

# BENEFITS, RISKS, AND REGULATION OF “CYBER PHARMACIES”

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## Introduction

In November of 1998, police in Illinois informed the Office of Criminal Investigations (OCI) that they had discovered a man, unconscious in a hotel parking lot. The individual was taken to a hospital for treatment of an apparent drug overdose. In contacting his family, police learned that he had been taking gamma hydroxy butyrate (GHB). It was suspected that the subject had been receiving GHB kits and instructions via the Internet. With OCI assistance, the source of the supply was traced to an Internet site based in Canada.<sup>1</sup> GHB is an unapproved drug that is used for muscle building but also used in sexual assaults by incapacitating the victim.<sup>2</sup>

This frightening scenario is becoming more common as people replace trips to the local pharmacy with a click on the Internet to receive prescription drugs and other medical products. While there are many benefits to acquiring medical information and products from the Internet, there are also serious risks. Regulation of this practice is needed in order to safeguard individuals. This paper will discuss the benefits and risks of purchasing drugs online and the federal and state efforts to address concerns regarding “cyber pharmacies.”

## Benefits of Online Pharmacies

Online pharmacies are beneficial in many respects. They are convenient, and they enable those who can't get out to the pharmacy a way to obtain needed medication without leaving home. They also facilitate comparison shopping for a virtually unlimited range of pharmaceutical products. The Internet permits individuals to easily shop across many sites to find the best product at the best price.<sup>3</sup> Online pharmacies such as Drugstore.com and DestinationRx.com allow a person to search for the best offer, which are usually cheaper than the local drugstore.<sup>4</sup>

These sites also provide privacy for people who don't want to discuss “sensitive” conditions, such as baldness, venereal disease, or impotence, with their physicians. Thus they are able to purchase a prescription for the ailment without the need to interact with their doctor or pharmacist. The relative anonymity of the Internet may even encourage some patients to get treatment that they otherwise might have avoided. Some Internet pharmacies have a licensed pharmacist available by e-mail or phone twenty-four hours a day. Patients can ask personal questions without fear of being overheard by others.<sup>5</sup>

Internet pharmacies will sometimes send e-mail alerts when prescriptions are due for a refill. These reminders may improve patient compliance with drug therapies. In addition to benefiting patient health, reminders may reduce the cost of healthcare by improving patient outcomes.<sup>6</sup> Product information is also more readily available on the Internet than in the traditional storefront, potentially enabling the individual to understand health issues better. Reports show that over 22 million Americans used the Internet to access medical information either through online discussions with health care professionals or by documented resources.<sup>7</sup>

The benefits of legitimate sites are widely recognized and supported by respected organizations such as the American Association of Retired Persons (AARP), which established an Internet pharmacy service for its members in 1999. The American Medical Association also supports online pharmacies with “appropriate safeguards.”<sup>8</sup> “The AMA believes that prior to writing a prescription a physician must: (1) have access to the patient's medical history; (2) discuss treatment alternatives with the patient and determine the best course of treatment; (3) educate the patient about the benefits and risks of the medication; (4) perform an examination under most circumstances; and (5) where necessary, provide additional treatment interventions and follow-up visits, especially when the medication might have serious side effects.”<sup>9</sup>

Many Internet pharmacies meet these standards. In fact, some Internet pharmacies will only fill prescriptions that are written by the patient's physician.<sup>10</sup> However, many online pharmacies dispense medications with little or no physician oversight, thus posing significant risks to patient health.

## Risks of Online Pharmacies

### *Legal vs. Illegal Internet Pharmacy activities*

Distinguishing legitimate Internet pharmacies from illegal operations is difficult. It is easy to create a web site that looks like it represents a reputable company. Obscuring the source of medication and the companies responsible for producing it is also easy to do.<sup>11</sup> “Rogue” sites, engaged in illegal activities, may provide patients with access to unapproved drugs, counterfeit medications, and products marketed with fraudulent health claims. Patients who are ill and without medical coverage need to find a cure for their ailment without visiting a doctor, so they become susceptible to false claims about medications over the Internet. If these medications are purchased from a rogue web site, the drug could contain unknown ingredients or dangerous sub-potent or super-potent versions that were improperly packaged, stored, or manufactured.<sup>12</sup>

