
The Internet pharmacy industry is growing, with illegal pharmacies—those offering drugs without a prior prescription—far outnumbering the legal ones. In the past, consumers might have been deterred from using these unregulated pharmacies by their unprofessional appearance; now their designs improved to boost perceived credibility. This study examines the use of trust-garnering features by 10 illegal Internet pharmacies and compares these sites to those of 10 pharmacies certified by the NABP. The illegal websites scored as well as the legal sites on 5/7 variables. The results indicate that, based on design, Internet users might be apt to trust the unregulated Internet pharmacies as much as their regulated counterparts. Therefore, consumers should be counseled not on purchasing from sites with certain indicators of credibility, but rather only from Internet pharmacies that require a prior prescription, as this may be the only obvious characteristic that differentiates the safe from the unsafe.

Headings:

Health
Healthcare
Internet
Pharmacy
Drugs
Internet Content
NO PRESCRIPTION NEEDED: USE OF TRUST-GARNERING FEATURES BY ILLEGAL ONLINE PHARMACIES

by
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A Master’s paper submitted to the faculty of the School of Information and Library Science of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in Information Science.

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Approved by

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Claudia Gollop
Introduction

In the past decade there has been an explosion in the number and popularity of online pharmacies. While the legal, regulated online pharmacies have offered consumers convenient, private, and often cheaper options for obtaining medications, their illegal counterparts have introduced a number of risks to unsuspecting customers. By prescribing and dispensing medications without a physician examination, selling drugs that are not FDA-approved, and marketing “miracle cures” to vulnerable populations, these so-called “rogue” pharmacies have created a mounting threat to the health of the public. Several governmental agencies, with the support of concerned professional organizations, have undertaken the task of creating and enforcing policies to protect consumers and eliminate this substantial and unlawful industry. However, the results of these policies have been modest in the face of the challenge of catching and prosecuting a virtual enemy that can disappear and reappear anywhere in cyberspace.

Considering the difficulty of protecting consumers with legal action, educating them on prudent decision-making where online pharmacies are concerned has become crucial. Public health officials can warn against buying drugs without a prescription. Realistically people are still going to do it, whether it be due to high healthcare costs, convenience, or embarrassment. With frequent stories in the media about Americans purchasing medications from Canadian pharmacies, many people might be led to do the same, with the most logical start being the Internet. In the past one might have been deterred when finding that most of the sites selling drugs without prescriptions had a very
unprofessional look. Now, many illegal pharmacy sites have designs that closely resemble other reputable e-commerce sites, making use of elements that have been demonstrated to garner trust from consumers, lifting the barrier that stopped many people from putting their health into the hands of unregulated pharmacies.

Health care providers should become thoroughly educated on the health risks that have been created or are exacerbated by the expansive nature of the Internet. Patients can now obtain health information (of varying quality) and medications (also of varying quality) with the click of the mouse. Many will not volunteer that they have sought or acquired them, creating untold health hazards. Clinicians must become aware of what their patients are finding on the Internet and be diligent at inquiring explicitly about medications obtained without the advice of a physician. It is possible that a clinician encounter would be the only time in a person’s life that he or she is counseled on the dangers of purchasing drugs from unregulated Internet companies regardless of how trustworthy they may appear.

Most of the literature found during the course of this project was not of the empirical nature, but instead reports and analyses of the attempts to regulate Internet pharmacies. An exhaustive literature review on regulatory practices can be found in Appendix 1. There were no empirical studies found on the use or characteristics of Internet pharmacies, specifically illegal ones. This study seeks to add to the literature by providing the groundwork on which other experimental studies can be based. The objective for this paper was to evaluate the extent to which illegal Internet pharmacies have been able to gain the trust of consumers while eluding the regulations and controls
imposed on other pharmacies. To reach that objective, this master’s project had the following goals:

- Gain extensive knowledge of regulatory practices for Internet pharmacies.
- Discover any previous empirical studies on illegal Internet pharmacies.
- Identify characteristics used in e-commerce in general to increase consumer trust in a website.
- Analyze the use of these characteristics by illegal Internet pharmacies and compare it to that of verified legal Internet pharmacies.

The author hypothesizes that trust-garnering features will be found with the same frequency on websites of illegal Internet pharmacies as legal Internet pharmacies.
Materials and Methods

For this study, twenty Internet pharmacy websites (10 legal; 10 illegal) were sampled to evaluate the prevalence of features that indicate credibility to consumers.

