnesses or conditions while also ensuring their safety. The FDA's role in prescription sales is to guarantee that drugs sold in the U.S. are FDA approved and properly manufactured. The FDCA is the basic food and drug law intended to ensure the consumer that drugs are safe and effective for their intended uses. The FDA has primary jurisdiction to regulate marketing and advertising of prescription drugs as well as the


100. Id.; House Hearings, supra n. 7, § Test. of Jodie Bernstein (stating that even though certification such as VIPPS can be valuable, legislature requiring disclosure may ultimately be necessary).

101. FDA, Requirements of Laws, supra n. 10, § II (stating that “the mission of the FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer’s health, safety, and pocketbook”). The Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 321-394, is the basic food and drug law that was enacted for this purpose. Id.; House Hearings, supra n. 7, § Test. of Janet Woodcock (indicating also the importance of the Customs Service, the Postal Service, and the DEA in taking action against the illegal importation of drugs). The DEA is primarily responsible for enforcing the provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances. Id.; see e.g. viagra-global.com <http://www.Viagra-Global.com> (including in their advertising a caveat explaining that they are not responsible for the drugs being delivered saying “we cannot accept any liability for the nondelivery of any products due to the actions of any government once shipment has left our port of exit.”). Customs and postal agents have intercepted packages of illegal products ordered online, but many packages still make their way through the mails. House Hearings, supra n. 7, § Test. of Janet Woodcock.

102. Oliver, supra n. 49, at 98.

103. House Hearings, supra n. 7, § Test. of Janet Woodcock.

104. See id. (stating that the mission of the FDA is to enforce laws enacted by the U.S. Congress and regulations established by the FDA to protect the consumer health, safety, and pocketbook). The Federal Food, Drug, & Cosmetic Act (21 U.S. Code (U.S.C.) 324 to 394) was enacted for this purpose. Id.
authority to take action against the sale of prescription drugs without a valid prescription.\textsuperscript{105} The increasing growth of Internet pharmacies along with a growing concern about the safety of drugs dispensed over the Internet has prompted the FDA to take action by sending warning letters to foreign rogue pharmacies.\textsuperscript{106}

2. \textit{The Federal Trade Commission}

The FTC's authority over Internet prescription sales is derived from the Federal Trade Commission Act ("FTCA"), which prevents "deceptive or unfair practices in commerce."\textsuperscript{107} The marketing of prescription drugs online is deceptive when it involves a misrepresentation or omission on which the consumer relies to his or her detriment.\textsuperscript{108} For example, the FTC would have authority to file suit against an online pharmacy for false or misleading claims about the safety of prescription drugs.\textsuperscript{109} However, the FTC does not have authority to revoke or enforce regulations relating to the licensing of pharmacists or pharmacies.\textsuperscript{110}

\textsuperscript{105} \textit{House Hearings}, supra n. 7, § Test. Janet Woodcock (citing a case from November 1998 where a consumer overdosed on GHB, contained in the GHB kits, and preparation instructions obtained from an Internet site located in Canada). In another case, the Office of Criminal Investigations ("OCI") "was advised by a state board of pharmacy that an Internet site was offering prescription drugs to U.S. customers from foreign manufacturer by acting as an authorized 'buyers club' using the 'personal importation policy' of FDA." \textit{Id.} OCI notified the U.S. Customs Service at a particular U.S. international mail facility to watch for suspicious shipments bound for the operator of the Internet site. \textit{Id.} "The Customs Service intercepted steroid shipments to the Web site's address and arrested and sentenced the primary suspect running the operation, who was tried, convicted, and sentenced." \textit{Id.} In addition, FDA has made a first step and issued cyber-letters to twelve operators of foreign-based Internet sites that offer to sell prescription drugs online. \textit{Id.} The letters warned the Web site that it may be engaged in activities that violate U.S. laws aimed at prescription drug sales. \textit{Id.}

\textsuperscript{106} \textit{Id.}

\textsuperscript{107} \textit{Federal Trade Commission Act}, 15 U.S.C. § 45(a) (2000) [hereinafter referred to as FTCA]. In addition to preventing deceptive or unfair practices under Section 5, Section 12 of the FTCA prohibits the false advertisement of food, drugs, devices, services, or cosmetics. \textit{See generally H.R. Subcomm., Drugstores on the Net: The Benefits and Risks of Online Pharmacies § Test. of Bob Michel (July 30, 1999) (available in 1999 WL 20010833) [hereinafter Drugstores on the Net]. Under Section 4, FTC has jurisdiction over marketers based outside the U.S. border selling in the U.S. market that violates Sections 5 and 12. \textit{Id.}

\textsuperscript{108} \textit{Natl. Cybercrime, supra} n. 3, at ¶ 14 illustrating that FTC would have the authority to file suit against an online pharmacy for false or misleading claims about the safety of medications). The FTC also monitors the practices of online pharmacy sites and uses their Internet expertise to assist other state and federal authorities in their enforcement efforts. \textit{Drugstores on the Net, supra} n. 107, § Test. of Bob Michel. The FTC has the technical capacity to monitor and investigate Internet marketing and is continuing to upgrade current technology, e.g. computer equipment permits staff to locate and preserve Web sites for evidentiary purposes. \textit{Id.}

\textsuperscript{109} \textit{Id.}

\textsuperscript{110} \textit{Id.}
The FTC believes that many of the concerns of online pharmacies are focused on the patient-physician relationship, which is the responsibility of the state medical boards.\footnote{111} 

3. The Drug Enforcement Administration

The DEA functions to prevent the unlawful distribution and use of controlled substances.\footnote{112} It performs this function in two ways.\footnote{113} First, the DEA conducts investigations and makes arrests of persons engaged in the unlawful distribution and abuse of controlled substances.\footnote{114} More importantly, the DEA prevents unlawful distribution and use of controlled substances by the regulation, registration and control of persons who are legitimately engaged in handling and distributing those substances.\footnote{115} The DEA deems it necessary to prevent or discourage the diversion of controlled substances into the illicit market by controlling the persons legally handling controlled substances.\footnote{116}

\footnote{111}{House Hearings, supra n. 7, § Test. of Jodie Bernstein (explaining that the FTC has “long refrained from challenging practices that fall within the doctor-patient relationship, including communications between doctors and patients about course of treatment decisions”). The FTC “does not have the [right] to revoke an individual physician’s license or to enforce state licensing requirements.” Id. “The licensing and regulation of pharmacies, like the licensing of physicians, has traditionally taken place at the state level by state pharmacy boards.” Id. The FTC believes that “state authorities should continue to have responsibility for enforcement of licensing requirements for physicians and pharmacists, [but] has and will continue to provide assistance to those authorities in individual investigations.” Id.}