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Many of these illegal drugs come from outside the borders of the United States, from places such as Thailand, China, Mexico, and Switzerland. In 1999, the United States Customs Service impounded 9,725 packages with prescription drugs, and the number of pills and tablets seized was 1.9 million. This was a dramatic increase from just the prior year. But officials state that confiscated shipments are only a small amount of what actually arrives into the United States daily in unmarked envelopes. This raises the enormous question as to what can be done to regulate United States and especially foreign web sites that sell drugs and other medical products.<sup>13</sup>

### ***Privacy Concerns***

While some patients are attracted to online pharmacies because they believe it is more private, personal medical information placed on web sites may in fact, be shared with many others. With the click of a mouse, health information can be easily sent to an unlimited amount of places. According to a survey in 1999, as a result of concerns regarding potential discrimination by insurers, employers, and others, one out of six adults in the U.S. have taken exceptional measures to protect the privacy of their medical data, including doctor hopping and giving inaccurate information about their health.<sup>14</sup> Congress also saw the importance of keeping patients' medical data safe, and as a result they passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under the authority of HIPAA, in December of 2000, HHS issued federal health privacy regulations that health care entities must conform to by April 2003. Ironically, individuals who use online pharmacies because of privacy concerns are unaware that many of their transactions may not be entitled to privacy protection under the new rules.<sup>15</sup>

The privacy regulations only apply to three kinds of health care entities. These groups are providers who electronically transmit health claims related information in "standard format;" health plans; and "clearinghouses," which process health claims data in a uniform format for providers and insurers. Many health-related web sites do not fall within these covered groups. Therefore, these sites may collect and share medical information without the patient's knowledge or consent without violating HIPAA.<sup>16</sup> They can sell confidential patient information to third parties, raising the possibility that the disclosure of private medical or prescription information may lead to employment discrimination, increased health or life insurance premiums, or even denial of insurance coverage.<sup>17</sup>

To determine whether a web site is a covered provider, three questions need to be answered with a "yes." First, is the web site a health care provider as defined by in the regulation? A health care provider is "any person who furnishes, bills or is paid for health care in the normal course of business." This would include doctors and hospitals. The second question is does the web site transfer health data in conjunction with one of the "standard transactions" in the HIPAA? This simply means that if the web site is conducting insurance related transactions than they are likely to come under the scope of the privacy regulation. The third and final question that has to be asked is does the web site transmit the health data electronically in the essential "standard format?" Whether filing a claim or verifying insurance coverage, the provider must incorporate specific information and use special codes for diagnosis and treatment.<sup>18</sup>

Even if the web site is a covered entity it doesn't necessarily mean that all the data collected at the web site is covered by the privacy rule. The regulation covers only information that relates "to the health or condition of a person or to the provision of health care to a person." It doesn't include the selling or distribution of health care items that do not require a prescription. Therefore when people see a notice of privacy posted on a web site, which is mandatory by the privacy rule, they believe that it applies to the entire web site and not just particular activities. An example of this is if an HIV/AIDS patient were to go online at Drugstore.com and purchase with one transaction AZT and condoms. Only the information regarding the AZT would be covered by the privacy rule.<sup>19</sup>

Some web sites are not covered at all by the privacy rule. Web sites that offer only health information such as general nutrition information and medical conditions are not covered by the privacy rule because they provide no health care. Even sites that ask for personal information in the form of "self-screening questionnaires" may not be covered: payments are made by credit card and insurance is not accepted at many of these sites. Therefore these transactions are not processed in "standard format," and are not covered by the privacy rule. Ironically, many rogue sites specialize in sales of medications to treat "embarrassing conditions" which patients do not want their doctors, pharmacists or neighbors to know about. Since rogue sites are unlikely to accept insurance, the personal information they obtain from patients is not protected by the privacy rules.<sup>20</sup>

### ***Reliance on Patient Self-Reporting***

The relative anonymity and convenience of Internet pharmacies poses risks as well as benefits. At some online pharmacies, prescription sales can be dispensed without a valid prescription. Prescriptions are replaced by online questionnaires that individuals fill out. A medical doctor then reviews the information and authorizes the medication. The danger lies in substituting a personal medical examination by a doctor with self-reporting by a patient.<sup>21</sup> There is no way of knowing whether or not the questions are understood and taken seriously by the patient or if they were answered correctly.<sup>22</sup> An example of this took place in Illinois where a 52 year old man, who had a history of heart disease and episodes of chest pain, died from a heart attack after taking Viagra from an online site that exchanged a medical examination for a questionnaire.<sup>23</sup>