Sampling

It was important that sampling for this project resembled actual search methods that would be used by a consumer in obtaining medications without a prior prescription. To that end, to search for illegal sites, the researcher used the Google search engine, which at the end of 2007 was used in 58.4% of searches. (Burns, 2008). The first 10 unique sites yielded from the search string “no prescription needed” that 1) sold drugs directly and 2) did not require a prior prescription, were used in the analysis. Given the highly transient nature of the Internet, it should be noted that sampling was conducted on March 12, 2008. Reproduction of the search on a later date would likely yield a different sample.

Internet pharmacies that are legal and regulated in the United States were used as controls. The only listing of such sites is by the National Association of Boards of Pharmacists (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) certification program. There are only fifteen sites currently approved by this program. The first ten listed at the VIPPS (2008) website that did not require member log-in to peruse the site were used as controls.

The twenty sites that were used for this study were:
<table>
<thead>
<tr>
<th>Legal Sites</th>
<th>Illegal Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.caremark.com">www.caremark.com</a></td>
<td><a href="http://www.exactfindrx.com">www.exactfindrx.com</a></td>
</tr>
<tr>
<td><a href="http://www.drugsoure.com">www.drugsoure.com</a></td>
<td><a href="http://www.bestrxonlinepharmacy.com">www.bestrxonlinepharmacy.com</a></td>
</tr>
<tr>
<td><a href="http://www.drugstore.com">www.drugstore.com</a></td>
<td><a href="http://www.drugspill.com">www.drugspill.com</a></td>
</tr>
<tr>
<td><a href="http://www.familymeds.com">www.familymeds.com</a></td>
<td><a href="http://www.prescriptionrxmedicinepharmacy.com">www.prescriptionrxmedicinepharmacy.com</a></td>
</tr>
<tr>
<td><a href="http://www.cvs.com">www.cvs.com</a></td>
<td><a href="http://www.reliablemedsdirect.com">www.reliablemedsdirect.com</a></td>
</tr>
<tr>
<td><a href="http://www.libertymedical.com">www.libertymedical.com</a></td>
<td><a href="http://www.withoutprescriptiondrugs.com">www.withoutprescriptiondrugs.com</a></td>
</tr>
<tr>
<td><a href="http://www.medco.com">www.medco.com</a></td>
<td><a href="http://www.medstore.biz">www.medstore.biz</a></td>
</tr>
<tr>
<td><a href="http://www.rxsolutions.com">www.rxsolutions.com</a></td>
<td><a href="http://www.ecornerdrugstore.com">www.ecornerdrugstore.com</a></td>
</tr>
<tr>
<td><a href="http://www.teldrug.ccom">www.teldrug.ccom</a></td>
<td><a href="http://www.pharmamixx.com">www.pharmamixx.com</a></td>
</tr>
<tr>
<td><a href="http://www.savon.com">www.savon.com</a></td>
<td><a href="http://www.shopmedsnow.com">www.shopmedsnow.com</a></td>
</tr>
</tbody>
</table>

Variables

Seven variables were chosen on which to rate and compare the sites. These variables were chosen based on other e-commerce and health information research. Five of the variables were identified by the eCommerce Trust Study (Cheskin Research and Studio Archetype/Sapient, 1999), which is highly cited in e-commerce and web design literature. It identified 27 characteristics that increase consumer trust in e-commerce sites. The researcher chose the five variables that were most relevant to this project and that did not require ordering from the site or interaction with those who administer it. Variables were also excluded if they required a purely subjective judgment by the author, such as craftsmanship or simplicity of process. The final two variables were chosen from
the literature on trustworthiness in health information sites. (Fogg, et al., 2003; Riegelsberger, Sasse, & McCarthy, 2003)

Security seals
A follow-up to the eCommerce Trust Study by Cheskin Research (2000) found that merchant and network security seals of approvals increase perceived trustworthiness in e-commerce consumers. The Visa logo is the most recognized merchant seal and TRUSTe the most recognized security seal, with 89% and 69%, respectively, of surveyed individuals recognizing them. The study also found that security symbols increase trust more than credit card symbols in the U.S., especially among heavy Internet users. The percentage of people who state that these symbols increase trust increased dramatically for all seals from 1999 to 2000. The report made the following recommendation:

In order to attract newcomers to websites, the seals of approval need to be easily seen. In particular, credit card symbols can be helpful. Over time, users may become somewhat inured, but the seals are crucial for those coming online without prior exposure and experience. (Cheskin, 2000, p.22)

Navigational Access
The Cheskin Research (2000) report emphasizes the importance of effective navigation, calling it a “necessary pre-condition to successful completion of a site’s trustworthiness.” (p.8). Though the 1999 study identified two other components to good navigation (navigation clarity and reinforcement), this project used only navigational access as it seemed to be the most fundamental element, and in order to preserve the objectivity of scoring.
Promise of Protection of Personal Information

Internet consumers fear that individuals or institutions will use their personal information for purposes other than that for which it was given. Cheskin (2000) reports that most people believe that hackers pose the greatest risk for identity theft, but also fear that institutions may sell their information to marketing companies or other websites. In general, Internet users feel that the “online environment is an uncontrolled place where almost anything goes.” (Cheskin, 2000, p.10). Cheskin recommends placing security statements in a conspicuous place on the site to let consumers know that the company takes security seriously and to describe the efforts it makes to ensure that security.

Return Policy

Fulfillment – providing a service or product as promised – is a very important factor in increasing trustworthiness with consumers. Customers fear that they will not be able to return a product that they bought should they be unsatisfied. Publishing a return policy is a way in which websites can demonstrate their commitment to ensuring the buying process goes as expected for both parties. Therefore, the author used this feature to measure the websites’ attempts at demonstrating a commitment to fulfillment and therefore increasing trustworthiness.

Display of “trustworthiness” through images or text

The ability of photographs to increase perceived trustworthiness is a phenomenon that has been tested by several researchers, with varying results. Of note, Riegelsberger, Sasse, and McCarthy (2003) found that photos improved consumers’ trust in sites of
untrustworthy vendors, but had the opposite effect on those of trusted vendors. This project provided an opportunity to expand on those findings. The use of text to portray credibility was included jointly with use of photos in this variable. Research (Fogg et al., 2003; Corritore, 2003) has shown that affiliation with a well-known brand or trusted entity increases the perceived credibility of a site. In the case of pharmacies, mentioning official certifications might be particularly effective. Illegal online pharmacies, specifically, might build trust among consumers by telling them why ordering medications without a prescription is perfectly safe.

**Multi-modality contact information**

Fogg et al. (2003), in a study of web credibility with over 2,600 participants, found that users ascribe more credibility to site operators that disclosed information about themselves, including how to contact them. Cheskin (1999) named recourse (the ability to seek help from the company in the event of a problem with ordering or the product) as one of its 28 ways in which e-commerce sites can convey trustworthiness. In general, consumers would like to have more than one way of contacting companies as a matter of personal preference or in case one method fails. Sites were scored as having adequate contact information if they listed at least three of seven possible modalities (see Table 1).

Table 1 contains a summary of the variables used to rate each of the Internet pharmacies.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seal of approval representing security of the computer network</td>
<td>Use of 1+ non-merchant seal denoting security of the site or network as a whole. Example: Verisign.</td>
</tr>
<tr>
<td>Seal of approval representing merchant service security</td>
<td>Use of 1+ merchant seal (i.e. Visa, MasterCard, Google Checkout) denoting security of the merchant service</td>
</tr>
<tr>
<td>Navigational Access</td>
<td>Consistent left-hand or top-of-page navigation throughout the site.</td>
</tr>
<tr>
<td>Promise of Protection of Personal Information</td>
<td>The information one provides is guaranteed to be used for no purpose other than what one gave it for, without their approval.</td>
</tr>
<tr>
<td>Return Policy</td>
<td>Return policy is clearly explained (conditions under which a return can be made and process by which a return is made).</td>
</tr>
<tr>
<td>Display of “trustworthiness” through images or text</td>
<td>Images - health professionals on home page. Text – counted as present if one of the following present on homepage or FAQ: “FDA Approved,” “US Licensed Pharmacists,” “US Licensed Physicians,” explanation of why buying medications without a prescription is acceptable, or publicizing affiliation with professional association.</td>
</tr>
<tr>
<td>Multi-modality Contact Information</td>
<td>Site provides at least three ways for consumers to contact the company (e-mail address, phone, fax, street address, embedded “contact us” form or “live chat”).</td>
</tr>
</tbody>
</table>

Scoring

Sites were given a dichotomous rating of present or not (1 or 0) for each element. If any of the features were not found on the home, order, FAQ, or “About Us” pages, then it was considered absent. A rating scale with a larger range of variables was considered, but no such scale already exists and using one would have required subjective scoring. Scores for each site were tallied. Average scores for each group (illegal vs. legal) were compared.
Results

Legal Internet pharmacies rated below illegal ones in the use of security seals, but above them for merchant seals. Six (6/10) of the legal sites displayed security seals compared to only one of the illegal sites. Conversely, only one (1/10) of the legal sites had one or more merchant seals compared to eight of the ten (8/10) illegal sites.