\footnote{112}{Nielsen, supra n. 41, at 67.}

\footnote{113}{Id.}

\footnote{114}{Id.; H.R. Subcomm. on Oversight & Investigations Comm. on Commerce, Enforcing the Laws on Internet Pharmaceutical Sales: Where Are the Feds? § Test. of Ethan M. Posner (May 25, 2000) (available in 2000 WL 19304379) [hereinafter Hearing on Internet Pharmaceutical Sales] (noting that in the 1950’s, the DEA prosecuted doctors and pharmacists who sold amphetamine and Benzedrine to undercover agents without any prior examination or diagnosis). In the 1980s and early 1990s, before steroids became a controlled substance, several doctors received significant sentences for supplying high-profile athletes and entertainers with prescription steroids for illegitimate cosmetic reasons. Id.}

\footnote{115}{Nielsen, supra n. 41, at 141-145.}

\footnote{116}{Id.; Hearing on Internet Pharmaceutical Sales, supra n. 114, § Test. of Ethan M. Posner (noting that in February 2000, “the U.S. Attorney’s Office in [the] Eastern District of Louisiana obtained an indictment [in a case] involving the Internet distribution of marijuana”). “The indictment followed a DEA investigation into the illegal sale of “medical marijuana” by Michael David Aronov via the Internet.” Id. The defendant and his business, Arizona Company Medical, “were indicted on seven drug distribution counts and one count of placing a written advertisement in a publication, the Internet, for the purpose of seeking, or offering illegally to receive, or distribute marijuana.” Id.}
ANALYSIS

A. FEDERAL AND STATE REGULATIONS OF THE INTERNET

1. Inadequate Regulation Through Federal Initiatives

The Department of Justice ("DOJ"), through its Civil and Criminal Divisions, local U.S. Attorney's Offices, the Federal Bureau of Investigation ("FBI"), the FDA, the DEA, and the FTC\footnote{Drugstores on the Net, supra n. 107, § Test. of Bob Michel. The FTCA protects consumers from unfair or deceptive acts or practices, including the false advertisement of drugs. Id.; Hearing on Internet Pharmaceutical Sales, supra n. 114, § Test. of Ethan M. Posner. Many online pharmacies make important representations to consumers on their Web sites. For example, online pharmacies may claim that a properly licensed physician will review the online medical questionnaire. Id. Also, an online pharmacy may represent that a product is safe. Id. Furthermore, Web sites may falsely represent that medical information collected from consumers will be kept confidential or that an online consultation is equivalent to a physical examination. Id. To the extent that such representations are false or deceptive, the online pharmacy would be violating the FTCA, thereby subjecting the Web site operator to a civil enforcement action. Id. For example, in December 1999, "the Department filed a civil action to enjoin a purported dietary supplement manufacturer from distributing products that are actually promoted for the cure or treatment of disease." Id. The products, including shark cartilage dietary supplement, a glycoalkaloid skin cream, and a rice bran extract dietary supplement, [are] promoted through Internet links and other sources as being effective in treating or preventing cancers and HIV infection." Id. "The complaint sought to enjoin the defendants from engaging in interstate commerce in these products, or any other products containing the same or similar ingredients, unless and until they are approved as drugs by the FDA." Id. Also in May 2000, "a jury in the Middle District of Florida convicted two individuals of distributing prescription drugs in the interstate commerce without a prescription with the intent to defraud and mislead." Id. "One individual was also convicted of distributing deprenyl, a misbranded prescription drug," which "was offered for sale on the Internet as a 'fountain of youth' drug and for a long list of other diseases." Id.}\footnote{Hearing on Internet Pharmaceutical Sales, supra n. 114, § Test. of Ethan M. Posner. The DEA has investigated and prosecuted many physicians for dispensing controlled substances without a legitimate medical purpose. Id. The recent surge in online prescribing is ultimately a new version of an old problem. Id. In the 1950s, individuals purchased drugs without valid prescriptions from doctors working out of truck stops, and in the 1980s, doctors sold steroids out of the back door of their offices. Id. Today, it is the Internet that serves as an unscrupulous doctor's means to peddle drugs without prescriptions. Id. In September 1999, "a grand jury in the Middle District of Florida returned a thirty-one count indictment against Jose A. Perez Menchaca, Paul Cabaniss, and Bondtech-Klebrig Corporation alleging Internet sales of the unapproved drug gamma butyrolactone (GBL), an ingredient of Gamma hydroxy butyrate (GHB)." Id. "GHB is a blackmarket drug sold illicitly throughout the country for its alleged ability to cause euphoria, induce sleep, increase sexual arousal, and increase muscle mass." Id. The criminal schemes were facilitated "by computers through electronic communications and the Internet": according to the indictment, the defendants used a Web site to both advertise and solicit orders from customers within the U.S. and from around the world; used various aliases to pose as a 'satisfied' customer while touting their GHB kits on computer 'newsgroups'; and used e-mail to com-} have successfully prosecuted doctors and pharmacists for prescribing drugs without a valid prescription.\footnote{Id.} The DOJ has also taken an active role in prosecuting
Web site operators who illegally sell FDA-regulated drugs over the Internet.119 "The federal government has little authority to bring criminals in other countries to justice."120 "However, it can freeze the U.S. assets of foreign sellers if given proper authority."121 "The DOJ has the ability to stop illegal foreign operators from collecting payments from U.S. customers."122 However, it is clear that the DOJ would not have been successful without the combined efforts of other agencies.123

2. Inadequate Regulation Through State Initiatives

"States have traditionally regulated pharmacies and doctors doing business within their borders via licensing requirements."124 Although