The use of electronic questionnaires as a replacement for personal examinations by physicians has been opposed by reputable medical organizations such as the American Medical Association, which states that "web sites that offer a prescription solely on the basis of a simple questionnaire do not meet appropriate standards of care for issuing a

prescription.”<sup>24</sup> The exclusive use of questionnaires also fails to meet the standard of care requirements set forth by the Federation of State Medical Boards (FSMB). The FSMB established four requirements that a physician must demonstrate so that a standard of care is met. First, there must be a documented patient evaluation that includes the patient’s history and physical examination. The evaluation must be “adequate to establish the diagnosis for which the drug is being prescribed and identifying underlying conditions and contra-indications.”

Secondly, extensive conversation must take place between the patient and physician to discuss options in treatment and the benefits and risks of each one. Thirdly, an assessment of the treatment must be made to see the efficiency and outcome of it. Lastly, the patient’s medical record must be continually updated and made readily available. So, if this standard is applied the FSMB has concluded that the “prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct.”<sup>25</sup>

### ***Effects on the Doctor-Patient Relationship***

E-medicine has the potential to change “the setting and nature of the patient-physician relationship and thereby alter how medicine is practiced.”<sup>26</sup> The goal of this relationship is to generate good medical care, which requires trust. Patients trust that their doctors provide competent care since they themselves do not have the medical knowledge; that the physicians will maintain confidentiality, and that the physicians’ first priority is the patients’ health and not their own self-interests. Noted ethicists Ezekial Emanuel and Nancy Dubler have identified six crucial elements of an ideal patient-physician relationship, and how the Internet technology affects each one. The “six C’s” are choice, competence, communication, compassion, continuity, and (no) conflict of interest.<sup>27</sup>

“Choice” refers to patients being able to choose their doctor and/or treatments. The Internet can help patients obtain useful information so that they can choose appropriate medical care. For example, the American Medical Association provides a web site called “Doctor Finder” that allows the patient to locate a physician according to specialty and where they live along with certification and education of that individual. The Internet also provides patients with a lot of material on alternative medicine and treatments. However, there are serious risks associated with obtaining medical information over the Internet. Most of the information that is on the Internet is unregulated, so it is not necessarily screened for accuracy and content. Therefore the health material can be misleading and dangerous.<sup>28</sup>

“Competence” of medical advice is a significant concern with respect to the Internet. If electronic communication is used as a substitute rather than a supplement to a personal examination, it erodes the ability of physicians to find out information about their patients and provide competent medical care.<sup>29</sup> Moreover, the anonymous nature of the Internet makes it difficult for patients to check on the technical expertise and qualifications of the doctor who dispenses prescriptions. Patients may believe that their medical care is being monitored by a competent, licensed physician. However, that may not be the case.<sup>30</sup>

“Communication” with patients is necessary in order to provide competent medical care. Even though new electronic means of communication may be better than the telephone, they are no substitute for personal contact with patients. Without the ability to see a patient’s expression, hear his voice, or conduct a physical examination, there is an increased risk of inaccurate diagnosis and treatment. Confidentiality concerns about using some of these new types of technology may make some patients hesitant to communicate freely; thus increasing the chance of misdiagnosis or treatment based on incomplete or inaccurate information.<sup>31</sup>

“Compassion,” the fourth critical element of the doctor-patient relationship, is also likely to suffer in an environment where physician and patient do not meet face-to-face. Electronic communication may prohibit the physician to convey to and feel compassion for a patient if they have never met. “Continuity” is a big concern when it comes to patients communicating with a particular web site rather than an individual physician. Most likely when a patient has contact with a web site, they are dealing with multiple individuals, rather than a single person. If each physician does not continually update an individual’s health records, then the patient’s health could suffer because of those records being incomplete.<sup>32</sup>

The final element is a “(no) conflict of interest.” Most of the conflicts arise because of a physician putting his financial interest above competent medical care for the patient. Incentives are created so that patients receive more care because the “care is reimbursed on a per-procedure basis.”<sup>33</sup> Doctors will therefore try to treat a large number of patients to increase their compensation. The danger here is that by treating a larger number of people, there is an increased risk of misdiagnosis or other health-threatening errors. Also, because online pharmacies may not accept insurance, there is a reduced chance of oversight by an outside party.