For all of the other variables except for contact information, the legal and illegal sites had similar scores. Eight out of ten (8/10) legal sites had good navigational access and privacy policies; all (10/10) of the illegal sites received credit for these two features. Eight (8/10) each of the legal and illegal sites published return policies. In the use of pictures or text to convey trustworthiness, illegal sites outscored legal pharmacies nine (9/10) to seven (7/10). Finally, nearly all (9/10) of the legitimate pharmacies provided contact information, but only one (1/10) of the illegal sites listed contact information in at least three modalities. Of note, the most commonly missing piece of contact information for the illegal sites was a physical address.

The average score for the legal Internet pharmacies was 4.9 (sd=0.64) and 4.7 (sd=1.04) for illegal sites. Legal site scores ranged from four (4/7) to seven (7/7); the range for illegal sites was four (4/7) to six (6/7). Only one site (drugstore.com) had all seven features.
Discussion

The results show that in most categories, the illegal Internet pharmacies are using features that increase perceived trustworthiness as much as, if not more than, the legal sites. The webmasters for both realize that the key to getting and keeping customers is to understand how consumers assess the risks of conducting business with a particular online company. Cheskin (1999) constructed a simple model to understanding e-commerce trust (Figure 1).

Figure 1. Model of eCommerce Trust. Studio Archetype/Cheskin Research, 1999.

According to this model, seals of approval are a gateway to gaining consumer trust. Patrons want to feel that they have some amount of control over the use of their personal and financial information; seals of approval seek to reassure customers that this control has been established. Cheskin (2000) reported that credit card symbols are especially effective, especially for novice users. Indeed, eight of the ten surveyed illegitimate pharmacies had merchant seals displayed. However, only one of the sites had security seals versus six of the legal pharmacies. This may reflect the fact that merchant seals are
easily copied from other sites and not policed, whereas security seals must be obtained through certification with the granting organization and are much more closely monitored.

The Cheskin trust model illustrates that once consumers are satisfied that their personal information is safe, they move on to evaluating other aspects of the site. One such aspect is navigation, a fundamental component to building trustworthiness. The fact that eighteen out of the twenty sites surveyed had persistent top- or left-hand navigation demonstrates the common understanding amongst webmasters of the importance of good navigation. Sean White, Chief Technical Officer of WhoWhere.com says that “mature, well designed sites feel more stable and trustworthy (not fly-by-night).” (Cheskin, 1999, p.14) That “fly-by-night” appearance is exactly what these illegal pharmacy websites are trying to avoid, and are doing so by improving their navigational design.

The value of published privacy and return policies is self-evident. As mentioned above, consumers want explicit statements on a company’s practices. Both the customers and the companies are protected by laying out expectations for the ordering, shipping, and return processes. Pharmacies represent a special case in that prescription drugs cannot be returned for any reason. Nonetheless, providing that information prior to ordering reduces the possibility of surprise and disappointment for consumers. Related to return policies is recourse; patrons want to the ability to contact the company for help in the event of a problem with the ordering process or product. Nine out of ten VIPPS-verified pharmacies listed at least three ways of contacting them. This comes as little surprise; most of these pharmacies are of the “brick-and-click” variety, meaning they have a store(s) that patrons can visit and a corporate office that is associated with the
website. Therefore, physical addresses, phone and fax numbers are pieces of contact information one would expect for these companies. Conversely, only one of the surveyed illegal sites had at least three modalities of contact information. Of note, only one site listed a physical address, reflecting the author’s suspicions that most of these sites’ sponsors do not want to be located. Furthermore, many of the customer service telephone numbers listed on the illegal sites were the same, suggesting that separate sites do not necessarily represent separate entities.