119. Id. (noting that in February 1999, a seller of a bogus HIV self-test kit was sentenced to sixty-three months for mail fraud, wire fraud, and money laundering). Also, in December 1999, "the U.S. Attorney's Office in Hawaii charged Kent Aoki Lee with one count of selling Viagra over the Internet." Id. "The defendant offered Viagra, for sale thought a Web site in the Japanese language [and] did not require any form of prescription." Id. In April 2000, "the defendant pled guilty to one count of wire fraud and one count of dispensing a misbranded drug." Id. In addition, in March 2000, "[the] U.S. District Court for the Eastern District of Missouri entered a preliminary injunction barring Syntrax Innovations, Inc., from manufacturing or distributing any product containing the thyroid hormone tiratricol." Id. "Prior to this order, the company had been marketing over the Internet a tiratricol-containing product called "Triax" as a dietary supplement for weight loss." Id. "The use of tiratricol can cause hyperthyroidism, which can lead to hypertension, insomnia, nervousness, cardiac arrhythmia, heart attacks, and strokes [and] the preliminary injunction barred Syntrax from selling any tiratricol products during the pendency of litigation." Id. In addition, in April 2000, the DEA "obtained a preliminary injunction against Christian Brothers Contracting Corp. and its president, Jason Vale, prohibiting them from making or distributing amygdalin, Laetrile, Vitamin B-17, or apricot seeds during the pendency of the action." Id. "[The DEA] brought suit after learning that the defendants were defrauding thousands of vulnerable cancer victims by advertising and selling apricot seeds and Laetrile products as a cure for cancer through numerous Web sites and millions of 'spam' e-mails." Id. In May 2000, "the proprietor of an Internet-based 'virtual' retail business was indicted by a federal grand jury in Roanoke, Virginia, for the interstate marketing of the misbranded drug, nitrous oxide, a substance blamed for the death of a Virginia college student." Id. The grand jury charged the defendant, with selling nitrous oxide to customers in the Western District of Virginia via Web site BONGMART.com, "which the defendant operated and also sold other drug paraphernalia." Id.

120. 146 Cong. Rec. §§ 10619-08, 10621.
121. Id. § 10620.
122. Id. (noting that if illegal foreign Web sites cannot make a profit, they will stop selling prescription drugs). Id. § 10621.
123. Hearing on Internet Pharmaceutical Sales, supra n. 114, § Test. of Ethan M. Posner.
some online pharmacies maintain a global license by obtaining a VIPPS
seal of approval, the vast majority of the 400 companies selling drugs
over the Internet do not.125 Consequently, online pharmacies without a
global license must continually be wary of where customers live in order
to avoid liability.126

The California Board of Pharmacy127 has recently "draft[ed] legisla-
tion to address the recent and potentially dangerous proliferation of
pharmacy practice activity on the Internet."128 However, the resolution
proposed by the California Board of Pharmacy may not be the best solu-
tion available.129 Inconsistencies will continue to develop between dif-
ferent jurisdictions and regulatory agencies.130

The only way to insure that uniform standards ensure consumer
health and safety with respect to the online distribution of licit drugs

125. Id. (naming the fourteen online pharmacies with the VIPPS certification); see e.g.

126. Id.

Health Care Regulatory Agencies) (available in WL at 17 CARLR 57) (explaining that the
California Board of Pharmacy is a consumer protection agency located within the Califor-
nia Department of Consumer Affairs). "To enforce the Pharmacy Law and its regulations,
the Board...investigates complaints" and "conducts fact-finding and disciplinary hearings"
regarding "all sales of dangerous drugs, controlled substances, and poisons." Id. The
Board is also "authorized by law to suspend or revoke licenses or permits for a variety of
reasons, including professional misconduct and any misconduct substantially related to the
practice of pharmacy." Id.

128. Id. at *62 (noting that "Although the Pharmacy Law requires an Internet phar-
macy which offers to compound, dispense, or refill a prescription for a resident of California
to be licensed by the Board as a non-resident pharmacy...enforcement of that requirement
in the Internet environment is difficult"). The Board's Licensing Committee has reached
the conclusion that "Internet practice is a global problem, far bigger than any state licens-
ing board or even federal agency can address" and determined that "perhaps the most a
state agency can do is educate consumers to exercise extreme caution when purchasing
dangerous drugs or devices over the Internet." Id.

The legislation drafted and proposed establish[ed] the following requirements for
an out-of-state Internet pharmacy dispensing prescription drugs to California re-
idents: (1) It must be licensed by the Board as a non-resident pharmacy, and
must be licensed as a pharmacy in its home state; (2) it may not be foreign-based
or owned by prescribers; (3) it may not offer prescribing-based sites where the pre-
scriber issues a prescription to a consumer based upon an online questionnaire; (4)
it may only accept a faxed prescription from a prescriber (it may also receive a
faxed prescription from a patient, but must receive the original prescription from
the patient prior to filling the prescription); (5) it must disclose on its home page
its name, location, toll-free number, and California license number; and (6) it must
be registered with the Verified Internet Pharmacy Practice Site (VIPPS) program
administered by the National Association of Boards of Pharmacy... similar to a
'Good Housekeeping' seal of approval.

Id.

129. See id.

130. See id.
while effectively minimizing distribution of illicit drugs are established is through new federal legislation. The FDA has made some effort to regulate foreign online pharmacies through its warning letters, and the states have made efforts through statewide regulation. However, this piecemeal approach does not provide for a uniform regulatory system that is necessary for consumer protection in prescription drugs sales over the Internet.

B. THE PROBLEMS ASSOCIATED WITH THE FDA’S CURRENT REGULATION

1. Inadequate Regulation Through Cyber-Letters

In order to deal with the growth of rogue pharmacies from foreign countries, the “FDA has issued cyber-letters . . . to a dozen operators of foreign-based” pharmacies suspected of illegally selling prescription drugs. The cyber-letters warn the “[W]eb[ ]site operators that they may be engaged” in activities that violate U.S. laws governing the sale of prescription drugs. The letters also warn that U.S. customs officials may detain and refuse entry to future shipments from the rogue Web site. The FDA has also contacted Web site managers of rogue pharmacies and asked for voluntary cooperation in removing violative sites.