Physicians can charge patients whatever flat fee or hourly rate that they choose. In the traditional setting a patient would know how long they spent in an examining room or on the phone with the doctor. But the time a physician spends in replying to an e-mail is not known by the patient, and therefore the physician can bill for an incorrect hourly rate and the patient has no way of knowing that he is being fooled. Thus the patient-physician relationship can be negatively affected if using new Internet technology is exchanged for rather than used in conjunction with conventional face-to-face meeting of patient and doctor.<sup>34</sup>

### **Efforts to Address Online Pharmacy Concerns**

#### ***Industry Initiatives***

The nature of online pharmacies requires a coordinated effort between private industry and government. The National Association of Boards of Pharmacy (NABP) is a collaborative organization of state and national pharmacy boards, with

additional membership from Canada and Australia. NABP works to protect public health by developing regulatory standards that can then be implemented by its member boards.<sup>35</sup>

At a February 1999 meeting, the NABP set up a program designed to verify that prescription dispensing sites on the Internet were legitimate, called the Verified Internet Pharmacy Practice Sites (VIPPS).<sup>36</sup> In order to obtain VIPPS certification, a web site must maintain all state licenses, to which they dispense to, in good standing. They must also allow information regarding their site to be displayed on the VIPPS Web site, allow an NABP-sanctioned team to inspect their operations, and display the VIPPS seal on their site.<sup>37</sup> Also, “VIPPS-certified pharmacies must respect patient rights to privacy, authenticated and secure prescription orders, adhere to a recognized quality assurance policy, and provide ‘meaningful consultation between patients and pharmacists.’”<sup>38</sup>

In November of 1999, the NABP formed a coalition comprised of federal and state governments, consumer and medical organizations, and Internet pharmacies. The coalition’s objectives are: 1) to put together a unit that would “develop legislative and enforcement initiatives;” 2) to form a plan to educate the consumers; 3) to receive complaints from consumers, which was achieved through the creation of Operation Safe Net; and 4) “to establish the proper relationships for patients and pharmacists at Internet pharmacies.”<sup>39</sup>

### ***Federal Regulatory Efforts: The FDA***

At the federal level, the FDA plays a key role in protecting the public from the dangers associated with online pharmacies. In addition to regulating and enforcing federal law, the FDA provides support for state and private initiatives to address online pharmacy concerns. The FDA has the authority to take action against the importation, sale or distribution of an adulterated or misbranded drug; the importation, sale or distribution of an unapproved new drug; illegal promotion of a drug; the sale or dispensing of a prescription drug without a valid prescription; and counterfeit drugs under the Federal Food, Drug, and Cosmetic Act. As a result of the steady increase of illegal Internet sales, the FDA has expanded and improved their response to these incidents with the adoption of the Internet Drug Sales Action Plan in July of 1999.<sup>40</sup>

This plan was devised by “internal deliberations, meetings with Federal and State regulatory and law enforcement bodies, as well as organization representing consumers, health care practitioners, and the pharmaceutical and pharmacy industries.” There are five basic elements to the plan. The first element is that of engaging in public outreach. The FDA plays a key role in providing the public with important information regarding the dangers of buying prescriptions online. The sources that are used to reach the public are *FDA Talk Papers*, *FDA Consumer Magazine*, and the web site for the FDA.<sup>41</sup>

On the FDA’s web site there is an article for consumers with tips and warnings regarding purchases of drugs via the Internet. These tips included: contacting the National Association of Boards of Pharmacy ([www.nabp.net](http://www.nabp.net)) to determine whether or not a web site is licensed; staying away from sites that claim “amazing” results or advertise a “new cure”; avoiding sites that don’t identify themselves and don’t have a U.S. address or phone number; and not purchasing from a site that sells drugs without a prescription or ones without FDA approval.<sup>42</sup> The FDA has also established a media campaign that includes advertisements on health-related web sites, public service announcements on radio and television, and the distribution of a “safety checklist”.