The final variable (use of images and text to improve perceived trustworthiness) that this study addressed represents what may be one of the most subtle, but influential ways in which illegal Internet pharmacies gain the trust of consumers. Seven of ten legal pharmacy sites scored in this category, mostly for the use pictures of pharmacists on their sites. The illegal sites made even more use of this technique; photos of people dressed as health professionals abounded on these websites. Also, several of the unregulated sites were peppered with phrases like “US Licensed Physicians” or “FDA Approved.” Expressions such as these are unsubstantiated and give a false sense of security. Some sites even go further to convince consumers to trust the site and its products. The following passage was found in the FAQ section of bestonlinexpharmacy.com:
Q: How does the online consultation work?

A: Online consultations are an innovation in health care that utilizes the Internet to improve patient access to the physician. Under this system, the patient no longer needs to receive a traditional physical exam by the physician, rather the patient completes an online questionnaire, and this questionnaire is then submitted to the physician using our secure order system. In must be said that online consultations can never take the place of traditional medicine, they do provide a valid means for patients to receive treatment for a number of conditions that, in many circumstances, do not actually require a physical exam.

Our company is committed to meeting and exceeding all government regulations covering this new form of health care provision. Best Rx Online Pharmacy will only refer your order to certified physicians that are fully licensed. We employ the services of highly trained and qualified pharmacists to provide you with the high standards of pharmaceutical care that you have come to expect. All medicines provided are obtained from legitimate pharmaceutical wholesalers, or in some cases directly from the manufacturer, in this way you can be sure that you receive at all times the same quality medication that you would receive from your neighborhood drugstore.

It is apparent that these illegal Internet pharmacies understand the doubts of the average consumer and are taking steps to dispel them. Unfortunately, it may be those very doubts that might save someone from purchasing medications from an unproven, unregulated source could also bring them physical or financial harm.
Conclusions

The results of this research indicate that the gap between the professional appearances of the legal regulated Internet pharmacies and the illegal ones is closing. No longer can the average Internet user rely on the usual indicators of credibility to distinguish between safe and unsafe e-commerce (especially health-related) websites. That is not to say that there are not plenty of illegal pharmacy sites that look amateurish, but there are enough that do not to the point that they may pose a serious threat. The fact that many of the illegal sites surveyed in this study rated comparably to the legal sites on most of the variables suggests that there is only one way to counsel consumers on this matter. That is, a person should never purchase medications without a previous prescription from a licensed physician who has interviewed and examined the patient. This study has several limitations, including, but not limited to, a small sample size and a dichotomous rating for arguably continuous variables. However, it does highlight an important issue that may have been flying under the radar of health professionals and medical librarians alike. Future studies should focus on understanding just how many people are buying from these unregulated Internet pharmacies. In the author’s opinion, there are important changes that need to be made in regulating this industry, but there are larger issues that need to be addressed. Healthcare in this country is getting prohibitively expensive for many people; it is these very people who seek other, less costly ways to access treatments, and they will continue to do so until it is no longer necessary. As long
as these illegal online pharmacies exist to fulfill their needs, people will take advantage of them, but it is important that they understand the perils of doing so.
Bibliography


Appendix 1: Literature Review

Potential Harms of Internet Pharmacies

There are some inherent dangers of conducting any transactions on the Internet compared to offline. The most important are breaches in privacy and security. These are harms that can be encountered with any online pharmacy, but there are other risks that are much higher at unregulated Internet pharmacies. (Rost, 2000). There have been several adverse incidents reported on sites where the consumer need only fill out a questionnaire to receive a prescription. One television reporter ordered and received Viagra for her 6-month old son, using his height, weight, and birth date. (Rice, 2001). Another investigator was able to get the prescription medication Celebrex, an arthritis drug, saying that she needed it for asthma, again illustrating that a physician does not scrutinize these questionnaires. Even when orders are rejected based on questionnaires, buyers seeking to abuse the system can simply revise the answers they give and resubmit the order. (Rice, 2001). When patients bypass a physician visit and examination, they put themselves at risk for serious interactions and side effects. For example, an Illinois man had a fatal heart attack after taking Viagra he obtained from an online pharmacy without a physician consultation. (Ward, 2003). Had he been seen by a physician, his heart disease may well have been discovered and he would have been instructed not to take the drug. (Ward, 2003).