For example, if a foreign Web site is selling prescription drugs to U.S. consumers without a valid prescription, the FDA sends a letter warning the site of its non-compliance with U.S. federal regulations. Although warning letters to foreign online pharmacies are shared with the government of the country the pharmacy is based in, these letters only provide for a warning. The warning letter does not demand that the illegitimate Web site comply with U.S. regulations, and indeed, the FDA lacks the authority to make such a demand. Therefore, the use of warn-

131. House Hearings, supra n. 7, § Test. of Ivan Fong.
132. Id.
133. Food & Drug Administration, FDA Launches “Cyber” Letters Against Potentially Illegal, Foreign-Based Online Drug Sites, FDA Talk Paper ¶ 1 <http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html> (accessed Feb. 2, 2000) [hereinafter FDA Cyber Letters]; see House Hearings, supra n. 7, § Test. of Janet Woodcock (explaining that warning letters were sent “to firms illegally selling unapproved new drugs online and issuing Import Alerts to online sellers of illegal foreign pharmaceuticals”).
134. FDA Cyber Letters, supra n. 133, at ¶ 1 (noting that sending warning letters was the first step by the FDA to reach out to potential violators of the federal Food, Drug, & Cosmetic Act).
135. Id. at ¶ 4.
136. House Hearings, supra n. 7, § Test. of Janet Woodcock (stating that FDA will continue to and escalate its efforts to protect the public against illegal and potentially dangerous products sold through Web sites).
137. FDA Cyber Letters, supra n. 133, at ¶ 2.
138. Id. at ¶ 5.
ing letters falls short of uniform, industry-wide regulation. Although the warning letters help provide some framework for regulatory procedure, the letters themselves provide no framework for the Internet pharmacy industry as a whole. 139 Without a framework or uniform laws in this area, state regulators are left with little guidance for prosecuting violations that occur over the Internet. 140

2. Inadequate Understanding of the Internet

The FDA has regulations in place to attack some of the problems that the Internet presents to the area of pharmacy law. However, the obstacles that the Internet community presents to these regulatory efforts may prove to be more challenging than the FDA expected.

The first obstacle the FDA faces is the issue of free speech. Absent any formal legislation, the FDA has placed itself in a challenging situation. On the one hand, the FDA has the job of encouraging the use of the Internet as a new and innovative way of benefiting from online pharmacies. 141 On the other hand, the FDA has the duty of protecting the public from any new dangerous developments in the area of online pharmaceutical sales. 142 Therefore, the FDA must meet two very challenging goals: respond quickly to any fraudulent activity and maintain the privacy of the Internet community. 143

One difficulty the FDA will face when trying to enforce regulation of Internet pharmacies is that the Internet's informal and uncensored environment creates a lawless mentality among its users. 144 The mentality of most Internet users makes it clear that the FDA will have difficulties implementing regulatory control devices on the Internet. 145 Therefore, the FDA will have the task of finding a balance between advocating free speech and prosecuting those who go too far by violating the laws governing the sale of prescription drugs. Thus, the question is whether federal legislation has been adequate in addressing the balance of benefits and risks involved with the sale of prescription drugs over the Internet.

139. See House Hearings, supra n. 7, § Test. of Janet Woodcock.
140. Id. Another problem with the use of warning letters is that they do not provide the adequate consumer protection that can be provided through legislation. Id. For instance, consumers rely on warning letters as an adequate means of protection when they should be lobbying Congress for better protection through federal legislation. Id.
141. Id. (explaining that the FDA cannot inhibit the use of the Internet).
142. Id.
143. Id.
144. Id.; see generally Joseph M. Kizza, Civilizing the Internet (McFarland & Co. 1998).
145. House Hearings, supra n. 7, § Test. of Janet Woodcock.
C. Inadequate Federal Legislation: The Food, Drug, and Cosmetic Act and the Controlled Substances Act

1. The Food, Drug, and Cosmetic Act

The FDCA\textsuperscript{146} is one of the statutes that controls the sale and distribution\textsuperscript{147} of drugs in the U.S.\textsuperscript{148} The FDCA is concerned with fixing the rules and regulations by which drugs are imported, manufactured, distributed, and sold in the U.S.\textsuperscript{149} The FDCA generally prohibits the manufacture and distribution of misbranded and adulterated drugs.\textsuperscript{150} The FDCA also requires that drugs are accurately labeled and handled in ways that prevent them from being contaminated and misused.\textsuperscript{151} The FDCA relies on physicians and pharmacists to protect patients from the knowing or accidental misuse of medicines that are toxic or that have the potential for causing harm.\textsuperscript{152}

Accordingly, the FDCA generally provides that only physicians can prescribe certain drugs.\textsuperscript{153} Similarly, the FDCA provides that pharma-

\begin{itemize}
  \item \textsuperscript{146} Nielsen, \textit{supra} n. 41, at 3. (noting that the FDCA established the FDA in the Department of Health & Human Services). The FDA is directed by a Commissioner who is appointed by the President and confirmed by the Senate. \textit{Id.}
  \item \textsuperscript{147} 21 U.S.C. § 802 (defining “distribute” to mean “to deliver, other than administering or dispensing, a controlled substance”). A distributor is one who delivers. \textit{Id.}
  \item \textsuperscript{148} Nielsen, \textit{supra} n. 41, at 3.
  \item \textsuperscript{149} \textit{Id.}
  \item \textsuperscript{150} 21 U.S.C. § 353(b)(1) (2000). A prescription drug is considered misbranded if it is not dispensed pursuant to a valid prescription in accordance with 21 U.S.C. § 353(b):
    \begin{itemize}
      \item Prescription by physician; exemption from labeling and prescription requirements, misbranded drugs; compliance with narcotic and marihuana laws. (1) A drug intended for use by man which—(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (B) is limited to by an approved application under section 505 21 U.S.C. § 355 to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and is filled by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.
    \end{itemize}
  \item \textsuperscript{151} \textit{Id.}; FDA, \textit{Requirements of Laws, supra} n. 10, § II (explaining that the term “adulterated” includes products that are defective, unsafe, filthy, or produced under unsanitary conditions and “misbranded” includes statements, designs, or pictures in labeling that are false or misleading, and failure to provide required information in labeling).
  \item \textsuperscript{152} 21 U.S.C. § 353(b)(1).
  \item \textsuperscript{153} \textit{Hearing on Internet Pharmaceutical Sales, supra} n. 114, § Test. of Ethan M. Posner (stating that Congress established the FDCA in 1951 that currently governs the sale of prescription drugs to protect the public from abuses arising from the sale of potent pre-
cists only distribute those drugs to someone who has a valid prescription from his or her doctor.\textsuperscript{154} The FDCA considers any prescription drug dispensed\textsuperscript{155} without a valid prescription misbranded.\textsuperscript{156} Therefore, introduction or distribution of misbranded drugs into interstate commerce violates the FDCA.\textsuperscript{157} Similarly, an online pharmacy that provides prescription drugs without a prescription from a doctor or pharmacist would be in violation of the requirements set by the FDCA.\textsuperscript{158}

\begin{quote}

\textsuperscript{154} 21 U.S.C. § 802 (10) (defining “dispense” to mean to deliver a controlled substance to the ultimate user). To dispense includes prescribing, compounding, packaging, and labeling the substance to prepare it for delivery to the dispenser. \textit{Id.}; see Nielson, supra n. 41, at 91-96 (providing examples where a controlled substance is dispensed). When a registered physician prescribes a controlled substance for a patient, he is dispensing. \textit{Id.} If a physician gives or prescribes a drug to the patient for later self-administration, he is dispensing. \textit{Id.} A pharmacy furnishing a patient with controlled substances upon the lawful prescription of a practitioner is also dispensing. \textit{Id.}

\textsuperscript{155} 21 U.S.C. § 353(b)(1).