The fourth element deals with cooperation internationally. FDA Associate Commissioner, William Hubbard has stated that “Ten years ago, it was hard for you to buy a foreign drug; you had to go to a foreign country. Now the Internet makes it simple, and you can’t do anything about these foreign sites because you don’t have the reach to foreign countries.”<sup>43</sup> The FDA and other Federal agencies possess limited investigatory jurisdiction over sellers in foreign countries, and as a result they must work closely with foreign governments in order to curtail these types of illegal transactions from occurring. Since this is a growing concern in the law enforcement arena, the OCI maintains an ongoing liaison with government agencies in the United Kingdom, Spain, Germany, Brazil, Singapore and many others countries.<sup>44</sup>

This cooperation can be seen in numerous cases. For example OCI cooperated with authorities in a Pacific Rim country where it was alleged by an operator of a medical web site, that two legitimate doctors reviewed the online questionnaires that were sent to him. With the help of foreign counterparts the OCI was able to question the doctors and through this were able to establish that the doctors had no part in this scheme and thus the operator was charged with mail and wire fraud along with other charges. A second case was where the OCI officials made an undercover purchase of drugs from a web site from a European country. Even though the OCI could not establish a domestic connection for charges to be brought in the United States, they were able to contact health authorities in that country and as a result a criminal investigation took place. Increased international coordination of efforts is clearly needed in order to address illegal transactions with foreign web sites.<sup>45</sup>

The final element of the Internet Drug Sales Action Plan involves customizing and expanding FDA enforcement activity. The FDA is enhancing its enforcement efforts by setting enforcement priorities, improving data acquisition, coordinating case assessment, and allocating more of their budget to addressing online pharmacy concerns. FDA enforcement priorities focus on the most severe health risks to the public: unapproved new drugs, health fraud, and drugs that are sold without a prescription. The FDA has upgraded their data handling capabilities and utilized unique search tools in order to better determine the types and the extent of illegal conduct, and the effectiveness previous enforcement efforts.<sup>46</sup>

The FDA has established a “triage” team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs, the Center for Drug Evaluation and Research, the Office of the Chief Counsel and the Office of Policy.

The FDA obtains information gathered from monitoring activities of various state and federal agencies in order to determine whether web sites are dispensing drugs illegally. The triage team then decides whether or not the web site should be pursued through civil or criminal investigation. “The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort.”<sup>47</sup> It also helps to ensure that certain decisions are made and carried out in a timely fashion, with there being “an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market.”<sup>48</sup> In the past the FDA has had to re-deploy their existing personnel to go and regulate online drug sales, thus taking away from supervision in other areas. For the Fiscal Year 2001 budget, President Clinton had requested \$10 million in additional funding for this Internet enforcement. These funds would be for the sustaining of the investigative forces that are already working in the area of Internet sales.<sup>49</sup>

The FDA has taken considerable action. As of March 2000 more than 400 sites were evaluated for potential violations, along with more than 40 sites facing possible civil or criminal action. Warning letters have been sent to 23 domestic sites and 13 foreign-based sites. With the help of the Department of Justice there have been 8 product seizures, 6 product recalls, and 7 products that were voluntarily destroyed because they violated standards. Through the OCI they have started 134 active investigations and as a result there have been 36 arrests and 17 convictions.<sup>50</sup>

### *State Initiatives*

While federal agencies play an important role, the states also share the responsibility of regulating and enforcing laws pertaining to Internet pharmacies. In fact, the FDA has taken the position that issues raised by Internet pharmacies should primarily be handled by state regulatory boards and other appropriate state agencies, since the FDA lacks the resources and staff needed to deal with issues raised by Internet pharmacies and online prescribing.<sup>51</sup> States have been updating their laws to address the challenges posed by online pharmacies and to improve their enforcement capacity.<sup>52</sup>

Several state Attorney General offices are collaborating by instituting actions against online pharmacies and physicians affiliated with them. A number of state attorney generals have brought suits against online pharmacies because of violations of state licensing, disclosure and quality of care laws. The first attorney general action against online pharmacies was brought in June of 1999 by Kansas’ Attorney General, with several other states following in the same manner and filing suits. In July of that same year, Missouri Attorney General filed suits against online pharmacies. The pharmacies were charged with violating a Missouri law that requires a license by the state of Missouri to prescribe and distribute medications to Missouri residents. The Texas-based pharmacy was permanently barred from dispensing in Missouri along with being fined \$15,000 and will be subject to an additional fine of \$5,000 if they ever distribute again in Missouri.<sup>53</sup>

In the state of Michigan, the attorney general’s office announced that they were planning to sue 10 online pharmacies including ConfiMed.com, Doctor ASAP, and RXLeader for violation of state regulations. Attorney General Jennifer Granholm planned to file lawsuits “alleging the companies sold prescription drugs to state residents, but the companies didn’t have valid Michigan licenses and didn’t verify that the patients had undergone examination by doctor.” The investigation reported to show that undercover investigators were able to purchase Viagra, Phentermine, and a controlled substance under Michigan law.<sup>54</sup> One month later all of the ten online pharmacies had agreed to stop the sale of prescription drugs to Michigan residents. In March of 2000, New Jersey’s Attorney General brought suit against eight online pharmacies for failure to abide by state licensing and disclosure laws and the “inadequacy of the physician’s online examinations of patients.” The remedies were similar to those of other states where the pharmacies were barred from selling prescription drugs in New Jersey along with fines being imposed.<sup>55</sup>