Finally, there is the issue of the quality of drugs imported into the United States. The U.S. Food and Drug Administration has issued several warnings to the public about counterfeit drugs. A recent release in May 2007 cautioned consumers about a wave of distribution of counterfeit Xenical. (U.S. Food and Drug Administration, 2007). This is
just one of many drugs that have been obtained by federal agents and found to have decreased potency, increased potency, or a different active ingredient altogether than the approved version of the drug. (Montoya, 2007). Clearly there are dangers of ordering prescription drugs from illegitimate pharmacies that the average consumer would not be able to protect himself against. Therefore, regulation by governmental agencies and professional organizations is absolutely necessary.

**Non-governmental regulatory bodies**

The American Medical Association (AMA), the largest association of medical doctors and medical students, has as one of its functions the self-regulation of the profession and establishment of ethical standards for physicians. As mentioned above, the AMA is staunchly against “cyberconsultation,” and condemns it as below the standard of care a physician is ethically bound to provide. (Hochberg, 2004). In 1999, the AMA Board wrote a report on Internet Prescribing known as Report A-99, in which it detailed its stance on the issue, as well as provided recommendations to ensure satisfactory safeguards for consumers. (American Medical Association, 2007). The underlying principle of all of those recommendations is the belief that prescription drugs can only be safely prescribed to a person who has been interviewed, examined, and will remain under the supervision of a physician. (AMA, 2007).

The National Association of Boards of Pharmacy (NABP) has created a set of standards on which it believes state regulations (discussed in the next section) should be founded to create some consistency. (Ward, 2003). In 1999, it created the Task Force on Expanded Use of the Internet in Pharmacy Practice and Regulation to study online
pharmacies in relation to traditional pharmacies and to determine whether additional regulations were necessary. (Ward, 2003).

The Verified Internet Pharmacy Practice Seal (VIPPS) was introduced by the NABP in 1999, and is a symbol to be displayed on online pharmacy websites indicating that it has met all the legal requirements to operate in the state in which it is located and each state to which it dispenses drugs. (NABP, 2007). The site must also have a certain standard of privacy and security measures, and make available some method of having a meaningful consultation with the pharmacist. It serves to let consumers know that the pharmacy is legal and trustworthy. Annual recertification is required for all VIPPS sites. (Ward, 2003). Though it is in theory a great program, there are some limitations and concerns. The first is that it is completely voluntary, so any online pharmacy can choose to ignore it. (Ward, 2003). To date, only fifteen online pharmacies are listed on the VIPPS website as having certification. (NABP, 2007). Second, it is not well publicized; most consumers are not aware of what the seal means, or are confused by other verification seals that websites can display. (Castronova, 2006). Finally, the NABP does not have the authority to impose sanctions besides removal of the seal on any site that does not meet its standards. (Ward, 2003). The NABP has urged the FDA and DEA to make VIPPS certification required, but that policy has not yet been adopted. (Yoo, 2001).

**Governmental Regulatory Agencies**

State governments and medical boards have the responsibility of policing the activity of physicians and pharmacists within their jurisdictions. (Hochberg, 2004). State regulations say that physicians must ensure that drugs are dispensed appropriately, and
many states have expanded the rules to require a physician-patient relationship to be established before the dispensing of drugs. (Hochberg, 2004). As of 2000, twenty states had taken action against illegitimate Internet pharmacies, including New Jersey, where eight online pharmacies were charged with consumer fraud violations, and Kansas where the Attorney General filed suit against eight online companies and six doctors for illegal sale of prescription drugs to Kansans. (Stolfi, 2000). Though many states are making strides in legislation and actions against these pharmacies, there are still barriers to be overcome. When a state successfully prosecutes an online pharmacy and prevents the pharmacy from selling drugs to its residents, the court action applies only to that state. (Stolfi, 2000).

While state governments are charged with regulating the practices of the professionals they license, the federal government’s primary role in regulating the pharmaceutical industry are to ensure that drugs are safe, appropriately labeled, and to regulate direct-to-consumer (DTC) advertising of drugs. There are multiple federal agencies working together to accomplish these tasks. They include the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the U.S. Customs Service, the FBI, and the National White Collar Crime Center.