\textsuperscript{156} 21 U.S.C. § 331(a)-(c) (2000).

The following acts and the causing thereof are hereby prohibited: (a) the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded (b) the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce (c) the receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. \textit{Id.}; see FDA, Requirements of Laws, supra n. 10, § II (noting that all drugs, as defined by the FDCA and related laws, are subject to examination by the FDA when they are being imported or offered for importation into the U.S.). All imported products are required to meet the same standards as domestic goods. \textit{Id.} Therefore, imported drugs must also be safe and effective for their intended uses. \textit{Id.} To ensure that the FDA is notified of all regulated products imported into the U.S., the general procedure requires the importer to file an entry notice and acquire a bond to cover their goods for release within the U.S. by the Customs Service. \textit{Id.} The FDA is notified by the Customs Service of the entry and makes a decision as to the drug’s admissibility upon examination in an FDA’s laboratory. \textit{Id.} If the analysis shows that the product is in compliance, the shipment is released into the U.S. commerce, but if there is a violation, the product is refused admission. \textit{Id.}

\textsuperscript{158} \textit{Id.} Foreign establishments offering drugs for importation into the U.S. are not required to register their establishments under the FDCA but must comply with the listing requirement of their products with the FDA. \textit{Id.}; see Hearing on Internet Pharmaceutical Sales, supra n. 114, § Test. of Ethan M. Posner (explaining that legal action to curtail such conduct may be brought criminally or civilly). For a felony conviction, the government must establish that the defendant acted with an intent to defraud or mislead either the consumer or the government that the defendant is a repeat offender. \textit{Id.} Civil cases and misdemeanor prosecutions do not require proof of an intent to defraud or mislead. \textit{Id.}; \textit{House Hearing}, supra n. 7, § Test. of Ivan Fong (noting that the DOJ has successfully prosecuted doctors and veterinarians for dispensing drugs without a valid prescription). For example, in several cases, certain doctors were prescribing and distributing anabolic ster-
Furthermore, the Internet Pharmacy Consumer Protection Act of 2000 ("IPCPA"), a statute that amends the FDCA with respect to the sale of prescription drugs through the Internet, sets forth the minimum requirements for an online pharmacy site.\textsuperscript{159} The IPCPA requires that online pharmacies display detailed information about their Web site operators and their locations and post accurate contact information.\textsuperscript{160} The IPCPA requires sites to list the name of the principal practitioner, oids to athletes and entertainers not to treat medical conditions, but for purely cosmetic purposes, and they did not examine the patients before dispensing the steroids. \textit{Id.} Under section 353(b), one may distribute prescription drugs only if (1) there is a bonafide doctor-patient relationship, and (2) the distribution is pursuant to a course of individualized treatment for a legitimate medical purpose. \textit{Id.;} 21 U.S.C. § 333(a). Legal action to curtail the distribution of misbranded drugs, including distribution of drugs without a valid prescription, may be brought criminally or civilly. \textit{Id.}


Sec. 503B. Internet Sales of Prescription Drugs.
(a) In General. A person may not introduce a prescription drug into interstate commerce or deliver the prescription for introduction into such commerce pursuant to a sale of the drug by such person if –

(1) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sale transaction for the drug, through an Internet site; and

(2) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in subsection (b) (other than a site or pages on a site that are not intended to be accessed by purchasers or prospective purchasers).

(b) Requirements. With respect to an Internet site, the requirements referred to in paragraph (2) of subsection (a) for a person to whom such subsection applies are as follows:

(1) The site shall include a page that provides the following information:

(A) The name of such person; the address of the principal place of business of the person with respect to sales of prescription drugs through the Internet; and the telephone number for such place of business.

(B) Each state in which the person is authorized by law to dispense prescription drugs.

(C) The name of each individual who serves as a pharmacist for purposes of the site, and each State in which the individual is authorized by law to dispense prescription drugs.

(D) If the person provides for medical consultation through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations; and the type or types of health professions for which the individual holds such licenses or other authorizations.

(2) Each other page of the site (if any) shall include either a link to the page referred to in paragraph (1) or the information described in such paragraph.

(3) A link to which paragraph (2) applies shall be clearly visible on the page involved, shall not be of a size smaller than other links on the page (if any), and shall include the caption for the link either the word ‘licensing’ or the word ‘license.’

\textit{Id.}

160. \textit{Id.}
the address and telephone number of the principal business location, and the states where the pharmacy and its pharmacists are licensed to operate.\textsuperscript{161} In addition, if the Web site provides medical consultations for prescriptions, it also must disclose the names and licensing information of the prescribers.\textsuperscript{162} The primary enforcement of the IPCPA is entrusted to the states.\textsuperscript{163}

However, the FDCA and IPCPA are inadequate in addressing the sale of prescription drugs over the Internet. There are numerous online pharmacies that do not register their Web sites. This makes it impossible to identify the Web site operators who are illegally selling prescription drugs over the Internet. The Internet is a breeding ground for small-growth companies because the costs for setting up are low.\textsuperscript{164} Moreover, most small online pharmacies are typically not registered on the Internet.\textsuperscript{165}

Clearly, an online pharmacy selling prescription drugs without a valid prescription violates the FDCA.\textsuperscript{166} Under the FDCA, it is extremely difficult to regulate Web site operators that are not registered over the Internet. Accordingly, the IPCPA requires that all online pharmacies provide detailed information regarding their Web site.\textsuperscript{167} However, Web site operators have refused to comply with the requirements set by the FDCA and IPCPA in order to circumvent the system. This creates a problem for Internet regulation because consumers have a

\textsuperscript{161} Id.
\textsuperscript{162} Id.
\textsuperscript{163} Id.
\textsuperscript{164} Sheryl Stolberg, \textit{Officials Struggle to Regulate On-Line Sale of Prescription Drugs}, N.Y. Times A12 (March 25, 1999) (explaining that because Web sites can be easily created and designed, patients may think they have purchased their medications from a U.S.-licensed pharmacy when, in fact, they have not).
\textsuperscript{165} Id.; \textit{House Hearings, supra} n. 7, § Test. of Janet Woodcock.
\textsuperscript{166} 21 U.S.C. § 353(b)(1).
\textsuperscript{167} H.R. 2763, 106th Cong.
right to know with whom they are dealing on the Internet, just as they
do with their traditional local pharmacy.