States have also passed laws or made proposals to enact regulation to better address abuses by online pharmacies. California has a law that “specifically prohibits practicing medicine from California into another state or country without first satisfying the other jurisdiction’s requirements for practicing medicine.” Illinois passed a law that “brings Internet pharmacies within the regulatory purview of the State Board of Pharmacy of the Department of Professional Regulation by classifying them as mail-order pharmacies.”<sup>56</sup>

In the previous example stated earlier in the paper, the family of the Illinois man who died from taking Viagra that he received from the Internet, couldn’t pursue any criminal or civil action because they didn’t know who was responsible for sending the drug. States are recognizing the need to develop and implement policies that require online pharmacies to disclose to consumers who is operating the site. Kansas has a bill that “requires sites to disclose names and addresses of parties involved in issuing and dispensing prescriptions and sites’ abilities to obtain liability waivers.”<sup>57</sup> States such as California, Kansas and New York have also issued laws that prohibit the prescribing and distribution of prescriptions over the Internet without a proper medical examination.<sup>58</sup>

While many states have individually taken significant steps to protect patient safety and welfare, and have worked collaboratively with other states, the broad reach of online pharmacies makes it essential to have a better-coordinated effort between the state and federal government. This requires a delicate balance, however. Regulations governing the practices

and licensure of doctors and pharmacists are largely a matter of state law. While consistent policy is important, states may be reluctant to allow the federal government to dictate standards of practice in these areas.<sup>59</sup>

## Conclusion

The Internet has forever changed the way people conduct their everyday business of banking, shopping, paying bills, etc. So, it should come as no surprise that the healthcare industry wants to have a piece of the Internet market.<sup>60</sup> Internet pharmacies are estimated to generate over \$15 billion in prescription drug sales by the year 2004.<sup>61</sup> Internet pharmacies can offer many benefits to consumers, including significant cost savings and easier access to medication. However, there are also serious—in some instances, life-threatening—risks associated with Internet sites that lack appropriate safeguards. It is increasingly clear that private industry along with state, federal, and international governments must engage in a coordinated effort to establish and enforce regulations to protect patients using this medium of distribution.

## Footnotes

<sup>1</sup> Janet Woodcock, M.D., “Hearing before the U.S. House of Representatives Subcommittee on Oversight and Investigations and Committee on Commerce,” July 30, 1999, at <http://www.fda.gov/ola/1999/drugsonline.html>, last accessed May 20, 2002.

<sup>2</sup> William K. Hubbard, “Hearing before the U.S. House of Representatives Subcommittee on Oversight and Investigations and Committee on Commerce,” May 25, 2000, at <http://www.fda.gov/ola/2000/internetsales.html>, last accessed May 20, 2002.

<sup>3</sup> Woodcock, *supra* note 1.

<sup>4</sup> Stacey Schultz, “When Drugs cost Sting, Look for Relief, Shop Around, Switch Medicines or Split Pills,” *U.S. News & World Report*, June 4, 2001, 69-70, at 69.

<sup>5</sup> Kerry Toth Rost, “Policing the ‘Wild West’ World of Internet Pharmacies,” *Chicago-Kent Law Review*, 2000, 1333-1361, at 1338.

<sup>6</sup> *Id.* at 1338.

<sup>7</sup> Jane E. Henney, M.D., “Hearing before U.S. Senate Committee on Health, Education, Labor and Pensions,” March 21, 2000, at <http://www.fda.gov/ola/2000/pharmsales.html>, last accessed May 20, 2002.

<sup>8</sup> Kerry A. Kearney and Celia M. Santander, “Telemedicine: Evolving into Cyberspace,” *Health Lawyer*, April 2001, 28-31, at 29.

<sup>9</sup> Rost, *supra* note 5, at 1346.

<sup>10</sup> *Id.* at 1334.

<sup>11</sup> *Id.* at 1338.

<sup>12</sup> *Id.* at 1339.