The Food and Drug Administration, through the Federal Food, Drug, and Cosmetic Act (FDCA), has the power and responsibility to ensure that drugs are effective and safe for use. It operates under the Department of Health and Human Services. (Castronova, 2006). Its regulation of prescription drugs through illegitimate online pharmacies lies largely in laws against importation of drugs into the United States.
Under the FDCA, it is illegal to obtain a prescription medication without a valid prescription. The FDA does not consider an online prescription to be “valid” because a face-to-face relationship between the prescribing physician and the patient has not been established. (Fung, Woo, & Asch, 2004). There are official and unofficial exemption policies, however. In evaluating the importation of unapproved prescription drugs, the FDA takes into consideration the factors listed in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Factors Considered by the U.S. Food and Drug Administration When Evaluating Importation of Unapproved Prescription Drugs from Fung, Woo, &amp; Asch, 2004.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product for personal use (90-day supply or less, and not for resale)</td>
</tr>
<tr>
<td>Intended use for serious condition for which effective treatment may not be available domestically (therefore, the policy does not permit inspectors to allow foreign versions of U.S.-approved drugs into the United States)</td>
</tr>
<tr>
<td>No known commercialization or promotion to U.S. residents by those involved in the distribution of the product</td>
</tr>
<tr>
<td>Product considered not to represent an unreasonable risk</td>
</tr>
<tr>
<td>Individual seeking to import the product affirms in writing that it is for the patient’s own use and provides the name and address of the U.S.-licensed doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.</td>
</tr>
</tbody>
</table>

Although section 956 exempts travelers who bring small quantities of prescription drugs across national borders in person, drugs delivered through mail carrier do not qualify for such an exemption. (Federal Food, Drug, and Cosmetic Act, 2004). Given that most online pharmacies are based outside of the United States, these laws cover the bulk of trade in the illegitimate pharmacy industry. Enforcing these laws, however, has been a challenge in recent years.
Though the FDA is the primary agency charged with regulating the use and standards of prescription drugs in the U.S., it often uses other federal organizations as its arms of enforcement in this matter. However, despite the laws, enforcement is often inconsistent and inadequate to get control over the problem at hand. The Drug Enforcement Administration (DEA) enforces the Controlled Substance Act, which prohibits the dispensing of physically or psychologically addicting drugs without prescription. (Castronova, 2006). It requires that drugs be sold only with a valid prescription, and says that individuals cannot purchase drugs from a foreign online pharmacy unless it is registered with the DEA. (Castronova, 2006). However, in order to enforce and prosecute based on these standards, the DEA must intercept the package and gain the cooperation of foreign nations to locate offenders. (Castronova, 2006). Furthermore, the DEA says it simply does not have the resources to devote to finding and taking down the many illegal online pharmacies, so they generally only go after the “big violators.” (Orr, 2007).

Other federal agencies play roles in the fight against the illegitimate pharmaceutical industry. The Federal Trade Commission (FTC) has authority to bring action against companies making false or misleading claims about the services or products it provides. (Stolfi, 2000). It also has the authority to “regulate marketing practices that cause or are likely to cause substantial consumer injury, which is not reasonably avoidable by consumers, and not outweighed by countervailing benefits to consumers or to competition.” (Stolfi, 2000, p.9) The FTC has recently taken action against Internet pharmacies that make false reports about the safety of their products, their privacy policy, and physician support of their sites. (Castronova, 2006). Finally, the
U.S. Customs Service cooperates with foreign governments to locate and raid shipment hubs of illegal Internet pharmacies. (Castronova, 2006). However, under the Department of Homeland Security Appropriations Act, Customs and Border Patrol are not allowed to prevent individuals from transporting personal use amounts, not to exceed a 90-day supply, of FDA-approved drugs. (Kaiser Family Foundation, 2006). At present, U.S. Customs does not seize packages from Canada. (Orr, 2007).

Results of Regulatory Action

Despite the many strides made in regulatory activities by federal and state governmental agencies, success against illegitimate Internet pharmacies has been very limited. Many officials and researchers argue that laws and policies are not aggressive enough and that enforcement of the laws that do exist is inadequate. As mentioned above, a state’s success in criminal prosecution of an online pharmacy is only effective within its borders; there are currently no provisions for a nationwide ban on a pharmacy after being outlawed in a state’s court. (Stolfi, 2000). Another problem is the federal government’s inability to prosecute criminals in other countries; it can only freeze the U.S. assets of those criminals. (Yoo, 2001). International cooperation has been increasing over time through mutual legal assistance treaties (MLATs), but other countries will not cooperate in investigations and extraditions unless the crime is also a crime in their country. (Hochberg, 2004). Finally, due to limited resources and the relative newness of this problem, laws are inconsistently enforced, fueling violators to continue their activities with little fear of prosecution.
Literature Review References