2. The Controlled Substances Act

The Controlled Substances Act ("CSA") also controls the sale and
distribution of drugs in the U.S. The CSA is concerned with the pre-
vention and control of the abuse of controlled substances. The CSA
provides that controlled substances may be distributed only between per-
sons who are registered with the DEA. The CSA requires that all per-
sons who manufacture, distribute, dispense, export, or import a
controlled substance in the U.S. register with the DEA unless exempted
under law or regulation. Accordingly, pharmacies registered as dis-

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168. Nielsen, supra n. 41, at 3 (stating that "the CSA is administered and enforced by
the Department of Justice [(DOJ)] under the Attorney General" and is a unit of the DEA,
which is itself part of Federal Bureau of Investigation).

169. Id.

(1) Schedule I. (A) The drug or other substance has high potential for abuse. (B).
The drug or other substance has no currently accepted medical use in treatment in
the U.S. (C) There is a lack of accepted safety use of the drug or other substances
under medical supervision. (2) Schedule II. (A) The drug or other substance has
high potential for abuse. (B) The drug or other substance has currently accepted
medical use in treatment in the U.S. or a currently accepted medical use with
severe restrictions. (C) Abuse of the drug or other substances may lead to severe
psychological or physical dependence. (3) Schedule III. (A) The drug or other
substance has a potential for abuse less than the drugs or other substances in sched-
ules I and II. (B) The drug or other substance has a currently accepted medical
use in treatment in the U.S. (C) Abuse of the drug or other substances may lead to
moderate or low physical dependence or high psychological dependence. (4) Sched-
ule IV. (A) The drug or other substance has a low potential for abuse relative to
the drugs or other substances in schedule II. (B) The drug or other substance has
a currently accepted medical use in treatment in the U.S. (C) Abuse of the drug or
other substance may lead to limited physical dependence or psychological depen-
dence relative to the drugs or other substances in schedule III. (5) Schedule V. (A)
The drug or other substance has a low potential for abuse relative to the drugs or
other substances in schedule IV. (B) The drug or other substance has a currently
accepted medical use in treatment in the U.S. (C) Abuse of the drug or other sub-
stance may lead to limited physical dependence or psychological dependence rela-
tive to the drugs or other substances in schedule IV.

Id.

171. Nielsen, supra n. 41, at 70 (noting that the CSA establishes a closed system for the
distribution of drugs and other substances of abuse because it only allows persons regis-
tered with the DEA to distribute the controlled substances).

172. 21 U.S.C. § 822 (2000). Applicant shall be owner, active partner, or any corporate
officer. Id. Federal law does not require applicant to be a pharmacist. Id. Persons who
dispense controlled substances also prescribe and administer them. Id.

(a) Annual registration. (1) Every person who manufactures or distributes any
controlled substances or list I chemical, or who proposes to engage in the manufac-
ture or distribution or any controlled substances or list I chemical, shall obtain
annually a registration issued by the Attorney General in accordance with the
rules and regulations promulgated by him. (2) Every person who dispenses, or
Pensers of controlled substances and practitioners who prescribe drugs are required to provide a written or oral prescription for dispensing such drugs.\textsuperscript{173}

who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registration. In no event, however, shall such registrations be issued for less than one year nor for more than three years. (b) Authorized activities. Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title. (c) Exceptions. The following persons shall not be required to register and may lawfully possess any controlled substances or list I chemical under this title: (1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment. (2) A common or contract carrier or warehouseman, or any employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment. (3) An ultimate user who possesses such substance for a purpose specified in section 102 (25) [21 U.S.C. § 802(25)]. (d) Waiver. The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety. (e) Separate registration. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals. (f) Inspection. The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

\textit{Id.}; see 21 U.S.C. §§ 841, 958.


(a) Schedule II substances. Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substances in schedule II, which is a prescription drug as determined by the Federal Food, Drug, & Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503 of that Act [21 U.S.C. § 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 307 of this title [21 U.S.C. § 827]. No prescription for a controlled substance in schedule II may be refilled. (b) Schedule III and IV substances. Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. § 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner. (c) Schedule V substances. No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medicinal purpose. (d) Non-prescription drugs with abuse potential. Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

\textit{Id.}
The CSA also prohibits the dispensing of a controlled substance without a valid prescription.\textsuperscript{174} The CSA places all substances that are regulated under the existing federal law into one of five schedules.\textsuperscript{175} This placement is based upon the substance's medicinal value, harmfulness, and potential for abuse or addiction.\textsuperscript{176} Based on a regulation that the DEA issued, some interpret the definition of prescription under the CSA to exclude a prescription written by a physician based on information obtained solely from an online questionnaire.\textsuperscript{177}

The CSA regulates conduct in a technology-neutral way and applies to online pharmacies and other Web sites that offer or dispense controlled substances.\textsuperscript{178} However, it is clear that the Internet provides an ideal environment for the sale of prescription drugs without a valid prescription. Anyone could put together a Web site and offer for sale a prescription drug without ever seeking approval by the FDA.\textsuperscript{179} In addition

\textsuperscript{174} 21 U.S.C. §§ 822, 829, 841 (2000);\textit{House Hearing, supra} n. 7, § Test. of Laura M. Nagel (noting that the “CSA, Title II of the Comprehensive Drug Abuse Prevention & Control Act of 1970, is the legal foundation of the government’s fight against the abuse of drugs and other substances”). This law is a consolidation of numerous laws regulating the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. Id.

\textsuperscript{175} Id.

\textsuperscript{176} 21 U.S.C. § 812 (b)(1)-(5) (explaining that Schedule I is reserved for the most dangerous drugs that have no recognized medicinal use, while Schedule V is the classification used for the least dangerous drugs). The CSA also provides a mechanism for substances to be controlled, added to a schedule, decontrolled, removed from control, rescheduled, or transferred from one schedule to another. Id.