<sup>13</sup> Robert Pear, “Online Sales Spur Illegal Importing of Medicines to U.S.,” *New York Times*, January 10, 2000, A1 & A17, at A1.

<sup>14</sup> Pew Internet & American Life Project, “Exposed Online: Why the New Federal Health Privacy Regulation Doesn’t Offer Much Protection to Internet Users,” November 2001, at <http://www.pewinternet.org>, 1-25, at 4. last accessed January 2, 2002

<sup>15</sup> *Id.* at 1.

<sup>16</sup> *Id.*, at 6.

<sup>17</sup> Rost, *supra* note 5, at 1342.

<sup>18</sup> Pew Internet & American Life Project, *supra* note 15, at 12.

<sup>19</sup> *Id.* at 14.

<sup>20</sup> *Id.* at 17.

<sup>21</sup> Woodcock, *supra* note 1.

<sup>22</sup> Rost, *supra* note 5 at 1340.

<sup>23</sup> John Henkel, “Buying Drugs Online: It’s Convenient and Private, but Beware of ‘Rogue Sites,’” June 2000, <http://www.fda.gov/fdac/features/2000/100online.html>, last accessed May 20, 2002.

<sup>24</sup> Richard L. Cleland, “Cross-Border Telemedicine: An Uncertain Future,” *Saint Louis University Law Journal*, 2002, 149-156, at 151.

<sup>25</sup> *Id.* at 152.

<sup>26</sup> Jessica W. Berg, “Ethics and E-Medicine,” *Saint Louis University Law Journal*, 2002, 61-83, at 63.

<sup>27</sup> *Id.* at 65.

<sup>28</sup> *Id.* at 67.

<sup>29</sup> *Id.* at 73.

<sup>30</sup> *Id.* at 71.

<sup>31</sup> *Id.* at 74.

<sup>32</sup> *Id.* at 76.

<sup>33</sup> *Id.* at 77.

<sup>34</sup> *Id.* at 78.

<sup>35</sup> Sara E. Zeman, "Regulation of Online Pharmacies: A Case for Cooperative Federalism," *Annals of Health Law*, 2001, 105-137, at 120.

<sup>36</sup> Henney, *supra* note 7

<sup>37</sup> Henkel, *supra* note 23.

<sup>38</sup> Rost, *supra* note 5, at 1347.

<sup>39</sup> Amy J. Oliver, "Internet Pharmacies: Regulation of a Growing Industry," *Journal of Law, Medicine & Ethics*, Spring 2000, 98-101, at 99.

<sup>40</sup> Hubbard, *supra* note 2.

<sup>41</sup> Henney, *supra* note 7.

<sup>42</sup> "Tips and Warnings for Consumers," September 6, 2001, <http://www.fda.gov/oc/buyonline/default.htm>, last accessed May 20, 2002.

<sup>43</sup> Henney, *supra* note 7.

<sup>44</sup> Sheryl Gay Stolberg, "Officials Struggle to Regulate On-Line Sale of Prescription Drugs," *New York Times*, July 31, 1999, A12.

<sup>45</sup> Hubbard, *supra* note 2.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> Henney, *supra* note 7.

<sup>50</sup> *Id.*

<sup>51</sup> Kearney, *supra* note 8, at 29.

<sup>52</sup> Rost, *supra* note 5, at 1345.

<sup>53</sup> Zeman, *supra* note 35, at 122.

<sup>54</sup> *Id.*, at 124.

<sup>55</sup> Sholnn Freeman, "Michigan Tells Net Pharmacies It Plans Suits," *Wall Street Journal*, December 16, 1999, B8.

<sup>56</sup> Zeman, *supra* note 35, at 126.

<sup>57</sup> *Id.*, at 133.

<sup>58</sup> *Id.*, at 134.

<sup>59</sup> *Id.*, at 135.

<sup>60</sup> *Id.*, at 119.

<sup>61</sup> Rost, *supra* note 6, at 1359.

<sup>62</sup> Oliver, *supra* note 39, at 98.

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<sup>1</sup> Janet Woodcock, M.D., "Hearing before the U.S. House of Representatives Subcommittee on Oversight and Investigations and Committee on Commerce," July 30, 1999, available at <http://www.fda.gov/ola/1999/drugsonline.html>, accessed October 1, 2001.

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<sup>9</sup> Rost, *supra* note 6, at 1346.

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- <sup>20</sup> Id., at 17.
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- <sup>57</sup> Id., at 134.
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