\textsuperscript{177}\textit{Hearing on Internet Pharmaceutical Sales, supra} n. 114, § Test. of Ethan M. Posner (noting that obtaining a prescription based on an online questionnaire raises concerns for online pharmacies offering diagnostic services as a means to ensure that prescriptions are valid and issued by licensed physicians);\textit{House Hearing, supra} n. 7, § Test. of Ivan Fong (explaining that “whether a particular online pharmacy, such as one that provides an online questionnaire for the consumer to complete before the drug is dispensed, can satisfy these standards will depend on the specific facts involved and evidence presented”). “It may also depend on whether the resulting prescription is a valid prescription under relevant state law.” Id. For example, prosecuting under the CSA, “[a] grand jury in Maryland recently returned a 34-count indictment against a physician for dispensing several controlled substances, including phentermine and fenfluramine, without a legitimate medical purpose.” Id.

\textsuperscript{178} Id.

\textsuperscript{179}\textit{House Hearings, supra} n. 7, § Test. of Janet Woodcock (indicating also the importance of the Customs Service, the Postal Service, and the DEA in taking action against the illegal importation of drugs). The DEA is primarily responsible for enforcement of the provisions of the CSA as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances. Id.; see generally \texttt{Viagra-Global.com} <http://www.Viagra-Global.com> (accessed Mar. 29, 2002) (including in their advertising a caveat explaining that they are not responsible for the drugs being delivered: “We cannot accept any liability for the nondelivery of any products due to the actions of any government once shipment has left our port of exit.”). Customs and postal agents have intercepted packages
to this fraudulent activity, an individual may give fraudulent medical consultations regarding the validity and legitimacy of illegal drugs sold over the Internet. This gives the fraudulent seller the opportunity to endorse his own illegal action.  

Clearly, it is unlawful to dispense controlled substances without a valid prescription.  

Therefore, problems can arise when a company, intending to comply with the CSA, offers prescription drugs over a Web site. Due to the vast audience that a Web site offers, the online pharmacy may not realize exactly to whom the drug is being offered. This could create a problem for a Web site making a sale of prescription drugs that is intended to be an intrastate offering, but may instead be deemed to be interstate or global because the access the Internet offers to out-of-state and foreign residents.

D. The Proposal: The International Coalition on Online Pharmacies

1. The Need for an International Coalition

It is apparent that problems exist with the current regulation efforts designed to deal with Internet pharmacies. It is also apparent that consumers are purchasing increasing amounts of prescription drugs from foreign Internet pharmacies because they offer much lower prices than pharmacies in the U.S. Additional legislation is necessary with respect to the sale of drugs on the Internet. In order to maintain adequate protections for consumers and to permit effective enforcement, new legislation is required. In this regard, this comment proposes the International Coalition on Online Pharmacies (“ICOP”). The ICOP would regulate Internet pharmacies by following the framework developed in the proposed Interagency Internet Working Group (“Working Group”)

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180. House Hearings, supra n. 7, § Test. of Janet Woodcock (citing a case from November 1998 where a consumer overdosed on GHB, contained in the GHB kits and preparation instructions obtained from an Internet site located in Canada).

181. Id.

182. Id.

183. David L. Scott, Personal Jurisdiction in Cyberspace: The Constitutional Boundary of Minimum Contacts Limited to a Web site, 15 J. Marshall J. Computer & Info. L. 819, 826 (1997). The Internet has a worldwide nature. Id. For example, when a site becomes available it is almost instantaneously available to anyone worldwide. Id. This allows users to access the site from any state or country. Id.

One of the most significant challenges in the area of online pharmacies is the coordination of enforcement policies and initiatives among a variety of federal, state and other foreign entities. Even if existing federal substantive law is adequate, unlawful online pharmacies raise difficult investigatory issues. Diagnosis of medical problems and the sale and distribution of prescription drugs are regulated by different federal and state agencies. The federal government, through the FDCA and CSA, has substantial jurisdiction over the illegal sale of prescription drugs. At the same time, the states have jurisdiction over doctors and pharmacies practicing within their borders.

Accordingly, the Working Group, created by Presidential Executive Order, analyzed existing federal law for its applicability in online-pharmacy cybercrime cases. The Working Group also determined that in most cases the laws governing the sale of prescription drugs and controlled substances over the Internet has been appropriate.

Another challenge facing law enforcement on the Internet is the difficulty of finding criminals in the Internet's multi-jurisdictional, global environment. The inability to track down sophisticated criminals who hide their identities online is a major obstacle. Therefore, the need for trained and well-equipped personnel at all levels of law enforcement is critical to fighting cybercrime. When addressing these challenges, the

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186. Id. § 3 (a)(i)-(ii) (listing the members of the Working Group being composed of the Attorney General who shall serve as chair of the Working Group; the Director of the Office of Management and Budget, the Secretary of Treasury, the Secretary of Commerce, the Secretary of Education, the Director of the FBI, the Director of the Bureau of Alcohol, Tobacco, and Firearms, the Administrator of the DEA, the Chair of the FTC, the Commissioner of the FDA, and other federal officials deemed appropriate by the chair of the Working Group).
187. See generally id.
188. See generally id.
189. See generally id.
190. See generally id.
191. Id. (recommending a three-part approach to address unlawful conduct on the Internet).

(1) Regulation of unlawful conduct involving the use of the Internet should be analyzed through a framework that ensures that online conduct is treated in a manner consistent with the way offline conduct is treated, in a technology-neutral manner, and in a manner that recognizes and protects privacy and civil liberties.

(2) Cybercrime presents unique and significant challenges to law enforcement which requires resources for training, new investigative tools, legal authorities and capabilities. (3) Continued support of private sector leadership is needed to promote and teach “cyberethics” to empower Internet users to prevent and minimize the risks of unlawful activity.

Id.
Working Group expected to review the unlawful conduct on the Internet in the context of current Administration Internet policy. In addition, the Working Group anticipated industry self-regulation where possible, as well as technology-neutral laws and regulations. The Working Group also acknowledged the Internet as an important medium, both domestically and internationally, for commerce and free speech.

The underlying goal of the new legislation must be to ensure that all online pharmacies are licensed and operated under the same regulatory system that Congress and the states have put in place for traditional “brick and mortar” pharmacies. Therefore, the legislation must required online pharmacies to post information on their Web sites about their ownership, state licensure, name of the pharmacist in charge, and a phone number where consumers can contact the pharmacist. Online pharmacies that fail to meet these requirements would be subject to federal civil and criminal penalties.

It is important that in addressing the online sale of prescription drugs, the U.S. must continue to enlist the cooperation of foreign governments in enforcing the laws of the U.S. relating to such sales. The concern with prescription drugs from foreign countries is not necessary with the Internet aspect of the sale, but with the illegal introduction of those drugs into the U.S. “Law enforcement agencies in the U.S. will have to obtain the cooperation of their counterparts in foreign countries with online pharmacies to prevent the shipping of prescription drugs into the U.S. Therefore, efforts must be made to develop a comprehensive and global response to crimes facilitated by the Internet.”

2. The International Coalition on Online Pharmacies ("ICOP")

The members of the ICOP must be experts in the laws involving the practice of pharmaceutical sales, importation/exportation of controlled

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192. See generally Exec. Or. 13133 (noting that the government should consider all societal interests). A balance must be struck when investigating and prosecuting criminals that takes into account free speech, protecting children, reasonable expectations of privacy, broad access to public information, and legitimate commerce. Id.

193. Id.

194. Id.


196. House Hearing, supra n. 7, § Test. of Ivan Fong (explaining that although international awareness and cooperation of fighting crime has grown, philosophical differences between countries on combating the sale of illegal goods online must be resolved and also practical ways to enforce laws must be developed).

197. Id.

198. Id. (“explaining that cooperation of foreign countries is particularly important because the interdiction of relatively small quantities of prescription drugs sent through traditional mailing channels is not feasible”).
substances, customs service, and most importantly the workings of the Internet.

The ICOP would function to complement existing federal laws regarding the sale of prescription drugs. Presently, consumers purchasing prescription drugs from online pharmacies are not provided with any mechanism for identifying the online pharmacy or verifying that it is properly licensed. The ICOP would fill this gap in the existing regulatory structure to protect consumers from illegitimate online pharmacies that seek to operate without complying with relevant laws regarding prescription sales. Consequently, the ICOP would address the important investigatory needs by requiring online pharmacies to disclose the name of the Web site operator, address and telephone number of the principal business location, and countries where the pharmacy and its pharmacists are licensed to operate. In addition, the ICOP would require all online pharmacies to register with the ICOP in order to conduct business on the Internet. Furthermore, the ICOP would require the customs service of all participating countries to prevent the shipping of drugs into their country.

It is evident that substantial increases in resources and personnel are required for the ICOP. It is crucial that participating foreign and U.S. law enforcement agencies receive training, funding, and other support necessary to conduct investigations into online pharmacies that threaten the public health without impairing those that provide prescription drugs in a safe, legal, and convenient way.

3. The Benefits and Problems of the ICOP

The benefits of the ICOP are clear. By working with foreign governments, the ICOP would increase import surveillance of prescription drugs into the U.S. In addition, the ICOP would deny rogue Web sites a safe harbor to sell prescription drugs illegally to U.S. consumers. Online pharmacies that operate without the required disclosures or certifications under ICOP would be subject to sanctions. The failure to disclose or to display proper certification would provide investigators with a fast and coordinated way in which to identify illegitimate online pharmacies. Furthermore, penalties for false disclosures or certifications would discourage such misrepresentations.

While some Internet pharmacies may welcome the ICOP as a way to deal with foreign rogue pharmacies, other Internet pharmacies may favor a more voluntary approach to regulation. For example, the president of Drugstore.com believes that additional regulatory burdens placed on legitimate online pharmacies would only make it more difficult

to operate a legitimate online pharmacy and potentially diminish the consumer benefit of valid Internet pharmacies. Some may also question the appropriateness of the federal government as the regulator of online pharmacies since pharmacy regulation has traditionally been the privilege of state boards of pharmacy. Others may argue that the federal government has no previous experience regulating this area. However, a single enforcement mechanism would permit efficient investigations, while retaining traditional authority to regulate pharmacies within that country.

CONCLUSION

The use of the Internet for buying prescription drugs is growing at a substantial rate. The FDA has already taken precautions to deal with the problems the Internet creates in the area of pharmacy law. FDA and other government enforcement agencies have increased their support for monitoring fraud through an approach that includes a combination of surveillance, prosecution, self-policing, education, and liaison work.

The current approach by the FDA and other government agencies may help deter fraud on the Internet. However, existing federal and state laws have had only limited success in protecting consumers from unlawful sellers of prescription drugs over the Internet. This comment illustrates that without changes to existing laws, the fraudulent prescription drug seller will still attempt to circumvent the law regardless of current federal and state efforts. Legislators have addressed the issues the Internet presents in other areas of law by proposing new legislation.

Given the potential threats and the global, trans-jurisdiction reach of the Internet associated with pharmaceutical sales and pharmacy law, it seems logical that Congress should create a coalition that can respond effectively to illegitimate prescription sales over the Internet. Congress must do more to protect patients when they buy prescription drugs on

200. Id. (stating that Web sites illegally dispensing drugs are not the result of a lack of appropriate laws and regulations). The real impediments to controlling rogue sites are “lack of funding for enforcement of current laws against domestic operators, the need for greater state and federal resources for cyber-tracking technology, and lack of jurisdiction over foreign operators.” Id.

201. Peter H. Lewis, Limiting a Medium Without Boundaries: How Do You Let the Good Fish Through the Net While Blocking the Bad, N.Y Times at D1 ¶ 13 (Jan.15, 1996). If the U.S. believes it can eliminate Internet gambling through regulation, it fails to understand the basic premises of the Internet structure. Id. Anthony Rutkowski, the former head of Internet Society, states that: “[t]he nature of the Internet, if not contemporary telecommunications and transportation technologies in general, make [restricting information access into a particular jurisdiction] intrinsically impossible to achieve.” Id. Therefore, any regulation that is proposed must proceed from an initial position that accounts for the global nature of the Internet. Id.
line. It seems appropriate that Congress should heavily scrutinize an activity, such as pharmaceutical sales, which is so vital to the preservation of our health and safety. Congress must address the issues presented by the sales of prescription drugs on the Internet and adopt new statutory protections for protecting consumers. If sufficient resources are made available, Congress can increase consumer awareness and enforce federal laws against these rogue Web sites which mislead and jeopardize the health and safety of U.S. consumers.

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† The author is a May 2002 JD candidate at The John Marshall Law School. Kristin would like to dedicate this paper to her loving and supportive parents and Andrew Hsieh—a best friend and a pharmacy student.